



Biotech Daily

Tuesday June 14, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 8%; MESOBLAST DOWN 42%**
- * **TEVA RETURNS MESOBLAST CARDIAC DRUG, DRAW-DOWN FACILITY**
- * **MEDICAL DEVELOPMENTS UNNAMED CANADIAN PENTHROX DEAL**
- * **PROTEOMICS CHINA PARTNER \$1.3m FOR PROMARKERD TEST, PATENT**
- * **AVITA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ASTRAZENECA TO USE ADHERIUM SMARTINHALER IN US COPD TRIAL**
- * **BONE BACKS \$3m BOTANIX BACKDOOR FOR CANNABIDIOL DERMATOLOGY**
- * **USCOM APPOINTS POZITRONICS AS VIETNAM DISTRIBUTOR**
- * **IMMURON TRAVELAN LISTED IN MAGELLAN'S TRAVEL CATALOG**
- * **AUSTRALIAN PATENT FOR NOVOGEN ATM-3500 COMPOUNDS**
- * **PRANA PLEADS SCHULTZ TO ASX 38% QUERY**
- * **REGAL FUNDS TAKES 7% OF AIRXPANDERS**
- * **FIL INCREASES TO 8% OF STARPHARMA**
- * **ANTEO CEO DR JEF VANGENECHTEN STARTS ON \$534k**
- * **MMJ APPOINTS STANISLAV SOLOGUBOV, JOHN HOLLISTER EXECUTIVES**
- * **GONGS FOR WEHI's PROF DOUG HILTON, DIMERIX PROF KEVIN PFLEGER**

MARKET REPORT

The Australian stock market fell 2.06 percent on Tuesday June 14, 2016 with the ASX200 down 109.3 points to 5,203.3 points. Nine of the Biotech Daily Top 40 stocks were up, 21 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Antisense was the best, up 8.1 percent to four cents with 14,600 shares traded. Genetic Technologies climbed 5.3 percent; Biotron and Cellmid were up more than three percent; with Airxpanders, Opthea and Uscom up more than two percent.

Mesoblast led the falls, down 81 cents or 42.2 percent to \$1.11, with 9.7 million shares traded. Factor and Universal Biosensors lost more than eight percent; Orthocell and Psivida fell more than seven percent; Admedus, Neuren and Oncosil were down more than six percent; Acrux fell 5.8 percent; Actinogen, Compumedics and Impedimed fell more than four percent; Bionomics, CSL, Sirtex and Viralytics were down more than three percent; Prima shed 2.2 percent; with Ellex, Polynovo, Pro Medicus, Resmed and Starpharma down more than one percent.

MESOBLAST

Mesoblast says Teva has handed back the phase III stem cell cardiac program and the company has arranged a draw-down equity facility with an unnamed funder to fund it. Following a 14-day trading halt, suspension and extension, Mesoblast announced a conference call 10 minutes before the 9am call to discuss the announcement.

Mesoblast chief executive Prof Silviu Itescu said the company had “regained full world-wide rights and full strategic flexibility to our mesenchymal precursor cell technology platform for the cardio-vascular field”, later saying the decision was Teva’s.

Prof Itescu said the company had full control over one its most important assets, MPC-150-IM with the phase III US trial about 40 percent recruited, and results expected in a further 18 months, with equity finance facility arranged to fund it.

Asked to name the company that was providing the equity draw-down facility, expected to be about \$50 million, Prof Itescu declined to provide details.

Prof Itescu said the facility would cover the cost of the trial but did not provide any numerical values for the facility, its discount rate, fees or charges.

Prof Itescu said that cardiac was not a core indication for Teva and Mesoblast was in discussions with a number of international, leading, cardiac-focused companies.

Prof Itescu said that Teva retained rights to other stem cell therapy indications other than cardio-vascular and retained its shareholding in Mesoblast.

In 2010, the then Cephalon acquired 55,785,806 shares or 19.99 percent of Mesoblast paying more than \$US100 million in upfront fees in a deal said to be worth up to \$1.7 billion for the cardiac, neurological and cord expansion uses of the adult mesenchymal precursor stem cells (BD: Dec 8, 2010; Feb 9, 2011).

Teva acquired Cephalon in 2011, and in 2012 Mesoblast appointed Teva executive Dr Ben-Zion Weiner as a director (BD: May 3, 2011; May 10, 2012).

Following last year’s \$95.8 million raising to list on the Nasdaq, Teva was diluted to 14.6 percent of the company (BD: Nov 16, 17, 19, 20, 2015).

Prof Itescu told the teleconference that taking control for the MPC-150-IM for advanced chronic heart failure program from Teva meant it would be able to apply for fast-track status in Japan.

Prof Itescu said that the return of the technology was at no cost from Mesoblast.

In a media release Prof Itescu thanked Teva “for having brought our phase III heart failure program to this advanced stage of development and acknowledge their decision is based on strategic reasons aligned to their core therapeutic areas of focus”. “Mesoblast now has unencumbered rights to partner with a leading cardiovascular company with a commitment to heart failure product commercialization,” Prof Itescu said.

Prof Itescu said that the US Food and Drug Administration had approved a second navigational catheter system for the cardiac program which was “likely to result in accelerated phase III trial recruitment and potentially a simplified distribution process through existing commercial channels” once the product was approved.

The media release said that more than 230 patients of the 600 patient target total had been enrolled in the trial.

Mesoblast said that along with the phase III advanced heart failure trial, a second trial of MPC-150-IM in 120 patients with end-stage heart failure and an implantable left ventricular assist device (LVAD) was about 60 percent recruited, and was fully funded by the US National Institutes of Health.

The company said that the LVAD trial results were expected by the end of 2017 and would be used to support the marketing approval application for the product candidate.

Mesoblast fell as much as 81 cents or 42.2 percent to close at \$1.11, with 9.7 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has a term sheet with an unnamed pharmaceutical company to distribute its Pentrox methoxyflurane analgesic in Canada.

Medical Developments said that the term sheet included upfront and milestone payments of \$C3.0 million (\$A3.17 million).

The company said the Canadian company had “expertise in the management and distribution of pain management products” and would invest in the sales and marketing of Pentrox including the costs of registration and approval of Pentrox.

Medical Developments chief executive officer John Sharman said the deal was “significant and another step towards globalizing Pentrox”.

Mr Sharman said potential sales would build to one million units a year.

Medical Developments chairman David Williams said that Canada had about 36 million people and “like many Australians, I see the similarities between our two countries and feel Pentrox will be eagerly adopted once registered”.

Medical Developments fell five cents or 0.85 percent to \$5.85.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that China’s Newsummit Biopharma will provide \$1.3 million to commercialize and market Promarkerd, which has been granted a China patent.

Proteomics said that the initial funding was secured from Chinese Government sources after the Shanghai-based Newsummit was granted approval in April by the National Health and Family Planning Commission of the People’s Republic of China to undertake diabetes prevention and treatment projects, under the ‘Prevention and Treatment of Major Diseases’ initiative.

Proteomics chief executive officer Dr Richard Lipscombe told Biotech Daily that the funds could come “from a variety of sources, be they government, internal or third parties” subject to Proteomics approval.

The company said that the Promarkerd in-vitro diagnostic used protein biomarkers in the blood to provide an early detection of the onset of diabetic kidney disease.

Proteomics said that the staged agreement with Newsummit provided for manufacture of the antibody components, development and validation of an enzyme-linked immunosorbent assay (Elisa) kit and registration with the Chinese Federal Drug Administration.

The company said that Newsummit had secured the initial \$100,000 tranche of funding to implement the first stage of kit manufacture, which would run in parallel to its own development activities and maximize the company’s opportunity to develop a commercial test, while producing kits tailored for their respective markets.

Proteomics said that the China patent entitled, ‘Biomarkers Associated with Pre-diabetes, Diabetes and Diabetes Related Conditions’ provided protection for the use of Promarkerd as both a predictive and diagnostic test in China until September 20, 2031.

Proteomics said that 120 million Chinese had diabetes and were at risk of kidney disease.

Proteomics was up four cents or 18.6 percent to 25.5 cents.

AVITA MEDICAL

Avita has requested a trading halt pending an announcement regarding “finalizing a capital raising”.

Trading will resume on June 16, 2016 or on an earlier announcement.

Avita last traded at 11.5 cents.

ADHERIUM

Adherium says that AstraZeneca will use its Smartinhaler platform for a US-based chronic obstructive pulmonary disease medication adherence trial.

Adherium said the study would be conducted at seven US healthcare centres and enrol about 400 patients, starting in August, 2016 and take 12 months.

Adherium chief executive officer Garth Sutherland said that chronic obstructive pulmonary disease adherence rates were low and the Smartinhaler was “the gold standard in recording and improving medication adherence in chronic lung disease”.

The company said that the Smarttouch Symbicort device would be used in the study and measured the dose and frequency of puffer use, which the company said improved medication adherence.

Adherium was up half a cent or one percent to 51.5 cents.

BONE MEDICAL

Bone says it has shareholder approval for the \$3 million capital raising for a back-door listing of Botanix Pharmaceuticals to develop cannabidiol dermatology products.

A Bone general meeting passed all resolutions including a 3,333 for 1,000 consolidation, approval of the change in nature and scale of activities, the name change and the election of directors Matthew Callahan, Graham Griffiths and Dr William Bosch, with Mr Griffiths replacing chairman Robert Towner who would continue as a director.

The company said the Philadelphia, Pennsylvania-based Botanix was developing products for skin diseases including acne, psoriasis and atopic dermatitis.

Bone said that Botanix had licenced the Permetrex novel transdermal drug delivery technology, which was designed to deliver pharmaceuticals through the skin more effectively than alternative approaches currently marketed.

The company said that the lead product was the BTX1503 topical gel for acne.

Bone was created by investors in Proxima and licenced compounds from Proxima subsidiaries, with Proxima co-founder and research director Dr Roger New formerly Bone's chairman (BD: Jul 11, Sep 22, 2011; Jan 29, Apr 4, May 12, Jun 20, 2014).

In 2014, Bone said it would “terminate the agreements with the Proxima Group” concluding that it was “not in the commercial interests of the company or its shareholders to continue with the Proxima Group” (BD: Nov 19, Dec 9, 2014).

Today, the Oxford, England-based Proxima Concepts said it had ceased its substantial shareholding selling 1,250,000 shares for \$11,250 or 0.9 cents a share.

Bone was in a suspension for the changes and last traded at 0.8 cents.

USCOM

Uscom says it has appointed the Hanoi-based Pozitronics as its distributor for Vietnam.

Uscom said that the appointment followed a visit by Vietnam's Minister for Health and a delegation of Vietnamese Health officials to its Sydney head office and manufacturing operations and reviewed its devices including the Uscom 1A ultra-sonic cardiac output monitor, the BP+ and the Spirosonic devices.

The company said that the sale of BP+ and BP+ Reporter in Vietnam would begin following approval by the Vietnam health regulatory authority.

Uscom said that Pozitronics distributed the Uscom 1A through Pacific Medical Systems in Hong Kong.

Uscom was up half a cent or 2.1 percent to 24.5 cents.

IMMURON

Immuron says that Travelan will be listed in the US-based Magellan's travel product catalog and on its website from late June 2016.

Immuron said that the Aurora, Colorado-based Magellan's Travel Supply was one of the largest travel catalogs in the US with 1.5 million subscribers receiving the catalog every month.

The company said that terms and conditions were confidential, but it had received its first Magellan's purchase order to ensure that product was available when the June 2016 catalog was distributed to customers.

Immuron was unchanged at 24.5 cents.

NOVOGEN

Novogen says it has been granted an Australian patent for its ATM-3500 series compounds including Anisina or ATM-3507.

Novogen said that the patent, entitled 'Functionalised and substituted indoles as anti-cancer agents', provided composition of matter, method of manufacture, and method of use protection to 2035.

The company said that Anisina was "the first of a novel class of investigational anti-cancer agents known as anti-tropomyosins (ATMs), which selectively target an essential structural component of the cancer cell, causing cell death and tumor reduction in experimental models".

Novogen was unchanged at 10.5 cents with 1.1 million shares traded.

PRANA BIOTECHNOLOGY

Prana has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 3.3 cents or 37.9 percent from 8.3 cents to 12 cents on June 10, 2016 and noted an increase in trading volume.

Prana was unchanged at 9.7 cents.

AIRXPANDERS

Regal Funds Management has become a substantial shareholder in Airxpanders with 14,857,392 shares or 6.25 percent of the company.

The Sydney-based Regal Funds said that it acquired 5,788,408 shares between April 13 and June 9, 2016 at prices ranging from 76 cents to \$1.14 a share.

Regal said that the registered holders of the shares included UBS Nominees, Credit Suisse Securities Europe and Merrill Lynch (Australia) Nominees.

Regal has recently become substantial in two other biotechnology companies, Oncosil and Adherium (BD: Feb 10, Mar 31, 2016).

In 2014, Regal underwrote expiring unlisted Suda options, returning about \$1.4 million to the company (BD: Jul 1, 2014).

Airxpanders was up two cents or 2.3 percent to 90 cents.

STARPHARMA

FIL Limited says it has increased its holding in Starpharma from 25,285,196 shares (6.89%) to 29,022,710 shares (7.91%).

The Sydney and Hong Kong-based FIL said it undertook a “custodian adjustment” and a “transition in” as well as buying and selling shares between February 25 and June 8, 2016 at prices ranging between 65 cents and 74 cents as well as zero cents for one share. Starpharma fell one cent or 1.3 percent to 74.5 cents.

ANTEO DIAGNOSTICS

Anteo says that Dr Jef Vangenechten has taken up his role as chief executive officer starting on a base salary of EUR350,000 (\$A534,140).

Anteo said that Dr Vangenechten would be entitled to up to EUR150,000 (\$A228,917) in short term incentives and a further EUR150,000 in long term incentives.

In March, Anteo said that Dr Vangenechten would replace Dr Geoff Cumming who joined the company in 2009 and would continue as a director until September 16, 2016, through the transition and the recruitment of a chief operating officer and chief financial officer. (BD: Mar 16, 2016)

The company said that Dr Vangenechten was the chief executive officer of Diasource Immunoassays SA and had agreed to take the combined role of global chief executive officer, effective from June 1, 2016.

Anteo was unchanged at 4.3 cents.

MMJ PHYTOTECH

MMJ Phytotech says it has appointed Stanislav Sologubov as chief executive officer of Satipharm Switzerland and John Hollister as a strategic pharmaceutical consultant.

MMJ said that Mr Sologubov had more than 15 years experience in sales and marketing and had previously worked for Johnson & Johnson and Bausch + Lomb.

The company said that Mr Hollister had more than 25 years experience as a healthcare industry executive working for pharmaceutical, biotechnology and medical device companies, with experience in commercialization and most recently was Nemus Bioscience chief executive officer.

MMJ was unchanged at 21.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH, DIMERIX

The Walter and Eliza Hall Institute says that director Prof Doug Hilton has been awarded an Officer of the Order of Australia medal in the Queen's Birthday honors.

The Institute said that the award recognized Prof Hilton's “service to medical research, in particular his advocacy for gender equity in science and his commitment to supporting young researchers”.

Separately, Dimerix said that the co-inventor of its DMX-200 combination drug for chronic kidney disease and chief scientific advisor, won the \$US3,000 British Pharmacological Society's Novartis Prize.

Dimerix said that the prize was for Prof Pflieger's research, including the discovery of DMX-200.

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