

Biotech Daily

Thursday June 8, 2017

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: AVITA UP 8%, LIVING CELL DOWN 8%
- * SIENNA \$6m IPO FOR CANCER DIAGNOSTICS
- * MELBOURNE UNI OPENS GRAEME CLARK INSTITUTE
- * MTP CONNECT, QUT LAUNCH BRIDGE PROGRAM
- * BOTANIX BTX1701 ACNE PILOT STUDY 'SAFE, REMOVES OILINESS'
- * MEDIBIO: 'STUDY BACKS HEART RATE ALGORITHM DEPRESSION TEST'
- * NON-CANCER EURO PATENT FOR PHARMAUST MONEPANTEL
- * IMMURON REQUESTS 'CAPITAL TRANSACTION' TRADING HALT
- * BVF, MARK LAMPERT TAKE 9% OF BIONOMICS
- * NOVOGEN LOSES CHAIR JOHN O'CONNOR, IAN PHILLIPS; CUTS COSTS

MARKET REPORT

The Australian stock market fell 0.17 percent on Thursday June 8, 2017 with the ASX200 down 9.4 points to 5,676.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and two were untraded.

Avita was the best, up 0.6 cents or 7.7 percent to 8.4 cents with 466,476 shares traded.

Mesoblast and Uscom climbed more than five percent; Factor Therapeutics improved 4.8 percent; Cellmid, CSL, Prima, Reva and Viralytics were up more than three percent; Starpharma rose 2.9 percent; Admedus and Opthea were up more than one percent; with Medical Developments, Pro Medicus, Psivida, Resmed and Sirtex up by less than one percent.

Living Cell led the falls, down one cent or 8.3 percent to 11 cents with 364,321 shares traded.

Polynovo lost 7.5 percent; Compumedics shed 5.3 percent; Neuren fell 4.8 percent; Actinogen, Benitec and Nanosonics were down three percent or more; Airxpanders, Clinuvel and Impedimed shed more than two percent; Bionomics and Osprey were down more than one percent; with Cochlear, Cyclopharm and Ellex down less than one percent.

SIENNA CANCER DIAGNOSTICS

Sienna says it hopes to raise up to \$6 million in an initial public offer at 20 cents a share to list on the ASX to commercialize its DNA telomerase-based cancer diagnostics. Under chief executive officer Dr Kerry Hegarty, Sienna developed the first telomerase-based adjunct diagnostic for bladder cancer, which was later approved in the US, Europe and Australia (BD: Dec 2, 2014; Dec 22, 2015; Nov 15, Dec 12, 15, 2016).

Today, the company said it hoped to list on the ASX under the code SDX.

The Sienna prospectus said that with 157,274,327 existing shares, if the offer was successful and a further 30,000,000 were issued at 20 cents each it would have an implied market capitalization of \$37.5 million.

The company chairman is former Roche executive and Anteo chief executive officer Dr Geoff Cumming with directors Dr John Chiplin, Carl Stubbings and Dr David Earp. In April, Sienna appointed chief operating officer Matthew Hoskins as its chief executive officer having appointed former Acrux chief financial officer Tony Di Pietro chief financial officer and company secretary in 2014 (BD: Nov 12, 2014; Apr 19, 2017).

Sienna said that the Sydney-based Sequoia Corporate Finance was the lead manager for the offer, which was expected to open tomorrow and close on July 17 with trading on the ASX expected to start by August, 2017.

The prospectus is available at: http://www.siennadiagnostics.com.au/investor.

UNIVERSITY OF MELBOURNE

The University of Melbourne says the Graeme Clark Institute for Biomedical Engineering opened today to develop new bionic devices and diagnostics.

The University said that named after the inventor of the cochlear ear implant, Prof Graeme Clark, the Institute would be a hub for biomedical engineering research and brought together biomedical engineers, clinical researchers and industry partners.

The University said the Institute would develop new bionic devices, implants, drug treatments and assistive technologies like prosthetics, as well as diagnostics.

A media release from the University said that Prof Mark Cook would be the Institute's inaugural director.

"It's fair to say that no biomedical engineering institutes, either in Australia or the wider world, have the scope and scale of the Graeme Clark Institute," Prof Cook said.

"The Institute is in a unique position to capitalise on multi-partner collaborations that are critical to innovation and commercialization," Prof Cook said.

"The novelty of the solutions we will develop comes through the direct interaction of the Melbourne School of Engineering, the Faculty of Medicine, Dentistry and Health Sciences and the Faculty of Science," Prof Cook said.

The University said that the Institute's success would be measured by the impact of clinically-driven research that solved clinical needs and engagement with industry to translate that research into clinical practice.

Institute researcher and Melbourne School of Engineering head of biomedical engineering Prof David Grayden said that projects would include modelling the human body in three dimensions "to virtually assess and insert implants for joint replacements, testing the University's world-first stentrode device in human trials, and building on its position as the top university for mechano-pharmacology" in which tissues cells were mechanically measured to develop effective drug therapies.

MTP CONNECT, QUEENSLAND UNIVERSITY OF TECHNOLOGY

MTP Connect and the Queensland University of Technology say the Bridge Program to translate innovation and discovery research to the market has officially opened. In April, Medicines Australia said that a 15-member consortium backed the Bridge Program, including pharmaceutical companies, Queensland University of Technology and the Federal Government–funded Medical Technologies and Pharmaceutical Growth Centre, or MTP Connect (BD: Apr 10, 2017).

Medicines Australia said at that time that the Bridge Program commercialization training would begin with 100 participants, of which two would be granted travel scholarships to visit offshore pharmaceutical research facilities and develop experience and business networks.

Today, a media release from MTP Connect said the Program would be launched in Sydney today and would "equip participants with the knowledge and skills to navigate the complex regulatory, financial, scientific and intellectual property issues involved in bringing new medicines to market".

The media release said that entrepreneurs, research scientists, patent attorneys and business development managers were among the 100 participants in the program. In May, MTP Connect announced the second round of its Project Fund Program, with expressions of interest to open on July 3, 2017 (BD: May 3, 2017). For more information, go to: www.mtpconnect.org.au.

BOTANIX PHARMACEUTICALS

Botanix says a pilot study of BTX1701 shows it is safe and has "prospective activity in removing excess skin oiliness and reducing bacterial infection".

Botanix did not cite the number of subjects in the trial of the over-the-counter facial cleanser, which it said was based on its Permetrex skin delivery technology.

The company said it was currently conducting a trial of the synthetic cannabidiol BTX1503 for moderate to severe acne (BD: Mar 30, 2017).

Botanix said that the facial cleanser market was worth \$US1.5 billion a year, but many cleanser products contained alcohol which could dry skin, as well as preservatives that could cause allergic reactions.

The company said that BTX1701 "avoids these challenges ... to provide superior cleansing effect" by using its Permetrex skin delivery technology in conjunction with a novel oil clearing agent.

Botanix said that BTX1701 "applied daily reduced oil levels on the skin and removed [Propionibacterium acnes], the bacteria responsible for the development of acne, from the surface of the skin more effectively than a leading facial cleanser product".

The company said that based on the results it would embark on further clinical development of BTX1701 to confirm these initial results in a larger clinical study and compile additional comparative data against leading facial cleanser products.

Botanix executive director Matt Callahan said the company was "very pleased with the outcome of this first human study that establishes the viability and commercial potential of the BTX1701 formulation as a novel skin cleanser".

"Because the safety of Permetrex has already been successfully established in a previous clinical study and the balance of formulation only includes ingredients that have previously been included in approved dermatology products, the development of BTX1701 facial cleanser does not require [US Food and Drug Administration] approval and provides an exciting near term partnering opportunity for Botanix," Mr Callahan said.

Botanix was up 0.2 cents or five percent to 4.2 cents with 27.1 million shares traded.

MEDIBIO

Medibio says that a 993-patient study concludes its heart rate algorithm "is encouraging for the identification of objective biomarkers of depression".

Medibio said that the study, entitled 'Heart rate sleep profile: a new biomarker for depression?' was presented by researchers from the University of Ottawa and the Université de Montréal at the Associated Professional Sleep Societies meeting in Boston, Massachusetts on June 7, 2017.

The abstract, number 1088, is available at: <u>http://bit.ly/2sPMJwZ</u>.

The company said that the abstract concluded that "the algorithm's ability to distinguish between clinical groups based on heart rate changes across sleep is encouraging for the identification of objective biomarkers of depression".

"The patho-physiological mechanisms underlying cardiovascular changes across sleep in the context of depression remain to be further investigated," the abstract concluded. "Yet, the present results suggest that heart rate profiles during sleep may be useful as

adjunctive assessment measures for depression," the abstract concluded.

Medibio said that retrospective electro-cardiogram(ECG) data was collated in 993 adults of which 545 had unipolar depressive syndromes referred to a specialized sleep clinic and 448 healthy controls, with electrocardiography started before bedtime and extended beyond sleep offset.

The company said that sleep-based heart rate profiles were defined by a classification algorithm using a panel of temporal and frequency domain variables designed to distinguish between depression and control cases.

"The algorithm classified individuals with depressive syndrome and healthy controls with a mean accuracy of 86 percent", the abstract said, with sensitivity showing 82 percent of the depression cases correctly identified by the algorithm and for specificity, or the cases not classified as depression by the algorithm 88 percent were from the control group.

Medibio said that it partly funded the research collaboration with the University of Ottawa's Institute of Mental Health Research.

Medibio chief executive officer Jack Cosetino said "the paper is an important milestone for the company, as it represents the first independent paper published by a group of world renowned research universities which validates Medibio's technology for the diagnosis of depression".

Medibio was up 1.5 cents or 4.5 percent to 35 cents.

PHARMAUST

Pharmaust says it has been granted a European patent covering monepantel for noncancer applications including diabetes, neuro-degenerative and age-related disorders. Pharmaust said the patent, entitled 'Compounds For The Treatment Of mTOR Pathway Related Diseases', related to the use of amino-acetonitrile derivatives for the treatment of mTOR pathway-related diseases and provided the company with protection until 2033. The company said that amino-acetonitrile derivatives included the Novartis animal health compound monepantel originally used for roundworm in sheep, which it had patented for cancer and non-cancer applications and was being evaluated in dog and human trials. Pharmaust chief executive officer Dr Richard Hopkins said that monepantel had been shown to act through the mTOR pathway, which was "increasingly recognized as playing a major role in non-cancer indications such as neurodegenerative diseases, diabetes and age-related disorders ... [and] the company is assessing potential applications of [monepantel] in these fields".

Pharmaust was up 0.1 cents or 1.3 percent to eight cents.

IMMURON

Immuron has requested a trading halt pending an announcement on "a proposed capital transaction".

Trading will resume on June 13, 2017 or on an earlier announcement. Immuron last traded at 50 cents.

BIONOMICS

BVF Partners and Mark Lampert say they have become substantial shareholders in Bionomics with 42,911,975 shares (8.91%).

The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said that on June 6, 2017 they bought 20,000,000 shares in five separate trades, with all shares acquired at 40 cents each.

Yesterday, Laurence Freedman and associated companies sold 22,500,000 shares for \$8,859,849 or 39.4 cents a share (BD: Jun 7, 2017).

Last year, a Bionomics extraordinary general meeting defeated resolutions to approve 16,082,988 warrants to four investment groups including BVF, triggering "a consultation process to consider the views of shareholders as to the governance arrangements and future direction of the company" (BD: Mar 3,7, 2016).

Later that month, shareholder CVC called for a board spill, demanding the resignation of chairman Graeme Kaufman and director Trevor Tappenden and by August they were gone (BD: Mar 16, Aug 9, 31, 2016).

In 2015, Bionomics raised \$US12 million (\$A16.4 million) through the issue of 40,207,472 shares at 40.8 cents a share in a placement to four US institutional investors, including BVF, along with 40,207,472 attaching warrants, or options, over shares, exercisable at 59.38 cents each by December 10, 2020, when the company had been trading around 48 to 50 cents (BD: Dec 8, 2015).

BVF is a substantial shareholder in Opthea (formerly Circadian), Pharmaxis and Viralytics. Bionomics fell half a cent or 1.2 percent to 40.5 cents.

<u>NOVOGEN</u>

Novogen says that chairman John O'Connor and Director Ian Phillips have resigned with general and administrative costs to be cut.

Novogen said that director lain Ross had been appointed chairman, effective immediately with chief executive officer Dr James Garner, Bryce Carmine and Steven Coffey continuing as directors.

The company said the announcement reflected "ongoing efforts to accomplish board refreshment" and that a four-person board was optimal for its current phase of life. Novogen said that Mr O'Connor and Mr Phillips had been "centrally involved in guiding the

company" through several transformative steps in recent months.

The company said that in addition to the board changes further savings had been identified in the general and administrative expense budgets and the funds would be redirected to the development of clinical assets.

Novogen was up one cent or 22.2 percent to 5.5 cents with 3.7 million shares traded.