

Biotech Daily

Tuesday June 28, 2016

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ONCOSIL UP 4%; FACTOR THERA DOWN 8%
- * HEARTWARE JUMPS 93% ON \$1.5b MEDTRONIC OFFER
- * MAYNE TO BUY 42 TEVA DRUGS FOR \$881m
- * WEHI MAPS PLASMODIUM VIVAX MALARIA GENOME
- * EUROPE GRANTS ANTISENSE ATL1103 ACROMEGALY ORPHAN STATUS
- * OPTISCAN TO PLACE \$750k, RIGHTS OFFER FOR \$1.4m
- * NUHEARA IQBUDS WIN WA 'MOST DISRUPTIVE TECHNOLOGY' GONG
- * AVITA DATA PUBLISHED IN REGENERATIVE MEDICINE
- * IDT REQUESTS CAPITAL RAISING TRADING HALT
- * MMJ REQUESTS 'CANADA MARIJUANA LICENCE' TRADING HALT
- * AUSTRALIAN ETHICAL TAKES 13% OF PRESCIENT
- * CRYSTAL AMBER TAKES 12% OF GI DYNAMICS
- * BIO-MELBOURNE, ROYAL SOCIETY PARTNERING BREAKFAST

MARKET REPORT

The Australian stock market fell 0.66 percent on Tuesday June 28, 2016, with the ASX200 down 33.9 points to 5,103.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Oncosil was the best, up 0.5 cents or 4.35 percent to 12 cents with 3.1 million shares traded. Avita, Cellmid and Compumedics climbed more than three percent; Benitec, Opthea and Polynovo rose more than two percent; with Admedus, Neuren, Orthocell and Pro Medicus up by more than one percent.

Factor Therapeutics led the falls, down 0.3 cents or 8.3 percent to 3.3 cents with 467,000 shares traded. Both Antisense and Bionomics lost 6.7 percent; Genetic Technologies shed 5.6 percent; Atcor, IDT and Prana fell more than four percent; Medical Developments, Nanosonics, Resmed and Starpharma were down more than three percent; Impedimed, Osprey and Sirtex shed more than two percent; Cochlear, Living Cell, Pharmaxis and Universal Biosensors were down more than one percent; with CSL, Mesoblast and Reva down by less than one percent.

HEARTWARE INTERNATIONAL

Heartware says Medtronic will pay \$US58.00 a share (\$A79.00, equivalent to \$A2.26 per CDI before Heartware left the ASX) to acquire the company for a total cost of \$US1.1 billion (\$A1.5 billion).

In 2010, Heartware listed on the Nasdaq, departing the ASX on September 10, 2013 and closing at \$2.37 (BD: Feb 3, 2010; Sep 10, 2013).

Heartware first listed in 2006 at 50 cents, fell as low as 31 cents in April 2008 and climbed as high as \$2.90 in May 2013.

In 2009, Thoratec Corp said it would acquire Heartware for \$US282 million (\$A429 million) paying half in cash and half in Thoratec common stock but the deal collapsed following US Federal Trade Commission's opposition (BD: Feb 12, Aug 3, 2009).

At June 30, 2006, Heartware had a market capitalization of \$90 million, compared to \$US1,865 million (\$A2,134 million) at January 31, 2014.

In June 2013, Heartware chief executive officer Doug Godshall said the Australian listing had been "really enabling for us as a company" (BD: Jun 13, 2013).

"Were it not for the ASX, we would not be here today," Mr Godshall said.

The company's value increased to a high of \$US102.61 a share in January 2014, but in 2015, the company lost 24.3 percent to \$US64.82 on news of a merger with the Tel Aviv, Israel-based Valtech Cardio which developed devices for mitral valve and tricuspid valve regurgitation (BD: Sep 2, 2015).

Following complaints from recent investor Engaged Capital, the deal with Valtech was terminated and Heartware signed a cooperation agreement with Engaged Capital to select an independent director and establish a business strategy committee.

In October 2015, Heartware fell a further 37.1 percent to \$US35.21 on an update to the halt of its Conformité Européenne (CE) mark trial of its miniaturized ventricular assist device to address a "controller manufacturing process issue" (BD: Oct 14, 2015). Last night, Heartware said the boards of both Medtronic and Heartware "unanimously approved the transaction" which was expected to close by Oct 28, 2016, subject to customary closing conditions.

On the Nasdaq, Heartware jumped \$US27.82 or 92.8 percent to \$US57.80 with 10,260,652 shares traded.

MAYNE PHARMA

Mayne says it will acquire 37 approved products and five US Food and Drug Administration filed products from Teva for \$US652 million (\$A880.7 million). Mayne said it had a binding agreement with the Israel-based Teva Pharmaceuticals to acquire a portfolio of US generic products "in attractive markets with limited competition, across a range of therapeutic areas".

The company said the acquisition "significantly transforms the scope and breadth of [its] US generics division" and was expected to place the company in the top 25 retail generic pharmaceutical companies and second largest US generic oral contraceptive supplier. Mayne said the portfolio would contribute sales of \$US237 million in 2016-'17 with gross margins greater than 50 percent.

The company said it would fund the acquisition through an extension of its existing debt facility and a fully underwritten \$601 million one-for-1.725 non-renounceable entitlement offer and \$287 million placement.

Mayne was in a trading halt at \$1.485.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the first large-scale genomic analysis of Plasmodium vivax malaria infections could help efforts to control malaria.

The Institute said that the research collaboration improved understanding of how the malaria parasite evolved, including links to past human migration.

WEHI said that while most malaria research focused on the parasite Plasmodium falciparum which was common in Africa, Plasmodium vivax was responsible for the majority of malaria infections elsewhere, causing an estimated 15.8 million clinical malaria cases each year, with the parasite becoming increasingly resistant to common anti-malarial drugs, posing challenges for malaria elimination.

The Institute said that researchers Dr Alyssa Barry and Prof Ivo Mueller were part of two international teams studying Plasmodium vivax using genomic techniques to analyze hundreds of clinical samples from malaria-infected people.

The research led to two complementary publications in this month's edition of Nature Genetics.

The first article is entitled 'Population genomics studies identify signatures of global dispersal and drug resistance in Plasmodium vivax' and an abstract is available at: <u>http://www.nature.com/ng/journal/vaop/ncurrent/full/ng.3588.html</u>.

The second article, entitled 'Genomic analysis of local variation and recent evolution in Plasmodium vivax' sequenced more than 200 samples and an abstract is available at: http://www.nature.com/ng/journal/vaop/ncurrent/full/ng.3599.html.

WEHI said that the teams discovered patterns of variation that were the result of both ancient events and recent selection.

"Overall we found that the parasites are remarkably diverse," Prof Mueller said.

"The patterns of genetic diversity appear to both result from ancient human migrations and follow historical routes of human movement, including those associated with colonization of the Americas in the 16th to 19th Century and links between Africa, India and Europe," Prof Mueller said.

The Institute said that the researchers found signs that the parasite population was continuing to evolve in response to recent factors such as drug treatment.

"Drug resistant parasites are firmly established in certain regions, including Indonesia and Papua New Guinea, creating huge challenges for malaria control efforts," Dr Barry said. "We found that parasites in these regions have strong genetic signatures of adaptation to antimalarial drugs," Dr Barry said.

"We can now use this information to study the causes of drug resistance and improve how we monitor the disease," Dr Barry said.

WEHI said that the researchers also examined parasite diversity within an individual and found that some people were infected with a single strain of Plasmodium vivax, but others had more complex, mixed infections with multiple strains of parasites.

"Understanding the diversity of parasites both within an individual and around the globe is an important step towards understanding how malaria is transmitted and in the longer term finding new strategies to control this deadly disease," Dr Barry said.

The Institute said that the research was supported by the Victorian State Government Operational Infrastructure Support Scheme, the National Health and Medical Research Council, Wellcome Trust, UK, the Medical Research Council, UK, the Department for International Development, UK, National Institutes of Health, USA, Sao Paulo Research Foundation, Brazil, National Institute of Public Health, Mexico, Armed Forces Health Surveillance Center, Global Emerging Infections Surveillance and Response System (USA) and the Bill & Melinda Gates Foundation.

ANTISENSE THERAPEUTICS

Antisense says the European Commission has granted orphan medicinal product designation for ATL1103 for acromegaly.

Antisense said that the approval followed the recommendation from the European Medicines Agency committee for orphan medicinal products, which assessed the scientific documentation for ATL1103 against the criteria for orphan designation, saying that ATL1103 "will be of significant benefit to those affected by that condition".

Antisense said that European orphan designation enabled sponsors to benefit from incentives, including 10 years market exclusivity, assistance in developing clinical protocols, reduced fees and access to EU research grants.

The company said ATL1103 was granted US orphan drug designation for acromegaly, which provided incentives including seven years of market exclusivity in the US. Antisense managing-director Mark Diamond said the European orphan designation was "another major step forward in the development of ATL1103".

Antisense fell 0.2 cents or 6.7 percent to 2.8 cents.

OPTISCAN IMAGING LIMITED

Optiscan says it has commitments to raise \$750,000 in a placement at 2.5 cents a share and will offer a two-for-nine rights issue to raise a further \$1.415 million. Optiscan said the Placement shares were expected to be issued on or about July 1, 2016 under the existing capacity to issue shares without shareholder approval. The company said that the funds were for working capital and its strategic plan. Optiscan was in a suspension at two cents.

NUHEARA

Nuheara says its Iqbuds won the most disruptive technology category in the Western Australian Information Technology and Telecommunications Alliance Incite Awards. Nuhear said the event was sponsored by China's Huawei Technologies and it would represent Western Australia at the national awards in Melbourne on September 1, 2016. Nuheara fell 0.1 cents or 1.6 percent to six cents with 5.8 million shares traded.

AVITA MEDICAL

Avita says that data presented at its April 2016 regeneration symposium in Cambridge, UK has been published in the journal Regenerative Medicine.

Avita said that the three-part review covered the Repair session on Recell for burns, the Restart session on Regenercell for chronic wounds such as venous leg ulcers and diabetic foot ulcers and the Restore session on the use of Renovacell for aesthetic applications including vitiligo and scarring.

Go to <u>https://www.regmednet.com/posts/7072-skin-regeneration-symposium-2016</u>. Avita was up 0.3 cents or 3.3 percent to 9.5 cents with 1.5 million shares traded.

IDT AUSTRALIA

IDT has requested a trading halt pending an announcement "in relation to a proposed capital raising".

Trading will resume on June 30, 2016 or on an earlier announcement. IDT last traded at 23.5 cents.

MMJ PHYTOTECH

MMJ has requested a trading halt pending an announcement regarding the status of its application for a Canadian marijuana cultivation licence. Trading will resume on June 30, 2016 or on an earlier announcement. MMJ last traded at 18 cents.

PRESCIENT THERAPEUTICS

Australian Ethical Investment says it has become a substantial shareholder in Prescient, acquiring 22,222,222 shares or 12.96 percent.

Australian Ethical said that between May 20 and June 23, 2016 it acquired the shares for \$2,000,000 or nine cents a share.

Prescient was up 0.6 cents or 7.2 percent to 8.9 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 47,359,151 shares or 9.96 percent to 57,359,151 shares (12.06%). The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said it acquired 10,000,000 shares for \$330,520 or an average price of 3.3 cents a share. The company's website said it was listed on London's Alternative Investment Market. The Crystal Amber Fund substantial shareholder notice was signed by Kevin Smith and Danny Felbabel as "company secretary".

GI Dynamics was unchanged at 2.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the August Bio-Breakfast entitled "Partnering through the healthcare product life-cycle" will be hosted by The Royal Society of Victoria. The Bio-Melbourne Network said that the challenges of taking an idea to market in the healthcare sector required "a well-planned and executed partnering strategy to deliver impact and outcomes".

Bio-Melbourne chief executive officer Dr Krystal Evans said that "new approaches to deal making, collaboration and engagement are providing significant productivity and efficiency gains for [biotechnology and medical technology] companies".

The Network said that the Bio-Breakfast speakers would be the winners of its Women in Leadership awards, Starpharma chief executive officer Dr Jackie Fairley and Swinburne University of Technology innovation precinct director Prof Sally McArthur, as well as Medcorp Technologies founder Jacqueline Savage.

The industry organization said that the panel would discuss multi-national and local strategic partnerships, new business models, supported by specific case studies, recent milestones and current projects.

The Network said the Bio-Breakfast would be held at the Royal Society of Victoria at 8 LaTrobe St, Melbourne on August 10, 2016 with registration from 7:15am, a networking breakfast from 7.30am to 8am followed by presentations and discussion until 9am. To register, go to: <u>http://biomelbourne.org/event/biobreakfast/</u>.