Biotech Daily

Wednesday November 18, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: KAZIA UP 32%; NEUREN DOWN 4%**

*** KAZIA: NEW DATA BACKS PAXALISIB FOR GLIOBLASTOMA**

*** CMRI, ALIA PARTNER FOR USHER SYNDROME**

*** REDHILL: FDA CLEARS PHASE II/III RHB-107 FOR COVID-19 TRIAL**

*** DORSAVI RIGHTS RAISE $300k OF HOPED-FOR $1.85m; TOTAL $2.15m**

*** IMPEDIMED SELLS 1st HEART FAILURE SOZO TO PHOENIX**

*** ORTHOCELL REQUESTS 'CELGRO NERVE RESULTS' TRADING HALT**

*** GENETIC SIGNATURES RECEIVES $2.6m R&D TAX INCENTIVE**

*** ANATARA, RIDLEY, MURDOCH UNI STUDY BROMELAIN FOR PIGLET E COLI**

*** RHYTHM: AGM 24% OPPOSE DIRECTOR EDUARDO VOM ELECTION**

*** MICRO-X 21% OPPOSE 10% PLACEMENT CAPACITY**

*** IMUGENE RELEASES 106m ASX ESCROW SHARES**

*** ALTHEA GERMANY MARIJUANA LICENCE**

*** MID WEALTH TAKES 9.7% OF LIFESPOT**

*** PYXIS INCREASES, DILUTED TO 6.6% OF LIFESPOT**

*** INCANNEX APPOINTS CANARY CAPITAL CORPORATE ADVISOR**

*** FEDERAL GOVERNMENT COVID-19 GLOBAL INNOVATION SUMMIT**

MARKET REPORT

The Australian stock market rose 0.51 percent on Wednesday November 18, 2020, with the ASX200 up 32.9 points to 6,531.1 points. Twenty-four Biotech Daily Top 40 stocks were up, seven fell, seven traded unchanged and two were untraded. All Big Caps rose.

Kazia was the best, up 38 cents or 31.9 percent to $1.57, with 4.3 million shares traded. Impedimed improved 9.5 percent; Telix climbed 7.3 percent; Next Science and Resonance rose six percent or more; Antisense was up five percent; Amplia, Prescient and Proteomics were up more than four percent; Cynata, Oncosil, Polynovo and Starpharma were up more than three percent; Alterity, Avita, Cochlear and Compumedics rose two percent or more; Clinuvel, Cyclopharm, Nanosonics, Opthea, Optiscan and Universal Biosensors were up one percent or more; with CSL, Genetic Signatures, Resmed and Volpara up by less than one percent.

Neuren led the falls, down six cents or 4.4 percent to $1.29, with 197,953 shares traded. Osprey fell 4.2 percent; Uscom lost three percent; Imugene shed two percent; Paradigm was down 1.6 percent; with Medical Developments and Pro Medicus down by less than one percent.

KAZIA THERAPEUTICS

Kazia says an interim analysis of its phase II, 29-patient study of GDC-0084, or paxalisib, for glioblastoma continued to outperform standard-of-care temozolomide.

Kazia said median progression-free survival was 8.4 months compared to 5.3 months for temozolomide and the median overall survival was 17.5 months compared to 12.7 months for temozolomide.

The company said that the further interim results were “highly consistent with prior data”.

In June, Kazia said interim data showed that median progression-free survival for paxalisib was 8.5 months compared to 5.3 months for temozolomide and median overall survival was 17.7 months with paxalisib, compared to 12.7 months for temozolomide (BD: June 22, 2002)

Today, the company said the most common toxicities included rash, stomatitis and hyper-glycaemia, which was consistent with other PI3K and mTOR inhibitors.

Kazia chief executive officer Dr James Garner said progression-free survival and overall survival had “remained extremely steady as the study has progressed”.

“This gives us a great deal of confidence that what we are seeing is representative and reliable,” Dr Garner said.

Kazia said interim results from its St Jude study of paxalisib for diffuse intrinsic pontine gliomas (DIPG) and diffuse midline gliomas determined the maximum tolerated dose was 27mg/m2, with dose limiting toxicities including hyper-glycaemia, oral mucositis and rash.

The company said the study was the first-in-paediatric trial to establish safety and pharmacokinetics in 27 patients aged from three years to 16 years, but four patients had discontinued participation before the first dose.

Kazia said it found no meaningful difference between intact capsules and the opening of capsules sprinkled onto a food carrier.

The company said that the study not “shown a clear survival for paxalisib in comparison to historical controls”.

Kazia said that although 96 percent of patients were progression-free and alive at six months compared to 58 percent in the historical control, “the authors note that [progression-free survival] can be a complex endpoint to interpret in DIPG trials due to the confounding effect of incidental radiological changes associated with radiation therapy”.

The company said both studies were ongoing, with final data expected by July 2021.

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CHILDREN’S MEDICAL RESEARCH INSTITUTE

Sydney’s Children’s Medical Research Institute says it has partnered with the Trento, Italy-based Alia Therapeutics for gene therapy research for Usher syndrome.

The Institute said Usher syndrome was a genetic conduction in children born with impaired hearing and involved progressive vision loss as they grew older.

The CMRI said that its Stem Cell Medicine Group led by Dr Anai Gonzalez Cordero took skin or blood samples to be transformed into stem cells, which were programmed to form organoids for research.

The Institute said the research project, using clustered regularly interspaced short palindromic repeats repetitive (Crispr) technology would focus on the most common type of the syndrome, Usher 2A.

Dr Cordero said the group hoped to study other types of Usher syndrome in the future, subject to funding.

"This technology combined with the infrastructure and gene therapy expertise in place at CMRI are crucial for the development and success of the project,"’ Dr Cordero said.

REDHILL BIOPHARMA

Redhill says the US Food and Drug Administration has cleared an investigational new drug application for a phase II/III study of its RHB-107 for Covid-19.

In April, Redhill said it would provide RHB-107 to the US National Institute of Allergy and Infectious Diseases for non-clinical studies of activity against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), following evaluation of the drug's possible mechanism of action and activity against Sars-Cov-2 (BD: Apr 21, 2020).

Yesterday, the company said it completed enrolment of its 40-patient, phase II US study of opaganib, or Yeliva, for severe Covid-19-related pneumonia (BD: Nov 17, 2020).

Today, Redhill said RBH-107, or upamostat, was licenced from Germany's Heidelberg Pharma, and was a potential inhibitor of several serine proteases, previously demonstrating anti-viral and potential tissue-protective effects, inhibition of Sars-Cov-2 viral replication and safety.

The company said the randomized, parallel-group, double-blind study was expected to begin enrolment early next year for patients with symptomatic Covid-19 not requiring hospitalization, but did not disclose the number of patients.

Redhill said it would administer RHB-107 once daily for 14 days, with an eight-week follow-up period, and the primary endpoints were time to recovery compared to placebo, as well as safety and tolerability.

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

On the Nasdaq, Redhill was up 6.0 US cents or 0.75 percent to $US8.10 ($A11.13) with 287,637 shares traded.

DORSAVI

Dorsavi says it has raised $300,000 of a hoped-for $1.85 million through its one-for-four entitlement offer at 3.2 cents a share, raising a total of $2.15 million.

In October, Dorsavi said it had raised $1.85 million in an "over-subscribed" placement and hoped to raise a further $1.85 million in the rights offer (BD: Oct 22, 2020).

Today, the company said that it reserved the right to issue the 48.5 million shortfall shares at its discretion to third parties within three months.

Dorsavi said the funds would be used for product development and commercialization activities.

Dorsavi was unchanged at 3.2 cents with 1.1 million shares traded.

IMPEDIMED

Impedimed says it has sold an initial five Sozo fluid analysis software units for heart failure to the Cincinnati, Ohio-based Phoenix Healthcare Network.

Impedimed said this was the first commercial sales of its heart failure application, which assessed fluid overload in heart failure patients using its HF-Dex heart failure index.

The company said Phoenix Healthcare Network operated cardio-pulmonary rehabilitation units in nursing homes and long-term care facilities and its Sozo units would be implemented from early 2021.

Impedimed managing-director Richard Carreon said that skilled nursing facilities were "a very important part of the continuum of care for elderly heart failure patients and provide Impedimed a great opportunity to demonstrate the clinical utility of the Sozo digital health platform".

Impedimed was up one cent or 9.5 percent to 11.5 cents with 22.8 million shares traded.

ORTHOCELL

Orthocell has requested a trading halt pending an announcement of “results of a clinical trial for the use of Celgro for enhancing repair of peripheral nerves”.
Trading will resume on November 20, 2020 or on an earlier announcement.
Orthocell last traded at 37.5 cents.

GENETIC SIGNATURES

Genetic Signatures says it has received $2,578,627 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Genetic Signatures said the rebate related to research and development expenditure for the year to June 30, 2020.
Genetic Signatures was up half a cent or 0.3 percent to $1.755.

ANATARA LIFESCIENCES

Anatara says it has an agreement with Ridley Corp for a study of its bromelain-based feed additive for enterotoxigenic Escherichia coli in piglets.
Anatara has been developing the pineapple stem bromelain as Detach for livestock diarrhoea as well as “Garp”, or gastrointestinal reprogramming, for irritable bowel syndrome and inflammatory bowel disease (BD: Feb 7, 2019; Jan 22, 2020).
Today, the company said that with Ridley, it had agreements with the Australasian Pork Research Institute, who would provide grant funding for a study of the delivery mechanism for weaner piglets at Perth’s Murdoch University.
Antara said the project aimed to test a modified formulation of its bromelain-based formulation in an Escherichia coli challenge model of “semi-moist extruded creep feed” on weaning piglets to determine the efficacy on piglet health, welfare and performance after weaning.
The company said the study had a targeted completion of mid-2021.
Anatara said the University of New England had begun a study of its bromelain-based formulation on poultry for sub-clinical and necrotic enteritis (BD: Aug 10, 2020).
Anatara fell 2.5 cents or 12.8 percent to 17 cents.

RHYTHM BIOSCIENCES

Rhythm says 14,773,781 votes (24.45%) at its annual general meeting opposed the election of director Eduardo Vom with 45,645,323 votes (75.55%) in favor.
Rhythm said the remuneration report faced 2.95 percent opposition with 97.05 percent in favor and all other resolutions, to elect chair Otto Buttula and Louis Panaccio as directors, approve a 10 percent placement facility, issue options to director Trevor Lockett, adopt its employee incentive plan and to amend its constitution, passed easily.
Rhythm’s most recent Appendix 2A new issue announcement said the company had 201,495,811 shares on issue, meaning the votes against Mr Vom amounted to 7.3 percent of the company, sufficient to requisition extraordinary general meetings.
Rhythm was up 4.5 cents or 9.6 percent to 51.5 cents with 5.7 million shares traded.

MICRO-X

Micro-X says 32,747,283 votes (20.82%) at its annual general meeting opposed the 10 percent placement capacity, with 124,515,063 votes (79.18%) in favor.
Micro-X said that all other resolutions passed overwhelmingly including the adoption of its remuneration report, the re-election of directors, the ratification of the issue of placement shares, the employee incentive plan and to issue performance and service rights for managing-director Peter Rowland.
The company's most recent Appendix 2A announcement said Micro-X had 359,341,753 shares on issue, meaning that the opposition to the placement capacity amounted to 9.1 percent of the company, sufficient to requisition extraordinary general meetings.
Micro-X was up four cents or 15.7 percent to 29.5 cents with 2.6 million shares traded.

IMUGENE

Imugene says it will release 105,955,065 shares from ASX escrow on November 27, 2020.
According to Imugene's most recent Appendix 2A, the company would have 4,594,453,305 shares on issue following the release of shares.
Imugene fell 0.2 cents or two percent to 9.8 cents with 52.9 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says Germany's Federal Institute for Drugs and Medical Devices has granted all necessary licencses for the sale and distribution of its marijuana products in Germany.
Althea said this was a "significant milestone" and would make it the first commercial supplier of Australian marijuana in Germany.
The company said that with its distributor Nimbus Health, it would expedite the application for required import and export permits, it expected the first shipment in December 2020 and it would receive a payment for product and 50 percent of the net profit on sales.
Althea was up half a cent or 1.1 percent to 47.5 cents with 1.55 million shares traded.

LIFESPOT HEALTH

Melbourne's Medical Investment Trust (MID) Wealth says it has become a substantial shareholder in Lifespot with 13,100,000 shares or 9.72 percent of the company.
In a substantial shareholder notice signed by director Paul Pettofrezza MID said it acquired the shares on November 13, 2020 for $720,500 or 5.5 cents a share.
Earlier this month, Lifespot said it had raised $720,500 through a private placement with MID Wealth and the shares would be subject to voluntary escrow for six months from the issue date (BD: Nov 4, 2020).
Lifespot fell 0.3 cents or 3.4 percent to 8.5 cents.

LIFESPOT HEALTH

Pyxis Holdings says it has increased and been diluted in Lifespot from 8,600,015 shares (7.32%) to 8,909,441 shares (6.61%).
The Claremont, Western Australia-based Pyxis failed to disclose the cost of its 309,426 shares as required under the Corporations Act, but said that it was diluted on November 13, 2020 (see above).

INCANNEX HEALTHCARE

Incannex says it has appointed the Sydney-based Canary Capital as its corporate advisor for an initial 12 months until November 2021.
Incannex said it would issue Canary 20 million unlisted options in consideration, with half exercisable at 15 cents and the balance at 25 cents by November 30, 2023.
Incannex was unchanged at 11.5 cents with 6.2 million shares traded.

FEDERAL GOVERNMENT

The Federal Government says it will share its approach to the Covid-19 pandemic in the free Global Innovation Summit 2020 over the next two days.
A media release from Federal Health Minister Greg Hunt said participants would explore the impact of Covid-19 from health, social and economic perspectives and the role of innovation in recovery.
The Federal Government said the program theme was 'Crossing the chasm: Health, Innovation and the Future Economy' and Australians could participate for free.
The media release said the summit would be co-hosted by the Global Federation of Competitiveness Councils and would include international leaders' perspectives, interactive panel discussions and presentations.
Mr Hunt said the summit "gives us the opportunity to outline how we have approached the most challenging of times and allows us to work with other global leaders to develop the innovative health solutions we need in the months and years ahead".
Registration for the free event is at: https://bit.ly/3faMS7m.