



Biotech Daily

Tuesday October 31, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ORTHOCELL UP 9%; KAZIA DOWN 12.5%**
- * **UNIQUEST FEDERAL \$1.9m BACKS SMALL MOLECULE DRUG DISCOVERY**
- * **PARADIGM RAISES \$21m IN PLACEMENT, INSTITUTIONAL OFFER**
- * **RADIOPHARM ENTITLEMENT OFFER TO RAISE UP-TO \$10m**
- * **KAZIA \$790k SHORT TERM PROMISSORY NOTE**
- * **DORSAVI 'COMMITMENTS' FOR \$500k PLACEMENT**
- * **FIREBRICK RECEIVES \$1.8m FEDERAL R&D TAX INCENTIVE**
- * **NOVA EYE: US MEDICARE CHANGES 'NO IMPACT ON SALES'**
- * **CHIMERIC: FDA OKAYS CHM2101 IND FOR G-I CANCERS**
- * **ALGORAE JOINS UNI NSW INDUSTRY PROGRAM**
- * **ALCIDION REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **BENJAMIN, ELIZABETH JANSEN REDUCE TO 20.7% OF VITURA**
- * **REGAL TAKES 6.9% OF VITURA**
- * **CLINUVEL AGM 40% REM REPORT 1st STRIKE, 41% PLAN DISSENT**
- * **ONCOSIL 91.5m CEO RIGHTS, 8m DIRECTOR, CHAIR OPTIONS AGM**

MARKET REPORT

The Australian stock market was up 0.12 percent on Tuesday October 31, 2023, with the ASX200 up 7.8 points to 6,780.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

Orthocell was the best, up three cents or 9.1 percent to 36 cents, with 317,211 shares traded. Next Science climbed 8.1 percent; Dimerix and Volpara were up more than five percent; Emvision was up 3.6 percent; Imugene, Neuren and Universal Biosensors rose two percent or more; Cyclopharm, Genetic Signatures, Opthea and Proteomics were up one percent or more; with CSL, Polynovo and Telix up by less than one percent.

Kazia led the falls, down one cent or 12.5 percent to seven cents, with 1.35 million shares traded. Nova Eye lost 9.8 percent; 4D Medical and Compumedics were down more than six percent; Atomo and SDI fell more than four percent; Pharmaxis was down three percent; Avita, Mesoblast and Pro Medicus shed more than two percent; Immutep, Medical Developments and Nanosonics were down more than one percent; with Clinuvel, Cochlear and Resmed down by less than one percent.

UNIQUEST, FEDERAL GOVERNMENT

Uniquet says that a Federal Government \$1.9 million grant has supported the opening of the University of Queensland's small molecule drug discovery facility.

Uniquet said the Federal grant, through the Federal Department of Education's National Collaborative Research Infrastructure Strategy was managed by Therapeutic Innovation Australia and would support the translation of medical research at the Queensland Emory Drug Discovery Initiative.

The commercialization arm of the University of Queensland said that the Initiative was established as one of its divisions with guidance from the Atlanta Georgia-based Emory University Institute for Drug Development and Drug Innovation Ventures.

The company said that the Initiative would "partner with research groups from across Australia who can benefit from its drug discovery services".

Uniquet said that it managed the Initiative, which prior to the Federal Government grant, had made its services solely available to researchers at the University of Queensland.

Uniquet chief executive officer Dr Dean Moss said it was "an exciting evolution for the university-based drug discovery engine to offer its services nationwide".

Dr Moss said the Initiative had "built a promising pipeline of projects from [University of Queensland] researchers since its inception".

"This funding injection will bolster its capabilities and allow [the Initiative] to offer its world-class drug discovery expertise to a wider audience and hails an exciting future for the established small molecule discovery entity," Dr Moss said.

Dr Moss said it was "the natural next step for the growing drug discovery group".

"By opening our doors to other prospective projects, we can prevent unnecessary duplication of resources and infrastructure, while providing Queensland with the ability to leverage its expertise and capabilities to translate Australian biomedical research locally into drug candidates, with commercial returns to Australia," Dr Moss said.

Uniquet said that about \$40 million had been invested in the Initiative to develop drugs, including through an Advance Queensland funding agreement with the Queensland Government.

The company said that the Initiative employed 20 drug discovery researchers and had the capability to perform drug discovery biology, medicinal chemistry, computational chemistry and pre-clinical development to identify promising small molecule drug candidates and develop them to a stage where they may be of interest to pharmaceutical companies or investors for further development.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised \$18 million in a placement and about \$3.1 million in the institutional component of its one-for-10 entitlement offer, at 43 cents a share.

Yesterday, Paradigm said it hoped to raise \$30 million through an \$18 million institutional placement and a \$12.1 million accelerated, non-renounceable institutional and retail entitlement offer (BD: Oct 30, 2023).

At that time, the company said the entitlement offer included three attaching options for every four shares acquired, exercisable at 65 cents each by November 30, 2024, Bell Potter Securities was the lead manager to the raise and that it was not underwritten.

Today, Paradigm said the institutional component of the rights offer had a 78 percent take-up and Bell Potter Securities had agreed to fully underwrite the raise.

Paradigm said the record date for the \$9 million retail rights offer would be November 1, it would open on November 6 and close on November 20, 2023.

Paradigm was in a trading halt and last traded at 61.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it hopes to raise up-to \$10 million in a one-for-2.35, non-renounceable, non-underwritten, entitlement offer at seven cents a share.

Radiopharm said the offer price was a 46.2 percent discount to the 15-day volume weighted average price of 13 cents.

The company said it would use the funds to progress its four clinical trials towards achieving multiple inflection points, including its phase I RAD301 trial to imaging readout, its phase IIb RAD101 trial recruitment, its phase I RAD204 therapeutic trial recruitment and its phase I RAD202 therapeutic trial recruitment, as well as for working capital.

Radiopharm said the offer had a record date of November 3, would open on November 8 and close November 24, 2023.

Radiopharm said it had appointed Bell Potter Securities as lead manager to the offer, including any shortfall.

Radiopharm fell 1.6 cents or 16 percent to 8.4 cents with 1.1 million shares traded.

KAZIA THERAPEUTICS

Kazia says it has a "firm commitment" to raise \$US500,000 (\$A786,000) through an of unsecured promissory note from an undisclosed European investor.

Kazia said the unsecured note included a 10 percent a year interest rate convertible on or after November 17, 2023 to either American depository shares (ADSs) at market price or half cash and half ADSs.

The company said no warrants options or discounts were part of the agreement and that the funds would be used for working capital.

Kazia said it expected the promissory note to settle by November 1, 2023.

Kazia fell one cent or 12.5 percent to seven cents with 1.35 million shares traded.

DORSAVI

Dorsavi says it has "binding commitments" to raise \$500,000 in a placement at one cent a share, a 10.1 percent discount to the 15-day volume weighted average price.

Dorsavi said the funds would be used for the sale and commercialization of its products in the clinical and workplace market, enhancements to products and technology including the development of artificial intelligence-enabled features, and for working capital.

The company said subscribers to the placement will receive one attaching option for every two shares purchased, subject to shareholder approval, exercisable at two cents each within two years from issue.

Dorsavi said it Sixty Two Capital was the lead manager to the placement and would receive a six percent raising fee on funds raised under the offer.

Dorsavi fell 0.1 cents or 7.7 percent to 1.2 cents.

FIREBRICK PHARMA

Firebrick says it has received \$1,816,127 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Firebrick said the rebate related research and development costs for the year to June 30, 2023 associated with its phase III trial of Nasodine for the common cold and phase II trial of Nasodine in Covid-19.

Firebrick was up 0.1 cents or 2.7 percent to 3.8 cents with 1.5 million shares traded.

NOVA EYE MEDICAL

Nova Eye says proposed US Medicare local coverage determination changes are not expected to have an impact on sales of its Itrack device for glaucoma surgery.

Nova Eye said the proposed local coverage determination changes by the Wisconsin Physician Service Insurance Corporation included limited or denied coverage for several minimally invasive glaucoma surgery procedures, including the ab-interno canaloplasty surgical procedure, effective from December 24, 2023.

The company said the Wisconsin Physician Service Insurance Corp was a Medicare administrative contractor which administered the insurance reimbursement claims of healthcare facilities in Kansas, Nebraska, Missouri, Iowa, Indiana and Michigan.

Nova Eye said the impact of the proposed changes on the revenue was dependent on the surgical technique with which surgeons are using Itrack portfolio in those states.

The company said that surgery with its Molteno3 product portfolio, which was typically used in cases of late-stage glaucoma, remained covered.

Nova Eye said Itrack had “several indications for use by doctors with or without cataract surgery” and surgeons could use the device “in a variety of surgical techniques and to seek reimbursement accordingly”.

The company said that unlike other devices referenced by the Wisconsin Physician Service Insurance Corp as losing coverage after December 24, 2023, “Itrack products have not been specifically denied coverage”.

Nova Eye managing director Tom Spurling said the company was “positioned well to adapt to the final draft [local coverage determination]”.

“The Itrack portfolio is used by surgeons via different surgical techniques, depending on the glaucoma disease state to be treated ... and is covered by multiple reimbursement codes,” Mr Spurling said. “Canaloplasty performed via an ab-interno surgical technique ... has been foreshadowed as excluded from coverage; however, the use of Itrack to perform canaloplasty via the ab-externo surgical technique has been proposed as retaining coverage.”

“Should the [local coverage determination] be implemented, our suite of products, regulatory clearances, and [intellectual property] portfolio, provide us with the opportunity to adapt to the proposed changes, take advantage of market consolidation, and, ultimately, maintain sales and sales growth,” Mr Spurling said. “The biggest challenge we see from the potential changes is the confusion it may cause with customers.”

Nova Eye fell two cents or 9.8 percent to 18.5 cents with 1.9 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says the US Food and Drug Administration has approved its investigational new drug application for a phase Ia trial of CHM2101 for gastro-intestinal cancers.

Chimeric said the phase Ia trial would be a multi-centre, open-label trial for patients with advanced colorectal cancer, gastric cancer and neuro-endocrine tumors.

The company said CDH17 was a cancer target associated with poor prognosis and metastasis in the most common gastrointestinal tumor.

Last year, Chimeric said a study published in Nature Cancer showed that CHM2102 “completely eradicated tumors” with no relapse or toxicity, in mice (BD: Mar 23, 2022).

Today, the preclinical study’s lead scientist from the University of Pennsylvania Prof Xianxin Hua said the approval was “a critical step forward in developing an entirely new Car-T therapy for gastrointestinal cancers and neuroendocrine tumors, providing new hopes for the cancer patients who are refractory to the existing therapies”.

Chimeric was up half a cent or 19.2 percent to 3.1 cents with 85.0 million shares traded.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says the University of New South Wales will recruit three doctoral candidates for the development of its Algorae operating system Algoraeos.

Algorae said the Next Generation Artificial Intelligence Graduate Program would be co-funded by the Commonwealth Scientific and Industrial Research Organisation and candidates would be supervised and managed by Algoraeos lead investigator Prof Fatemeh Vafaee.

The company said CSIRO would provide about two thirds of the funding and that it would provide the remaining third for the three-year term of the candidate scholarships.

Algorae said Algoraeos would build on “a sophisticated artificial intelligence model trained for pharmaceutical prediction already developed by data specialists within the University of New South Wales Data Science Hub”.

Algorae said it intended to expand and refine the University’s model specifically for its purposes, including generating novel drug candidates for clinical investigation.

Algorae was up 0.2 cents or 16.7 percent to 1.4 cents with five million shares traded.

ALCIDION GROUP

Alcidion says it has requested a trading halt “pending an announcement by the company to the market regarding a capital raising”.

Trading will resume November 2, 2023, or on an earlier announcement.

Alcidion last traded at 9.7 cents.

VITURA HEALTH

Benjamin Jansen, with Elizabeth Jansen and Stanford Investment Trust, says he reduced his Vitura holding from 124,290,842 shares (22.33%) to 119,291,098 shares (20.71%).

In September, Vitura said it had received a notice from Elizabeth Jansen as trustee for the Stanford Trust, under section 249N of the Corporations Act 2001, to appoint Shane Tanner, Nathan Hight and Benjamin Jansen as directors (BD: Oct 6, 2023).

Last week, the company said in its annual general meeting notice that its board “unanimously recommends” shareholders vote against the resolutions to elect Mr Tanner, Mr Hight and Mr Jansen as directors (BD: Oct 27, 2023).

Today, Mr Jansen said he and the related parties sold shares in 31 transactions from June 29 to August 31, 2023, with the single largest sale of 433,823 shares on July 3 for \$232,659, or 53.6 cents a share, and were diluted following the issue of shares as part of the Doctors on Demand acquisition (BD: Oct 19, 2023).

Vitura fell 2.5 cents or seven percent to 33 cents.

VITURA HEALTH

Regal Funds Management Pty Ltd says it has become a substantial shareholder in Vitura with 39,907,394 shares, or 6.93 percent.

The Sydney-based Regal said that between June 27 and October 26, 2023 it bought a total of 1,726,097 shares in 11 transactions for \$918,467.22, or an average 53.2 cents a share and converted convertible notes on October 26 into 17,380,423 Vitura shares.

Last week, Vitura said it had completed the purchase of Brisbane’s Doctors on Demand Pty Ltd, and that it would pay majority shareholder Regal Funds \$6.25 million through the issue of 17,380,423 shares at 35.96 cents a share (BD: Oct 27, 2023).

CLINUVEL PHARMACEUTICALS

Clinuvel says its annual general meeting voted up to 39.74 percent against the adoption of its remuneration report and 41.42 percent against its performance rights plan.

Clinuvel said that 12,217,829 votes (60.26%) supported the remuneration report resolution with 8,058,247 votes (39.74%) in opposition.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election within 90 days.

The company said the resolution to renew shareholder approval of its performance rights plan faced 8,324,414 votes (41.42%) dissent with 11,772,682 votes (58.58%) in favor.

Clinuvel said outgoing chair Willem Blijdorp was opposed for re-election by 25.02 percent of votes with director Prof Jeffrey Rosenfeld opposed by 14.12 percent of votes.

Last month, Clinuvel said Mr Blijdorp would step down from chair to non-executive director, from January 1, 2024 pending re-election as a non-executive director at its November annual general meeting (BD: Sep 29, 2023).

Today, in a separate announcement, Clinuvel said it had appointed Prof Rosenfeld as chair, effective from January 1, 2024.

According to its most recent notice, Clinuvel had 49,410,338 shares on issue, meaning that the 8,058,247 votes against the remuneration report amounted to 16.3 percent of the shares on issue, sufficient to requisition extraordinary general meetings.

Clinuvel fell 14 cents or 0.9 percent to \$14.69.

ONCOSIL MEDICAL

Oncosil says investors will vote to issue 91,500,000 rights to executive director Nigel Lange and 8,000,000 options each to directors Dr Gabriel Liberatore and Douglas Cubbin. Oncosil said the annual general meeting would vote to issue Mr Lange 91,500,000 performance rights under its incentive plan, vesting in four equal tranches conditional on hurdles in addition to his EUR250,000 (\$A416,000) yearly salary.

The company said shareholders would vote to issue Dr Liberatore and chair Mr Cubbin 3,000,000 options and 5,000,000 options as long-term incentives, respectively, exercisable at three cents each within five years from the grant date.

Oncosil said the option price was 2.28 times the 10-day volume weighted average price of 1.05 cents, rounded up to three cents.

The company said Dr Liberatore received \$55,000 a year in director fees and Mr Cubbin was paid \$134,772 annually.

Oncosil said the meeting would vote to adopt the remuneration report, elect Dr Liberatore and Mr Cubbin as directors and approve the 10 percent placement facility.

The meeting will be held at K&L Gates, Level 25, 525 Collins Street, Melbourne, on November 29, 2023 at 10.30am (AEDT).

Oncosil was up 0.1 cents or 11.1 percent to one cent with 10.8 million shares traded.