

Biotech Daily

Thursday February 15, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: DIMERIX UP 8%; FACTOR THERAPEUTICS DOWN 5%
- * J&J, MONASH UNI PARTNER; J&J, VICTORIA \$300k DEVICE CHALLENGE
- * KINOXIS RAISES \$4m FOR SUBSTANCE ABUSE TREATMENTS
- * VAXART TAKES AVIRAGEN (BIOTA); 11-FOR-1 CONSOLIDATION
- * BI PAYMENT TAKES PHARMAXIS H1 REVENUE UP 354% to \$31m, \$6m PROFIT
- * POLYNOVO H1 REVENUE UP 31% to \$2.7m, LOSS UP 64% TO \$3.2m
- * DORSAVI H1 REVENUE UP 14.5% TO \$2.2m, LOSS UP 56.1% TO \$1.9m
- * RECCE SUBMITS MORE RECCE-327 DATA TO FDA
- * NUHEARA PETITIONS FDA TO ACCELERATE O-T-C HEARING AID ACT
- * HYDROPONICS QUEENSLAND MARIJUANA PLANT COMPLETES 1st STAGE
- * KINETIC TAKES 6.4% OF IMPEDIMED
- * NUHEARA RELEASES 151m SHARES, 50m OPTIONS FROM ESCROW
- * OBJ APPOINTS STEVEN SCHAPERA INTERIM CHAIRMAN

MARKET REPORT

The Australian stock market climbed 1.16 percent on Thursday February 15, 2018 with the ASX200 up 67.8 points to 5,909.0 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and three were untraded.

Dimerix was the best, up one cent or eight percent to 13.5 cents with 248,876 shares traded. Uscom climbed 6.5 percent; ITL was up 5.4 percent; Telix improved four percent; Acrux, Medical Developments, Opthea and Prana were up more than three percent; Impedimed, Mesoblast, Nanosonics, Pro Medicus and Volpara rose more than two percent; Actinogen, Avita, Bionomics, CSL, Polynovo and Resmed were up one percent or more; with Sirtex up 0.25 percent.

Factor Therapeutics led the falls, down 0.2 cents or five percent to 3.8 cents with 280,000 shares traded. Ellex fell 3.95 percent; Admedus, Compumedics and shed two percent or more; Airxpanders, Clinuvel, Osprey, Pharmaxis and Viralytics were down more than one percent; with Cochlear and Neuren down by less than one percent.

JOHNSON & JOHNSON INNOVATION, VICTORIA GOVERNMENT, MONASH UNI

The Johnson & Johnson Innovation Partnering Office at Monash University was opened by Victoria Health Minister Jill Hennessy who launched the \$300,000 Quickfire Challenge. The Johnson & Johnson Innovation head of Australia and New Zealand new ventures Kathy Connell said that the Office at Monash University's Clayton campus was the second partnering office following the establishment at Queensland University of Technology. Ms Connell said that Johnson & Johnson Innovation believed in diversity of thinking innovation and science and said that her company was involved in 50 collaborations in Australia "providing financial support and access to expertise to accelerate development. Ms Connell said that Johnson & Johnson had "a long term to getting things done". Monash University pro-vice-chancellor Sarah Newton said that the public-private partnering office would give researchers access to world leading technologies to develop treatments for a range of diseases.

A joint media release said the partnership would "focus on nurturing the next generation of innovators by delivering training, mentoring and networking programs to connect Victorian innovators with stakeholders from around the global Johnson & Johnson Innovation network".

Johnson & Johnson pharmaceuticals chairman Joaquin Duato said his company had been developing medical technologies for more than 130 years, was the biggest in the world and had invested \$11 billion in research.

Mr Duato said "we recognize that the best science is not just in Johnson & Johnson, but at Monash and with researchers and hospitals.

Citing the \$1.3 billion deal with Protagonist for inflammatory bowel disease, Mr Duato asked "Can we do better in Australia? Yeah, we can."

Mr Duato said that the right incentives were required for innovation to reduce the time taken for approvals to bring drugs to patients".

In a media release, Mr Duato said that his company sought "to bring together the brightest minds in science to take on some of the biggest healthcare challenges of our time".

"To do this, we are focusing on partnering with governments and universities in the world's leading innovation hotspots, including Australia, to translate research into global healthcare solutions for patients everywhere," Mr Duato said.

Ms Hennessy said that global health care spending was increasing at four percent a year and developments in technology from artificial intelligence to robotics and nanotechnologies were needed to meet health challenges.

"We are only limited by our imagination," Ms Hennessy said.

Ms Hennessy said that the motivator of medical research was "the reduction of human suffering" and that innovation was rebellion against the existing technologies.

She said she gave "my heart-felt appreciation for the people who get up every day to innovate".

"The new Johnson & Johnson Innovation Partnering Office at Monash will give our worldclass researchers the support they need to transform their findings into everyday care for Victorians while also supporting local jobs," Ms Hennessy said.

Ms Hennessy said the Victoria Quickfire Challenge: 'Driving Device Innovation' was a joint venture with Johnson & Johnson and three finalists would share a cash prize of \$300,000 as well as receive mentoring and support from Johnson & Johnson.

The media release said that the Victoria Quickfire Challenge aimed "to help kick-off the search for new medical device innovation".

The media release said that the Victorian Quickfire Challenge would be launched in the coming weeks at: https://jlabs.jnjinnovation.com/quickfire-challenges.

KINOXIS THERAPEUTICS

Kinoxis says it has raised \$3.86m to develop small molecules that mimic oxytocin to treat substance abuse disorders with the University of Sydney.

Kinoxis said a University of Sydney research team led by Prof Michael Kassiou and Prof lain McGregor would research small compounds that stimulated the oxytocin system to treat addiction and substance abuse disorders including the abuse of alcohol, illicit and prescription drugs.

The company said the University of Sydney research team were developing the lead candidate molecule SOC-1, a small, orally bio-available compound that mimicked the anti-addictive properties of oxytocin.

Kinoxis said that Uniseed, a venture fund operating at the Universities of Melbourne, New South Wales, Sydney and Queensland, and the Commonwealth Scientific and Industrial Research Organisation invested \$750,000 of the \$3.86 million raised in an initial investment round that would progress SOC-1 through pre-clinical testing, with the balance raised by high net worth investors and family wealth offices.

Kinoxis chief executive officer Hugh Alsop said the formation of the company to advance the SOC-1 candidate through a pre-clinical program was an "important step towards the development of a potential new therapeutic for addiction disorders".

"The strong support shown by our investors will allow us to develop the data package required to commence human clinical trials," Mr Alsop said.
Kinoxis is a private company.

VAXART INC (FORMERLY AVIRAGEN THERAPEUTICS, BIOTA PHARMACEUTICALS)

Vaxart says it has completed the merger with Aviragen, the entity will be called Vaxart and following an 11-for-one consolidation it will trade under the Nasdaq code of VXRT. The San Francisco-based Vaxart's chief executive officer Dr Wouter Latour said the merger "provides us with the necessary funding to support operations and enables us to

advance the development of our pipeline of proprietary oral vaccines and direct-acting antivirals".

"We expect to have several value-creating events this year, including a data readout from

the phase II study of BTA074, which we acquired in the merger, and the start of a phase II norovirus challenge study," Dr Latour said.

Former Biota shareholders own 49 percent of the merged entity.

The company said its shares fell 55 US cents or 6.1 percent to \$US8.50 (\$A10.72, equivalent to 12.2 cents, compared to the \$1.00 share price before Biota left the ASX).

<u>PHARMAXIS</u>

Pharmaxis says that revenue for the six months to December 31, 2017, was up 353.6 percent to \$31,344, 000 turning the previous net loss after tax to a \$5,920,000 profit. Pharmaxis said it received \$27.0 million from Boehringer Ingelheim for the phase II trial of BI 1467335, formerly PXS4728A, for non-alcoholic fatty liver disease, with other revenue including \$1.2 million reimbursed for research and development by Chiesi, \$2.5 million from sales of Bronchitol for cystic fibrosis and \$980,000 for the Aridol test.

Pharmaxis said that the previous diluted loss per share of 0.03 cents turned to a diluted earnings per share of 0.02 cents for the six months to December 31, 2017, with net tangible assets per share down 3.1 percent to 3.1 cents and cash and cash equivalents of \$25,045,000 at December 31, 2017, compared to \$29,245,000 at December 31, 2016. Pharmaxis fell half a cent or 1.8 percent to 27 cents.

POLYNOVO

Polynovo says that revenue for the six months to December 31, 2017, was up 31.3 percent to \$2,746,420 with net loss after tax increasing 64.2 percent to \$3,227,300. Polynovo said the revenue mainly came from its US Biomedical Advanced Research and Development Authority contract with \$868,924 in sales of its Novosorb wound treatment. The company said that diluted loss per share rose 54.3 percent to 0.54 cents for the six months to December 31, 2017, with net tangible assets per share up 46.5 percent to 4.3 cents and it had cash and cash equivalents of \$25,709,407 at December 31, 2017, compared to \$9,783,318 at December 31, 2016.

Polynovo was up half a cent or one percent to 52 cents.

DORSAVI

Dorsavi says that revenue for the six months to December 31, 2017, was up 14.5 percent to \$2,239,089 increasing net loss after tax 56.1 percent to \$1,972,062.

Dorsavi said that sales revenue for its wearable body movement sensor systems increased by 12.8 percent to \$1,949,440.

The company said that diluted loss per share rose 40.5 percent to 1.18 cents for the six months to December 31, 2017 and it had cash and cash equivalents of \$6,749,478 at December 31, 2017, compared to \$8,726,634 at December 31, 2016.

Dorsavi was unchanged at 22.5 cents.

RECCE PHARMACEUTICALS

Recce says it has submitted additional data and communication request to the US Food and Drug Administration for its Recce-327 synthetic antibiotic.

Recce said the submission included expanded pre-clinical data, a proposed phase I clinical trial program and a communication request that were additions to the its investigational new drug application for Recce-327 to treat sepsis from Staphylococcus aureus and Escherichia coli bacteria, including their superbug or resistant forms. Last year, the company said it had filed preclinical data and related documentation to the FDA for human clinical trials of Recce-327 (BD: Sep 7, 2017).

Recce chairman Dr Graham Melrose said that "further communication with the FDA would be an opportunity to further support our new class of antibiotics as we seek to help address urgent human health needs".

Recce was up half a cent or 2.9 percent to 18 cents.

<u>NUHEARA</u>

Nuheara says it has petitioned the US Food and Drug Administration to accelerate the implementation of the Over-The-Counter Hearing Aid Act of 2017.

Nuheara said it had written to FDA commissioner Dr Scott Gottlieb to request he accelerate the implementation of the 2017 Act to allow hearing aids to be sold directly to the customer without a prescription from a doctor and to consider a set of standards prepared by the US Consumer Technology Association that would regulate over-the-counter hearing devices.

The company said that the FDA was required, within three years, to develop standards and a regulatory plan before over-the-counter hearing aids could be sold. Nuheara fell 0.1 cents or 1.7 percent to 5.9 cents with 3.2 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it has completed the first stage of its research and development and marijuana growing facility in Queensland.

Hydroponics said the first stage included greenhouses, a drying and shredding facility and an extraction laboratory for the cultivation, growth and processing of medicinal cannabis. The company said the facility would function as a laboratory for the development of new strains and the testing and quality control of harvested products.

Hydroponics said the facility was ready to grow its first crop pending government approval and that the growing capacity was scalable as demand increased and exports began. Hydroponics was up five cents or 6.5 percent to 81.5 cents.

IMPEDIMED

Kinetic Investment Partners says it has increased its substantial shareholding in Impedimed from 19,302,767 shares (5.17%) to 24,235,677 shares (6.42%).

The Melbourne-based Kinetic said that between June 11, 2016 and February 13, 2018 it sold 1,059,714 shares for \$1,316,608 or \$1.24 cents a share and bought 6,016,338 shares for \$6,669,505 or \$1.11 a share.

Kinetic is part of Challenger Financial Services, its principals are Jonathan Findlay, Richard Sharp and Mark Skocic.

The company said that the registered holders of the shares were JP Morgan Nominees, National Nominees, Cogent Nominees, Northern Trust and Citigroup Nominees. Impedimed was up two cents or 2.9 percent to 70 cents.

NUHEARA

Nuheara says it will release 151,088,035 shares and 50,000,000 unquoted options from ASX escrow on March 2, 2018.

Nuheara said that of the unquoted options, 20,000,000 would be exercisable at three cents each by February 24, 2019 and that 30,000,000 would be exercisable at five cents each by May31, 2019.

The company's most recent Appendix 3B new issue announcement said that it had 647,227,793 shares quoted on the ASX, meaning that after the release there would be 798,315,828 shares available for trading.

OBJ

OBJ says it has appointed director Steven Schapera as interim chairman following Glyn Denison's retirement earlier this month (BD: Feb 5, 2018).

OBJ was up 0.1 cents or 2.9 percent to 3.6 cents.