Biotech Daily

Wednesday December 16, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 10%, OPTISCAN DOWN 12%**

*** PHARMAXIS: 'BRONCHITOL PAEDIATRIC CYSTIC FIBROSIS EFFICACY'**

*** BENITEC'S LOSS OF CEO DR FRENCH 'LOOKS LIKE RETALIATION'**

*** BIOTECH WINS 13 OF 50 FEDERAL ARC FUTURE FELLOWS GRANTS**

*** STARPHARMA SIGNS MOU FOR CHINESE VIVAGEL CONDOMS**

*** ATCOR SIGNS A&D FOR SPHYGMOCOR XCEL JAPAN DISTRIBUTION**

*** ORTHOCELL PERTH CELGRO SHOULDER TENDON TRIAL APPROVED**

*** IDT SHARE PLAN RAISES $2m, TOTAL $8m**

*** ADHERIUM APPOINTS DR WILLIAM HUNTER DIRECTOR**

*** SOLAGRAN 2015 REVENUE UP 21% TO $2.5m, LOSS UP 64% TO $6.4m**

MARKET REPORT

The Australian stock market climbed 2.42 percent on Wednesday December 16, 2015 with the ASX200 up 118.85 points to 5,028.4 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and two were untraded.

Atcor was the best, up two cents or 10 percent to 22 cents with 602,305 shares traded.

Pharmaxis climbed eight percent; Universal Biosensors was up 7.95 percent; Oncosil and Polynovo improved more than six percent; Prana was up five percent; Genetic Technologies, Orthocell, Osprey and Pro Medicus were up more than four percent; Acrux, Bionomics and Nanosonics rose more than two percent; Admedus and Medical Developments were up more than one percent; with CSL, Mesoblast, Resmed and Sirtex up by less than one percent.

Optiscan led the falls, down 0.4 cents or 12.1 percent to 2.9 cents with 230,417 shares traded. Benitec lost 7.6 percent; Uscom fell 5.9 percent; Antisense and Living Cell fell more than four percent; Biotron was down 3.7 percent; Compumedics shed 2.6 percent; Clinuvel fell 1.8 percent; with Cochlear, Ellex, Impedimed and Psivida down by less than one percent.

PHARMAXIS

Pharmaxis says its 92-patient phase II CF204 paediatric trial of Bronchitol for cystic fibrosis met its primary endpoint.

Pharmaxis said the results confirmed Bronchitol (mannitol 400mg) efficacy, regardless of concomitant dornase alfa use and an absolute improvement of 3.42 percent (p = 0.004) in forced expiratory volume over one second (FEV1) which equated to a relative change in FEV1 of 4.97 percent (p = 0.005).

The company said the 39 centre Europe and Canada trial was a crossover design with patients aged six to 17 years receiving either 400mg of Bronchitol or placebo twice a day for eight weeks as well as standard of care, before a washout of eight weeks, followed by a further eight week treatment period on the alternate treatment.

Pharmaxis said the trial was designed with the European Medicines Agency as a condition of the authorization granted for Bronchitol for treating adult cystic fibrosis patients in Europe and to meet the condition it would submit a detailed report in 2016.

The company said it would consider an application to extend the European Union authorization to include children and adolescents but it was not known if the trial results alone would be sufficient to gain an approval.

Pharmaxis said that during the Bronchitol treatment period patients had a statistically significant improvement in the primary endpoint of lung function compared to placebo with an absolute improvement in FEV1 as well as the relative change in FEV1, irrespective of whether patients were taking dornase alfa.

The company said the secondary endpoints included absolute change in forced expiratory flow between the 25 and 75 percent of the flow (FEF25-75) which was believed to have significance in younger patients and “Bronchitol produced an absolute improvement of 5.75 percent (p = 0.005) in FEF25-75 equating to a relative improvement of 10.5 percent” and treatment-induced sputum weight was significantly increased (p = 0.012) with a positive trend in forced vital capacity.

The company said that although not an endpoint, patients on Bronchitol experienced about 25 percent fewer lung infections and exacerbations which was supportive of the improvements seen in earlier studies, despite the short duration of this study.

Pharmaxis chief executive officer Gary Phillips said the results were “very pleasing”.

“The positive results were seen in a group of patients with a range of genetic subtypes and reinforce the view that Bronchitol has a clear place in the treatment of [cystic fibrosis],” Mr Phillips said.

“The trial utilised a number of different design features to overcome some of the issues seen in this age group in the earlier phase III studies, in particular the European Medicines Agency agreed to the use of large particle size non-respirable mannitol as the placebo in this study rather than a smaller dose of the active drug as used in the phase III trials,” Mr Phillips said.

Mr Phillips said that the minimal placebo effect provided reassuring evidence on the benefit of Bronchitol and indicated that the results of the earlier phase III studies where a control effect was seen in younger patients might have been understated.

The company said the 92 treated patients had a mean age of 12 years with a mean lung function on trial entry of 72.2 percent of the predicted normal FEV1; 60 percent were female; 69 percent were taking dornase alfa; and 70 percent were on antibiotics.

Pharmaxis said Bronchitol was well-tolerated and had a favorable safety profile, with no difference in the rate of adverse or serious adverse events between the treatment groups and the most common adverse event was mild to moderate cough, three patients experienced scant or mild haemoptysis on Bronchitol and two on placebo.

Pharmaxis was up two cents or eight percent to 27 cents with 1.4 million shares traded.

BENITEC

A US market analyst says the departure of Benitec chief executive officer Dr Peter French "looks like retaliation for the stock price".

In what was described as a "conference call and live audio webcast", Benitec acting chief executive officer Greg West outlined the company's pipeline and said that the non-small cell lung cancer program was "on hold to focus on other programs".

Mr West said that the four continuing programs were the current phase I/II trial of TT-034 for hepatitis C, the Hepbarna for hepatitis B program, the wet and dry age-related macular oedema program with TT-211 and TT-231, and the Pabparna oculo-pharyngeal muscular dystrophy program.

Benitec provided US telephone numbers for "interested participants and investors" but no Australian numbers.

Benitec executives told Biotech Daily that the decision to allow only "analysts" to ask questions, excluding investors and media, was led by US investor relations staff.

Last week, Benitec announced the unexpected departure of chief executive officer Dr Peter French, despite the company being in the middle of a first-in-human, single infusion trial of TT-034 for hepatitis C (BD: Dec 9, 2015).

The company said at that time that it wished Dr French "all the best for the future" and noted his achievements in five years with the company, but gave no reason for the sudden departure.

In August, Benitec raised $US13.8 million ($A18.8 million) of a hoped for $US70 million, at a discount of 22.5 percent to its last ASX closing price, which precipitated a share price slide from 96.5 cents to the present 30 cent level (BD: Aug 19, 2015).

Today, the New York-based Maxim Group head of healthcare research and senior biotechnology analyst Jason Kolbert, who was given permission to ask questions, said: "We really like Benitec, but don't get it."

"Why would Peter step down? The timing doesn't make sense to me?" Mr Kolbert asked.

"It looks like retaliation for the stock price," Mr Kolbert said.

Mr West denied the accusation and said that the decision was by mutual agreement and Benitec was looking for a US-based chief executive officer with capital market and business development experience as well as deals and partnering experience.

Lodge Partners biotechnology and life sciences analyst Marc Sinatra was also allowed to ask questions and questioned the sort of chief executive officer the company wanted and whether he or she would "run with what you've got or take three months to [conduct a] review?"

Mr West said that the company had "no formulated view … we remain true to our pipeline" but open to review.

"We would expect a new guy to put his fingerprints on things," Mr West said.

Mr West said that an international search process was underway and the appointment would be expected to understand and deliver the DNA-directed RNA-interference technology as well as have knowledge of US capital markets.

Mr West said that Benitec had about $33 million in cash.

Mr West said that the first patient in the fourth cohort, the eighth patient of 14, had been dosed with TT-034.

Benitec chief clinical officer Georgina Kilfoil told Biotech Daily that the trial was on-track to complete dosing in July 2016 with final data by the end of 2016.

In November 2014, Dr French said that the trial was expected to take a further 12 to months to be completed, in-line with current expectations (BD: Nov 13, 2014).

Benitec fell 2.5 cents or 7.6 percent to 30.5 cents.

FEDERAL GOVERNMENT, AUSTRALIAN RESEARCH COUNCIL

The Federal Government says the Australian Research Council Future Fellows grants will provide $38.6 million for 50 projects, of which 13 are medical and biotechnology.
The Minister for Education and Training Simon Birmingham said the Future Fellows would "help the nation innovate, invent and apply new ideas across key research areas, forming part of the Turnbull Government's Innovation Agenda".
"These 50 fellows will build on the nation's innovation efforts and deliver research outcomes that will improve the lives of everyday Australians, like Dr Timothy Dargaville from Queensland University of Technology, whose $812,460 Future Fellows funding will help him develop a [three dimensional] moulding process that could be used for tissue transplants," Mr Birmingham said.
The details of the grants are at http://www.arc.gov.au.

STARPHARMA HOLDINGS

Starpharma says it has a memorandum of understanding with an unnamed Chinese company to supply Vivagel-coated condoms to the Chinese Government.
Starpharma said the agreement outlined the key terms for its partner to manufacture and sell Vivagel condoms to the Government segment of the Chinese market.
The company said it would work with the unnamed Chinese partner to proceed with the regulatory process for a market launch and to finalize a binding commercial agreement.
Starpharma chief executive officer Dr Jackie Fairley said the agreement was "an important step towards expanding the availability for the Vivagel condom to a market not captured by our current licencees".
"In addition, partnering with a local Chinese company has the potential to facilitate entry into this important market," Dr Fairley said.
Starpharma said that the Chinese Government annual condom demand was estimated at about three billion condoms and covered the Government's Birth Control Department and the Disease Prevention Department.
Starpharma was unchanged at 70 cents.

ATCOR MEDICAL

Atcor says it has signed a multi-year exclusive Sphygmocor XCel distribution contract for Japan with the Tokyo-based A&D Company.
Atcor said that A&D was "the market leader in the hospital and clinic blood pressure market in Japan", but did not disclose the value of the contract.
The company said that Sphygmocor XCel would be marketed initially to researchers as a class one device under the Japanese Ministry of Health's regulations while a class 2 submission to allow clinical use was submitted and reviewed in 2016.
Atcor said that the 2014 Japanese Society of Hypertension Guidelines identified central blood pressure and augmentation index as markers of advanced cardiac disease, and pulse wave velocity as a marker of end organ damage, which was damage occurring in the body's major organs such as the heart, kidneys or brain and Sphygmocor XCel provided both measurements, unlike other devices in Japan which measured only one parameter.
The company said that A&D would promote the Sphygmocor XCel device through their sales force, which had completed training to demonstrate and use the system and marketing had commenced.
Atcor was up two cents or 10 percent to 22 cents.

ORTHOCELL

Orthocell says the St John of God Hospital has approved a 30-patient trial of its Celgro SMRT Graft collagen scaffold with surgical repair of shoulder rotator cuff tendons.
Orthocell said that the Perth Western Australia St John of God Hospital had given ethics approval for the trial and Prof Allan Wang would be the principal investigator.
The company said that large rotator cuff repairs tear again at a rate of 57 percent in a series of 500 patients and previous research showed that 20 to 90 percent of rotator cuff repairs tore again.
Orthocell said that its Celgro SMRT Graft collagen scaffold aimed to reduce the re-tear rate by improving mechanical stabilization and providing a more cell friendly environment to improve healing.
Orthocell managing-director Paul Anderson said the rotator cuff “can be a problematic tendon to heal so it is hoped that Celgro will improve surgical outcomes”.
The company said that unlike collagen scaffolds used in surgical procedures Celgro had been shown to actively promote and improve tissue ingrowth and repair and had been developed for use in surgical applications such as tendon repair, dental applications and restructuring of damaged soft tissue in the body.
Orthocell said that the global orthopaedic soft tissue repair market was worth about $US7 billion in 2013 and was expected to be worth more than $US10 billion by 2020.
Orthocell was up 1.5 cents or 4.2 percent to 37 cents.

IDT AUSTRALIA

IDT says that its share plan at 35 cents a share is expected to close full subscribed, raising a further $2 million.
In November, a placement at the same price raised $6 million (BD: Nov 19, 2015).
IDT said the share plan was fully underwritten by Wilson HTM Corporate Finance.
IDT was unchanged at 34.5 cents.

ADHERIUM

Adherium says it has appointed Canada-based pharmaceutical entrepreneur Dr William Hunter as a non-executive director.
Adherium said that Dr Hunter was currently the chief executive officer of the Vancouver, Canada-based Cardiome Pharma Corp, had 200 patents and patent applications to his name and had been involved in the discovery and development of devices and products used in more than 10 million patients with total revenues exceeding $12 billion.
The company said that Dr Hunter’s latest venture Canary Medical used sensor technology to allow implanted medical devices to self-report on function, activity, wear, complications and patient outcomes and analyze the data generated by those devices.
Adherium said that while in medical school Dr Hunter co-founded Angiotech Pharmaceuticals and led the company through three rounds of private equity financing listing on the Toronto Stock Exchange and Nasdaq with eight separate corporate acquisitions and annual revenues of more than $250 million.
The company said that Dr Hunter held a Bachelor of Science from the Montréal, Quebec-based McGill University and a Master of Science and Doctor of Medical degree from the University of British Columbia.
Biotech Daily was unable to ascertain at the time of publication whether the revenue values were US or Canadian.
Adherium was up four cents or 5.9 percent to 72 cents.

SOLAGRAN

Solagran says that its revenue for the year to June 30, 2015 was up 21.45 percent to $2,533,081 with the net loss after tax up 63.92 percent to $6,441,971.

Solagran said that diluted loss per share increased from 1.14 cents in the year to June 30, 2014 to 1.88 cents for the year to June 30, 2015, while net tangible assets per share increased from negative 2.55 cents to negative 4.88 cents.

In filing its accounts ahead of a request to resuming trading on the ASX Solagran executive chairman Dr Vagif Soultanov said the year "has been another challenging time for Solagran since the company shares stopped trading on March 1, 2012".

"In the previous three to four years, the company went through difficult times which involved several court cases that thankfully finished in [Solagran's] favour," Dr Soultanov said.

"Nevertheless, we managed to achieve many positive results and even attracted investors into the company who provided sufficient funds to move forward," Dr Soultanov said.

The South Melbourne-based Solagran describes itself as a "healthcare and wellness company" and was developing a treatment for liver cancer, Alzheimer's disease and a raft of other indications based on its Siberian pine needle extract Ropren and 'Bioeffectives' (BD: Feb 25, 2009; Feb 5, 2010).

Despite claims of expected large contracts and the building of a manufacturing plant in Russia, Solagran was suspended by the ASX for failing to lodge accounts on two occasions (BD: Mar 1, 2011; Mar 9, 2012).

In February 2012, Solagran said it would form a joint venture with Russia's Art Life to develop and manufacture food additive products using its conifer needle extract 'Bioeffectives' and quoted Art Life founder and owner Prof Alexander Avstrievskih "forecasting revenues in the order of $US100 million [$A93.6 million] for 2012".

Despite Solagran personnel joining Bioprospect, an agreement between the two companies relating to the use of Bioeffectives was terminated with Bioprospect alleging it could source the same pine needle extract cheaper elsewhere and the two companies were involved in litigation (BD: Jun 28, Aug 5, Sep 20, Oct 27, 2010).

On May 14, 2007, Solagran's share price reached a peak of $1.55, but today the company remained suspended at 3.9 cents.