



# Biotech Daily

Tuesday September 30, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: PATRYS UP 17%, OPTISCAN DOWN 10%**
- \* **ASCEND \$11m IPO FOR SKIN, BREAST CANCER**
- \* **EMA FINDS MORE TISSUE THERAPIES VITROGRO QUESTIONS**
- \* **SA UNI, SEMENTIS WORK ON VIRUS, ALLERGY, CANCER VACCINES**
- \* **PROCTOR & GAMBLE LAUNCH 1<sup>st</sup> OBJ MAGNETIC COSMETIC**
- \* **VIRALYTICS CAVATAK COMBINATION MOUSE EFFICACY**
- \* **CORRECTION: BIONOMICS**
- \* **PATRYS ANTI-CANCER COMPOUND PAT-LM1 AUSTRALIAN PATENT**
- \* **UP TO 27% OPPOSE GENETIC TECHNOLOGIES IRONRIDGE NOTES**
- \* **MC MANAGEMENT TAKES 5% OF ADMEDUS**
- \* **BIO-MELBOURNE BREAKFASTS ON INFECTION READINESS**

## MARKET REPORT

The Australian stock market climbed 0.54 percent on Tuesday September 30, 2014 with the S&P ASX 200 up 28.6 points to 5,292.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and three were untraded. All Big Caps rose.

Patrys was the best, up 0.3 cents or 16.7 percent to 2.1 cents with 595,000 shares traded, followed by Anteo up 16.0 percent to 14.5 cents with 4.0 million shares traded. Both GI Dynamics and Viralytics climbed 10.3 percent; Oncosil was up 9.5 percent; Acrux and Admedus were up more than seven percent; Clinuvel and Phosphagenics rose more than five percent; Starpharma was up 3.2 percent; Avita and Cochlear rose more than two percent; Bionomics, CSL, Mesoblast and Sirtex were up one percent or more; with Resmed up 0.5 percent.

Optiscan led the falls, down 0.4 cents or 9.8 percent to 3.7 cents with 557,351 shares traded, followed by Biotron down 9.1 percent to 10 cents with 1.9 million shares traded. Compumedics lost 7.7 percent; Medical Developments was down 6.25 percent; Psivida and Uscom fell more than four percent; Circadian, Prana and Prima shed more than two percent; with Benitec, Ellex and Tissue Therapies down more than one percent.

## ASCEND BIOPHARMACEUTICALS

Ascend says it hopes to raise up to \$11 million in its initial public offer at 35 cents a share to develop immunotherapy drugs, initially for breast cancer and basal cell carcinoma.

Ascend chief executive officer Dr Clement Leong told Biotech Daily that the offer opened yesterday September 29 and would close on October 31, 2014.

Dr Leong said that the funds raised would support two clinical trials.

Dr Leong said the company expected to begin an 18 to 36 patient phase II trial of ASN002 for nodular basal cell carcinoma by July 2015 with interim results in six to eight months and final results in 12 months from initiation.

He said a phase Ib trial of ASN004 for breast cancer was expected to begin enrolling 24 to 36 patients by the end of 2015, with results by the end of 2016.

Dr Leong said that if successful, Ascend expected to expand the indications to other forms of cancer, including cutaneous B-cell lymphoma.

Dr Leong said that current treatments for nodular basal cell carcinoma, which most frequently were on the face or exposed skin, included daily injections or surgery, which were not clinically or cosmetically acceptable for many patients.

He said that ASN002 would be injected once every two weeks for three to five injections.

Dr Leong said that ASN004 was first developed at Melbourne's Austin Hospital and had been further developed to induce both the T-cell and Mucin-1 antibody immune responses.

Dr Leong said that should the phase Ib trial be successful Ascend would follow it with a randomized phase II trial of 100 to 150 patients.

In February, Ascend detailed its clinical program to an investor conference in Melbourne (BD: Feb 21, 2014).

In a media release, Ascend said its chairman was former Alchemia chief executive officer Dr Peter Smith, with former Amgen medical director Dr Richard Stead and Mark Ewing as non-executive directors, and the chief medical officer was Dr Paul Weiden.

The prospectus is available at: <http://www.ascendbiopharma.com/prospectus/>.

Ascend is a public unlisted company.

## TISSUE THERAPIES

Tissue Therapies says it has received further questions on the manufacture of its Vitrogro wound treatment from the European notified body, the British Standards Institute.

Tissue Therapies said that the European Medicines Agency had classified most of the issues raised in the 120-day questions as "completely resolved", but followed with 180-day questions which would require further data from the manufacturer.

The company said that while the answers were compiled, the maximum 210 calendar day review clock would stop, but the clock stop would be "much shorter than that required to respond to the 120-day questions but was likely that the time necessary to prepare the best answers to the 180-day questions will mean that this response will be considered at the December 2014 meeting of the ... [Committee for Medicinal Products for Human Use]" and Conformité Européenne (CE) mark might not be finalized until early 2015.

Last year, following changes to its regulatory pathway by the European Commission Medical Devices Group, Tissue Therapies expected to have approval and first sales by the end of that year (BD: Jul 29, 2013).

In 2011, Tissue Therapies quoted its European Union regulatory consultant saying they were "confident that the human trial data already announced is sufficient for approval for sale" and expected first sales in July 2012 (BD: Sep 30, 2011).

Tissue Therapies fell half a cent or 1.6 percent to 30 cents with one million shares traded.

## UNIVERSITY OF SOUTH AUSTRALIA, SEMENTIS

The University of South Australia says it is collaborating with Melbourne's Sementis on vaccines for Chikungunya virus, peanut allergy, prostate cancer and melanoma.

In a media release the University of South Australia said that its Experimental Therapeutics Laboratory and Sementis were undertaking research at its City East campus, worth more than \$1 million a year.

The head of the Experimental Therapeutics Laboratory Prof John Hayball said the partnership was aimed at developing a vaccine platform to rapidly apply to unmet medical conditions which affected hundreds of thousands of people.

"From our vaccine platform, we're using genetic engineering techniques to insert antigens from different diseases like Chikungunya virus to make the Chikungunya vaccine, allergens from peanuts to make the peanut allergy vaccine and tumor-specific antigens for prostate cancer and melanoma vaccines," Prof Hayball said.

"The platform is a bit like a cassette system that we can plug and play, so we plug the platform with different antigens to target a specific condition," Prof Hayball said.

"With Chikungunya outbreaks on the rise world-wide, a protective vaccine is desperately needed," Prof Hayball said.

"In pre-clinical testing, our vaccine has provided protective immunity to mice challenged with Chikungunya virus," Prof Hayball said.

The next step is to manufacture a batch of the vaccine ready for clinical trials," Prof Hayball said.

Prof Hayball said that the pre-clinical peanut allergy vaccine would be both a treatment vaccine and could be used as a preventative.

"The peanut allergy vaccine will work by re-educating the immune system in such a way that people no longer respond to peanuts with anaphylactic shock," Prof Hayball said.

"With three percent of Australian children now allergic to peanuts, we're working to reduce the impact of peanut allergy on the community," Prof Hayball said.

Prof Hayball said that the prostate cancer and melanoma vaccines were longer-term goals, with research on both still in the discovery phase.

Sementis chief executive officer and chief scientific officer Dr Paul Howley said that through the partnership with the University, the company hoped to deliver practical therapeutic solutions to diseases affecting many people.

"This partnership gives us access to high quality scientists with expertise in the field of immunology and molecular virology and we provide the environment and infrastructure required for vaccine development that enables academic research to be transitioned smoothly into product development that meets industrial and regulatory needs," Dr Howley said.

"This is a great example of academic and industry-led research coming together to develop the advances from our clinical work into products and treatments for the wider community," Prof Hayball said.

The University said that the partnership with Sementis began in 2012 and had grown rapidly to six full-time staff employed in the Experimental Therapeutics Laboratory and supporting a doctoral candidate.

The University said that the partnership was awarded a Department of Industry Entrepreneurs' Infrastructure Program 'Researchers in Business' postdoctoral fellowship to fund Dr Tamara Cooper as a research fellow in the vaccines project.

Dr Howley told Biotech Daily that Sementis was a public unlisted, virtual biotechnology company supported by high net worth investors.

## VIRALYTICS

Viralytics says preclinical studies have generated further evidence of improved Cavatak anti-cancer activity in combination with 'immune checkpoint inhibitors'.

Viralytics said that immune checkpoint inhibitors were a new class of cancer immunotherapies and the study assessed the activity of Cavatak in combination with either the mouse homologue of the cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) monoclonal antibody ipilimumab, or an anti-programmed cell death protein 1 (PD-1) monoclonal antibody.

The company said that in both cases, the combination of the checkpoint inhibitor with Cavatak produced superior efficacy outcomes in a two-phased mouse melanoma study, compared to the efficacy of either agent alone.

Viralytics said that the studies were presented by chief scientific officer Dr Darren Shafren at the European Society for Medical Oncology congress in Madrid, Spain and provided encouragement that the combination might provide significant clinical benefits to patients. The company said that ipilimumab and the anti-PD-1 monoclonal antibodies were cancer immunotherapy agents known as immune checkpoint inhibitors and ipilimumab was launched in 2011 for the treatment of late-stage melanoma and was marketed by Bristol-Myer Squibb as Yervoy, which in 2013 had sales of \$US960 million.

Viralytics said that the anti-PD1 monoclonal antibodies had activity across a broad range of cancer types, including melanoma, lung and bladder cancer and Merck achieved the first US approval for an anti-PD-1 therapy, pembrolizumab, in early September 2014.

The company said that sales of checkpoint inhibitor agents were estimated to be up to \$US24 billion a year in the next decade.

Viralytics chief executive officer Dr Malcolm McColl said the preclinical data was "further evidence of enhanced activity when Cavatak is administered with checkpoint inhibitors and believe that these preclinical data strongly support investigation in human clinical trials".

Viralytics was up three cents or 10.3 percent to 32 cents with 1.7 million shares traded.

## OBJ

OBJ says the SK-II 'magnetic eye care kit' developed with Procter and Gamble will be launched today in Seoul, South Korea.

OBJ said that SK-II was Procter and Gamble's "fastest growing prestige skincare and cosmetic brand" and was marketed in Japan, China, South East Asia, Australia and in selected global markets.

The company said that the SK-II Eye Wand would be the world's first commercial product to incorporate its magnetic micro-array technology.

OBJ said that the SK-II Eye Wand development was led for Procter and Gamble by director Dr Suda Sudarsana and OBJ technical director Jeff Edwards.

"Working in collaboration with OBJ has allowed us to leverage its expertise in diamagnetic physics which, in combination with P&G's biology and chemistry expertise, is resulting in record development speed in a key strategic growth area of beauty," Dr Sudarsana said.

OBJ said that the SK-II project focused on the development and testing of its magnetic micro-array that enhanced delivery and efficacy of molecules in the SK-II formulations.

The company said that the SK-II Eye Wand was the first of three work plans with for Procter and Gamble (BD: Apr 28, 2014).

OBJ climbed two cents or 22.2 percent to 11 cents with 33.9 million shares traded.

## BIONOMICS

Bionomics says that yesterday's announcement of further data from its phase II BNC105 for late stage melanoma trial reported that 57 percent were positive for four-biomarkers. Today the company said that the expression that "with 60 percent of these disease-free at six months" should have been "with 60 percent of these disease progression-free at six months".

No sub-editors were hurt in making this correction.

Bionomics was up one cent or 1.6 percent to 62.5 cents.

## PATRYS

Patrys says it has been granted the first Australian patent for its anti-cancer compound PAT-LM1.

Patrys said that the patent, entitled 'LM-antibodies, functional fragments, LM-1 target antigen, and methods for making and using same'.

The company said that the patent was derived from one of a series of patent applications to cover the PAT-LM1 product, target and epitope, or the part of an antigen recognized by the immune system.

Patrys said the claims in the patent covered the use of PAT-LM1 or binding fragments of PAT-LM1 for the treatment of metastasis in various cancers including brain, breast, stomach and liver as examples.

The company said that four patents across the PAT-LM1 families had been granted in three jurisdictions including the US, New Zealand and Australia.

Patrys chief executive officer Dr Marie Roskrow said that the patent "strengthens and enhances the current intellectual property position for PAT-LM1".

The company said it had completed the process development for PAT-LM1 and was moving into the scale-up part of the development and manufacturing plan and continued to explore the best clinical indication for the antibody, especially those with a significant unmet medical need, orphan indications and niche markets.

Patrys said it had additional applications pending across the PAT-LM1 families in Europe, Canada, Japan and the US.

Patrys was up 0.3 cents or 16.7 percent to 2.1 cents.

## GENETIC TECHNOLOGIES

A Genetic Technologies general meeting to approve the issue of convertible notes to Ironridge was opposed by up to 17,857,463 proxy votes or 26.58 percent votes cast.

Two resolutions asked shareholders to ratify the prior issue of 88,092,330 shares to Ironridge and approve the issue of further shares to Ironridge.

The approval of the issue of 100,000,000 further shares was supported by 49,320,969 votes cast or 73.42 percent with 17,857,463 proxy votes or 26.58 percent of votes cast opposed.

The first resolution was passed with a slightly larger margin.

Genetic Technologies said it had 668,106,442 shares on issue, meaning the larger opposition amounted to 2.67 of the company, not sufficient to call extraordinary general meetings.

Genetic Technologies was untraded at 2.3 cents.



## ADMEDUS

MC Management Group has become a substantial shareholder in Admedus with 73,498,007 shares or 5.1 percent of the company.

The Applecross, Western Australia-based MC Management said that between May 22 and September 22, 2014 it acquired 35,097,657 shares for \$5,133,311 or 14.6 cents a share.

The initial substantial shareholder notice was signed by directors Mathew Ratty and Christopher Ratty.

Admedus was up one cent or 7.1 percent to 15 cents with 1.6 million shares traded.

## BIO-MELBOURNE NETWORK, WEHI, D3 MEDICINE

The Bio-Melbourne Network says that emerging infectious diseases are imminent, real serious threats to Australia's healthcare, economy and security and "readiness is all".

The Network said that its October 23, 2014 Bio-Breakfast would discuss the ability to develop drugs, vaccines, diagnostics and medical devices as countermeasures to emerging infectious diseases including Ebola, influenza, Hendra virus, multidrug resistant bacteria and Middle East respiratory syndrome (MERS).

The Network said that Victoria had a strong history of basic and applied research and development in infectious diseases, including world leading institutions, researchers, practitioners and outstanding capabilities in advanced manufacturing and clinical trials.

The Bio-Melbourne Network said that the Defense Science and Technology Organisation had commissioned workshops to understand Australia's capability and infrastructure in medical preparedness and lead to the establishment of Medical Countermeasure Products Australia (MCPA), an industry-led, public and private sector partnership for medical countermeasures product development.

The Network said that the Bio-Breakfast panel will discuss how Melbourne could bring together existing strengths and capabilities in academia, research agencies and industry to explore solutions and accelerate progress towards new products for emerging infectious diseases.

The Network said that speakers at the Bio-Breakfast would be Nobel Laureate and, University of Melbourne professor of immunology Prof Peter Doherty; Medical Countermeasure Products Australia development committee chair and D3 Medicine chief executive officer Dr Craig Rayner; Medical Countermeasure Products Australia steering committee chair and D3 Medicine chief operating officer Dr Leigh Farrell and the Walter and Eliza Hall Institute's infectious diseases clinician and laboratory head Dr Marc Pellegrini.

The Bio-Melbourne Network quoted Prof Doherty saying: "Contagion has been described as the thinking person's horror movie".

The Bio-Breakfast will be hosted by the Walter and Eliza Hall Institute for Medical Research, 1G Royal Parade, Parkville on October 23, 2014.

Registration is from 7:15am with buffet breakfast until the presentations at 8am.

To register go to: <http://www.biomelbourne.org/events/view/340>.