



Biotech Daily

Tuesday September 26, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: ONCOSIL UP 15%, PRANA DOWN 7%**
- * **REGENEUS: 'STEM CELLS BEAT MORPHINE FOR PAIN IN RATS'**
- * **PHOSPHAGENICS LICENCES TPM-DICLOFENAC TO SICHUAN CREDIT**
- * **PHOSPHAGENICS RIGHTS OFFER TO RAISE \$4.7m**
- * **CYCLOPHARM ENROLS PATIENTS IN US PHASE III TECHNEGAS TRIAL**
- * **EPAT PAIN SOFTWARE LAUNCH AT ALZHEIMER'S MEETING**
- * **IM TO BECOME BABYLON PUMP & POWER, DEPART BIOTECH**

MARKET REPORT

The Australian stock market fell 0.22 percent on Tuesday September 26, 2017 with the ASX200 down 12.72 points to 5,671.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and four were untraded.

Oncosil was the best on no news, up 1.5 cents or 15.0 percent to 11.5 cents with two million shares traded.

Ellex and Factor Therapeutics climbed more than seven percent; Pro Medicus was up 5.2 percent; Cellmid, Cyclopharm and Opthea was up more than four percent; Polynovo was up 3.7 percent; Actinogen, Compumedics, ITL, LBT, Pharmaxis and Starpharma were up more than one percent; with Cochlear up 0.3 percent.

Prana led the falls, down 0.4 cents or 6.7 percent to 5.6 cents with 6,000 shares traded, followed by Viralytics down 6.4 percent to 80 cents with 194,384 shares traded.

Avita and Living Cell lost more than five percent; Bionomics fell 4.1 percent; Admedus and Benitec were down more than three percent; Sirtex shed 2.05 percent; CSL, Impedimed, Mesoblast, Nanosonics, Neuren and Universal Biosensors were down one percent or more; with Airxpanders and Clinuvel down by less than one percent.

REGENEUS

Regeneus says a post-operative pain study in rats shows that its topical Sygenus has greater and longer-lasting analgesic effect than injected morphine.

Regeneus said that Sygenus was an allogeneic, or off-the-shelf, cell secretions technology platform comprising cytokines, growth factors and exosomes from fat-derived mesenchymal stem cells and the bioactive molecules reduced pain and inflammation as well as encouraged accelerated healing and repair.

The company said it trialled high and low dose Sygenus applied topically to a wound area compared to an injected dose of morphine and vehicle.

Regeneus said that analgesia was assessed using a reflex response time to a heat stimulus and Sygenus showed a dose-dependent pain relief with the beneficial effect of the high dose lasting up to three hours.

The company said morphine had short-lived benefits and lost its effect within three hours. Regeneus said the “promising results show that Sygenus is having a sustained analgesic effect above and beyond the anti-inflammatory effect that others have observed with [mesenchymal stem cells] and their secretions”.

The company said the results would inform its Australian Research Council Linkage collaboration with Macquarie University and the University of Adelaide investigating the use of stem cell technology for the treatment of pain.

The University of Adelaide’s Prof Mark Hutchinson said the results were “very impressive”. Prof Hutchinson said the cell secretions were “having a powerful and rapid analgesic effect that rival and outlast the gold standard opioid analgesic”.

“We are keen to translate this work into our current research programs with the potential to explore this further in clinical trials on pain in humans,” Prof Hutchinson said.

Regeneus climbed 2.5 cents or 20 percent to 15 cents.

PHOSPHAGENICS

Phosphagenics says it will licence tocopheryl phosphate mixture (TPM) diclofenac gel to Sichuan Credit Pharmaceutical Co for China, Hong Kong, Macau and Taiwan.

Phosphagenics said that it had signed a term sheet for a development and licencing agreement which would grant Sichuan Credit Pharma exclusive rights to develop, market and sell the TPM-diclofenac gel and it would receive a non-refundable payment of \$US100,000 (\$A125,917) within the next 30 days and \$US300,000 within 30 days of signing a definitive agreement, expected by the end of January 2018.

The company said it would be entitled to a 10 percent royalty on net sales by Sichuan Credit Pharma and the parties would negotiate a formal exclusive TPM supply agreement.

Phosphagenics chief executive officer Dr Ross Murdoch said that “with this agreement, our TPM-diclofenac gel should soon be available to almost half of the world’s population”.

“China represents a very important market for Phosphagenics’ products and we look forward to finding ways to build on this partnership with Credit Pharma,” Dr Murdoch said.

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

Diclofenac is marketed by Novartis as Voltaren and in 2013, Phosphagenics said Themis would manufacture and supply TPM-diclofenac gel to Novartis India (BD: Apr 15, 2013).

Last year, the company said an expanded agreement with Themis provided the rights to Armenia, Belarus, Georgia, Kazakhstan, Kenya, Kyrgyzstan, Moldova, Philippines, Rwanda, Sri Lanka, Tanzania, Turkmenistan, Uganda, Ukraine, Uzbekistan and Vietnam (BD: May 18, 2016).

Phosphagenics fell 0.2 cents or 11.1 percent to 1.6 cents with 1.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says it hopes to raise \$4.7 million through a one-for-four non-renounceable rights offer at 1.5 cents a share.

Phosphagenics said that it had commitments for \$567,000 from existing investors, along with underwriting agreements for \$980,000 of shares, of which chief executive officer Dr Ross Murdoch, chairman Dr Greg Collier and director David Segal had committed \$25,000, \$30,000 and \$30,000, respectively.

The company said that the group of underwriters included the three directors, as well as existing and new investors.

Phosphagenics said the record date for the rights offer was October 2, the offer would open on October 3 and close on October 12, 2017.

The company said that proceeds from the raising would fund the Mylan arbitration as well as continue the development and partnership of the tocopheryl phosphate mixture (TPM) opioid patches, the TPM injectable portfolio, the TPM animal health opportunities as well as cash for working capital and other purposes.

CYCLOPHARM

Cyclopharm says the first two of up to 240 patients have been enrolled in its US phase III trial of Technegas for lung imaging.

Last year, Cyclopharm says the US Food and Drug Administration had approved a special protocol assessment for a phase III trial of its Technegas lung imaging technology comparing Technegas with Xenon-133 (BD: Nov 23, 2016).

Cyclopharm managing-director James McBrayer said last year that the trial, known as CYC-009, was agreed by the US Food and Drug Administration without request for clarification or variation and was announced earlier than expected.

Today, the company said the trial was a non-inferiority structural ventilation protocol comparing Xenon-133 with Technegas in 240 patients, with broad participant selection criteria allowing a more efficient and expeditious completion of the trial.

Cyclopharm said the trial was expected to have a 40-patient review by the end of 2017 and completion by mid-2018 at a cost of \$US7 million.

Mr McBrayer said that Technegas was sold in 56 countries and had been the subject of 3.7 million patient studies since 1987.

Mr McBrayer said the US, with half the world's nuclear medicine departments, was "the greatest immediate opportunity to Cyclopharm".

He said the existing US market was estimated at 600,000 patients and valued at about \$US90 million a year.

"Canada is our largest single country market," Mr McBrayer said.

"With 14 years of sales, Canada represents an excellent indicator of ultimate acceptance in the US," Mr McBrayer said.

"Based on our experience there, we believe that we will be able to convert 80 percent of the total US market to Technegas," Mr McBrayer said.

Cyclopharm said that Technegas had been used primarily for the diagnosis of pulmonary embolism but had potential in other disease states, including chronic obstructive pulmonary disease, asthma, pulmonary hypertension and certain interventional applications such as lobectomies in lung cancer and lung volume reduction interventions.

Cyclopharm was up 3.5 cents or five percent to 74 cents.

EPAT

Epat says it will launch its pain recognition software with Dementia Support Australia at the National Alzheimer's conference in Melbourne in October 17 to 20, 2017.

Earlier this month, Epat said it signed its first commercial deal for its pain assessment software application with Dementia Support Australia, founded by the Sydney-based non-denominational Christian aged-care provider Hammond Care (BD: Sep 7, 2017).

The company said at that time that Dementia Support Australia provided nationwide consultant support and advice to carers of people with dementia with behavioral and psychological symptoms of dementia impacting on their care.

Today, Epat said that up to 800 dementia and aged care specialists would attend the conference and with Dementia Support Australia it would co-hosting an October 17 launch of the pain assessment tool for delegates.

The company said Epat scientific officer Mustafa Atee would present 'The Electronic Pain Assessment Tool (Epat): A novel pain scale for patients with dementia' on October 18.

Epat said it would exhibit in the trade show and present the application with a number of meetings with aged care management scheduled.

Epat managing-director Philip Daffas said that "participation at this conference is another positive step in our commercialization strategy".

"Following a successful capital raising, we now have market credibility and funding in place to build a sustainable business model and revenue stream in Australia and into international markets over the next year," Mr Daffas said.

Epat said that the commercial agreement with Dementia Support Australia provided credibility for the software and the organization's 150 consultants would use Epat as a baseline tool to assess pain in up to 5,000 people with dementia each year who reside at the 1,500 aged care and home care providers in Australia.

The company said that at the end of the four to six week consultation, the aged care or community care group would be made aware of the software and would have the option to continue to use it for their residents for the longer term through a separate licence.

Epat fell 0.3 cents or 6.5 percent to 4.3 cents with 16.9 million shares traded.

IM MEDICAL

IM Medical says it will acquire Babylon Operations Pty Ltd a provider of equipment rental and diesel maintenance services to the resource maintenance sector.

In May, IM said raised \$500,000 to become Babylon Pump & Power (BD: Apr 5, 2017).

IM Medical said it had a six month option to acquire the Perth, Western Australia-based Babylon Operations which was "a recently established provider" of equipment rental and diesel maintenance services to the resource maintenance sector.

The company said that if it exercised the option to acquire Babylon it would undertake a capital raising of up to \$6 million, consolidate stock on a one-for-20 basis, change its name to Babylon Pump & Power and seek re-listing on the ASX following re-compliance with Chapters 1 and 2 of the ASX Listing Rules Rights.

In 2015, IM said its attempt to acquire data centre service provider Syncom Australia Pty Ltd through a reverse takeover had failed (BD: Jan 18, May 22, Jul 23, 2015).

Previously, IM Medical had been attempting to commercialize cardiac testing.

IM was untraded at 0.1 cents.