



# Biotech Daily

Wednesday May 18, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ONCOSIL UP 15%  
- ANTISENSE, PHARMAXIS DOWN 6%**
- \* **REVA FANTOM SAFE, 'LOW LATE LUMEN LOSS'**
- \* **POLYNOVO BTM CLOSES SKIN OVER BURNT SKULL BONE**
- \* **PRESCIENT PLACEMENT RAISES \$7m, RIGHTS ISSUE FOR \$3.4m MORE**
- \* **CLINUVEL SCENESSE RESTRICTED EURO APPROVAL, NO FREE USE**
- \* **PHOSPHAGENICS, THEMIS EXPAND TPM-DICLOFENAC LICENCE**
- \* **UBS AG REDUCES TO 6% of GI DYNAMICS**
- \* **RESPIRI (ISONEA) TAKES CAPITAL RAISING HALT TO SUSPENSION**
- \* **ONCOSIL APPOINTS MICHAEL WARRENER FOR SALES, MARKETING**
- \* **TBG CHAIRMAN JITTO ARULAMPALAM RETURNS TO EXECUTIVE**

## MARKET REPORT

The Australian stock market fell 0.74 percent on Wednesday May 18, 2016 with the ASX200 down 39.7 points to 5,356.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and two were untraded.

Oncosil was the best, up 1.75 cents or 14.6 percent to 13.75 cents with 1.7 million shares traded, followed by Clinuvel up 11.8 percent to \$4.75 with 42,671 shares traded and Polynovo up 10.6 percent to 26 cents with 621,924 shares traded.

Reva climbed 9.1 percent; Atcor was up 6.7 percent; Acrux and Viralytics were up more than three percent; Ellex rose 2.5 percent; Actinogen, Biotron and Opthea were up more than one percent; with CSL up 0.8 percent.

For the second trading day in a row Antisense led the falls, today with Pharmaxis, both down 5.7 percent to five cents and 25 cents, respectively, with 492,595 shares and 485,330 shares traded, respectively. Avita, Benitec and Prima fell more than four percent; Starpharma was down 3.6 percent; Admedus, Anteo, Medical Developments and Orthocell shed more than two percent; Airxpanders, Cochlear, Mesoblast, Pro Medicus, Psivida, Resmed and Universal Biosensors were down more than one percent; with Nanosonics down 0.4 percent.

## REVA MEDICAL

Reva says that six-month results from its first cohort of Fantom II trial patients showed a low 1.7 percent rate of cardiac safety events with low “late lumen loss”.

Reva said that an analysis of angiographic imaging of the first 100 patients at six months in its Fantom II trial showed that the treated coronary arteries had a mean in-segment late lumen loss or late loss of 0.21mm.

The company said that the low late loss, the difference between the stented vessel diameter and follow-up at six months, was “a desirable result that historically corresponds to positive long-term outcomes and compares to permanent drug-eluting stents and competitive bio-resorbable scaffolds that generally have late loss values in the range of 0.20mm to 0.40mm”.

Reva said the six-month follow-up of the 117 patients in the first cohort (cohort A) showed “a very low rate of major adverse cardiac events”, a composite of cardiac death, myocardial infarction, or heart attack, and clinically-driven revascularization.

The company said that the six-month major adverse cardiac events rate of 1.71 percent showed Fantom’s ability to treat patients with coronary artery disease.

Reva said that the Fantom II trial was evaluating the safety and performance of the Fantom sirolimus-eluting bioresorbable coronary scaffold.

Reva said the data was presented this week at the Paris Course on Revascularization.

Reva climbed 10 cents or 9.1 percent to \$1.20.

## POLYNOVO

Polynovo says its biodegradable temporizing matrix has been used to repair skin over a large area of burnt skull bone.

Polynovo said that research by its collaborator Royal Adelaide Hospital’s Prof John Greenwood and his colleague Dr Marcus Wagstaff were presented with a complex challenge of a large area of burnt bone with no possibility of closure using a rotational full thickness flap or biological scaffold.

The company said that its biodegradable temporizing matrix (BTM) enabled the closure over burnt skull bone which showed the ability of the BTM to close a significant wound where biological based scaffolds might not work.

The article, entitled ‘Reconstruction of Extensive Calvarial Exposure After Major Burn Injury in 2 Stages Using a Biodegradable Polyurethane Matrix’, was published in the online journal Eplasty and is available at: <http://bit.ly/1XyN1no>.

The article said that soft-tissue coverage of calvarial exposure, that is the superior, or outer, portions of the frontal bone, occipital bone and parietal bones of the skull, was “a significant surgical challenge” specifically the reconstruction of extensive calvarial exposure after a major burn injury.

“This novel, biodegradable, polyurethane-based material offered a hitherto unavailable resource and safely allowed us to exploit a previously described technique for calvarial coverage and reconstruction,” the article said the process “minimized physiological insult to the patient during critical early treatment and allowed us to stage the reconstruction to best optimize robustness of the skin graft donor sites for reharvest”.

“In the general literature, burns exposing the calvarium are usually the sequelae of major, normally fatal, burn injuries, with patients not surviving to a point where reconstruction can be considered,” the Eplasty article said.

“However, BTM represents a new, effective and rapid solution for temporizing such burns, which might mean that we see more of these cases surviving in future,” the article said.

Polynovo was up 2.5 cents or 10.6 percent to 26 cents.

## PRESCIENT THERAPEUTICS

Prescient says it has raised \$7.0 million in a placement at 9.0 cents a share and hopes to raise a further \$3.4 million through a rights issue at the same price.

Prescient said the placement and rights issue shares would come with one attaching option for every two shares acquired, exercisable at 18 cents by June 30, 2018.

The company said that placement would be undertaken in two tranches, with shareholder approval required for the second tranche and the attaching options.

Prescient said that the one-for-three, non-renounceable rights issue at for shareholders on the record date of May 26, would open on May 31 and close on June 21, 2016.

The company said the funds would be used for its clinical programs, additional drug manufacture and trial management, as well as for general working capital purposes.

Prescient was unchanged at 11 cents.

## CLINUVEL

Clinuvel says European marketing authorization for Scenesse is “under a strict risk management plan” and it has closed its compassionate use program.

Clinuvel said the European Medicines Agency management plan for Scenesse (afamelanotide 16mg) for adults with erythropoietic protoporphyria comprised a post-authorization safety study as well as a retrospective chart review to follow up those who did not consent to participate in the safety study.

The company said that the process of regulatory drug release and the approval of the pharmaco-vigilance systems required a further 18 months of discussions with the EMA. Last year, Clinuvel said the EMA approval of a post-authorisation study allowed Scenesse to be sold to adults with erythropoietic protoporphyria, and although the company was granted European authorization in December 2014, it had taken a further nine months to gain agreement from the EMA’s Pharmaco-vigilance and Risk Committee for a post-authorisation safety study protocol (BD: Jan 18, Sep 24, 2015).

Today, Clinuvel said that the final regulatory and clinical steps prior to the start of the treatment were a review of the post-authorization safety study and the retrospective chart review protocols by some of the local ethics committees and the approval of patient and physician educational materials by various national competent authorities.

The company said that Scenesse was “only being made available to EPP patients through porphyria expert centres”, which required training and accreditation by Clinuvel.

No one at Clinuvel was available to say whether the restricted access was a path to full approval or whether Scenesse would be only available through porphyria expert centres.

Clinuvel said that it expected Germany’s first three centres would be able to prescribe the treatment and 13 German insurance firms had agreed to make Scenesse available, with discussions underway with authorities in nine countries and further submissions expected.

Clinuvel said it expected to set a uniform price across Europe.

Clinuvel chair Stan McLiesh said the “success of Scenesse lies in the safety profile of the product for EPP patients and, hence, our and regulators’ focus on pharmaco-vigilance”.

“After years of subsidising the treatment and providing it free of charge, Clinuvel needs to move towards the next stage of development: investing in a treatment for children with EPP,” Mr McLiesh said.

Clinuvel said that subsidised access to Scenesse, prior to the drug’s commercial approval, was made possible in both Italy and Switzerland from 2010 and 2012 respectively, enabling 115 patients to benefit from treatment with Scenesse, but it was “no longer in the position to provide access to Scenesse on a subsidised basis”.

Clinuvel jumped as much as 17.6 percent closing up 50 cents or 11.8 percent at \$4.75.

## PHOSPHAGENICS

Phosphagenics says it has expanded its tocopheryl phosphate mixture (TPM) diclofenac gel Themis Medicare agreement to include an additional 16 countries.

Phosphagenics said that in 2011, the Mumbai, India based Themis was granted exclusive rights to TPM-diclofenac gel in India alone.

The company said that the expanded agreement provides Themis with rights to Armenia, Belarus, Georgia, Kazakhstan, Kenya, Kyrgyzstan, Moldova, Philippines, Rwanda, Sri Lanka, Tanzania, Turkmenistan, Uganda, Ukraine, Uzbekistan and Vietnam.

In 2013, Phosphagenics said that Themis would manufacture and supply TPM-diclofenac gel to Novartis India to distribute and sell (BD: Apr 15, 2013).

Phosphagenics said at that time that diclofenac was a non-steroidal anti-inflammatory drug with a range of medical uses, marketed by Novartis as Voltaren.

The company said that Novartis India was a subsidiary of the Swiss Novartis International AG, the global market leader of diclofenac products with sales exceeding \$700 million for both the transdermal and oral forms.

Today, Phosphagenics said that Themis would pay it an undisclosed upfront fee and royalty payments on sales in line with those specified in the original agreement.

Phosphagenics said that Themis expected to apply for marketing authorizations to launch the product in the 16 countries "over the next few years".

The company said that in 2014 Themis launched the product under the brand name, Instanac TPM gel, while Novartis launched the same product under the brand name, Voveran TPM gel.

Phosphagenics chief executive officer Dr Ross Murdoch said that TPM-diclofenac gel was "well accepted by physicians and patients in the Indian market and creates a solid blueprint for expansion into new markets".

The company said that it was advised on the licencing transaction by the Naperville, Illinois-based Aagami Inc.

Phosphagenics climbed half a cent or 22.7 percent to 2.7 cents with 20.5 million shares traded.

## GI DYNAMICS

UBS AG says it has reduced its substantial shareholding in GI Dynamics from 33,870,658 shares (7.13%) to 28,927,841 shares (6.08%).

The Hong Kong-based UBS said that between December 18, 2015 and May 13, 2016, it sold shares in 37 transactions, with the largest sales of 2,000,000 shares for \$60,038 or three cents a share.

GI Dynamics was unchanged at 1.7 cents.

## RESPIRI (FORMERLY ISONEA)

Respiri has requested a voluntary suspension to follow the trading halt requested on May 16, pending "an announcement to the market in relation to a proposed capital raising via a rights issue" (BD: May 16, 2016).

Respiri last traded at 3.2 cents.

### ONCOSIL MEDICAL

Oncosil says it has appointed Michael Warrener as sales and marketing director effective from June 1, 2016.

Oncosil said that Mr Warrener would be based in Sydney to oversee the initial market launch in Europe, Australia and Asian markets and would be responsible for the commercialization strategy and infrastructure.

The company said that Mr Warrener's appointment completed the senior leadership team. Oncosil said that Mr Warrener had more than 23 years experience in the pharmaceutical and medical device sector including eight years with Sirtex, where he held a number of management roles including sales and marketing director for Europe and Middle East where he helped introduce and then drive adoption of Sir-Spheres and during his tenure the company achieved several positive reimbursement and sales outcomes in Europe and other jurisdictions.

The company said that most recently, Mr Warrener was the Sydney-based Sirtology Pty Ltd sales and marketing director responsible for commercialization of its lead product, including regulatory submissions in Europe and the United States.

Oncosil said that Mr Warrener held a Bachelor of Science from the University of Sydney and a Master of Business in Marketing from the University of Technology Sydney.

Oncosil was up 1.75 cents or 14.6 percent to 13.75 cents with 1.7 million shares traded.

### TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG says that chairman Jitto Arulampalam will return to his previous role of executive chairman.

TBG said that Mr Arulampalam would be responsible for investor relations, capital raising and, in conjunction with chief executive officer Eugene Cheng and the management team "explore business development and corporate opportunities that will help drive the company's growth and transformation".

The company said that Mr Cheng would continue as an executive director and chief executive officer and would assume the role of chief operations officer.

TBG said that the changes "follow a recent decision by the board to approve an aggressive development timetable with the purpose of getting its new [in-vitro diagnostics] products to market".

The company said that Dr Stanley Chang, Edward Chang and Emily Lee continued as non-executive directors.

TBG fell 2.5 cents or 8.8 percent to 26 cents.