



Biotech Daily

Thursday October 15, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 9%;
- ACTINOGEN DOWN 14%**
- * **PRO MEDICUS, LMU KLINIKUM 7-YEAR, \$10m VISAGE 7 DEAL**
- * **ACTINOGEN UP-TO \$11m CAPITAL RAISING FOR XANAMEM TRIALS**
- * **FDA ORPHAN STATUS FOR REDHILL RHB-204 FOR NTM**
- * **ACRUX RECEIVES \$1.8m R&D TAX INCENTIVE**
- * **PARADIGM 1.1m DIRECTOR LOAN SHARES AGM**
- * **PRESCIENT 17m DIRECTOR OPTIONS AGM**
- * **CANN GLOBAL PLEADS SCHULTZ, 'LOW PRICE' TO ASX 100% QUERY**
- * **LAZARD TAKES 5% IN MAYNE**
- * **CORRECTION: MEDICAL DEVELOPMENTS**
- * **CRYOSITE: JOHN HOGG CEO ON \$250k, BRYAN DULHUNTY NON-EXEC**

MARKET REPORT

The Australian stock market was up 0.5 percent on Thursday October 15, 2020, with the ASX200 up 31.1 points to 6,210.3 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, six traded unchanged and two were untraded.

Universal Biosensors was the best, up 2.5 cents or 9.1 percent to 30 cents, with 268,200 shares traded. Oncosil climbed eight percent; Pro Medicus was up 7.65 percent; LBT improved four percent; Polynovo rose two percent; Prescient and Telix were up more than one percent; with Cochlear, Next Science and Resmed up by less than one percent.

Actinogen led the falls, down 0.4 cents or 14.3 percent to 2.4 cents, with 17.1 million shares traded. Opthea and Proteomics lost more than five percent; Optiscan fell 4.2 percent; Antisense, Avita, Dimerix, Immutep and Orthocell were down more than three percent; Amplia, Genetic Signatures, Impedimed, Medical Developments, Neuren, Paradigm, Pharmaxis and Volpara shed more than two percent; Clinuvel, Cynata, Imugene, Mesoblast and Starpharma were down more than one percent; with CSL, Kazia and Nanosonics down by less than one percent.

PRO MEDICUS

Pro Medicus says it has a \$10 million, seven-year agreement with Ludwig-Maximilians-Universität Klinikum for its Visage 7 imaging technology.

Pro Medicus said the Munich, Germany-based LMU Klinikum, one of the largest university hospitals in Europe, would pay \$10 million for the Visage 7 technology to be implemented across its radiology and imaging departments to replace the existing picture archiving and communication systems with a centralized Visage 7 enterprise imaging platform.

The company said Visage would be used in the hospital's theatre suite for high definition video documentation and point-of-care ultrasound archival and viewing.

LMU Klinikum chief information officer Dr Kurt Kruber said that "the Visage platform provides a highly scalable and reliable platform combined with sophisticated clinical features that will support us in both day-to-day patient care and advanced research."

Pro Medicus chief executive officer Dr Sam Hupert said that "traditionally, large European teaching hospitals like LMU Klinikum have standardized on [information technology] platforms from large, multinational imaging equipment ... vendors, making this a difficult market to penetrate ... so this is a very significant milestone for us in this highly competitive market".

Pro Medicus said the Visage 7 roll-out was scheduled to start in December 2020.

Pro Medicus was up \$2.22 or 7.65 percent to \$31.23 with 786,074 shares traded.

ACTINOGEN

Actinogen says it will raise \$6 million in an "over-subscribed" placement at 2.2 cents a share and hopes to raise \$4.9 million in a rights offer for two phase II Xanamem trials.

Actinogen said the trials would evaluate the efficacy of Xanamem for Fragile X syndrome and for mild cognitive impairment as a result of Alzheimer's disease.

Last year, the company said its 186-patient, phase II, Xanadu trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" (BD: May 7, 2019).

In October, Actinogen said its 42-patient Xanahes study showed "statistically significant ... cognitive improvement" in healthy, elderly subjects (BD: Oct 1, 2019).

Today, Actinogen said the 'Xanafx' trial for Fragile X syndrome at Melbourne's Royal Children's Hospital would be a 12-month, phase II, double-blind, placebo-controlled study of up-to 40 males with Fragile X syndrome aged between 12 and 18 years, dosed for 12 weeks.

The company said Xanamem in Fragile X could meet US Food and Drug Administration orphan drug designation and rare paediatric disease designation criteria, and if approved, could facilitate fast-track development and commercialization.

Actinogen said the 72-patient, two-year 'Xanamia' trial of Xanamem for mild cognitive impairment in patients with Alzheimer's disease would leverage the "efficacy results from the Xanahes trial" to show safety, tolerability, and efficacy, of 10mg of Xanamem daily.

The company said it expected both trials to begin recruitment by July 2021.

Actinogen said the "over-subscribed" placement at 2.2 cents a share had commitments from institutional, sophisticated and professional investors to raise \$6 million.

The company said the one-for-five rights offer for shareholders on the record date of October 20 would open on October 23 and close on November 3, 2020.

The company said the share price was a 21.4 percent discount to the last closing share price of 2.8 cents.

Actinogen said Bell Potter Securities was the lead manager to the capital raising.

The company said the funds raised would be primarily used for the Xanamia study.

Actinogen fell 0.4 cents or 14.3 percent to 2.4 cents with 17.1 million shares traded.

[REDHILL BIOPHARMA](#)

Redhill says the US Food and Drug Administration has granted orphan drug designation for RHB-204 for pulmonary non-tuberculous mycobacteria (NTM).

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

In August, the company said it had submitted an FDA orphan drug designation application, after the FDA approved an investigational new drug application for a 125-patient trial III of RHB-204 for non-tuberculous mycobacteria and granted RHB-204 qualified infectious disease product (QIDP) designation (BD: Aug 3, 2020).

Today, Redhill said non-tuberculous mycobacteria was a debilitating lung disease caused by Mycobacterium avium complex bacteria which could lead to bronchitis and pneumonia and respiratory failure.

The company said the FDA granted orphan status to drugs intended to treat rare disorders that affect fewer than 200,000 people in the US.

Redhill said the designation provided development incentives including extended market exclusivity on approval, prescription drug user fee waivers and tax credits for qualified clinical testing.

Redhill head of regulatory affairs Patricia Anderson said that non-tuberculous mycobacteria infections were "resistant to most antibiotics and are extremely challenging to treat".

"With no FDA-approved first-line therapy available to patients today, there is a tremendous urgent need for new treatments for this debilitating and potentially fatal infectious disease," Ms Anderson said.

"Along with the QIDP designation already granted to RHB-204 by the FDA, the orphan drug designation extends potential market exclusivity to a total of 12 years," Ms Anderson said.

Redhill said the 125-patient multi-centre, randomized, double-blind, placebo-controlled, parallel-group phase III safety and efficacy study of RHB-204 would be conducted at up-to 40 US sites and was expected to begin "in the coming weeks".

On the Nasdaq, Redhill was down 31 US cents or 2.98 percent to \$US10.08 (\$A14.14) with 352,645 shares traded.

[ACRUX](#)

Acrux says it has received \$1,806,428 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Acrux said the rebate related to expenditure for the year to June 30, 2020.

Acrux was up half a cent or 2.8 percent to 18.5 cents.

[PARADIGM BIOPHARMACEUTICALS](#)

Paradigm says shareholders will vote to issue 1,100,000 interest-free loan shares to chief executive officer Paul Rennie and executive director Donna Skerrett.

Paradigm said it proposed to issue Mr Rennie 600,000 loan shares and Ms Skerret 500,000 loan shares, vesting in three equal tranches on November 19, 2021, 2022 and 2023, and repayable in five years.

The company said its annual general meeting would vote to approve the remuneration report, elect directors Chris Fullerton and Ms Skerrett, and ratify placement shares.

The meeting will be held online on November 19, 2020 at 11am (AEDT).

Paradigm fell eight cents or 2.6 percent to \$3.00 with 1.1 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says its annual general meeting will vote to issue 17,000,000 options to Steven Yatomi-Clarke, Steven Engle, Dr James Campbell and Dr Allen Ebens.

Prescient said it would issue 12,900,000 options to chief executive officer Mr Yatomi-Clarke, 2,100,000 options to non-executive chair Mr Engle, and 1,000,000 options each to directors to Dr Campbell and Dr Ebens.

The company said the options would be exercisable at a 43 percent premium to the 5-day volume weighted average price of the grant date within four years vesting in four equal tranches

Prescient said shareholders would vote to adopt the remuneration report, elect directors Dr Ebens and Mr Engle, ratify the appointment of an auditor, ratify the prior issue of shares, renew the proportional takeover provision, amend the constitution, and approve a 10 percent placement facility.

The meeting will be held online on November 24, 2020 at 2pm (AEDT).

Prescient was up 0.1 cents or 1.6 percent to 6.4 cents with 2.9 million shares traded.

CANN GLOBAL

Cann Global has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 100.0 percent from a low of 0.4 cents on October 13 to a high of 0.8 cents on October 14, 2020 and noted a "significant increase" in the trading volume.

Cann Global said the low share price on October 13, 2020 represented "a historically low valuation for the company's businesses from which base the observed price increase to date represents only a minor recovery when compared to 2019 levels".

Since June 30, 2020 Cann Global has closed at either 0.4 cents or 0.5 cents every day, apart from two days.

Cann Global was up 0.1 cents or 14.3 percent to 0.8 cents with 72.8 million shares traded.

MAYNE PHARMA GROUP

Sydney's Lazard Asset Management Pacific Co says it has become substantial shareholder in Mayne with 86,044,209 shares or 5.13 percent of the company.

In August, Lazard said it had ceased to be a substantial shareholder in Mayne and Biotech Daily calculated that Lazard held 78,097,616 shares or 4.7 percent of the company (BD: Aug 25, 2020).

Today, Lazard said it bought shares between June 17 and October 12, 2020, with the single largest purchase 3,346,703 shares for \$1,080,399 or 32.3 cents a share.

Mayne was up 1.5 cents or 4.7 percent to 33.5 cents with 7.3 million shares traded.

CORRECTION: MEDICAL DEVELOPMENTS INTERNATIONAL

Last night's edition mistakenly reported that Medical Developments non-executive director Gordon Naylor held a range of roles at CSL including as Seqirus chief financial officer.

In fact, Mr Naylor was CSL's chief financial officer and head of the Seqirus division.

The mistake was made by the Wednesday sub-editor who has been summarily dismissed. We apologize unreservedly to Mr Naylor and Medical Developments.

Medical Developments fell 16 cents or 2.7 percent to \$5.72 with 374,374 shares traded.

CRYOSITE

Cryosite says it has appointed John Hogg as chief executive officer starting on \$250,000 a year, with executive chair Bryan Dulhunty to become non-executive chair.

Cryosite said Mr Hogg joined the company in 2018 and was appointed as general-manager of operations in December 2019.

The company said Mr Hogg specialized in warehousing, logistics and supply chain management and had previously worked for Allergan, Boots International Healthcare, Johnson & Johnson and Philips Electronics.

Cryosite said Mr Hogg was be entitled to short-term cash bonus incentives of up-to 20 percent of his base salary, and long-term incentives of 650,000 options exercisable at six cents each within three years.

Cryosite fell 1.5 cents or 5.9 percent to 24 cents.