



Biotech Daily

Tuesday January 31, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: DIMERIX UP 12.5%, ADMEDUS DOWN 8%**
- * **EYE CO TO TRIAL FLUDROCORTISONE ACETATE FOR RETINOPATHY**
- * **ADMEDUS H1 REVENUE UP 85% TO \$12m**
- * **CLINUVEL H1 CUSTOMER RECEIPTS UP 533% TO \$10m**
- * **IMPEDIMED H1 CUSTOMER RECEIPTS \$3m**
- * **INNATE FALLS, BOUNCES AS DIRECTOR BACKS TRUMP'S MUSLIM BAN**
- * **SIRTEX REQUESTS 'SALES GROWTH LEGAL ACTION' TRADING HALT**
- * **PHOSPHAGENICS, TERUMO SIGN TPM-OXYMORPHONE PATCH DEAL**
- * **ANALYTICA \$1.4m CONDITIONAL PLACEMENTS**
- * **EURO PATENT FOR ORTHOCELL 'CELL FACTORY'**
- * **JAPAN PATENT FOR DIMERIX DMX-200 FOR KIDNEY DISEASE**
- * **US PATENT FOR CELLMID MIDKINE ALOPECIA TREATMENT**
- * **GEORGIA APPROVES NOXOPHARM NOX66 CANCER TRIAL**
- * **REVA HAS ONE QUARTER CASH; EU SALES, FINANCE, US IPO**
- * **RHINOMED HAS LESS THAN ONE QUARTER CASH; \$2m CHAIR LOAN**
- * **CRESO PHARMA REQUESTS 'HEMP DEAL' TRADING HALT**
- * **NAOS TAKES 5% OF BIOTECH CAPITAL**
- * **MESOBLAST'S DR ERIC ROSE WINS THORACIC SURGEONS GONG**

MARKET REPORT

The Australian stock market fell 0.72 percent on Tuesday January 31, 2017 with the ASX200 down 52.5 points to 5,620.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and three were untraded.

Dimerix was the best, up 0.1 cents or 12.5 percent to 0.9 cents with 15.9 million shares traded. Cellmid and Cyclopharm climbed more than seven percent; Living Cell, Opthea and Universal Biosensors were up more than four percent; Polynovo was up 3.8 percent; with Neuren and Orthocell up by more than two percent.

Admedus led the falls, down three cents or eight percent to 34.5 cents with 1.3 million shares traded. Factor Therapeutics and Oncosil fell more than four percent; Actinogen, Airxpanders, Impedimed, Nanosonics and Starpharma lost more than three percent; Anteo, Atcor, Bionomics, Clinuvel, Osprey and Uscom shed two percent or more; with Acrux, Pharmaxis and Pro Medicus down by more than one percent.

EYE CO PTY LTD

Eye Co says it hopes to licence its mineralo-corticoid, fludrocortisone acetate, for retinopathy targeting oedema and begin clinical trials by August this year.

Eye Co chief scientist Prof Philip Penfold told Biotech Daily that he invented the intra-vitreous method of drug delivery to the back of the eye in 1990 and subsequently developed fludrocortisone acetate specifically to modulate fluid movement or oedema in the eye. Prof Penfold said that pre-clinical studies in mice and rabbits had confirmed the mechanism of action of the new class of corticosteroid for retinal pathologies and patents had been filed to protect the intellectual property.

A media release from the Sydney-based Eye Co said that fludrocortisone acetate was “part of a yet-to-be commercialized class of steroids, the mineralo-corticoids”.

Prof Penfold said that the company had filed provisional Australian patents, following a grant of patent claims for the product class in Europe and Australia.

Eye Co said its drug development program targeted the retinal and macula therapeutics segment of the ophthalmology market, estimated to be worth \$US2.6 billion by 2018.

Eye Co chief executive officer Peter Abrahamson told Biotech Daily the company had completed its pre-clinical work and was working with an unnamed manufacturer to produce quantities of the injectable drug for the planned clinical trial program.

Mr Abrahamson was previously the chief executive officer of Helicon which became Consegna and renamed Rhinomed (BD: Oct 26, 2011; Mar 1, 2012; Nov 18, 2013).

The company said it worked with Monash University, the Australian National University and the University of Western Australia on the pre-clinical studies.

“This recent scientific work shows that, when the mineralo-corticoid nuclear receptor is activated, it triggers a series of events that lead to improvement in ocular cell barrier-function, decreased cell permeability and reduced tissue damage, demonstrating great promise as we commercialize this Australian developed technology,” Prof Penfold said.

“The results confirm that corticosteroids such as triamcinolone and potentially this new class of mineralo-corticoids have a key role to play in the treatment of retinal disease, particularly in the context of some of the major clinical reversals by some competitors in the eye therapy sector and the emergence of clinically limiting refractility amongst market leading therapies such as Novartis’s Lucentis,” Prof Penfold said.

Eye Co said that Prof Penfold was the co-inventor of triamcinolone acetonide which was licenced to the Novartis-owned and Hünenberg, Switzerland-based Alcon Laboratories and was marketed as Triesence for ophthalmic indications.

The company said it established its Vistaplast generic version of triamcinolone acetonide for ophthalmic indications, with first revenues in 2010, from eye clinics, day hospitals and public hospitals throughout Australia under a compounding pharmacy arrangement and expects to begin overseas sales in the near future.

Eye Co is a private company.

ADMEDUS

Admedus says its revenue for the six months to December 31, 2016 was up 85 percent to \$12.1 million.

Admedus said it was “on-track for its full year revenue forecast of \$21 million”

The company said that the Adapt treated bovine cardiac patch business grew strongly by 50 percent to about \$3.5 million, with infusion sets revenue up 100 percent to \$8.6 million, driven in part by a new Royal Adelaide Hospital contract.

Admedus said it had \$14,344,000 in cash at December 31, 2016.

Admedus fell three cents or eight percent to 34.5 cents with 1.3 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says customer receipts for the six months to December 31, 2016 amounted to \$10,080,000, up 533.2 percent compared to the previous corresponding period. Clinuvel posted its second consecutive cash-flow-positive Appendix 4C quarterly report, following European approval for Scenesse for erythropoietic protoporphyria and said that it had \$19,550,000 in cash and equivalents at December 31, 2016. Clinuvel fell 17 cents or 2.1 percent to \$8.04.

IMPEDIMED

Impedimed says that for the six months to December 31, 2016, receipts from customers were \$3,001,000, with \$2.0 million in lymphoedema sales. The company said it had \$73,236,000 in cash at December 31, 2016. Impedimed fell three cents or 3.85 percent to 75 cents with 4.1 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Last night, following condemnation of US President Donald Trump's controversial travel ban, Innate's share price fell 64 cents or 45.1 percent from \$1.42 to 78 cents. Innate previously told two ASX queries that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities, when its price rose 120.5 percent from 83 cents on December 22, 2016 to \$1.83 on January 25, 2017 and 47.8 percent to \$1.16 between December 20 and 30, 2016 (BD: Jan 22, 27, 2017). It was widely reported in January that people associated with US President Donald Trump had shares in the company, including major shareholder US Republican Representative Chris Collins, who has been a director of Innate since 2006. Innate did not mention this in either ASX query, but said in the latter response that "in recent weeks there have been a number of media articles in the US that may have brought the company to the attention of new US investors". "There have been similar reports in the Australian media which may also have generated increased interest in the company's prospects," Innate said. There has been widespread condemnation of President Trump's travel ban, including from world leaders, the Ford Motor Co, Apple, Google and Goldman Sachs, with the Australian Industry Group critical of the implementation and its impact on Australian business travellers. According to the US biotechnology publication 'Endpoints' a poll of its 13,000 subscribers had 1,400 responses with 87 percent opposing the ban. Endpoints said that "three out of four felt that the ban is certain to have a negative impact on the industry, threatening diversified staffs, attendance at US conferences and throttling back key recruiting efforts". According to his website, Mr Collins introduced three Bills "to improve Medicaid" earlier this month, supported the Presidential executive order withdrawing from the Trans Pacific Partnership and re-introduced legislation to curb wind turbines near military installations. Mr Collins' most recent announcement was to support the Presidential ban on people born in the seven named, predominantly Muslim countries, without a history of terror attacks in the US, while countries with a history of terror attacks on the US, including Saudi Arabia and Egypt, were exempted from the ban. Biotech Daily attempted to contact Innate chief executive officer Simon Wilkinson several times today, but without success. Innate recovered 46 cents or 59.0 percent to \$1.24 with 5.3 million shares traded.

SIRTEX MEDICAL

Sirtex has requested a trading halt pending an announcement regarding legal action relating to its “double digit dose sales growth” forecast, last year.

Trading will resume on February 2, 2016 or on an earlier announcement.

Sirtex said it had received a letter from a law firm “foreshadowing the commencement of a representative proceeding against the company based on alleged breaches of its continuous disclosure obligations and alleged misleading and deceptive conduct, arising out of a statement made by the company on August 24, 2016 that the company would achieve “double digit dose sales growth” in the year to June 30, 2017.

Sirtex said it was considering the foreshadowed claim and taking legal advice, but considered the claim material.

Last year, Sirtex tumbled as much as 52.5 percent to \$12.20 following forecast lower sales growth of four to six percent for the six months to December 31, 2016, compared to growth in the prior corresponding period of 15.7 percent (BD: Dec 9, 2016).

On December 19, Sirtex chief executive officer Gilman Wong stepped aside for an inquiry into his sale of shares in October (BD: Nov 7, Dec 19, 2016).

On January 13, Sirtex said it had “terminated Mr Wong’s employment ... with immediate effect” (BD: Jan 22, 2017).

Sirtex last traded at \$14.38.

PHOSPHAGENICS

Phosphagenics says it has signed a term sheet with Japan’s Terumo Corp for its tocopheryl phosphate mixture (TPM) oxymorphone patch.

Phosphagenics said it would receive a non-refundable payment of JPY35 million (\$A400,000) within 30 days of signing the term sheet, in exchange for granting exclusive negotiation rights.

The company said the term sheet followed a six-month technical due diligence period and an additional three-month due diligence extension and the agreement granted Terumo exclusive rights to develop, market and sell the TPM-oxymorphone patch in Japan.

Phosphagenics said the parties would finalize a development plan for the TPM-oxymorphone patch in Japan and might request a formal consultation with the Japanese regulatory agency.

The company said that it would continue to support some development, with Terumo funding the development and commercial activities required for Japan.

Phosphagenics said the final agreement would include upfront, development and sales milestones, as well as single to double digit royalties on net sales in Japan.

Phosphagenics was unchanged at 2.7 cents with 8.7 million shares traded.

ANALYTICA

Analytica says it expects to raise \$1,442,000 in a series of conditional placements at 0.59 cents a share.

Analytica said that the first placement for \$383,000 would be made to an entity associated with chairman Dr Michael Monsour, subject to shareholder approval and if approved Inov8 LLC would buy \$277,000 in shares, along with a \$60,000 placement was proposed for an entity associated with executive director Mr Ross Mangelsdorf, subject to shareholder approval and a \$722,000 placement to non-related parties.

Analytica said the funds would be used for working capital.

Analytica was up 0.1 cents or 20 percent to 0.6 cents.

ORTHOCELL

Orthocell says it has been granted a European patent relating to its technology which produces tissue-specific growth factors and bioactive proteins to enhance tissue repair. Orthocell said that the patent, entitled 'Cell Factory-derived method of producing native components, such as growth factors or extracellular matrix proteins, through cell culturing of tissue samples for tissue repair' would provide intellectual property coverage until 2027. Orthocell was up one cent or 2.3 percent to 44.5 cents.

DIMERIX

Dimerix says the Japan Patent Office has allowed a patent covering the use of DMX-200 for kidney disease.

Dimerix said the patent, entitled 'Combination Therapy', covered the use of the chemokine receptor blocker propagermanium and angiotensin receptor blocker irbesartan in combination for a range of diseases and provided exclusivity in Japan through to 2032. Dimerix was up 0.1 cents or 12.5 percent to 0.9 cents with 15.9 million shares traded.

CELLMID

Cellmid says the US Patent and Trademark Office has allowed a patent entitled 'Method of Treatment or Prevention of Hair Loss or for Enhancement of Hair Growth'.

Cellmid said the midkine alopecia patent would expire in February 2031 and added to its subsidiary Advangen's intellectual property rights for its hair loss technologies.

The company said that other Advangen patents related to the Evolis products that inhibit the FGF5 protein to prevent hair loss and increase hair growth.

Cellmid was up 0.2 cents or 7.1 percent to three cents with 1.7 million shares traded.

NOXOPHARM

Noxopharm says the Georgia Ministry of Health has approved its 16-patient phase Ia/Ib studies of NOX66 for cancer.

Last year, Noxopharm said the studies had been approved at two clinical sites in Tbilisi, Georgia and were expected to begin by the end of 2016 (BD: Aug 10, Oct 26, 2016).

Today, the company said the study involved patients with a range of late-stage cancers and had been delayed by a change to the protocol with recruitment planned to begin for the last week of February following shipment of the drug.

Noxopharm fell seven cents or 12.3 percent to 50 cents.

REVA MEDICAL

Reva says its net operating cash burn for the three months to December 31, 2016 was \$US5,106,000 (\$A6,750,430) with cash at the end of the quarter of \$US6,674,000.

Reva said it was awaiting Conformité Européenne (CE) mark approval for its Fantom bioresorbable coronary stent which previously was expected in December 2016 and now was expected "early this year".

The company said it "continued to pursue a financing that would provide working capital for commercialization, follow-on clinical trials and general operations" expected to be completed by April 2017 and it continued to pursue a listing on the Nasdaq or another US exchange by mid-2017.

Reva was untraded at \$1.005.

[RHINOMED](#)

Rhinomed says its net operating cash burn for the three months to December 31, 2016 was \$951,000 with cash at the end of the quarter of \$799,000.

In a separately announcement Rhinomed said it had a \$2 million working capital financing facility provided by an entity related to chairman Ron Dewhurst, the facility was unsecured and could be drawn in multiples of \$250,000, with interest at commercial rates and repayable by July 31, 2018.

The company said that it had record unaudited revenue of \$1.2 million for the six months to December 31, 2016.

Rhinomed was up 0.1 cents or 6.25 percent to 1.7 cents with 2.5 million shares traded.

[CRESO PHARMA](#)

Creso has requested a trading halt "pending an announcement in relation to a binding letter of intent with the company's subsidiary Hemp Industries".

Trading will resume on February 2, 2017, or on an earlier announcement.

Creso last traded at 23 cents.

[BIOTECH CAPITAL](#)

Naos Asset Management has become a substantial shareholder in Biotech Capital with 5,561,812 shares or 5.12 percent of the company.

The Martin Place, Sydney-based, Naos said it was acting as investment manager for "various trustee companies" and the registered holder was Australian Executor Trustees, but failed to cite the cost of the shares as required under the Corporations Act 2001.

Biotech Capital was untraded at 12 cents.

[MESOBLAST](#)

Mesoblast says that director Dr Eric Rose was awarded the 2017 Earl Bakken scientific achievement award by the Society of Thoracic Surgeons.

Mesoblast said the award, established by Medtronic, was granted during the Society's meeting last week in Houston, Texas and "honors individuals who have made outstanding scientific contributions that have enhanced the practice of cardiothoracic surgery and patients' quality of life".

The company said that Dr Rose was a cardiovascular surgeon and heart failure expert, providing it with insight in the design and conduct of its cardiovascular programs.

Mesoblast fell one cent or 0.6 percent to \$1.61.