Biotech Daily

Tuesday April 18, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TELIX UP 13%; EMVISION DOWN 11%**

*** NEUREN TROFINETIDE/DAYBUE US LAUNCH EARNS $60m**

*** PACIFIC EDGE 32k RECORD CXBLADDER TESTS**

*** ORTHOCELL NERVE REPAIR RAT STUDY**

*** DORSAVI $100k ROCHESTER UNI WEARABLE SENSOR RESEARCH DEAL**

*** HYDRIX SIGNS $1.5m 'REVOLVING' LOAN FACILITY**

*** LIVING CELL $690k RIGHTS OFFER SHORTFALL**

*** CORRECTION: TELIX**

*** CORRECTION: AVITA**

*** CLARITY RECEIVES $6.7m FEDERAL R&D TAX INCENTIVE**

*** IMMUTEP TELLS ASX: 'TRIAL DATA WAS CONFIDENTIAL'**

*** EMYRIA, PAX WORK ON PSILOCYBIN 'CARE MODEL'**

*** MEDICAL DEVELOPMENTS LOSES EX-CHAIR DAVID WILLIAMS**

MARKET REPORT

The Australian stock market fell 0.29 percent on Tuesday April 18, 2023, with the ASX200 down 21.3 points to 7,360.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Telix was the best, up $1.00 or 12.7 percent to $8.89, with 4.8 million shares traded. Impedimed improved 10 percent; Kazia, Neuren and Pharmaxis climbed more than five percent; Orthocell and Resonance rose more than four percent; Immutep and Prescient were up more than two percent; with Amplia, Next Science and Starpharma up by more than one percent.

Emvision led the falls, down 18.5 cents or 10.8 percent to $1.525, with 39,285 shares traded. Oncosil lost 9.1 percent; Antisense was down 8.5 percent; Cynata shed 7.5 percent; Nova Eye was down 5.3 percent; Dimerix and Proteomics fell more than four percent; Opthea and Paradigm were down three percent or more; Avita, Clinuvel, Medical Developments and Volpara shed more than two percent; Actinogen, Nanosonics, Pro Medicus and Universal Biosensors were down one percent or more; with Cochlear, CSL, Cyclopharm, Genetic Signatures, Mesoblast, Polynovo and Resmed down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it will receive $US40 million ($A59.6 million) following the first US commercial sale of its trofinetide, or Daybue, for Rett syndrome.

Last month, Neuren said its North American partner, the San Diego-based Acadia Pharmaceuticals had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome for people over the age of two years (BD: Mar 13, 2023).

Today, the company said trofinetide was the first and only drug approved by the FDA for the treatment of Rett syndrome.

Neuren said its Acadia agreement included royalties on net sales of trofinetide in North America and up to $US350 million in payments for four thresholds of annual net sales.

Neuren said it would also receive one third of the market value of the Rare Paediatric Disease Priority Review Voucher awarded to Acadia by the FDA after the approval of the new drug application for trofinetide, which had an estimated value of $US33 million.

The company said that no royalties or costs were payable by it to third parties, meaning the revenue from Acadia would “flow through to pre-tax profit”.

Neuren was up 75 cents or 5.6 percent to $14.20 with 895,851 shares traded.

PACIFIC EDGE

Pacific Edge says it processed 31,566 Cxbladder tests for bladder cancer for the year to March 31, 2023, up 36.7 percent to compared to the prior corresponding period.

Last year, Pacific Edge said revenue from sales of its Cxbladder non-invasive urine tests for bladder cancer for the year to March 31, 2022 was up 48.62 percent to $NZ11,445,000 ($A10,459,000) (BD: May 26, 2022).

Today, the company said that US sales volume was up 44 percent to 27,218 tests, with Asia Pacific sales up three percent to 4,348 tests reflecting the “maturity of the New Zealand market and the regions ongoing healthcare reforms”.

Pacific Edge was untraded at 38 cents.

ORTHOCELL

Orthocell says it has begun a comparator study of its Remplir regenerative nerve wrap using rat sciatic nerve injury models in 72 rats across three study groups.

Last year, Orthocell said the final data from its in-human study of Remplir, a Celgro product, showed 23 of 27 (85.2%), nerve reconstructions resulted in functional recovery of target muscles closest to the reconstruction site (BD: Jun 7, 2022).

Today, the company said the rat study would provide information on mechanism-of-action that would be unobtainable in human trials, with outcomes supporting product marketing and international regulatory approval and reimbursement strategies for its Remplir device.

Orthocell said the study at Sydney’s Prince of Wales Hospital would be conducted by Prof Bill Walsh, with completion expected by April 2024.

Orthocell managing director Paul Anderson said he was confident the study would confirm Remplir’s clinical performance to date and validate that it was “easier to use, reduces the need for sutures and results in more consistent and predictable return of muscle function”.

“This study is an important next step in our international market access program with the potential to provide data demonstrating the impact and advantages of using Remplir over traditional nerve repair methods,” Mr Anderson said.

Mr Anderson told Biotech Daily that with Remplir already approved in Australia, the company was developing further data, primarily for US regulators.

Orthocell was up two cents or 4.8 percent to 44 cents.

DORSAVI

Dorsavi says it has a $100,000, one-year sponsored research support agreement with the New York State-based University of Rochester Medical Centre.

Dorsavi said the agreement would generate about $100,000 in sponsored research support over an initial 12-month period with the potential to extend the project for up to five years.

The company said that the University of Rochester Medical Centre would use its wearable sensor technology with the university's motion laboratory to study spinal motion and patterns of movement and would be led by the Medical Centre director Prof Ram Haddas.

Dorsavi said the study would investigate the capacities of its technology "which the company believes will confirm its position as a leading provider of wearable sensor devices".

Dorsavi chief executive officer Dr Andrew Ronchi said the University of Rochester was a "well-respected and widely regarded institution" and Prof Haddas was "one of the leading experts in the spinal motion industry and whose research is at the forefront of the sector".

"I am excited that our technology will help generate new insights to patterns of movement and potentially improve outcomes for patients with spinal conditions," Dr Ronchi said.

Dorsavi fell 0.1 cents or 7.1 percent to 1.3 cents.

HYDRIX

Hydrix says it has a $1.5 million "revolving loan facility agreement" with Tradeplus 24 Australia Pty Ltd, at an initial interest rate of 10.7834 percent a year.

Hydrix said that trade debtors, or unpaid receipts from customers, were $1.54 million on December 31, 2022, and that its revolving loan facility had a borrowing base percentage of 70 percent of its eligible trade debtors.

The company said the loan's variable interest rate was the bank bill swap rate plus a facility margin of 7.10 percent (initially 10.7834%) and it must also pay a facility fee of 1.50 percent a year.

Hydrix said the loan facility would expire on May 31, 2024 but could be renewed by mutual agreement.

Hydrix executive chairman Gavin Coote said the company was pleased with the loan as it provided "working capital to support the growth of the services business and is more capital efficient than using equity".

Hydrix fell 0.4 cents or 10 percent to 3.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell says its one-for-eight entitlement offer to raise $1.2 million at 0.75 cents a share has closed with a shortfall of $693,972.

In March, Living Cell said it hoped to raise $1.2 million in the rights offer, in which investors would receiving one option for every two shares bought, exercisable at 1.2 cents each by March 31, 2026 (BD: Mar 1, 2023).

At that time, the company said Melbourne's Alignment Capital was its corporate adviser and would receive "market-rate fees".

Today, Living Cell said it had appointed Alignment Capital as lead manager of the shortfall.

According to the Alignment Capital website, Living Cell chair David Hainsworth and director Brad Dilkes were associate directors of Alignment Capital.

Living Cell was unchanged at 0.9 cents.

CORRECTION: TELIX PHARMACEUTICALS

Last night's edition reported that Telix had revenue of $97.5 million for the three months to March 31, 2023. The correct amount was $100.1 million.
In his haste, the former Monday sub-editor missed the $2.6 million in revenue from "pre-commercial sales".
Apologies for the error.
Telix was up $1.00 or 12.7 percent to $8.89 with 4.8 million shares traded.

CORRECTION: AVITA MEDICAL

Last night's edition reported that the Avita virtual annual general meeting would be held on April 14, 2023, which was last week.
The already sacked Monday sub-editor misread the US Securities and Exchange Commission form and reported the record date for shareholders.
The meeting will be held on June 7, 2023 at 8am (AEST) or June 6, 2023 at 3pm (USPDT).
As the hapless sub-editor has been dismissed, we can only dock his long service leave.
Avita fell 11 cents or 2.4 percent to $4.50.

CLARITY PHARMACEUTICALS

Clarity says it has received $6,726,900 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.
The company said the rebate related to expenditure for the year to June 30, 2022.
Clarity fell 2.5 cents or 3.4 percent to 72 cents.

IMMUTEP

Immutep says it was unable to release the final data from its efti for metastatic non-small cell lung cancer trial until March 31, 2023 due to "stress testing" and "confidentiality".
After the market closed on March 31, Immutep said its 36-patient, phase II trial of eftilagimod alpha, or efti, formerly IMP321, for second line non-small cell lung cancer showed a median overall survival of 9.9 months and a 39 percent overall survival rate at 21 months compared to a median overall survival rate of six-to-nine months and a 10-15 percent survival rate for standard-of-care chemotherapy. (BD: Apr 3, 2023).
In response to an ASX query, the company said today that although it had finalized the data from that trial on March 15, 2023 and expected it to have a material effect on its share price, it delayed the publication of the material.
Immutep said the delay was due to an ongoing process of "stress testing … and analyzing the implications and degree of market sensitivity of the data while preparing the ASX announcement" which included seeking quotes from the trial investigator to ensure accuracy and the context of the data.
The company told the ASX it delayed publication while seeking approval from its trial partner the Kenilworth New Jersey-based Merck & Co and the information was under strict embargo until March 31 when it was presented at the European Lung Cancer Congress.
Immutep said that given the highlights of the data and the expected release of the full data were announced in an abstract on March 23, 2023, and the final data was embargoed until the conference, it was in compliance with the ASX Listing Rules and Code of best practice for reporting by life sciences companies in respect to its disclosure obligations.
Immutep was up half a cent or two percent to 25 cents.

EMYRIA

Emyria says it has extended its collaboration with Perth's Pax Centre to include the development of a "care model" for psilocybin-assisted therapy for mental illnesses.
Last month, Emyria said it had an agreement with Perth's Pax Centre to use its 3,4-methylene-dioxy-methamphetamine (MDMA) with therapy for complex post-traumatic stress disorder (BD: Mar 7, 2023).
Today, the company said the addition of psilocybin-assisted therapy would complement the existing MDMA-assisted therapy care model and address "the substantial overlap between symptoms of post-traumatic stress disorder and major depression".
Emyria said that with the support of Mind Medicine Australia it had appointed psychiatrist and MDMA researcher Dr Ben Sessa to provide therapist training.
According to his Linkedin page, Dr Sessa was most recently London's Awakn Life Sciences chief medical officer and held a Bachelor of Medicine, Bachelor of Surgery from University College London.
Emyria fell half a cent or three percent to 16 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that former chair David Williams has resigned effective from April 26, 2023.
Medical Developments said that Mr Williams had resigned "to focus on other personal and business interests".
Mr Williams is the chair of Polynovo and the principal of Melbourne advisory firm Kidder Williams, whose clients include Bega Cheese, Coca Cola and Mondelez.
Mr Williams said that with Gordon Naylor as chair and Brent MacGregor as chief executive officer Medical Developments was "in great hands [and] I leave the board with confidence that the team has the capability to execute on the company's exciting strategic agenda, including plans for the commercial launch of Penthrox in the US".
"To the extent I am able, I will remain keenly interested in the company's search for a partner for this market," Mr Williams said.
Mr Naylor said the company would "miss David's wisdom and experience on the board".
"David was instrumental in building the company and his thoughtful transition of the chair role to me was invaluable," Mr Naylor said.
"On behalf of my fellow directors, I thank David for his remarkable contribution to the company," Mr Naylor said.
Medical Developments fell three cents or 2.7 percent to $1.07.