



Biotech Daily

Thursday August 31, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market edged up 0.1 percent on Thursday August 31, 2023, with the ASX200 up 7.6 points to 7,305.3 points. Nineteen Biotech Daily Top 40 stocks were up, 16 fell, three traded unchanged and two were untraded.

Mesoblast was the best, up 5.5 cents or 12.1 percent to 51 cents, with 10.4 million shares traded. Patrys climbed 11.1 percent; Resonance rose 7.3 percent; Nova Eye and Prescient were up more than five percent; Alcidion and SDI improved more than four percent; 4D, Atomo, Imugene, Kazia, and Starpharma were up more than three percent; Impedimed and Opthea rose more than two percent; Immutep and Proteomics were up more than one percent; with CSL, Emvision, Polynovo and Telix up less than one percent.

Next Science led the falls, down 13 cents or 20 percent to 52 cents, with 736,153 shares traded. Paradigm lost nine percent; Micro-X shed eight percent; Pharmaxis fell seven percent; Antisense and Genetic Signatures were down more than six percent; Medical Developments was down 5.4 percent; Cyclopharm fell 4.4 percent; Clinuvel was down 3.1 percent; both Dimerix and Neuren shed 2.9 percent; Avita, Nanosonics, Orthocell, Pro Medicus and Volpara were down more than one percent; with Cochlear and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: CURVEBEAM AI

By TIM BOREHAM

ASX code: CVB

Share price: 47.5 cents; **Shares on issue:** 320,138,492; **Market cap:** \$152.1 million

Chief executive officer: Greg Brown

Board: Robert Lilley (chair), Mr Brown, Arun Singh, Hashan De Silva, Kate Robb

Financials (Year to June 30, 2023 – pro-forma, unaudited): revenue \$11.48 million (up 55%), pro-forma loss of \$16 million, post-initial public offer (IPO) cash of \$29.24 million

Major shareholders: Arun Singh 12.8%, Firetrail 12.3% Ilwella Pty Ltd (Brian Flannery) 9.5%, Pinnacle Investment Management 7.8%, Karst Peak 6.8%, Greg Brown 5.9%, Tenmile Ventures (Andrew Forrest) 1.9%.

In this dubious era of online influencers, winning (or buying) the endorsement from a Kardashian or similar can be worth millions in sales if you're selling - say - cosmetics or Uber Eats.

But how about the seal of approval from POTUS himself? The newly-listed Curvebeam AI can claim US President Joe Biden's advocacy of its weight-based computed tomography (WBCT) device, to monitor orthopaedics and bone health conditions.

The leader of the free world underwent WBCT to monitor healing progression of a hairline fracture in his foot, sustained while playing with his dogs.

The procedure, at Pennsylvania University, was carried out with one of Curvebeam's earlier devices - the Pedcat - in 2020.

Initial x-rays were clean, but a follow-up computed tomography (CT) scan confirmed a small hairline fracture in his foot.

The fracture meant POTUS had to wear a moon boot, prompting conspiracy theorists to claim he was concealing an ankle bracelet - something to do with a Donald Trump inspired crackdown on a Democrat child sex ring.

Only in America! Mind you, the prospect of having a convicted criminal in the White House isn't that fanciful.

About Curvebeam

Curvebeam is Melbourne-based but its operational nerve centre is in Hadfield, Pennsylvania.

Curvebeam AI (artificial intelligence) evolved in April last year from a merger between Straxcorp, a Melbourne University spin-off and the US-based Curve Beam LLC.

"It made so much sense to come together," CEO Greg Brown says. "We were licencing each other's platforms and had royalties going back and forth."

The new Curvebeam listed on the ASX on August 24, having raised \$25 million at 48 cents per share.

Curvebeam's devices are based on cone-beam CT imaging, which can generate high-resolution, three-dimensional images of bones, soft tissue and dental structures.

"I can show you hundreds of CT scans covering foot, knee and ankle and hip where the CT looks fine, but when you see a weight-bearing stance you know exactly what's going on," Mr Brown says.

Overlaid on that, artificial intelligence (AI) modalities create high-quality CT images. For example, the granular assessment of a patient's bone mineral density (BMD) could help to appraise the risk of a fracture.

"This is a world's first in deep-learning AI and it is all from Melbourne," Mr Brown says.

About 60 percent of patients presenting for a partial or total joint restoration will have an undiagnosed problem.

"Nothing annoys a surgeon more than a beautifully fitted joint, but then [finding] a fracture in the bone," he says. "One of the highest risk factors for total joint replacement is this undiagnosed, untreated fragility."

Inspired by a real BBQ stopper

A medical scientist, Mr Brown has a personal motive for joining Curvebeam: 10 years ago, his mother had an “unremarkable fall” at a family barbeque. A bone mineral density (BMD) test failed to pick up any fracture.

“She was sent home with no therapy but went on to have a second fracture, which could have been prevented if they had picked up this fragility,” he says.

At the time, Mr Brown was CEO of the ASX-listed Impedimed. Before then he had offshore roles at Baxter Diagnostics, Roche Molecular and Digne Corp.

Major shareholder Arun Singh founded Curvebeam LLC, where he developed the first commercial cone-CT imaging system, for dental and maxillofacial uses.

Currently he is also Curvebeam’s chief operating officer, chief technology officer and US head,

Curvebeam has 50 employees here and in the US, with 18 regional distributors.

In the US, Curvebeam has a distribution and co-marketing compact with the New York listed Stryker Corp, enabling access to 500 Stryker sales reps and 40 regional specialists.

Heads, shoulders, knees and toes ...

Curvebeam’s first-generation device - the POTUS-approved Pedcat - was for foot and ankle scanning only. A second product called Lineup added knees to the repertoire.

The key benefits of Hirise, the company’s flagship product, is that the procedure is quicker and easier than traditional CT or magnetic resonance imaging (MRI) scans, taking one to three minutes.

Because they are in their natural pose, patients are more comfortable and are subject to 66 percent less radiation than with CTs.

To date, 170 Hirise units have been placed, 132 of them in the US. Early adopters include the University of California Los Angeles, the Mayo Clinic, Duke Orthopaedics and the New York Hospital for Special Surgery.

Six are in use in Australia.

Hirise has also been placed in 43 orthopaedic practices in the US and Europe.

Then there’s Inreach HR-PQCT - as in high-resolution peripheral quantitative CT – a wrist scanner for bone microstructural assessment: “the first product capable of natural bilateral WBCT from hip to foot”.

The thesis here is that traditional bone fragility detection is based on measuring bone mineral density (BMD), but 80 percent of women with a fragility fracture had normal BMD measurements.

The current method of assessing BMD is via a DEXA machine, which has low energy x-rays that only measure the surface density of the bone.

Hirise and Inreach HR-PQCT have been approved by the US Food and Drug Administration, the Australian Therapeutic Goods Administration and have Conformité Européenne (CE) mark.

Reach for the sky ...

Curvebeam is also developing Skyrise, a platform that scans the neck, shoulder and spine right through to the foot. About 20 percent of the IPO funds raised are earmarked for developing this product.

Mr Brown says accurate soft and hard tissue measurements are crucial to treat back and shoulder disorders.

The company expects to complete product testing in financial year 2025, with a launch, assuming regulatory clearance, in financial year 2026.

AI products

Curvebeam's key AI products are Cubevue Autometrics (advanced visualisation tools, BMD and Ossview (bone fragility software).

A French clinical trial covering 2,000 women over eight months showed that Ossview predicted 70 percent of fractures, while the standard-of-care predicted a mere 30 percent.

A BMD AI module is targeted for FDA submission by July 2024, using the predicate device approval route, with US commercialisation slated by mid-2025. The idea is that surgeons don't have to send a patient elsewhere for a BMD test, which can result in them getting 'lost' for months. The tests can be done in the clinics and the clinics get reimbursed.

"BMD is indicated for most people having a joint replacement, yet published figures show only 15 percent are getting [a BMD scan]," Mr Brown says.

Ossview has FDA breakthrough device designation, but the company expects the BMD device to deliver 95 percent of AI revenues.

Addressable market

Curvebeam estimates the size of the point-of-care CT imaging sector at \$10 billion and the bone health and fracture protection at a further \$4.1 billion. The latter is a potential \$1.4 billion for Ossview scan revenue and \$2.7 billion for BMD analysis.

The CT imaging market is roughly equally divided between orthopaedic surgeons, imaging chains and hospitals.

In the US, Hirise is reimbursed at an average Medicare rate of \$US138.77 per scan.

At a cost of \$US410,000 per device, a clinic could recoup its investment in just under 18 months, or five years under a lease financing model.

With the AI modules, Curvebeam estimates revenue of \$A150,000 to \$A200,000 per device per annum (based on an average five BMD tests per day).

“So, for every 100 Hirises we place, that is \$15 million to \$20 million of revenue and this annuity income builds over time,” Mr Brown says.

He adds that the clinics should be happy too, as they are reimbursed for their BMD tests and will have fewer revision surgeries to contend with.

Curvebeam also expects to be reimbursed in Germany, where it has created a subsidiary company in readiness.

Finances and performance

Curvebeam’s proforma revenue of \$11.48 million in the 2022-’23 year derived from only 16 initial Hirise devices and three sales reps.

“We are now rolling out the Stryker relationship with 500 [sales representatives] on the ground, so we hope to build this footprint very quickly,” Mr Brown says.

The IPO raised \$25 million at 48 cents apiece, implying a day-one valuation of \$153 million.

To date, the company has raised \$85 million.

The company expects about 80 percent of sales to come from the US market, with most of the rest emanating from Europe.

In the main, the IPO proceeds have been earmarked for sales and marketing (\$11.3 million), research and development (\$4.1 million) and working capital (\$4.4 million).

Curvebeam shares debuted well under par, trading between 33 cents and 37 cents on the day of the IPO.

But the company briefly hit 54 cents this week after fund manager Perennial outed itself as a major holder.

Along the way the company has raised \$85 million, helped by a strong rota of investors including mining barons Brian Flannery and Andrew Forrest.

Scanning the rivals

According to the prospectus, rivals include key bone imaging products in x-ray and upright CT.

Competing offerings include the EOS Biplanar full body x-ray, Siemens' Multitom Rax Twin robotic x-ray and the Planmed Verity CT.

"The rivals are 'unilateral'," Mr Brown says. "The [patient's] weight is on one limb and is not naturally weight bearing.

"Other products have limitations in terms of patient positioning."

The company says it is "not aware of any other company that has developed, or is developing, AI-driven software aids for BMD assessment and complete bone microstructure risk."

So there!

Dr Boreham's diagnosis:

The way to look at Curvebeam is that its first-to-market hardware provides the 'steak' while the AI overlays provide the sizzle.

Given the broader investor hype about artificial intelligence, Curvebeam's ASX debut has been somewhat undercooked.

Mr Brown feels the pain, having invested \$6.1 million in the company along the way and pouring \$750,000 into the IPO. So too does Mr Singh, who has invested \$15 million.

"I love this company," Mr Brown says. "By putting my money where my mouth is I am showing investors not to take any risks that I would not be taking."

Unlike most start-up device plays, Curvebeam distinguishes itself by generating significant revenue even without the annuity AI streams. The patient need clearly exists: musculoskeletal disorders affect about 1.7 billion people worldwide, 700 million of whom have osteoporosis or osteoarthritis.

Curvebeam chair Robert Lilley opines: "The consequences of undiagnosed bone fragility, in particular, can be severe, both in the general ageing population and in total joint replacement patients."

As usual, the challenge is to convince clinicians to adopt the best techniques and equipment, rather than the ones they are simply used to.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would put his money where his mouth is, if he was a genuine on-line influencer, but is yet to create an Instagram account.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Walter and Eliza Hall Institute says with the Doherty Institute venetoclax has shown potential to kill latent human immunodeficiency virus (HIV) cells, in mice.

WEHI said the discovery “could lead to a future cure for the disease”.

The Institute said that latent infections were responsible for the virus “permanently remaining in the body and cannot be treated by current therapy options”.

WEHI said that the hibernating, infected cells were the reason people living with HIV required life-long treatment to suppress the virus.

The Institute said that a discovery at WEHI led to the development of venetoclax, currently approved in Australia for chronic lymphocytic leukaemia and acute myeloid leukaemia.

WEHI said that further research found that venetoclax could kill hibernating HIV-infected cells and delay the virus from re-emerging.

WEHI said that a trial based on the findings would be launched in Australia and Denmark, to test venetoclax “as a potential pathway to develop a cure for HIV”.

The research article, titled ‘Venetoclax, alone and in combination with the BH3-mimetic S63845, depletes HIV-1 latently infected cells and delays rebound in humanized mice’ was published in Cell Reports Medicine and the full article is available at:

[https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791\(23\)00331-2](https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(23)00331-2).

WEHI’s Dr Philip Arandjelovic said the discovery was “an exciting step towards developing treatment options for the tens of millions of people currently living with HIV globally”.

“In attacking dormant HIV cells and delaying viral rebound, venetoclax has shown promise beyond that of currently approved treatments,” Dr Arandjelovic said.

“Every achievement in delaying this virus from returning brings us closer to preventing the disease from re-emerging in people living with HIV,” Dr Arandjelovic said.

The Institute said the phase I/IIb trial using venetoclax for HIV would start at the end of the year in Denmark, with plans to expand the study to Melbourne in 2024.

WEHI said the trial would be led by Doherty Institute director Prof Sharon Lewin, the Centenary Institute director Prof Marc Pellegrini and Dr Thomas Rasmussen from Denmark’s Aarhus University.

ENA RESPIRATORY

Ena says the US Government has awarded it \$3.8 million for a phase II INNA-051 program for community-acquired viral respiratory infections, and it has appointed staff.

Ena said the US Department of Defence funding was for non-clinical safety studies of its INNA-051 a “first-in-class, intra-nasal, innate immune modulator for the prevention of complications associated with respiratory viral infections in at-risk populations”.

The company said that the safety studies would support a three-month seasonal prophylaxis phase IIb study

Ena said that the \$3.8 million was additional to the previous \$4.38 million initial funding for INNA-051 larger-scale manufacturing and development of a dry powder formulation expected to provide long-term stability of at least 24 months at room temperature.

Ena chief executive officer Dr Christophe Demaison said that “early studies validated the safety of INNA-051 and provided proof of pharmacology by accelerating virus clearance and boosting host defence responses against common respiratory viruses”.

The company said it had appointed Dr Ruth Tal-Singer as medicine development leader, Dr Courtney Crim as clinical consultant and acting chief medical officer and Dr Bruce Miller as a clinical consultant.

Ena is a private company.

MAYNE PHARMA

Mayne Pharma says revenue for the year to June 30, 2023 was up 56.8 percent to \$183,586,000, with a previous net loss of \$273,950 turned to a profit of \$117,157,000. Last year, Mayne Pharma reported its 2021-'22 revenue as \$424,797,000 but today restated the prior revenue as \$157,143,000 and net loss as \$291,893 due to "the accrual for anticipated copay charges at June 30, 2022 had not taken into account higher customer inventory ... which were in part due to the addition of several new products ... during the year as well as sales volume trends" (BD: Aug 26, 2023).

Today, the company said its branded products revenue was up 484 percent to \$61.9 million including women's health products Anovera, Imvexxy and Bijuva and pre-natal vitamins.

Mayne Pharma said it had paid a special fully franked post-consolidation interim dividend of 54 cents a share but did not declare a final dividend.

Mayne Pharma chief executive officer Shawn O'Brien said the year to June 30, 2023 had "been one of significant change" having "reshaped the business to focus on our core areas of Women's Health, Dermatology and our International operations".

"With accelerating sales momentum and ongoing cost discipline, Mayne Pharma enters 2023-'24 well positioned for sustainable long-term growth," Mr O'Brien said.

The company said last year's diluted loss per share of \$3.42 was turned to diluted earnings of \$1.48 per share for the year to June 30, 2023.

Mayne Pharma said that its net tangible assets per share was down 84.4 percent from \$1.35 in the prior period to 21 cents.

Last year, Mayne reported its diluted loss per share and net tangible assets for the year to June 30, 2022 as 16.0 cents and 8.0 cents, respectively (BD: Aug 26, 2023).

Today, Mayne Pharma said it had cash and cash equivalents of \$92,616,000 at June 30, 2023 compared to \$96,672,000 at June 30, 2022.

Mayne fell \$1.08 or 22.7 percent to \$3.67 with one million shares traded.

SOMNOMED

Somnomed says revenue for the year to June 30, 2023 was up 15.2 percent to \$83,616,164 with net loss after tax up 80.3 percent to \$7,999,044.

Somnomed said revenue was from sales of its Somnodent product range for obstructive sleep apnoea.

The company said that sales were up 11.4 percent in Europe to \$47.3 million, North America was up 22.2 percent to \$30.2 million and sales in the Asia Pacific region were up 12.8 percent to \$6.1 million.

Somnomed said that its diluted loss per share for the year to June 30, 2023 was up 80.2 percent to 10.18 cents.

The company said that last year's 5.7 cents net tangible asset backing per share turned to a negative 7.6 cents.

Somnomed said it had cash and cash equivalents of \$11,956,406 at June 30, 2023 compared to \$15,644,331 at June 30, 2022.

Separately, Somnomed requested a trading halt pending "an announcement regarding [a] proposed capital raise".

Trading will resume on September 4, 2023 or on an earlier announcement.

Somnomed last traded at 76 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the year to June 30, 2023 was up 47.4 percent to \$32,337,000 with net loss after tax down 54.8 percent to \$5,609,000.

Medical Developments said that sales were primarily from its Pentrox inhaled methoxyflurane analgesic and respiratory equipment.

The company said diluted loss per share fell 61.7 percent to 6.66 cents, net tangible asset backing per share was up 159.7 percent to 40.0 cents, and it had cash and equivalents of \$24,661,000 at June 30, 2023, compared to \$20,398,000 at June 30, 2022.

Medical Developments fell five cents or 5.4 percent to 87.5 cents.

NEXT SCIENCE

Next Science says revenue for the six months to June 30, 2023 was up 86.9 percent to \$US10,112,775 (\$A15,559,204) with net loss after tax up 30.7 percent to \$US8,613,091 (\$A13,285,956).

Next Science said revenue increased from sales of its Xperience and Blastx products for wound treatment as well as its durable medical equipment business.

The company said its diluted loss per share rose 25.3 percent to 4.01 US cents, with last year's net tangible asset backing per share of 5.51 US cents turned to a negative 1.11 US cents, and it had cash and equivalents of \$US3,483,501 at June 30, 2023, compared to \$US11,024,787 at June 30, 2022.

Next Science fell 13 cents or 20 percent to 52 cents.

MACH7 TECHNOLOGIES

Mach7 says its revenue for the year to June 30, 2023 was up 11.0 percent to \$30,049,766 with net loss after tax down 74.9 percent to \$1,048,112.

Mach7 said that the revenue was a combination of medical imaging licence fees, annual support fees, professional service fees and interest.

The company said that North America revenue was up 21.5 percent to \$25.0 million, Asia Pacific revenue fell 29.3 percent to \$3.8 million, and Middle Eastern revenue was down 17.95 percent to \$828,580, with \$394,695 of sales in Europe and other regions.

Mach7 said that diluted loss per share was down 77.8 percent to 0.4 cents, net tangible asset backing per share was up 58.7 percent to 10.0 cents, and it had cash and cash equivalents of \$23,394,568 at June 30, 2023 compared to \$25,747,608 at June 30, 2022.

Mach7 was up 2.5 cents or 3.3 percent to 78 cents.

GENETIC SIGNATURES

Genetic Signatures says revenue for the year to June 30, 2023 was down 52.2 percent to \$16,939,000, with last year's \$3,063,000 profit after tax turned to a \$14,052,000 loss.

Genetic Signatures said revenue came from sales of its 3base assays and automated instruments as well as its Easyscreen Sars-Cov-2 detection kit, and its reduced revenue was "due to the reduction of public health molecular testing for Sars-Cov-2".

The company said that sales in Asia Pacific were down 51.4 percent to \$15.4 million, and sales in Europe, Middle East and Africa were down 58.6 percent to \$1.6 million.

The company said diluted earnings per share turned to a loss of 9.80 cents, net tangible asset backing per share fell 29.5 percent to 26.1 cents and it had cash and equivalents of \$16,349,000 at June 30, 2023, compared to \$36,897,000 at June 30, 2022.

Genetic Signatures fell three cents or 6.45 percent to 43.5 cents.

MESOBLAST

Mesoblast says revenue for the year to June 30, 2023 was down 26.5 percent to \$US7,501,000 (\$A11,614,000) with net loss after tax down 10.4 percent to \$US81,889,000 (\$A126,787,000).

Mesoblast said revenue came from sales royalties for its Temcell for acute graft-versus-host disease in Japan and Alofisel for perianal fistulas in Crohn's disease in Europe.

The company said its reduced revenue was due to a one-off milestone payment of \$US1.2 million from distribution partner Takeda Pharmaceuticals in the prior period.

Mesoblast said that diluted loss per share for the year to June 30, 2023 was down 21.3 percent to 11.08 US cents, and it had cash and cash equivalents of \$US71,318,000 at June 30, 2023, compared to \$US60,447,000 in 2022.

Mesoblast was up 5.5 cents or 12.1 percent to 51 cents with 10.4 million shares traded.

IMPEDIMED

Impedimed says revenue for the year to June 30, 2023 was up 7.4 percent to \$11,344,000 with net loss after tax up 3.25 percent to \$20,521,000.

Impedimed said Sozo body fluid assessment revenue was up 6.9 percent to \$10,563,000 with legacy revenue from L-Dex down 12.1 percent to \$686,000.

The company said that its recent capital raise had helped it strengthen its balance sheet and move to a higher revenue target, although it would be until "mid 2024 financial year" before "steady, predictable" impact occurred.

Impedimed said diluted loss per share was constant at 1.0 cent, as was net tangible asset backing per share at 2.0 cents, and it had cash and equivalents of \$45,710,000 at June 30, 2023 compared to \$40,730,000 at June 30, 2022.

Impedimed was up half a cent or 2.9 percent to 18 cents with 2.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the year to June 30, 2023 was up 27.8 percent to \$8,686,118, with net loss after tax up 64.8 percent to \$11,750,923.

Genetic Technologies said revenue came from sales of its Genetype, Easydna and Affinitydna genomics-based health and disease tests.

The company said diluted loss per share was down 85 percent to 0.012 cents, net tangible asset backing per share fell 41.7 percent to 0.07 cents, and it had cash and equivalents of \$7,851,197 at June 30, 2023, compared to \$11,731,325 at June 30, 2022.

Genetic Technologies was up 0.05 cents or 25 percent to 0.25 cents with 1.5 million shares traded.

RHINOMED

Rhinomed says revenue for the year to June 30, 2023 fell 17.9 percent to \$7,472,451 with net loss after tax up 109.35 percent to \$11,056,088.

Rhinomed said that revenue came from its Rhinoswab and Rhinoswab Junior Sars-Cov-2 test swabs, as well as its Mute anti-snoring nasal dilators.

The company said that diluted loss per share was up 91.6 percent to 3.87 cents, with last year's net tangible asset backing per share of 1.13 cents turned to a negative 2.28 cents.

Rhinomed said that it had cash and cash equivalents of \$190,412 at June 30, 2023, compared to \$1,989,949 at June 30, 2022.

Rhinomed fell 0.2 cents or 2.8 percent to 6.9 cents.

CONTROL BIONICS

Control Bionics says revenue for the year to June 30, 2023 was up 25.3 percent to \$5,642,386 with net loss after tax down 7.7 percent to \$5,631,141.

Control Bionics said revenue came from sales of its disability communications technology including Neuronode Trilogy and Neuronode 3 devices for computerized speech, electronic communications, entertainment and external device control.

The company said its diluted loss per share was down 12.7 percent to 6.24 cents, compared to the previous year, with net tangible asset per share down 63.9 percent to 3.22 cents.

Control Bionics said that it had cash and cash equivalents of \$935,503 at June 30, 2023 compared to \$5,214,003 at June 30, 2022.

Control Bionics was up 0.1 cents or 1.3 percent to 7.6 cents.

NEXT SCIENCE

Next Science says it has raised \$12 million in a placement at 42 cents a share to institutional and sophisticated investors and hopes to raise \$6.5 million in share plans.

Next Science said the 42 cent share price was a 33.2 percent discount to the 5-day volume-weighted average price.

The company said it would retire the \$10m Walker Group convertible notes to and replaced with a share subscription commitment, pending shareholder approval.

The company said that an Australian and New Zealand share plan hoped to raise \$5 million and a US share plan hoped to raise a further \$1.5 million.

Next Science said that the share plan record date was August 30, both plans would open on September 1 and close on September 18, 2023.

CARDIEX

Cardiex says it will offer 1,333,333 American depository shares (ADSs), representing 100,000,000 Australian shares to list on the Nasdaq under the code CDEX.

Cardiex said that it had updated its registration statement with the US Securities and Exchange Commission.

In July, Cardiex said it had filed a registration statement with the US Securities and Exchange Commission for an initial public offer on the Nasdaq (BD: Jul 26, 2023).

Today, the company said the ADSs would be deposited with JPMorgan Chase Bank and Roth Capital Partners was lead book-running manager for the offer.

Cardiex was up two cents or 13.8 percent to 16.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says the Indian Central Drugs Standard Control Organisation has approved its Xprecia Prime blood coagulation test, with the first order delivered.

Universal Biosensors chief executive officer John Sharman said the company had been “working on the approval of Xprecia Prime in India for more than 12 months, and we are delighted with this significant step forward”.

“While this first order is not material in value, under \$100,000, India is a powerful and emerging market, and we are excited for the opportunities Xprecia Prime represents to disrupt this market,” Mr Sharman said.

Universal Biosensors was unchanged at 24 cents.

[ALTERITY THERAPEUTICS](#)

Alterity says its Biomuse study shows that biomarkers are “a critical component for diagnosis” of multiple system atrophy.

Alterity said the Biomuse natural history study was in partnership with the Nashville, Tennessee-based Vanderbilt Medical Centre and aimed to track the progression of individuals with multiple system atrophy (MSA).

The company said it presented two posters at the International Congress of Parkinson’s Disease and Movement Disorders in Copenhagen, on August 27 to 31, 2023.

Alterity said the first poster was titled ‘A multimodal approach for diagnosis of early multiple system atrophy’ and the second was ‘Preliminary evidence for evolution of myoinositol and N-acetylaspartate as biomarkers of disease severity in early-stage multiple system atrophy’.

Alterity said the first set of results described three clinically “probable” patients with divergent magnetic resonance imaging and fluid biomarker data, supporting the use of biomarkers to improve diagnostic accuracy in early MSA”, and the results showed “that no one biomarker could be relied on to aid in the diagnosis of early MSA”.

Alterity said the second set of results from 13 early-stage MSA patients showed that metabolite concentration from magnetic resonance spectroscopy may be useful for assessing the clinical measures of disease severity and treatment response.

Alterity chief executive officer Dr David Stamler said “the approach of using a diverse set of biomarkers to augment clinical criteria for MSA will greatly improve the diagnosis of this devastating disease”.

Alterity fell 0.1 cents or 12.5 percent to 0.7 cents.

[ANATARA LIFE SCIENCES](#)

Anatara says it has dosed all 70 patients in the first stage of its phase I/II trial of its gastrointestinal reprogramming medication (Garp) for irritable bowel syndrome (IBS).

Earlier this year, Anatara said it had revised the randomized, blinded, placebo-controlled study protocol and had enrolled 50 of 90 patients (BD: Mar 10, 2023).

The company said that Garp was a “multi-component, coated complementary medicine” that included its pineapple stem-based bromelain.

In June, the company said a review of the “small data set” of 31 patients treated in its trial showed no safety concerns reported, and it expected to enrol more than 70 patients to complete stage one (BD: Jun 6, 2023).

Today, Anatara said results were expected to be released in late September 2023 and that no safety concerns were noted during the dosing.

Anatara chair Dr David Brookes said the trial would “deliver an evidence-based result and the [enrolment] criteria excluded ‘milder’ IBS sufferers which meant all participants were IBS patients with significant symptoms”.

Anatara was up 0.4 cents or 14.3 percent to 3.2 cents.

[NEUROTECH INTERNATIONAL](#)

Neurotech says it has dosed all 15 patients in its phase I/II clinical trial of its marijuana-based NTI164 for paediatric neuropsychiatric disorders, with results expected by October.

In May, the company said it had recruited 15 children with paediatric auto-immune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (Pans) (BD: May 3, 2023).

Neurotech was unchanged at five cents.

EMYRIA

Emyria says it has requested a trading halt “pending an announcement concerning a capital raising”.

Trading will resume September 4, 2023, or on an earlier announcement.

Emyria last traded at eight cents.

AROVELLA THERAPEUTICS

Arovella 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 that Arovella’s share price increased 20.0 percent from an intraday low of 50 cents to a high of 60 cents yesterday and noted a “significant” increase in volume.

Arovella said that Blue Ocean Equities had circulated a report highlighting its progress and upcoming milestones, and announced a “non-deal” roadshow for interested parties.

The company referred to its June news of a cytokine study which enhanced Arovella’s invariant natural killer T-cells and anti-tumor activity, in mice (BD: Jun 26, 2023).

In addition, Arovella said it was in “early-stage negotiations” for a licence with Sparx Therapeutics, although no formal agreement had been signed.

Arovella was up 0.2 cents or 3.3 percent to 6.2 cents with 12.0 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Perennial Value Management says it has reduced its substantial shareholding in Lumos from 61,260,190 shares (13.81%) to 56,441,831 shares (12.73%).

The Sydney-based Perennial said that between August 11 and 28, 2023 it bought and sold shares in 11 separate transactions, with the single largest sale on August 22 of 1,577,571 shares for \$165,281, or 10.5 cents a share.

Lumos fell one cent or 9.1 percent to 10 cents with 37.5 million shares traded.

INVEX THERAPEUTICS

Perth’s Jason Peterson says he has become a substantial shareholder in Invex with 3,995,076 shares or 5.3159 percent.

Mr Peterson said that through Sunset Capital Management Pty Ltd, Cityscape Asset Pty Ltd and Celtic Capital, between August 23 and 31, 2023, he acquired 1,289,401 shares for \$230,021 or 17.84 cents a share.

Invex was up one cent or 5.1 percent to 20.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Stephen Carter as its chief executive officer, starting on a base salary of \$300,000 a year, effective from September 11, 2023.

Neuroscientific said interim executive chair Paul Rennie would be the non-executive chair.

The company said Mr Carter had 30 years’ experience in pharmaceuticals and medical devices and previously was with Pfizer, Pharmacia and Upjohn.

Neuroscientific said that Mr Carter had experience in development, design and management of pre-clinical studies as well as human phase I, II and III clinical trials.

The company said that Mr Carter would be entitled to short term incentives up to 20 percent of his base salary and long-term incentives as per the company plan.

Neuroscientific fell 0.1 cents or 1.1 percent to 8.9 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has appointed Dr Russell Basser as a director, effective from September 1, 2023.

Medical Developments said Dr Basser was a physician with more than 30 years of medical and bio-pharmaceutical experience.

The company said that Dr Basser had worked at CSL for 21 years including as chief medical officer, head of research and development and head of global clinical development, and was previously an oncologist.

The company said Dr Basser was a director of Starpharma and Doherty Clinical Trials and had previously been on the board of the ANZ Breast Cancer Trials Group and the Hadassah Australia Medical Research Collaboration.

AUDEARA

Audeara says as part of its internal restructure and staff costs plan chief financial officer Stuart Smith has resigned, effective from September 30, 2023.

Audeara said Mr Smith was appointed in December, 2022 and would continue in his position until the completion of the company's full year financial results for 2022-'23.

The company said it would use existing resources to manage its chief financial officer duties until it engages additional financial resources.

Audeara said its national sales manager John Krajewski would be the head of international sales and marketing and its head of growth and corporate partnerships Bill Peng would be the chief operating officer.

Audeara said the changes followed an ongoing review of its cost base, which included reducing staffing costs, and said it would reduce wage costs and optimize operations.

Audeara was up 0.3 cents or 7.5 percent to 4.3 cents.