

# Biotech Daily

Monday April 29, 2024

## Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: MESOBLAST UP 17%; SYNTARA DOWN 12%
- \* BIO-MELBOURNE WOMEN IN LEADERSHIP AWARDS
- \* SOMNOMED 9-MONTH RECEIPTS UP 9% TO \$66m
- \* MEDICAL DEVELOPMENTS \$26m 9-MONTH RECEIPTS
- \* MICRO-X 9-MONTH RECEIPTS UP 162% TO \$6m; LESS THAN 1Q CASH
- \* ECS 9-MONTH MARIJUANA RECEIPTS UP 39% TO \$15m
- \* ADALTA TO RAISE UP-TO \$3.7m; EXTENDS RDTI LOAN; 1Q CASH
- \* LBT SIGNS \$700k APAS PHARMAQC CONTRACT
- \* RESPIRI \$472k/YEAR US PATIENT MONITORING CONTRACT
- \* CLINUVEL WINS EURO SCENESSE XP ORPHAN DRUG STATUS
- \* ARGENICA: PHASE II ARG-007 STROKE TRIAL CONTINUES
- \* PYC VP-001 FOR RP11 MULTIPLE ASCENDING DOSE STUDY
- \* ALTERITY: ATH434 'MAY SLOW NEURO-DEGENERATIVE DISEASE'
- \* BOD DOCA FOR BIORTICA AGRIMED BACKDOOR LISTING
- \* ANTERIS 300k M-D, 175k DIRECTOR OPTIONS AGM
- \* CARDIEX: 2m DIRECTOR OPTIONS EGM
- \* EXOPHARM (TRYP) COMPLETES 2.5-TO-ONE CONSOLIDATION
- \* ANATARA REQUESTS 'CAPITAL RAISING' TRADING HALT
- \* HERAMED 2nd 'FINANCING, BOARD' SUSPENSION EXTENSION
- \* REGAL TAKES 7.8% OF CYCLOPHARM
- \* PLATINUM REDUCES TO 11% OF PERCHERON
- \* VITURA DIRECTOR GUY HEADLEY REDUCES TO 18%

## MARKET REPORT

The Australian stock market climbed 0.81 percent on Monday April 29, 2024, with the ASX200 up 61.5 points to 7,637.4 points.

Twenty-three of the Biotech Daily Top 40 stocks were up, eight fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Mesoblast was the best, up 15.5 cents or 16.7 percent to \$1.085, with 20.7 million shares traded.

Actinogen, Dimerix, Immutep and Nanosonics climbed six percent or more; Clinuvel and Percheron were up more than five percent; Telix was up four percent; Atomo, Avita, Impedimed, Imugene, Neuren, Polynovo, Resmed and Universal Biosensors improved more than three percent; Genetic Signatures, Opthea and Pro Medicus rose more than two percent; 4D Medical, Clarity, Cochlear, Micro-X and Orthocell were up one percent or more, with CSL and Cyclopharm up by less than one percent.

Syntara led the falls, down 0.2 cents or 11.8 percent to 1.5 cents, with 1.9 million shares traded.

Next Science lost 8.8 percent; Amplia was down 6.15 percent; Paradigm fell 5.6 percent; Resonance was down 4.7 percent; Emvision shed 2.3 percent; with Medical Developments and Proteomics down by more than one percent.

#### **BIO-MELBOURNE NETWORK**

Bio-Melbourne says Prof Michelle McIntosh, Prof Mimi Tang and Dr Amanda Vrselja have won the 2024 Women in Leadership Awards for women innovators in biotechnology. The Bio-Melbourne Network said the awards were presented, today, at an event sponsored by the Victoria Government.

The Network said that Prof McIntosh won the 'Inspiring Leadership Award' for her work as the director, of Monash University's Institute of Pharmaceutical Sciences Medicines Manufacturing Innovation Centre.

Bio-Melbourne said that Prof Tang was awarded the 'Distinguished Leadership Award' as the Murdoch Children's Research Institute's director of allergy translation and the group leader of allergy immunology, as well as the scientific founder and chief executive officer of Prota Therapeutics and the founder and director of Allergypal.

The Network said that Dr Amanda Vrselja was the program head of Brandon Capital's Cureator and won the 'Emerging Leadership Award'.

Bio-Melbourne Network deputy chair Dr Elane Zelcer said that 2024 was "10th anniversary of our Women in Leadership Awards, a significant milestone for Bio-Melbourne Network and the Victorian health [technologies] industry,"

"All our award recipients are innovators in their fields and are transforming our sector in research translation, commercialization and development of new pharmaceuticals, and venture capital," Dr Zelcer said.

"Their achievements are outstanding and highlight the importance and value of knowledge, collaboration and hard work, which have contributed to their successes," Dr Zelcer said.

## SOMNOMED

Somnomed says receipts from customers for the nine months to March 31, 2024 were up 9.0 percent to \$66,078,000, compared to the previous corresponding period.

Somnomed said receipts were from sales of its devices for obstructive sleep apnoea and other sleep-related breathing devices.

The company said it had a cash burn of \$2,146,000 for the three months, with cash and equivalents of \$9,107,000 at March 31, 2024 compared to \$14,649,000 the prior year. Somnomed was up half a cent or 2.4 percent to 21.5 cents.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says receipts from customers from its Penthrox and other pain relief and respiratory products for the nine months to March 31, 2024 were \$26,440,000. Medical Developments has not previously reported quarterly results.

Medical Developments chief executive officer Brent MacGregor told Biotech Daily that the company had been required by the ASX to file quarterly reports under "Listing Rule 4.7B regarding our cash position".

Today, the company said it had a cash burn of \$3,946,000 for the three months, with cash and cash equivalents of \$10,722,000, providing 2.72 quarters of cash.

Medical Developments fell one cent or 1.85 percent to 53 cents.

## MICRO-X

Micro-X says receipts from customers for the nine months to March 31, 2024 were up 162.0 percent to \$5,710,000, compared to the previous corresponding period. Micro-X said receipts were from sales and contracts of its mobile digital radiology devices including the Rover plus and Rover x-ray system for hospital and military applications. The company said it had a cash burn of \$2,837,000 for the three months, with cash and cash equivalents of \$2,228,000 at March 31, 2024 compared to \$8,568,000 at March 31, 2023, leaving it with about 0.79 quarters of cash.

Micro-X said it expected positive cash flows for the three months to June 30, 2024 to increase by \$900,000, had reduced operating costs by about \$700,000, expected to receive about \$4 million from a Federal Research and Development Tax Incentive and had an ongoing share purchase plan to raise \$1 million.

Micro-X was up 0.1 cents or 1.1 percent to 9.3 cents.

#### ECS BOTANICS HOLDINGS

ECS says receipts from customers for the nine months to March 31, 2024 were up 38.6 percent to \$14,936,000, compared to the previous corresponding period.

ECS said receipts from sales of its white-label tetrahydro-cannabidiol (THC) marijuana products and its raw medical marijuana harvest increased due to a "strong growing season, [which was] on track for record annual production".

The company said it had a cash burn of \$998,000 for the three months, with cash and equivalents of \$4,716,000 at March 31, 2024 compared to \$2,114,000 at March 31, 2023. ECS fell 0.1 cents or 4.55 percent to 2.1 cents with 8.7 million shares traded.

#### **ADALTA**

Adalta says it will raise up-to \$3.7 million in a facility and placement and has extended its Victoria Government loan against its Federal Research and Development Tax Incentive. Adalta said it hoped to raise up-to \$3,000,000 in a draw-down equity facility with New York's Bergen-managed New Life Sciences Capital LLC and up-to \$700,000 from existing shareholder the Meurs Group.

The company said the New Life Sciences Capital placement price would be six cents a share initially, a 93.5 percent premium to the last closing price, and that after a month would reset to a 10 percent discount to the average of five daily volume-weighted average prices in the 20 days prior to the issue date, chosen by New Life Sciences Capital. Adalta said the New Life Sciences facility would raise \$800,000 initially and it had the option to raise an additional up-to \$1,400,000 in the next 12 months, with Meurs to invest \$400,000 initially with an option to place an additional \$300,000 in the next month. The company said the funds would be used to further its agreement with Synthesis Bioventures and progress its I-body programs (BD: Apr 8, 2024). Separately, Adalta said it had extended final repayment of its research and development tax incentive loan with the Treasury Corporation of Victoria from April 30 to October 31, 2024, with loan interest rate unchanged and expected to be repaid when it received its Federal Research and Development Tax Incentive for the year to June 30, 2024. In its Appendix 4C, Adalta said it had 1.0 quarters cash at March 31, 2024. Adalta fell 0.4 cents or 12.9 percent to 2.7 cents with 3.3 million shares traded.

## LBT INNOVATIONS

LBT says it has a five-year, \$700,000 contract with Perth contract development and manufacturing organization Novacina for its Apas Pharmaqc software.

LBT said Novacina had a 34,000 sq metre facility for the development and manufacture of aseptic and terminally sterilised injectables, and it would use its automated plate assessment system (Apas) Pharmaqc for microbiology culture analysis for five years. The company said total cash proceeds from the contract would be about \$700,000 for the five-years and that delivery and installation were expected to be completed by June 2024. LBT managing-director Brent Barnes said "the sale to Novacina reflects the ongoing positive momentum and interest we have received from customers in the biopharmaceutical market".

LBT was up 0.1 cents or five percent to 2.1 cents with 7.5 million shares traded.

## **RESPIRI**

Respiri says the Hawaii Independent Physicians Association will use its patient management software, with expected yearly revenue about \$US310,000 (\$A472,230). Respiri said the three-year contract included full medical evaluation and patient management services and Medicare and Medicaid reimbursement services. The company said Honolulu's Hawaii Independent Physicians Association managed 41,000 patients and it expected about US\$310,000 a year under the initial contract in annualized reimbursement revenues and would use the three years of data to co-design a "unique patient profiling algorithm" with the Association.

Respiri chief executive officer Marjan Mikel said the Association was "a particularly progressive organization that is driven by patient and physician empowerment and they see their partnership with us as a clear way of supporting this". Respiri was up 0.1 cents or 2.9 percent to 3.5 cents.

#### CLINUVEL PHARMACEUTICALS

Clinuvel says it has received European Medicines Agency (EMA) orphan drug designation for Scenesse, or afamelanotide 16mg, for xeroderma pigmentosum (XP).

Clinuvel said the designation acknowledge the drug's "potential to treat or prevent ultraviolet skin damage and enhance DNA repair in the genetic disorder [xeroderma pigmentosum]".

The company said it had submitted clinical data from its ongoing DNA repair program to support the submission, and it was the first time a regulator had reviewed the data. Clinuvel said the designation entitled it to receive incentives throughout the development of Scenesse and, following authorization, included reduced fees for regulatory activities and 10 years of market exclusivity post-approval.

The company said since Scenesse was already an approved medication, marketing authorization for an additional indication would be added as a label extension, rather than a completely separate authorization application process.

Clinuvel head of regulatory affairs Dr Rose Quadbeck-Diel said the status gave the company further interaction on final study design and expansion of the marketing label. "The EMA have now conducted their first review of evidence acknowledging that afamelanotide reduced photodamage provoked by ultraviolet radiation and activated relevant cellular DNA repair mechanisms [in patients with xeroderma pigmentosum]," Dr Quadbeck-Diel said. "The next step in 2024 is to analyse an additional set of clinical data before seeking an important meeting with the EMA to secure a path to market." Clinuvel was up 75 cents or 5.15 percent to \$15.32 with 82,951 shares traded.

## ARGENICA THERAPEUTICS

Argenica says following a five-patient safety data review it has approval to continue its up-to 92-patient phase II study of ARG-007 for acute ischaemic stroke.

Earlier this month, Argenica said that it had dosed the first cohort in the study of ARG-007 for acute ischaemic stroke, with no adverse events reported (BD: Apr 10, 2024).

Today, the company said the data safety monitoring board had reviewed the five patients and recommended the study continue with no modifications to the protocol.

Argenica said that patient safety reviews were scheduled for at least every six months, subject to recruitment rates, with meetings to be held post-dosing of 23 patients, 46 patients, 69 patients, and at the completion dosing all 92 patients.

Argenica fell 1.5 cents or 2.65 percent to 55 cents.

## **PYC THERAPEUTICS**

PYC says it will conduct an up-to 12-patient, multiple ascending dose study of VP-001 for retinitis pigmentosa type 11 (RP11), expected to begin by May 2024.

PYC said the study followed a safety review of the first three doses of 3 micrograms, 10 micrograms and 30 micrograms studied in its single ascending dose trial of VP-001, with a fourth cohort of three patients expected to receive the final 75 microgram dose by June. The company said a 24-week safety follow-up assessment of the 12 patients from the single ascending dose study would assess any treatment-emergent adverse events. PYC said it could begin the multiple ascending dose study having confirmed the dose at

which patients were expected to derive a benefit from VP-001.

The company said the two studies were expected to complete in "early 2025", and it

hoped to conduct a trial in 2025 for an initial new drug application, expected by 2027. PYC was unchanged at 9.2 cents with 2.2 million shares traded.

#### **ALTERITY THERAPEUTICS**

Alterity says a laboratory study shows its ATH434 has the potential to "reduce labile iron levels and thus slow disease progression" for Friedreich's ataxia.

Alterity said the study evaluated ATH434's ability to target ferrous, or labile, iron, which promoted oxidative stress in diseases like Friedreich's ataxia, as well as Parkinson's disease and multiple system atrophy.

The company said the study evaluated traditional iron chelators that were designed to bind iron and remove iron from the body, and iron chaperons which were designed to bind and redistribute iron within the body.

Alterity said that ATH434 bound to ferric, or stored, iron and labile iron and acted as an iron chaperon by selectively targeting labile iron and redistributing it within the body. The company said the data showed ATH434 had a "dramatically lower affinity for ferric iron than traditional iron chelators that are approved for treating system iron overload". Alterity said the study by Detroit, Michigan's Wayne State University was presented in a poster, titled 'Biophysical Characteristics of ATH434, a Unique Iron-Targeting Drug for Treating Friedreich's Ataxia' at the World Orphan Drug Congress in Boston, Massachusetts on April 23 to 25, 2024, and was available at: <a href="https://bit.ly/3UDTpNh">https://bit.ly/3UDTpNh</a>. Alterity was unchanged at 0.6 cents with 22.8 million shares traded.

## **BOD SCIENCE**

Bod Science says it has agreed to a backdoor-listing deed of company arrangement with Melbourne's Biortica Agrimed for marijuana cultivation, packaging and distribution. Last year, Bod said it had appointed Andrew Barnden and Brent Morgan of Rodgers Reidy as joint administrators on November 29, 2023 to maximize the outcome for shareholders, with all securities suspended and shareholders unable to transfer their shares during the administration period (BD: Nov 30, 2023).

Today, the company said Biortica would invest \$380,000 into a deed fund for Bod Science to acquire the issued capital of Biortica in exchange for the shares of Bod Science to be issued to the shareholders and noteholders of Biortica.

Bod said Mr Barnden had been appointed administrator to the deed of company arrangement and that it would remain suspended throughout the administration process. Separately, Bod said its Appendix 4D and half-yearly report for the six months to December 31, 2023 had been delayed and were expected to be filed by May 24, 2024. Bod was in a suspension and last traded at 2.4 cents.

## **ANTERIS TECHNOLOGIES**

Anteris says its annual general meeting will vote to issue 300,000 options to managing director Wayne Paterson and 175,000 options to its chair and directors.

Anteris said the meeting would vote to issue Mr Paterson 300,000 options, chair John Seaberg 75,000 options and directors Stephen Denaro and Dr Wenyi Gu 50,000 options, each, exercisable at \$23.00 each within five years from the grant date.

The company said the options were in addition to Mr Paterson's \$5,325,650, Mr Seaberg's \$962,840, Mr Denaro's \$529,929 and Dr Gu's \$400,874 yearly remunerations.

Anteris said investors would vote on the prior issue of 2,664,150 shares, to elect Dr Gu as a director, approve the 10 percent placement facility and adopt the remuneration report. The meeting will be held online and in-person at the Sheraton Grand, Hyde Park, 161 Elizabeth Street, Sydney on May 29, 2024 at 10am (AEST).

Anteris fell 74 cents or 3.25 percent to \$22.01.

## **CARDIEX**

Cardiex says its extraordinary general meeting will vote to issue 1,000,000 options each to non-executive directors Randall Nelson and Charles Taylor.

Cardiex said Mr Nelson and Mr Taylor's 1,000,000 options would be exercisable at 20 cents each by November 30, 2025, and would be in addition to their \$US40,000 (\$A61,000) and \$60,000 a year salaries, respectively.

The company said shareholders would vote to approve the issue of up-to 75,000,000 shares and 25,000,000 options to chair Niall Cairns and chief executive officer Craig Cooper's C2 Ventures Pty Ltd under a conversion agreement.

Earlier this year, Cardiex said it had been reinstated on the ASX, following an \$8 million capital raising and \$6 million in funding from C2 Ventures (BD: Feb 26, 2024).

The meeting will be held online and in-person at 24-26 Kent Street, Millers Point, Sydney on June 3, 2024 at 9.30am (AEST).

Cardiex was unchanged at 5.9 cents.

## **EXOPHARM**

Exopharm says its 2.5-to-one consolidation and merger with Tryp Therapeutics was due to be completed today, and it will be renamed to Tryptamine Therapeutics.

Earlier this year, Exopharm said investors approved its merger with Tryp Therapeutics for its intra-venous psilocybin, change its name to Tryptamine Therapeutics and hold a 2.5-to-one consolidation (BD: Mar 8, 13, Apr 11, 2024).

Exopharm was in a suspension and last traded at a post-consolidation 2.75 cents.

## ANATARA LIFESCIENCES

Anatara has requested a trading halt pending "an announcement to the market in relation to a proposed capital raising".

Trading will resume on May 1, 2024, or on an earlier announcement.

Anatara last traded at 4.8 cents a share.

## **HERAMED**

Heramed says it has extended its voluntary suspension for a second time until it releases "an announcement in relation to a proposed financing and board changes".

Earlier this month, Heramed requested a suspension following a trading halt regarding "board changes, business restructure and the rights issue shortfall" and later said it had "experienced challenges" placing a \$1,060,344 rights off shortfall and had to consider immediate "alternative financing options" (BD: Apr 3, Apr 5, Apr 8, 2024).

Heramed said it expected trading to resume on May 9, 2024, or on an earlier announcement.

Heramed last traded at 1.7 cents.

## **CYCLOPHARM**

Regal Funds Management Pty Ltd says it has become a substantial shareholder in Cyclopharm with 7,376,061 shares, or 7.83 percent.

The Sydney-based Regal Funds said that on February 29 and April 23, 2024 it bought 5,762,253 shares for \$9,729,577, or \$1.688 a share.

Cyclopharm was up one cent or 0.6 percent to \$1.76.

## PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Platinum Investment Management says it has reduced its substantial shareholding in Percheron from 110,755,158 shares (12.29%) to 96,266,694 shares (10.68%).

The Sydney-based Platinum said that between October 17, 2023 and April 24, 2024 it sold shares in more than 35 transactions, with the single largest sale 7,221,392 shares on April 24, 2024 for \$395,139, or 5.5 cents a share.

Percheron was up 0.4 cents or 5.9 percent to 7.2 cents with 1.45 million shares traded.

## VITURA HEALTH

Vitura director Guy Headley says he has reduced his substantial shareholding in the company from 112,202,151 shares (20.16%) to 103,702,151 shares (18.01%). The Gold Coast-based Mr Headley said that with Jessimine Jansen he had received 1,500,000 shares on August 25, 2023 through the exercise of options at 27 cents each and on April 23, 2024 sold 10,000,000 shares at 11 cents a share. Vitura was unchanged at 11.5 cents.