



Biotech Daily

Thursday April 21, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ORTHOCELL UP 7.5%; DIMERIX DOWN 9%**
- * **CSL \$5.4b NOTES FOR VIFOR ACQUISITION**
- * **UNIVERSAL BIOSENSORS PLACEMENT RAISES \$6m; \$20m RIGHTS TO GO**
- * **CLARITY TREATS 1st PROSTATE CANCER PATIENT**
- * **KAZIA 60mg PAXALISIB 'SAFE' FOR GLIOBLASTOMA; TRIAXIAL NOTE**
- * **CYNATA ENROLS 1st CYP-006TK DIABETIC FOOT ULCER PATIENTS**
- * **OPTHEA EGM: 25% OPPOSE 2m DIRECTORS OPTIONS**
- * **IMEX: 174k FREE DIRECTORS' OPTIONS AGM**
- * **PALLA LOSES DIRECTORS SUE MACLEMAN, IAIN ROSS, STUART BLACK**
- * **TERI THOMAS TO REPLACE VOLPARA CEO DR RALPH HIGHNAM**
- * **ANTEO APPOINTS EWEN CROUCH CHAIR**

MARKET REPORT

The Australian stock market was up 0.31 percent on Thursday April 21, 2022, with the ASX200 up 23.6 points to 7,592.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Orthocell was the best, up three cents or 7.5 percent to 43 cents, with 282,865 shares traded. Clinuvel, Impedimed and Resonance climbed more than four percent; Cochlear and Compumedics were up more than three percent; Alcidion, Kazia and Nanosonics rose more than two percent; Genetic Signatures, Oncosil and Resmed were up more than one percent; with CSL, Neuren and Starpharma up less than one percent.

Dimerix led the falls, down 1.5 cents or 9.4 percent to 14.5 cents, with 575,506 shares traded. Paradigm lost 6.3 percent; Uscom retreated 5.3 percent; Antisense, Atomo, Immutep and Pharmaxis fell more than four percent; Amplia, Cyclopharm, Polynovo and Universal Biosensors shed more than three percent; Micro-X, Medical Developments and Opthea were down more than two percent; with Emvision, Mesoblast, Next Science, Pro Medicus and Telix down by less than one percent.

CSL

CSL says it hopes to raise \$US4 billion (\$A5.4 billion) through the issue of notes to partly finance its acquisition of Vifor Pharma.

Last year, CSL said it would acquire the St Gallon, Switzerland-based Vifor Pharma for \$US12.3 billion for its renal disease and iron deficiency expertise (BD: Dec 14, 16, 2021).

Today, the company said the six notes would be priced at a range of rates, including a \$US500 million five-year note at 3.85 percent, a \$US500 million seven-year note at 4.05 percent, a \$US1 billion 10-year note at 4.25 percent, a \$US500 million 20-year note at 4.625 percent, a \$US1 billion 30-year note at 4.75 percent and a \$US500 million 40-year note at 4.95 percent.

CSL said that apart from partially funding the Vifor acquisition, it would also allocate some proceeds for general corporate purposes.

CSL chief financial officer Joy Linton said the company was "pleased with the outcome of the bond issue from both a demand and pricing perspective".

"It also provides depth and flexibility for our long-term capital management program," Ms Linton said.

"The strong support shown by investors towards our inaugural US dollar bond issue reflects positively on our track record of disciplined financial management, as well as confidence in our strategy to invest in our leading therapeutic capabilities and generate sustainable growth," Ms Linton said.

CSL said the regulatory approval process for the Vifor acquisition was on track to be completed by June 2022.

CSL was up \$2.48 or 0.9 percent to \$266.98 with 638,733 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says its institutional placement at 77 cents per Chess depositary instrument raised \$6 million and expects to raise \$20 million in an underwritten rights offer. Yesterday, Universal Biosensors said that it hoped to raise \$5 million in the placement and expected to raise \$20 million in the one-for-6.85 rights offer (BD: Apr 20, 2022).

Today, Universal Biosensors chief executive John Sharman said the company was "delighted with the support we have seen from the market".

"We believe we have raised the right amount of money to secure the opportunities we have in front of us, and we look forward to building a successful future," Mr Sharman said.

Universal Biosensors fell 2.5 cents or 3.3 percent to 76 cents.

CLARITY PHARMACEUTICALS

Clarity says it has treated the first of up to 50 patients in its phase I/II open-label trial of copper-64-SAR-bis-PSMA in biochemically recurrent prostate cancer.

In February, Clarity said that the US Food and Drug Administration had approved the trial to investigate the safety, tolerability and efficacy of copper-64 sarcophagene-bis-prostate specific membrane antigen (SAR-bis-PSMA) with positron emission tomography (PET) for prostate cancer imaging (BD: Feb 7, 2022).

Clarity said the trial would examine the ability of copper-64-SAR-bis-PSMA to correctly detect recurrence of prostate cancer.

Clarity executive chair Dr Alan Taylor said the company was "excited to have dosed the first participant in the Cobra trial at the Urology Cancer Centre and GU Research Network in Omaha, Nebraska, which continues to actively screen and recruit patients".

Clarity was up 2.5 cents or 4.4 percent to 59.5 cents.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says its 30-patient, phase II paxalisib for glioblastoma trial shows that a 60mg dose is safe with indications of increased survival, triggering the conversion of a note.

Kazia said that the median overall survival in the 30 intent-to-treat patients was 15.7 months, compared to 12.7 months historically reported with temozolomide in the same patient group.

The company said that median progression-free survival was 8.4 months, “a substantial increment over the comparable figure of 5.3 months associated with temozolomide”.

Kazia said the trial recruited patients with newly diagnosed glioblastoma and unmethylated MGMT-promotor status, a genetic profile which confers primary resistance to temozolomide, the only existing US Food and Drug Administration-approved drug for first-line treatment.

The company said that in the 27-patient modified intent-to-treat population which included only those patients evaluable for efficacy, overall survivability increased to 15.9 months.

Kazia said the paxalisib safety profile was “highly consistent with previous clinical studies: hyperglycaemia, oral mucositis, and skin rash”.

Kazia chief executive officer Dr James Garner said “we are very pleased to have successfully completed this last step in the phase II study of paxalisib, and we look forward to sharing detailed data with clinicians and investors over coming months.”

“This study has greatly expanded our understanding of paxalisib, and the insights it has provided have informed all our subsequent work with the drug,” Dr Garner said.

“Paxalisib is now the subject of an ongoing pivotal study in glioblastoma, GBM AGILE, and we hope to see results from that study confirm the very positive signals seen in this phase II trial,” Dr Garner said.

Kazia said that under an agreement entered into by the then Novogen in November 2013, completion of the study “satisfies the criteria for the third and final conversion event associated with a convertible note issued to certain shareholders of Triaxial Pty Ltd”.

According to ASX data, Novogen, then with Dr Graham Kelly as chief executive officer announced the issue of a convertible note on November 15, 2013, to provide the company with \$2 million.

The company filed seven Appendix 3B new share announcements and six cleansing notices in that month but Biotech Daily was unable to find a reference to Triaxial Pty Ltd.

In 2016, Novogen said it had reached a milestone which triggered the conversion 16,000,000 shares of its convertible notes (BD: Nov 2, 2016).

According to Novogen’s 2016 annual report it signed an agreement with the convertible note holder, former shareholders of Triaxial Pharmaceuticals Pty Ltd on November 4, 2013, allowing \$400,000 of the convertible note to be exercised for 16,000,000 shares on completion of a phase Ia clinical trial.

In 2012, Novogen said it had an agreement to acquire Triaxial Pharmaceuticals for \$1.88 million in scrip and debt, based on clinical milestones (BD: Nov 12, 2012). Shortly after, Novogen appointed Dr Kelly its chief executive officer and said it had acquired 100 percent of Triaxial for \$1,885,000 consisting of 15.4 million Novogen shares and a \$1.5 million loan payable to the Triaxial shareholders.

At that time, according to Dr Kelly’s Noxopharm website, in 2011, Dr Kelly “joined private biotechnology company Triaxial Pharmaceuticals Pty Ltd as executive chairman”.

“Concerned at the direction being taken by the Novogen board in having stripped all assets from the company and leaving it without a business, [Dr Kelly] engineered a reverse takeover of Novogen by Triaxial in December 2012,” Noxopharm said.

Kazia was up three cents or 2.8 percent to \$1.11.

CYNATA THERAPEUTICS

Cynata says it has enrolled the first of 30 patients in its phase I trial of its CYP-006TK wound dressing with mesenchymal stem cells as a treatment for diabetic foot ulcers. Last year, Cynata said it would begin the randomized, 24-week, trial comparing its CYP-006TK to standard-of-care dressings for diabetic foot ulcers (BD: Jan 16, 2022).

Today, Cynata chief medical officer Dr Jolanta Airey said the company was “pleased with enrolment of subjects following the commencement of the trial in late December.”

“Covid-19-related changes to patient management at the study sites, initiated shortly after the trial opened, posed a significant number of unforeseen challenges which had a serious impact on enrolment rates,” Dr Airey said.

Dr Airey said the challenges had been addressed.

Cynata was unchanged at 39 cents.

OPTHEA

Opthea said its extraordinary general meeting voted more than 25 percent dissent against the issue of 1,000,000 options each to directors Quinton Oswald and Susan Orr.

In March, Opthea said it proposed to issue Ms Orr and Mr Oswald one million options each, exercisable at the five-day volume weighted average price to the grant date, and within four years, vesting in four equal tranches from the grant date and over the subsequent three years, as well as doubling the aggregate maximum of remuneration of non-executive directors from \$500,000 to \$1,000,000 to “accommodate the appointment of additional directors bringing expertise to the board necessary for the current stage of its development” (BD: Mar 15, 2022).

Today, the company said that along with opposition to the directors options issue, a special resolution requiring a 75 percent majority to amend the company constitution was passed with 78.64 percent of the vote, with all other resolutions carried easily.

According to its most recent filing, the company had 351,189,280 shares on issue meaning that the opposition to Mr Oswald’s options amounted to 8.03 percent, sufficient to requisition extraordinary general meetings.

Opthea fell 2.5 cents or 2.4 percent to \$1.00.

IMEX HEALTH SERVICES

Imex says its annual general meeting will vote to issue 173,612 free options exercisable at no cost to its managing-director and four directors.

Imex said investors would vote to issue managing-director German Arango 73,393 options, exercisable at no cost within 10 years, vesting in two tranches, pending total shareholder return relative to an appropriate index.

The company said the meeting would vote to grant 40,087 options to director Douglas Flynn, and 20,044 options each to directors Damian Banks, Dr Doug Lingard and Carlos Palacio, equivalent to 50 percent of their directors’ fees.

Imex said the options would have no exercise price, no performance hurdles and lapse four years after the date of grant.

The company said shareholders would vote on the remuneration report, the re-election of Mr Palacio, and issue of shares in lieu of payment to Mr Banks, Mr Flynn, Dr Lingard and Mr Palacio and the approval of the 10 percent placement capacity.

The virtual meeting will be held on May 19, 2022 at 10am (AEST) and will be available at: https://us02web.zoom.us/webinar/register/WN_pQLWseSiR5-eD3iP_bsKEw.

Imex was untraded at 84 cents.

[PALLA PHARMA \(FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES\)](#)

Korda Mentha as liquidators of Palla Pharma say that Susan MacLeman, Iain Ross and Stuart Black have resigned as non-executive directors of the company.

In March, Korda Mentha said it had sold Palla Pharma UK and Palla Pharma Norway Holdings AS, but did not expect that recoveries would be sufficient to provide returns to shareholders (BD: Mar 29, 2022).

Today, Korda Mentha said that Simon Moore remained a director.
Palla last traded at 29.5 cents.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says Teri Thomas will replace chief executive officer Dr Ralph Highnam, who has resigned from the board and continues as chief science and innovation officer.

Volpara said Dr Highnam had founded and led the company for 13 years.

The company said that as chief science and innovation officer, Dr Highnam would focus on the application of Volpara's dataset of mammography images, which it said was "one of the world's biggest datasets of breast images" and included more than 56 million images assessing the breast composition of more than 13 million women in 39 countries.

Volpara said Dr Highnam would leverage the data "to develop the next wave of [artificial intelligence] enhancements and strengthen Volpara's portfolio for its extensive customer network".

Dr Highnam said the company had developed "a team of bright scientists and a diverse set of industry and academic partners ... [and its] customers are among the most prestigious healthcare institutions in the world".

Volpara said Dr Highnam would host investor presentations and financial year results at the end of May 2022, while Ms Thomas would engage with its US sales and marketing teams and meet strategic partners and customers.

Volpara said Ms Thomas had worked for Epic Health for 20 years and other companies in the healthcare industry.

The company said that Ms Thomas was a US citizen living in New Zealand and would spend about 25 percent of her time in each country.

The company said that Ms Thomas held a Bachelor of Arts in Zoology from the University of Wisconsin at Madison, and a Master of Nursing Science from the Hamilton, New Zealand-based Waikato Institute of Technology.

Volpara was unchanged at 89 cents.

[ANTEOTECH](#)

Anteo says it has appointed Ewen Crouch as its non-executive chair, to succeed Dr Jack Hamilton, effective from April 30, 2022.

Anteo said Mr Crouch was currently the chair of Corporate Travel Management and a director of Bluescope Steel and non-profit organization Jawun and was previously a partner at law firm Allens and a director of Westpac Banking Corp.

Anteo fell one cent or 7.1 percent to 13 cents with 8.8 million shares traded.