

Biotech Daily

Monday December 11, 2023

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: ALCIDION UP 14%; PRESCIENT DOWN 21%
- * LTR UP 105% ON \$7m SPONTAN ERECTILE DYSFUNCTION IPO
- * ALCIDION \$23m SOUTH TEES NHS CONTRACT
- * 4D MEDICAL RAISES \$35m FOR \$39m IMBIO ACQUISITION
- * VITURA SELLS 2m CANVIEW MARIJUANA UNITS
- * VICTORIA \$2m for CYBAN BRAIN MONITOR
- * PRESCIENT RECRUITS PHASE Ib PTX-100 T-CELL LYMPHOMA TRIAL
- * AROVELLA CAR-INKT CELLS 'IMPROVE ANTI-TUMOR ACTIVITY', IN MICE
- * MEDLAB 'NO INTEREST' IN ASSET SALE
- * RHINOMED \$1.25m PLAN, DELISTING EGM, SMALL HOLDING FACILITY
- * COMPUMEDICS REQUESTS 'MORE CHINA ORDERS' TRADING HALT
- * PHARMAUST REQUESTS 'CAPITAL RAISING' TRADING HALT
- * AUSBIOTECH: PROF JOHN SKERRITT, DR LIZ DALLIMORE DIRECTORS

MARKET REPORT

The Australian stock market edged up 0.06 percent on Monday December 11, 2023, with the ASX200 up 4.1 points to 7,199.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and one was untraded. All three Big Caps rose.

Alcidion was the best, up one cent or 14.1 percent to 8.1 cents, with 8.2 million shares traded. Clarity climbed 10.8 percent; Genetic Signatures was up 7.4 percent; Atomo and Nova Eye were up more than four percent; Dimerix and Resonance improved more than three percent; Avita rose two percent; Cochlear, Pro Medicus and Telix were up more than one percent; with CSL, Cyclopharm, Nanosonics and Resmed up less than one percent.

Prescient led the falls, down 1.9 cents or 21.1 percent to 7.1 cents, with 8.4 million shares traded. 4D Medical lost 14.1 percent; Micro-X was down 8.3 percent; Amplia, Antisense, Mesoblast and Universal Biosensors were down five percent or more; Cynata, Imugene, Next Science and Proteomics fell four percent or more; Curvebeam, Emvision, Medical Developments, Opthea and Syntara (Pharmaxis) were down three percent or more; Paradigm and Polynovo shed more than two percent; Clinuvel and Immutep were down more than one percent; with Neuren and SDI down by less than one percent.

LTR PHARMA

LTR opened up 75 percent at 35 cents following its \$7 million initial public offer at 20 cents a share to list under the code 'LTP' to commercialize Spontan for erectile dysfunction. LTR said the offer was "heavily oversubscribed" and the funds would be used to

commercialize its Spontan intra-nasal spray for erectile dysfunction, including a bioequivalence study, and regulatory filings in Australia and the US "within one to two years" for sales, marketing and general working capital".

In November, LTR said that if it raised the maximum amount of \$7 million it would have an indicative market capitalization of \$27.9 million (BD: Nov 17, 2023).

The company said at that time that Spontan was PDE5 inhibitor vardenafil, marketed by Bayer as Levitra, but with an intra-nasal mechanism of action, rather than an oral tablet. LTR executive chair Lee Rodne said the trial was expected to begin in February 2024, he expected results by July 2024, and hoped Spontan would be available through a special access scheme from mid-2024, with full approval in 2025.

The company said Mr Rodne was the former chief executive officer of Allied Medical, now Anteris, with former Avexa chief executive officer, Admedus chief operating officer and current Cann Group chair Dr Julian Chick and Maja McGuire as non-executive directors. LTR said that that Alpine Capital was the lead manager of the offer.

LTR climbed as much as 105.0 percent to 41 cents before closing up 18 cents or 90.0 percent to 38 cents with 11.5 million shares traded.

ALCIDION GROUP

Alcidion says England's South Tees National Health Service (NHS) has extended its management services contract by 10 years to 2033, worth more than \$23.3 million. Alcidion chief executive officer Kate Quirke told Biotech Daily the agreement with South Tees NHS was "the largest single contract in the company's history".

In 2020, Alcidion said it had a \$9.5 million deal with South Tees NHS to integrate its Miya Precision to digitize patient care and records and its Better Openep to digitize prescription and medicine administration; and later that year, said it had extended the contract by \$2.0 million to include internet cloud systems (BD: Nov 9, Dec 14, 2020).

Today, the company said the extended contract period was for an additional 10 years, which included two years remaining on the existing contract.

Alcidion said the extended contract included further options for its Silverlink Patient Care System, Emergency Department and Virtual Care modules, which, if taken, would add an additional \$9.3 million to the contract value.

The company said the contract included the option for a further up-to five-year additional extension, giving the contract a total potential value with the optional modules of up-to about \$54 million.

Alcidion said South Tees was the largest hospital trust in the Tees Valley, with more than 1,000 beds and about 9,000 employees providing care for more than 1.5 million people. Ms Quirke said the extension confirmed "the value Miya Precision has been able to unlock for South Tees in harnessing the power of their own data".

"South Tees committed to the rollout of Miya Precision during the pandemic and have successfully rolled out the modules to complete an [electronic patient record] that provides operational insights and provides their clinicians with digital tools that support them by providing them better information to underpin their decision making," Ms Quirke said.

"The data insights and success metrics we have received to date are extremely positive and reinforce our purpose of giving clinicians time to care for patients," Ms Quirke said. Alcidion was up one cent or 14.1 percent to 8.1 cents with 8.2 million shares traded.

4D MEDICAL

4D Medical says it has raised \$35 million in a placement at 79 cents a share for the \$US25 million (\$A38.6 million) upfront costs of acquiring the Imbio imaging company. 4D said the share price was a 17.3 percent discount to the last closing price, and subject to shareholder approval investors would receive one option for every two shares bought. The company said E&P Corporate Advisory and Bell Potter Securities were joint lead managers for the capital raising.

4D Medical said the Minneapolis, Minnesotta-based Imbio was a "medical imaging artificial intelligence company transforming how patients with lung and cardiothoracic conditions are detected, diagnosed and treated".

The company said it would pay \$25 million upfront, a contingent earnout of up-to \$US10 million by 2025 and two \$US5 million payments by 2026, subject to milestones.

4D Medical said Imbio gave physicians comprehensive information extracted from standard-of-care computer-tomography scans, which optimized diagnoses and patient care outcomes through the use of its visual and quantitative reports.

The company said the acquisition was part of its strategy to provide physicians with four additional lung diagnostic tools and offer structure and function products for assessing lung disease, and it would accelerate the US commercialization of its XV technology. 4D Medical said Imbio expected to report \$US3.0 million in revenue for the year to December 31, 2023, and \$US6.3 million for the year to December 31, 2024.

4D chief executive officer Prof Andreas Fouras said "Imbio's market leading suite of [artificial intelligence] solutions provide life-changing insights from [computer-tomography] scans, and perfectly complement 4DMedical's functional imaging technology".

"We now offer a comprehensive cardiothoracic imaging solution set to providers and their patients," Prof Fouras said.

"Importantly, the Imbio acquisition also significantly boosts our capacity to improve the respiratory health of veterans, especially for those impacted by toxic exposures during service," Prof Fouras said.

4D Medical fell 13.5 cents or 14.1 percent to 82 cents with 3.6 million shares traded.

VITURA HEALTH

Vitura says it has sold its two millionth unit of medical marijuana through its Canview platform, which has been shipped to one of its more than 4,100 pharmacist/prescriber customers.

Vitura said Canview was launched in June 2020, stocked more than 280 product lines from about 39 suppliers of medical marijuana in Australia.

The company said it had reached the one-and-a-half millionth unit milestone earlier this year, and that it had taken it two and a half years to sell the first million units and only one year to sell the second million.

Vitura said its acquisition of Doctors on Demand, with Canview, CDA and Cannadoc was expected to drive further adoption, usage and positive network effects.

Vitura managing-director Rodney Cocks said "with the continued growth of unit sales, we anticipate that the three millionth unit should be sold through the platform during ... 2024". "The deployment of the Canview 2.0 software has offered patients, prescribers,

pharmacists and suppliers increased functionality, ease of use and efficiencies that is expected to drive further adoption and usage," Mr Cocks said.

"The ongoing transition of patients onto the Canview 2.0 platform builds on the successful launch of the pharmacy app, and the prescriber and patient app," Mr Cocks said. Vitura was unchanged at 29 cents.

VICTORIA GOVERNMENT

The Victoria Government says Breakthrough Victoria has provided Cyban Pty Ltd \$2 million to fund US Food and Drug Administration approval of its brain oxygen monitor. A media release from Victoria Treasurer and Minister for Economic Growth Tim Pallas said Cyban's technology allowed brain oxygen monitoring without invasive surgery, reducing the risk of further injury by delivering reliable continuous data to clinicians. The Government said Cyban founder Dr Barry Dixon was an intensive care specialist at Melbourne's St Vincent's Hospital and the company was completing a US Food and Drug Administration submission, and hoped for US clearance in 2024.

Earlier this year, Hydrix said it had a \$1.48 million contract to develop Cyban's noninvasive, red and infrared, brain oxygen patient monitoring unit and deliver "detailed design, construction and testing of engineering prototypes ... [and to] support a streamlined path for this product to achieve class II medical device US Food and Drug Administration regulatory submission" (BD: Feb 28, 2023).

Today, the media release said the company was conducting clinical trials at Melbourne's St Vincent's Hospital, The Alfred Hospital, Royal Melbourne Hospital and Ballarat Hospital as well as Scotland's Royal Edinburgh Infirmary and the Cleveland Clinic in Ohio. The Victoria Government said that Cyban's device aimed to enable early detection of brain hypoxia to improve mortality rates, minimize damage such as long-term disabilities, reduce the need for surgery, accelerate the time to treatment, shorten hospital stays, cut costs for hospitals and improve patient outcomes.

The Government said the investment would help Cyban expand its workforce in Victoria from 13 employees to about 50 employees by 2027.

Dr Dixon said the funds would "help bring our brain monitoring technology to market faster and achieve our goal of advancing the way brain injuries are detected and managed". The Cyban website said that former Victoria Health Minister Jaala Pulford and former Ausbiotech chief executive officer Dr Anna Lavelle were directors.

Cyban is a private company.

PRESCIENT THERAPEUTICS

Prescient says it has recruited its 25-patient phase lb trial of PTX-100 for relapsed and refractory T-cell lymphomas, continuing to show "excellent safety and promising efficacy". In March, Prescient said an interim analysis of 12 patients in the dose escalation trial showed PTX-100 had "positive response rates with two new complete responses" and "an excellent safety profile at the highest dose of 2,000mg/m²" (BD: Mar 16, 2023). Today, the company said the trial had recruited 11 peripheral T-cell lymphoma, eight cutaneous T-cell lymphoma and six non-T cell lymphoma patients, including three pancreatic cancer, two colorectal cancer and one myeloma cancer patients.

Prescient said PTX-100 was well tolerated at all three doses, with no serious adverse events related to the treatment, and PTX-100 had exhibited "an excellent safety profile, especially in light of the fragile patient population and the relatively high toxicities of many incumbent therapies for [relapsed and refractory T-cell lymphomas]".

Prescient said no efficacy was observed in the six non-T-cell lymphoma patients. The company said the trial resulted in two patients with complete eradication of disease, four with overall response and clinical benefit for six of nine patients.

Prescient said it was planning a phase II study for "mid-2024".

Prescient managing-director Steven Yatomi-Clarke said the data "surpassed our expectations, from both safety and early efficacy perspectives".

Prescient fell 1.9 cents or 21.1 percent to 7.1 cents with 8.4 million shares traded.

AROVELLA THERAPEUTICS

Arovella says its chimeric antigen receptor invariant natural-killer T cells (CAR-iNKT) show "substantially improved anti-tumor activity" for multiple myeloma, in mice.

Arovella said the study used its CAR-iNKT cells targeting B-cell maturation antigen to eliminate multiple myeloma and described the optimization of the chimeric antigen receptor construct.

The company said the research found that the cluster of differentiation 28 (CD28) costimulatory domain incorporated into its ALA-101 product was more effective than other co-stimulatory domains, and led to improved anti-tumor activity.

Arovella said the study highlighted "the potential of its iNKT cell platform and demonstrates its broad applicability across multiple tumor types by incorporating different [chimeric antigen receptors]".

Arovella said the data reflected "the benefit of the CD28 co-stimulatory domain and its superiority over other co-stimulatory domains when used individually or in combination". The company said the research was presented at the American Society for Hematology conference in San Diego, California from December 9-to-12, 2023, with a video available at https://www.arovella.com/investor-presentations.

Arovella managing-director Dr Michael Baker said it was "excellent to see the additional data using the CAR-iNKT cell platform".

"We firmly believe in the platform's potential, and this data highlights there are avenues to expand the use of the platform in multiple tumor types," Dr Baker said.

"To have this accepted and presented at [the American Society for Hematology] is a testament to the exciting research that continues at Imperial College London and the promise of the iNKT cell platform," Dr Baker said.

Arovella was up 0.3 cents or 3.4 percent to 9.1 cents.

MEDLAB CLINICAL

Medlab says despite marketing by its financial consultants Hall Chadwick, there has not been "any significant amount of interest" in its asset sale process.

In March, Medlab said it had retrenched 78 percent of staff and Hall Chadwick had been appointed to assist a "restructure of the company's financial affairs", and later that month said it would either sell its intellectual property and pharmaceutical inventory, merge, court a major investor, start a joint venture or sell its shell (BD: Mar 7, 16, 21, 2023).

In September, Medlab said that it had received "several" indicative bids regarding its proposed restructure and would consider the offers; and last month said its executive director Dr Sean Hall would buy the Medlab Pty Ltd subsidiary and intellectual property, and licence its products to T2 Pharma Pty Ltd, as well as raise capital and make board changes (BD: Sep 13, Nov 10, 2023).

Today, the company said it had receipts from customers for the three months to September 30, 2023 of \$173,000, with a zero cash burn and cash of \$1,135,000. Medlab said it had 1.25 quarters cash, and it was expecting net operating cash flows to reduce as remaining staff terminations and significant creditors had been made.

The company said it was not raising further cash to fund existing care and maintenance operations, and any future re-purposed corporate shell transaction would include a capital raise that had not been determined.

Medlab said it had discontinued its normal operations and was currently in the process of a restructure through either the sale of its intellectual property or the transfer of its corporate ASX vehicle to be used by another entity to re-list on the ASX.

Medlab was in a suspension and last traded at a post-consolidation \$6.60.

<u>RHINOMED</u>

Rhinomed says, it hopes to raise up-to \$1.25 million in a share plan for its delisting from the ASX and offer an unmarketable parcel facility.

Rhinomed said an extraordinary general meeting would vote to delist from the ASX and become a public unlisted company.

The company said delisting was in investors' best interests because the register was "insufficient to maintain an orderly and liquid market for trading", raising capital was highly dilutive and delisting would reduce costs and reduce time spent on ASX matters.

The company said it would hold an unmarketable parcel facility for holdings worth less than \$500, based on the closing price of four cents on the December 8, 2023 record date. Rhinomed said the buy-back was separate to its proposal to delist and the facility would proceed regardless of whether delisting occurred; and the buy-back would reduce costs and allow shareholders to dispose of their shares without incurring brokerage.

Rhinomed said the funds raised would be used to pay for the buy-back, pay debts and provide general working capital.

Rhinomed said the share plan had a record date of December 8, would open on December 18, 2023 and close on January 26, 2024.

The extraordinary general meeting will be held at HWL Ebsworth, Level 8, 447 Collins Street, Melbourne, on January 16, 2024 at 9am (AEDT).

Rhinomed fell 1.2 cents or 30.0 percent to 2.8 cents with 1.8 million shares traded.

<u>COMPUMEDICS</u>

Compumedics has requested a trading halt in relation to "correspondence received from its China-based distributor ... in relation to additional MEG orders".

Trading will resume December 12, 2023, or on an earlier announcement. Compumedics last traded at 24 cents.

PHARMAUST

Pharmaust has requested a trading halt "pending an announcement of a capital raising". Trading will resume December 13, 2023, or on an earlier announcement. Pharmaust last traded at 10.5 cents.

AUSBIOTECH

Ausbiotech says it has appointed Prof John Skerritt and Dr Liz Dallimore as non-executive directors, and Dr Megan Baldwin had been reappointed for her third term.

Ausbiotech said Prof Skerritt had been Deputy Secretary of the Australian Department of Health and Aged Care and had led the Therapeutic Goods Administration for 10 years. The industry organization said Dr Dallimore was currently managing-director of Argenica and a co-founder and chair of Inspiring Holdings.

Ausbiotech said its current board comprised Dr James Campbell, Erica Kneipp, Dr Megan Baldwin, Dr Dean Moss, Dr Iris Depaz, Dr Marthe D'Ombrain, Prof John Skerritt, Dr Liz Dallimore and Lorraine Chiroiu.

Last month, Ausbiotech said it appointed Dr Iris Depaz as a director (BD: Nov 3, 2023).

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