

Biotech Daily

Thursday October 17, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: PARADIGM UP 29%; ORTHOCELL DOWN 7%
- * COMPUMEDICS: Q1 SALES UP 136%
- * LITTLE GREEN H1 RECEIPTS UP 41% TO \$19m
- * CONTROL BIONICS RIGHTS RAISE \$1.5m; TOTAL \$2.7m
- * ENLITIC COMPLETES \$7.3m LAITEK ACQUISITION
- * NEUREN: CANADA OKAYS DAYBUE (TROFINETIDE) FOR RETT SYNDROME
- * IMRICOR: 'NORTHSTAR 3-D MAPPING WORKS WITH PHILIPS MRI'
- * OSTEOPORE, CYTOMED FOR STEM CELLS IN SCAFFOLDS
- * IMMUTEP 'READY FOR PART B OF PHASE I IMP761 STUDY'
- * VITURA PAYS \$2.5m, 6m SHARES TO CODE4 CANNABIS FOR CANVIEW
- * MESOBLAST 9.3m M-D, CMO, DIRECTOR OPTIONS AGM
- * ANTERIS RECEIVES \$1.4m FEDERAL R&D TAX INCENTIVE
- * GENETIC TECHNOLOGIES REQUESTS 'OPERATION REVIEW' TRADING HALT
- * INVION 100-1 CONSOLIDATION DATES
- * NIGHTINGALE INCREASES, DILUTED TO 13.5% OF CONTROL BIONICS
- * CHIMERIC CHAIR PAUL HOPPER INCREASES, DILUTED TO 10.5%
- * WASHINGTON H SOUL PATTINSON TAKES 7.7% OF ENLITIC
- * BRICKWORKS TAKES 7.7% OF ENLITIC
- * MTP CONNECT PARTNERS WITH MINNEAPOLIS' MEDICAL ALLEY

MARKET REPORT

The Australian stock market was up 0.86 percent on Thursday October 17, 2024, with the ASX200 up 71.2 points to 8,355.9 points. Twenty of the Biotech Daily Top 40 companies were up, 13 fell, six traded unchanged and one was untraded.

Paradigm was the best on no news, up six cents or 29.3 percent to 26.5 cents, with 4.3 million shares traded. Syntara climbed 9.3 percent; Cynata was up 8.7 percent; Mesoblast improved 7.6 percent; 4D Medical and Amplia climbed more than six percent; Micro-X and Proteomics were up more than five percent; Atomo, Avita and Compumedics were up more than four percent; Neuren was up 3.2 percent; Aroa and Pro Medicus rose two percent or more; Dimerix, Emvision, Genetic Signatures and Nanosonics were up one percent or more; with Clarity, CSL and Opthea up by less than one percent.

Orthocell led the falls, down five cents or seven percent to 66 cents, with 1.2 million shares traded. Actinogen, Curvebeam and Resonance lost more than three percent; Cyclopharm, Nova Eye, Prescient and Starpharma shed more than two percent; Cochlear, Medadvisor, SDI and Telix were down one percent or more; with Clinuvel, Polynovo and Resmed down by less than one percent.

COMPUMEDICS

Compumedics says US sales were up 136 percent for the three months to September 30, 2024, and it reaffirms full year sales of more than \$55 million.

Earlier this year, Compumedics said revenue for the year to June 30, 2024 was up 17.2 percent to \$49,719,000, with net loss after tax down 91.8 percent to \$499,000; and later, said it expected revenue for the year to June 30, 2025 to be up about 10.7 percent to more than \$55 million. (BD: Aug 30, Sep 6, 2024).

Today, the company said sales of its Somfit device for sleep apnoea in the US were about \$US600,000 (\$A1,000,000) compared to no sales in the prior period.

Compumedics said it had taken "another significant order in Europe ... for a significant customer in Poland and was won against all major competitors", with the contract worth about \$US500,000 (\$A800,000).

Compumedics said the sale continued to build its "business base in Europe with Compumedics having a strong presence in France and Germany from its offices there and from which to build business further throughout Europe".

Compumedics was up 1.5 cents or 4.9 percent to 32 cents.

LITTLE GREEN PHARMA

Little Green says receipts from customers for the six months to September 30, 2024 were up 40.65 percent to \$18,963,000, compared to the previous corresponding period. Little Green said receipts were from sales of its medical marijuana products, with "German, UK and French cannabis markets driving strong growth in European industry demand".

The company said it continued "to outperform the majority of its competitors ... [with] seven of [its] original 20 cannabis peers from 2022 currently delisted or suspended from ASX [and] ... of [the] remaining group Little Green Pharma [was] one of only two companies with positive operating cashflow, and of these the only one with growth". Little Green Pharma said it had a positive cash flow of \$1,038,000 for the three months to September 30, 2024, with cash and cash equivalents of \$4,832,000.

Little Green was up 2.7 cents or 30.7 percent to 11.5 cents with 1.6 million shares traded.

CONTROL BIONICS

Control Bionics says it has raised \$1.53 million in its one-for-seven rights issue at seven cents a share, taking the total to \$2.68 million and leaving a shortfall of \$560,000. Last month, Control Bionics said it hoped to raise \$2,092,868 through a one-for-seven rights issue at 7.0 cents a share, and \$1 million in a placement (BD: Sep 20, 2024). Later, the company said it had raised \$1,150,000 in a placement (BD: Sep 23, 2024). Today, Control Bionics said the entitlement offer raised \$695,000 from shareholders, with \$833,000 subscribed for by the underwriters; and the shortfall could be placed by the directors over the next three months.

Control Bionics was unchanged at 6.9 cents.

<u>ENLITIC</u>

Enlitic says it has completed its \$US4.95 million (\$A7.3 million) acquisition of the US medical imaging data migration company Laitek Inc (BD: Aug 29, 2024). Enlitic fell 0.1 cents or 1.4 percent to 7.2 cents with three million shares traded.

NEUREN PHARMACEUTICALS

Neuren says Health Canada has approved Acadia Pharmaceuticals' Daybue, previously trofinetide, for Rett syndrome in patients above the age of two years.

Neuren said the approval made Daybue the "first and only drug" approved in Canada for the treatment of Rett syndrome.

Last year, Neuren said that North America partner Acadia had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome in adults and children two years of age and older (BD: Mar 13, 2023).

In April, the company said Health Canada had granted its submission to market trofinetide for Rett syndrome "priority review", and that the acceptance was supported by its phase III study of the drug, marketed in the US by Acadia as Daybue, in 187 Rett syndrome patients (BD: Apr 23, 2024).

At the time, Neuren said Acadia estimated there were between 600 to 900 Rett syndrome patients in Canada.

The company said Acadia had exclusive rights to develop and commercialize trofinetide in North America, which included Canada, with the development and commercialization of trofinetide in Canada to be fully-funded by Acadia and sales would be combined with US sales to determine Neuren's entitlement to milestone payments and royalties.

Neuren managing-director Jon Pilcher said the company was "excited to see this first approval outside the US, which is a significant milestone in the ongoing program to expand access to Daybue".

Neuren was up 41 cents or 3.2 percent to \$13.11 with 764,483 shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has achieved all technical goals necessary for its consortium with Philips Medical Systems and others for its Northstar three-dimensional mapping system. Earlier this year, Imricor said Amsterdam University had begun using its Northstar threedimensional mapping system for cardiac ablation imaging using magnetic resonance imaging (MRI) after a delay due to the Covid-19 pandemic (BD: Apr 5, 2024).

Today, the company said that via the 'Sensing and Image-Guided Neurological therapies, cardiac Electrophysiology and Tumour treatments' or Signet consortium, it was collaborating with the Eindhoven, Netherlands-based Philips to develop the software necessary to operate its Northstar with Philips' MRI platforms.

Imricor said it had conducted "extensive testing" at Amsterdam University Medical Centre on October 10, 2024 with "all technical goals ... achieved" and it was working on commercialization efforts for Northstar on the Philips platform.

Imricor executive chair Steve Wedan said the company expected "Northstar to be commercially available next year for use with the Siemens MRI platform".

"Upon the completion of this Signet milestone, we now have a clear path to commercialization on the Philips MRI platform as well," Mr Wedan said.

"In addition, we continue to make progress with [General Electric] Healthcare to deliver Northstar on the [General Electric] MRI platform, and we hope to report on that effort soon," Mr Wedan said.

"Northstar is highly significant for Imricor in many ways," Mr Wedan said.

"Not only does it enhance procedures for doctors, it also provides ongoing licensing revenue to the business which builds on the consumable device revenue we generate with each procedure," Mr Wedan said.

Imricor was up 13 cents or 21.3 percent to 74 cents.

OSTEOPORE

Osteopore says it will combine its bioresorbable scaffolds with Singapore's Cytomed Therapeutics' allogeneic, umbilical cord-derived mesenchymal stem cells. Osteopore said its 18-month collaboration with Cytomed, which specialized in off-theshelf, cancer therapeutics and regenerative medicine, would lead to the design of scaffoldbased cellular products for clinical trials and potential commercialization.

The company said it would set up a technology advisory committee, with one nominee from both it and Cytomed, to assess co-development and resource utilization

opportunities, and might later seek third-party funding to support the project.

Osteopore did not disclose the commercial terms of the agreement.

The company said chair Mark Leong was a Cytomed independent, non-executive director. Osteopore was up 0.1 cents or 2.6 percent to 3.9 cents.

IMMUTEP

Immutep says it has dosed all five volunteers in the single dose, part A portion of its 49participant, phase I study of IMP761, with no safety issues.

In July, Immutep said the Leiden, Netherlands' Centre for Human Drug Research would conduct a 49-participant, phase I trial assessing the safety, pharmaco-kinetics and pharmaco-dynamics of its IMP761 LAG-3 agonist antibody for autoimmune disease; and later, said it had dosed the first healthy volunteer (BD: Jul 17, Aug 14, 2024).

Today, the company said the trial would progress to the part B dose escalation phase, with single IMP761 dosing planned to move from 0.03mg/kg up-to 0.90mg/kg.

Immutep said both safety and pharmaco-kinetic and, or pharmaco-dynamic modelling would be assessed in the 30-participant, second cohort of healthy volunteers.

The company said that subject to no safety issues in the second group, the trial would then continue to a multiple ascending dose cohort of 14 volunteers, in which pharmacokinetics would be further evaluated.

Immutep said it expected the first safety data from the trial by the end of 2024, with pharmaco-kinetic and pharmaco-dynamic assessments to follow by July 2025. Immutep was unchanged at 30.5 cents with 5.5 million shares traded.

VITURA HEALTH

Vitura says it will pay Code4 Cannabis \$2.5 million and 5,787,037 shares, worth about \$500,000, for a copy of the Canview platform and will withdraw all legal proceedings. Last year, Vitura said it would not extend its software licence with the Brisbane-based Code4 Cannabis Pty Ltd, used for its Canview online marijuana marketplace platform, beyond August 10, 2024, due to "issues with their … conduct" (BD: Jan 21, 2024). In April, the company said it had taken legal action against Code4 following confirmation that Code4 intended to terminate its agreement (BD: Apr 23, 2024).

Later, Vitura said wholly-owned subsidiary Canview Pty Ltd had stopped its software licensor Code4 from terminating the services agreement early (BD: Apr 26, 2024). Today, the company said it would own and operate its own copy of the Canview platform in perpetuity and take direct ownership of managing that copy, in exchange for withdrawing all legal proceedings against Code4.

Vitura said Code4 Cannabis was, for a 90-day period, obligated to provide it with "all support and information necessary to ensure the orderly and timely establishment of the [fully operational] copy of the Canview platform".

Vitura was up 1.5 cents or 16.7 percent to 10.5 cents with 2.9 million shares traded.

MESOBLAST

Mesoblast says investors will vote to issue 9,333,342 options to managing-director Prof Silviu Itescu, chief medical officer Dr Eric Rose and director Dr Philip Krause. Mesoblast said its annual general meeting would vote to issue Prof Itescu 3,108,000 longterm incentive options for the year to June 30, 2025, as well as 1,010,000 options and 1,212,000 options as part of his short-term incentive for the years to June 30, 2023 and June 30, 2024, respectively, and 466,154 options in lieu of 30 percent of his salary. The company said investors would vote to issue Dr Rose 946,000 long-term incentive options for the year to June 30, 2025, as well as 1,829,502 options as part of his shortterm incentive for the two years to June 30, 2024 and 436,686 options in lieu of 30 percent of his annual pay.

Mesoblast said the shareholders would vote to issue Dr Krause 785,000 milestone-based options and 540,000 time-based options as part of his consultancy fees.

The company said Prof Itescu and Dr Rose's long-term incentive options would vest on clinical and regulatory milestones and be exercisable at 97 cents each.

Mesoblast said Prof Itescu and Dr Rose's short-term incentive options would vest if it received US Food and Drug Administration approval of remestemcel-L for graft-versus-host disease, exercisable at one cent each.

The company said Dr Krause's consultancy milestone-based options would be exercisable at 97 cents each, and the time-based options at 32 cents each.

Mesoblast said the options were in addition to Prof Itescu's \$1,010,000 annual pay, Dr Roses \$US615,000 base salary and Dr Krause's undisclosed "monthly cash retainer". The company said the meeting would vote to issue options in lieu of 50 percent of its directors' fees, adopt the remuneration report, re-elect Dr Krause as a director, approve the issue of Dr Rose's placement shares, ratify the prior issue of shares, approve the issue of convertible note shares, and renew the proportional takeover provisions. The meeting will be held at Minter Ellison, Collins Arch, Level 20, 447 Collins Street, Melbourne on November 15, 2024 at 12pm (AEDT).

Mesoblast was up 10.5 cents or 7.6 percent to \$1.48 with 6.65 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has received \$1.4 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program. Anteris said the incentive was for research and development expenditure for the year to December 31, 2023.

Anteris fell two cents or 0.2 percent to \$11.48.

GENETIC TECHNOLOGIES

Genetic Technologies has requested a trading halt pending an announcement on "its strategic options, operational review and progress on its fund raising" (BD: Jul 26, 2024). Trading will resume on October 21, 2024, or on an earlier announcement. Genetic Technologies last traded at 3.9 cents.

INVION

Invion says its 100-to-one consolidation will have a record date of November 21, with the consolidation expected to be finalized by November 28, 2024 (BD: Oct 15, 2024). Invion fell 0.05 cents or 20 percent to 0.2 cents with 5.9 million shares traded.

CONTROL BIONICS

Sydney's Nightingale Partners says it has increased its shareholding in Control Bionics and been diluted from 21,287,595 shares (14.69%) to 33,480,280 shares (13.52%). Nightingale said it acquired 9,285,715 shares for \$650,000, or 7.0 cents a share.

CHIMERIC THERAPEUTICS

Chimeric executive chair Paul Hopper says he has increased but been diluted from 94,137,432 shares (17.8%) to 94,994,574 shares (10.5%). Mr Hopper said that on June 23, 2023 he acquired 875,142 shares in a share purchase plan for 3.5 cents a share and was diluted through "various share issues".

Chimeric was in a suspension and last traded at 1.4 cents.

ENLITIC

Sydney's Washington H Soul Pattinson says it has become a substantial shareholder in Enlitic through its more than 20 percent holding in Pengana Capital Group Ltd. Yesterday, Pengana said it had become substantial in Enlitic (BD: Oct 17, 2024).

ENLITIC

Sydney's Brickworks Ltd says it has become a substantial shareholder in Enlitic through its 25.7 percent holding in Washington H. Soul Pattinson (see above).

MTP CONNECT

MTP Connect says it will partner with the Minneapolis, Minnesota-based medical technology network Medical Alley to support US opportunities for Australian investors. MTP Connect said it signed an agreement with Medical Alley at the 2024 Medtech Conference in Toronto, and committed to "ongoing collaboration to support the growth of medical technology companies".

The industry organization said the collaboration was about "opening-up new US market, commercial and collaboration opportunities for Australian medical technology innovators". MTP Connect said Medical Alley was a network of health organizations and the partnership would facilitate connections between Minnesota and Australia.

MTP Connect chief executive officer Stuart Dignam said Medical Alley was "deeply connected to Minnesota's health industry which our companies were able to see first-hand during our recent visit and we are looking forward to opening further connections between the exciting innovations in our countries".

"Building on an already strong relationship, our two organizations will work together on activities like providing introductions and in-market support, exchanging information on key issues and trends and supporting inbound and outbound missions," Mr Dignam said. "It is fitting that we've signed this agreement at the Medtech Conference in Toronto where we are leading a delegation of 18 Australian companies to showcase their innovations and build valuable pathways into international markets," he said. "Medical Alley's history with Australia dates back to the development of the pacemaker."

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: <u>editor@biotechdaily.com.au;</u> <u>www.biotechdaily.com.au</u>