Biotech Daily

Wednesday March 8, 2017

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: COMPUMEDICS UP 12%, AVITA DOWN 9%**

*** MCRI: 'FAST, ACCURATE TEST FOR BONE MARROW TRANSPLANT'**

*** REDHILL: CONCORDIA WINS $3m 'GENERIC' DONNATAL DAMAGES**

*** TGA APPROVES ACTINOGEN XANAMEM FOR ALZHEIMER'S TRIAL**

*** BIOTECH CAPITAL SHARE PLAN RAISES $595k, TOTAL RAISED $2.4m**

*** PRESCIENT COMPLETES 1st PTX-200 FOR AML COMBINATION COHORT**

*** RHINOMED ADDS TWO US CHAINS, EXPANDS SYMBION MUTE SALES**

*** NUHEARA SIGNS AMAZON, BROOKSTONE FOR IQBUD DISTRIBUTION**

*** MGC ISSUES 10m LONGEVITY 'PERFORMANCE' RIGHTS**

*** FIL TAKES 8% OF COGSTATE**

*** NOXOPHARM TO RELEASE 4.3m SHARES, 3.3m OPTIONS FROM ESCROW**

*** PHARMAUST APPOINTS DR RICHARD MOLLARD CSO, STARTS ON $183k**

*** BIO-MELBOURNE 5th ANNUAL 'DEVICES + DIAGNOSTICS LAB'**

MARKET REPORT

The Australian stock market slipped 0.03 percent on International Women's Day, Wednesday March 8, 2017, with the ASX200 down 1.7 points to 5,759.7 points. Eighteen Biotech Daily Top 40 stocks rose, 13 fell, eight traded unchanged and one was untraded.

Compumedics was the best, up six cents or 11.9 percent to 56.5 cents with 109,785 shares traded. Benitec climbed 9.4 percent; IDT was up 6.9 percent; Airxpanders, Impedimed, Mesoblast and Uscom were up five percent or more; Prima improved 3.2 percent; ITL rose 2.2 percent; with Admedus, Factor Therapeutics, Pharmaxis, Psivida, Starpharma and Viralytics up more than one percent.

Avita led the falls, down one cent or 9.1 percent to 10 cents with 1.4 million shares traded. Orthocell lost 7.2 percent; Reva and Universal Biosensors were down more than six percent; Opthea fell 4.1 percent; Cellmid and Polynovo were down more than three percent; Bionomics and Neuren shed more than two percent; with Acrux; Genetic Signatures and Oncosil down more than one percent.

THE MURDOCH CHILDREN'S RESEARCH INSTITUTE

Melbourne's Murdoch Children's Research Institute says it has developed a new blood test to monitor the success of bone marrow transplants.

The Institute said the test would allow doctors to measure whether the bone marrow transplant had successfully engrafted and identify rejection or recurrence of disease earlier than current approaches and could save lives by giving clinicians more time to react to changes in the transplant.

A research article, entitled 'Use of ubiquitous, highly heterozygous copy number variants and digital droplet polymerase chain reaction to monitor chimerism after allogeneic haematopoietic stem cell transplantation' was published in the journal Experimental Hematology, with an abstract available at: http://bit.ly/2lVsfic.

The Institute said that the Organ Health BMT test had been in use at the Royal Children's Hospital since the beginning of 2016, with lead scientist Prof Howard Slater saying it had been well-received by Royal Children's Hospital doctors.

"Using current tests, it can be challenging to monitor the success of bone marrow transplants," Prof Slater said. "This is because existing tests don't work for all transplant recipients, are relatively expensive and time consuming to perform."

"Newer technologies now permit more sensitive and precise measurements [and] our test leverages these," Prof Slater said.

Royal Children's Hospital clinician and MCRI researcher Dr Rachel Conyers said that "from a clinical perspective this new technique gives us an extremely quick and sensitive way of monitoring the success of the transplant".

"It gives the clinician the opportunity to act early if post-transplant alterations to the graft are necessary," Dr Conyers said.

"This can, and will, impact upon patient survival," Dr Conyers said.

The MCRI cited the example of a two-year-old girl diagnosed with juvenile myelomonocytic leukaemia at six months of age, who had a bone marrow transplant.

The Institute said that the transplant was monitored with the Organ Health BMT test, which detected a slight drop in her chimerism, or the proportion of blood cells produced by the transplant, and the physicians advised that she cease immunosuppression medications early to improve this.

The MCRI said that further testing showed improvement to 100 percent chimerism, indicating the transplant had recovered completely.

The Institute said that more than 2,000 bone marrow transplants were performed in Australia and New Zealand every year.

"The Organ Health BMT test gives doctors more accurate and timely information to make important treatment decisions," Prof Slater said.

The Institute said the Organ Health BMT test used genetic technology to analyze markers called copy number variations, or CNVs, in the DNA of transplant recipients and donors.

The MCRI said that scientists identified CNVs that were unique to the transplant donor and absent in the recipient, or vice versa, and used these to monitor the function of the bone marrow transplant.

The Institute said that transplants were used to replace diseased or cancerous bone marrow with healthy bone marrow to treat a range of diseases including leukaemia, lymphoma and immune deficiency disorders.

"Bone marrow transplants are often the treatment of last resort and come at a critical time in a person's fight against disease," Prof Slater said. "Coupling this with the fact that transplants are a costly procedure, it is imperative we know how well they are working so that health outcomes can be maximized."

The MCRI said it wanted partners for further implementation of the Organ Health BMT.

REDHILL BIOPHARMA

Redhill says that Donnatal co-promoter Concordia International has won $US2.2 million ($A2.9 million) in damages from Method Pharmaceuticals.

Redhill said that a US District Court granted a subsidiary of the Oakville, Ontario-based Concordia damages related to false claims about the gastro-intestinal drug made by the Arlington, Texas-based Method Pharmaceuticals and its principal owner.

The company said that the court awarded Concordia damages of $US2.2 million, an increase from the original damages award of $US733,000, concluding that Method willfully engaged in false advertizing under the Lanham Act by falsely listing the product on pharmaceutical databases and asserting that its medication was a legal generic alternative to Concordia's Donnatal drug.

In January, Redhill said it had an exclusive co-promotion agreement with a Concordia subsidiary, granting Redhill certain promotional rights in the US for Donnatal, which it expected to promote by July 2017.

Redhill quoted Concordia saying that the treble damages awarded by the US District Court "vindicates their marketing rights of the Donnatal brand and should serve as notice to any other company marketing an illegal copy of Donnatal that the judicial system in the US will hold them financially accountable".

The company said that Donnatal was a combination of phenobarbital, hyoscyamine sulfate, atropine sulphate and scopolamine hydrobromide prescribed with other drugs in the treatment of irritable bowel syndrome and acute enterocolitis.

On the Nasdaq, Redhill was up four US cents or 0.41 percent to $US9.79 with 118,168 shares traded.

ACTINOGEN MEDICAL

Actinogen says that Australian Therapeutic Goods Administration has approved its 174-patient 'Xanadu' phase II trial of Xanamem for Alzheimer's disease.

Actinogen said that both the US Food and Drug Administration and UK Medicines and Healthcare Products Regulatory Agency had approved the double-blind, 12-week, randomized, placebo-controlled trial to assess the safety, tolerability and efficacy of Xanamem in subjects with mild dementia due to Alzheimer's disease and would begin recruitment by July 2017.

The company said that Xanamem's mechanism of action differentiated it from other Alzheimer's drugs under development, because it was designed to block excess production of the stress hormone cortisol in the areas of the brain most affected by Alzheimer's disease.

Actinogen said that raised cortisol levels had been "strongly associated with Alzheimer's disease and lowering cortisol … [was] an important new target for treating the disease".

Actinogen was unchanged at six cents with 2.3 million shares traded.

BIOTECH CAPITAL

Biotech Capital says its share plan at 11 cents a share raised $595,000, following an oversubscribed placement which raised $1,791,864 (BD: Feb 14, 2017).

Biotech Capital said the funds would be used to build greater capabilities in regulatory, quality and clinical services and promote the group's services to overseas clients.

The company said that its wholly-owned subsidiary Bioimpact was pursuing opportunities to in-licence intellectual property rights to novel drugs and medical devices.

Biotech Capital was untraded at 12 cents.

PRESCIENT THERAPEUTICS

Prescient says it has completed the first cohort of three patients in its phase Ib trial of PTX-200 plus cytarabine for acute myeloid leukaemia (BD: Dec 14, 2016).
Prescient said that the first cohort of patients with relapsed or refractory acute myeloid leukaemia was treated with a dose of 25mg/m2 of PTX-200 given as a one hour intravenous infusion on day-1, day-8 and day-15 and in combination with 400mg/m2 of cytarabine as continuous infusion on day-2 to day-6 of each 21-day cycle.
The company said that the dose was safe, with no dose limiting toxicities.
Prescient principal investigator Prof Jeffrey Lancet said the trial was “proceeding well to date, with no significant safety issues, along with some early signals of efficacy”.
“We’re looking forward to the next stage of dose escalation,” Prof Lancet said.
Prescient said that the next dose level was 35mg/m2 of PTX-200.
Prescient was up 0.1 cents or 1.2 percent to 8.7 cents.

RHINOMED

Rhinomed says it has been added as a vendor by two US pharmacy wholesalers and its Mute anti-snoring nasal plugs have been accepted by Symbion in Australia.
Rhinomed said that it had been accepted as a vendor by the Chesterbrook, Pennsylvania-based pharmacy wholesaler Amerisource Bergen, which handled about 20 percent of all of the pharmaceuticals sold and distributed throughout the US, supplying about 15,000 retail pharmacies, including 3,200 shops in its good neighbor pharmacies program.
The company said it had been added as a vendor with Dublin, Ohio-based health care services company Cardinal Health whose subsidiary Independence Medical was a distributor of wholesale medical supplies, with an electronic commerce platform, call centre and national sales force, focusing on durable medical equipment retailers, hospitals, sleep labs and independent pharmacy chains.
Rhinomed said it had expanded its Mute anti-snoring technology to Symbion, which began distributing Mute in 2015, and would take the Mute nasal plugs to its 900 Pharmacy Choice network and expanded access to Mute to its network of about 3,500 pharmacies.
Rhinomed said that it expected to see the impact of this expansion in distribution on revenue over the rest of this calendar year.
Rhinomed was up 0.2 cents or 14.3 percent to 1.6 cents with 2.5 million shares traded.

NUHEARA

Nuheara says its sound-filtering and device Iqbuds will be available from on-line retailer Amazon and Brookstone shops from mid-April 2017.
Nuheara said that it was completing backorders from its Indiegogo crowd-funding campaign and its website pre-order sales.
Last year, Nuheara said it had crowd-sourced orders worth $US393,428 ($A513,747) in two weeks for the discounted Iqbuds at $US199 a pair (BD: Apr 18, 2016).
By June, the company said it had pre-orders for more than $1 million of Iqbuds and in July said it would launch the product from January 5, 2017 (BD: Jun 9, Jul 26, 2016).
In October, Nuheara said it had sold its more than $1 million of Iqbuds for 2016 and raised $4,984,000 in a placement to fund production and marketing (BD: Oct 12, 27, 2016).
Earlier this year, the company said it had European and Canadian approval to sell the devices (BD: Feb 1, 2017), and last week, Nuheara said that for the six months to December 31, 2016 it had revenue of $9,153, all of which was from interest on deposits.
Nuheara was up 0.2 cents or 2.1 percent to 9.7 cents with 5.2 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says a conversion milestone for the conversion of 10,026,000 free employee "performance rights" has been met and the shares have been issued.
MGC said the conversion was dependent on meeting milestone 1 of the employee performance rights resolution passed at the September 27, 2016 general meeting.
The notice of meeting did not include a milestone 1 for the employee performance rights, but milestone 1 for related party performance rights required the holder to remain employed to December 31, 2016.
No one from the company was available to clarify the matter at the time of publication.
MGC was up 1.4 cents or 25.9 percent to 6.8 cents with 69.3 million shares traded.

COGSTATE

FIL Limited says it has increased its substantial shareholding in Cogstate from 8,163,578 shares (7.21%) to 9,344,356 shares (8.26%).
The Hong Kong-based FIL said it bought the 1,180,778 shares between February 7 and March 3, 2017 at prices ranging from $1.05 to $1.30.
Cogstate was up two cents or 1.9 percent to $1.05.

NOXOPHARM

Noxopharm says that 4,261,214 shares and 3,277,858 unlisted options exercisable at 30 cents each by February 28, 2021will be released from ASX escrow on April 1, 2017.
Noxopharm said 36,885,465 shares and 10,000,000 "performance" shares remained in ASX escrow until August 9, 2018.
Following the April 1 release from escrow, Noxopharm will have 38,285,964 shares available for trading.
Noxopharm fell 3.5 cents or 7.45 percent to 43.5 cents.

PHARMAUST

Pharmaust says it has appointed Dr Richard Mollard as its chief scientific officer effective from March 13, 2017, starting on $182,650 a year.
Pharmaust said that Dr Mollard had more than 15 years' experience as a pharmaceutical executive, and had been a consultant to the company for two years.
The company said Dr Mollard would take charge of the clinical and scientific development of monepantel, formerly PPL-1, and would work closely with chief executive officer Dr Richard Hopkins in preparing for a planned phase II human trial of monepantel for cancer.
Pharmaust said that Dr Mollard held a Doctorate of Philosophy from Melbourne's Monash University and a Master of Business Administration from the University of Melbourne's Business School.
The company said that Dr Mollard was hired on the same terms as Dr Hopkins and apart from his salary of $182,650 a year, plus statutory superannuation, Dr Mollard would receive 10,125,000 options in three tranches, with 1,875,000 exercisable at 7.5 cents, 3,750,000 at 15 cents, 4,500,000 at 23 cents, all expiring at March 31, 2020, along with 3,375,000 performance rights, pending the completion of a phase II monepantel (PPL-1) dog trial by March 31, 2018, the start of a phase II human trial by December 31, 2018 and the exercise of a collaboration and option agreements with Novartis Animal health by the end of 2018 (BD: Mar 1, 2017).
Pharmaust fell 0.3 cents or 5.7 percent to five cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold its fifth annual 'Devices + Diagnostics Lab' workshop on implantable medical technology next Wednesday March 15, 2017.

The Network said the full day event would include an address from the Victoria Minister for Small Business, Trade and Innovation Philip Dalidakis, presentations from 11 speakers and panel discussions with the speakers as well as six expert panellists.

The Bio-Melbourne Network said that the event coincided with the Victorian Invitation Program and delegates would be joined by participants from Japan, China and the US.

Bio-Melbourne Network interim chief executive officer Lusia Guthrie said that "the implantable medical devices market has been growing and diversifying at great pace for some time, transforming healthcare delivery and improving the quality of life for patients".

Ms Guthrie said the speakers would address how implantable technology was meeting clinical needs as well as commercialization pathways, including whole of venture funding budget and funding strategies.

The Network said that more than 135 people had registered for the event which was sponsored by the Victoria Government, the Commonwealth Scientific and Industrial Research Organisation, Piper Alderman and the Federal Department of Industry, Innovation and Science.

The Network said that the workshop would will be held in the auditorium at 452 Flinders St, Melbourne on March 15, 2017, with registration from 8.30am and presentations until 5.30pm to be followed by networking.

To view the full program or register go to: http://bit.do/dndl2017.