Biotech Daily

Friday March 13, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALCHEMIA UP 31%; BENITEC DOWN 8%**

*** ALCHEMIA'S GENERIC HEPARIN ANDA FILED TO FDA**

*** PSIVIDA EYE INSERT SAFETY, EFFICACY MEET EXPECTATIONS**

*** LEN ROSS REPLACES MICHAEL SOJA AS PSIVIDA CFO**

*** TISSUE THERAPIES APPOINTS MEL BRIDGES AS A DIRECTOR**

*** VIRALYTICS PAYS NEWCASTLE INNOVATION SHARES FOR RESEARCH**

*** IMPEDIMED RELEASES 27m ESCROW SHARES**

*** IM MEDICAL AGM DIVIDED ON PLACEMENT TO FORTREND ET AL**

*** NUSEP SUSPENDED FOR NXGEN'S LONGER LASTING LISTING**

MARKET REPORT

The Australian stock market climbed 3.39 percent on Friday March 13, 2009 with the S&P ASX 200 up 109.7 points to 3,345.2 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, five traded unchanged and eight were untraded.

Alchemia was best, up 5.5 cents or 31.43 percent to 23 cents with 2,990,404 shares traded, followed by Cytopia up 11.11 percent to 10 cents.

Labtech, Pharmaxis and Psivida climbed more than nine percent; Bionomics, Cellestis, Clinuvel and Resmed were up five percent or more; Acrux, Peplin and Phosphagenics improved more than four percent; Avexa, Prana, Universal Biosensors and Viralytics rose more than two percent; with Chemgenex, Nanosonics and Novogen were up more than one percent; with Biota and CSL up less than one percent.

Benitec led the falls, down 0.3 cents or 7.89 percent to 3.5 cents with 63,285 shares traded followed by Optiscan down 7.5 percent to 3.7 cents.

Circadian lost 6.25 percent; Polartechnics fell five cents; Cathrx and Cochlear shed more than two percent; Progen was down 1.13 percent; with Heartware and Sirtex down less than one percent.

ALCHEMIA

Alchemia's synthetic heparin could be on sale by the end of the year following Dr Reddy's submission of an abbreviated new drug application to the US Food and Drug Administration.

Alchemia said Dr Reddy's was its global manufacturing and US marketing partner.

The application for fondaparinux sodium for injection in 2.5mg, 5.0mg, 7.5mg and 10.0mg doses has been filed with a paragraph II certification indicating that there is no remaining patent listed for the drug.

Alchemia said fondaparinux was an anticoagulant marketed by Glaxosmithkline under the brand name Arixtra.

The company said it was approved for a number of indications including the treatment and prevention of deep vein thrombosis or blood clots in a number of medical settings such as post-operative knee and hip surgery.

In 2008, global sales of Arixtra were $US315 million US sales were $US163 million.

Alchemia chief executive officer Dr Pete Smith said the filing of the application was "a major achievement for Alchemia".

"Of all the drugs used in modern medicine, fondaparinux is one of the most challenging molecules to synthesize and we are proud to have accomplished this feat with Dr Reddy's, our partner for its manufacturing and commercialization," Dr Smith said.

"Whilst the key patents on Arixtra expired in 2002, no company has filed for the approval of its generic until now and we are not aware of any other generic manufacturers currently capable of making this molecule at commercial scale," Dr Smith said.

"Because we do not foresee the entry of other competitors in the near term, we expect pricing, market share and profitability to remain higher compared to a typical generic product," Dr Smith said.

Alchemia said the manufacturing process for fondaparinux used by Dr Reddy's used a novel, synthetic pathway developed by Alchemia. One patent has been issued in the US and another is pending that cover key steps in this pathway.

Under the terms of the 2007 licence agreement between Alchemia and Dr Reddy's, profits from US sales of generic fondaparinux will be divided in an agreed proportion between the partners.

Dr Reddy's also has a right of first refusal to market generic fondaparinux in Europe once data exclusivity expires in 2012.

Under the FDA's Generic Initiative for Value and Efficiency (the GIVE initiative), the agency has a stated objective of reviewing first generics within six months of filing.

Alchemia said it believed that fondaparinux would be eligible for this priority review.

"Because fondaparinux is a fully synthetic molecule, Alchemia does not believe it will face the regulatory issues of other anticoagulant drugs, such as the low molecular weight heparins, which are complex mixtures derived from animal material," the company said.

Alchemia said an abbreviated new drug application (ANDA) contained data that provided for the review and approval of a generic drug product.

Once approved, an applicant may manufacture and market the generic drug product as an alternative to the branded drug.

Generic drug applications are termed 'abbreviated' because they are generally not required to include preclinical and clinical data to establish safety and effectiveness, but must demonstrate that their product is equivalent to the branded drug, Alchemia said.

For those drugs that do not receive priority review, the average review time for an ANDA submission was 15 to 18 months based on FDA data from 2007, although this average includes several different types of filings. The quality of the filing influences review time.

Alchemia was up 5.5 cents or 31.43 percent to 23 cents with 2.99 million shares traded.

PSIVIDA

Psivida says 12-month safety and efficacy results from the first human pharmacokinetic study of Iluvien (formerly Medidur) are “consistent with [its] expectations”.

Psivida said Iluvien was an intra-vitreal insert being developed for the treatment of diabetic macular oedema and the 36-month open-label phase II study was conducted by licencing partner Alimera Sciences was designed to assess systemic exposure of the corticosteroid, fluocinolone acetonide, after administration of Iluvien in patients with diabetic macular oedema.

The study was run concurrently with a pivotal phase III study of fluocinolone acetonide in diabetic macular oedema and was designed to provide safety and efficacy information.

A total of 37 subjects were enrolled in the study with 20 patients on the low dose of 0.23µg of Iluvien per day, and 17 patients on the high dose of 0.45µg per day.

Psivida said that in the 12-month interim readout, no adverse events related to intraocular pressure (IOP) were seen in low dose patients, but 23.5 percent of the high dose patients experienced IOP increases of 30mm of mercury (mmHg) or greater at some time point and one of those patients required surgery to address their elevated IOP.

The company said that results from clinical studies of patients using sustained release intra-vitreal fluocinolone acetonide in its Retisert treatment licenced to Bausch & Lomb, 35 percent of the patients experienced IOP increases of 30 mmHg or greater at some time point during the first year.

Psivida said Retisert was an approved surgically implanted intra-vitreal drug delivery device containing 0.59mg of fluocinolone acetonide for the treatment of chronic non-infectious posterior uveitis.

Psivida president and chief executive officer Dr Paul Ashton said the 12 month interim safety analysis of Iluvien was consistent with results at the three and six month readouts.

“The lower incidence of IOP changes in high dose Iluvien patients compared to the published clinical data on Retisert and the lack of IOP adverse events in low dose patients is encouraging and indicates that Iluvien has the potential to offer a very important safety advantage in the delivery of [fluocinolone acetonide],” Dr Ashton said.

“Efficacy data from the subgroup of patients with the same visual acuity inclusion criteria as the larger phase III … trial revealed that 27.3 percent of the high dose patients had an improvement in best corrected visual acuity of 15 letters or greater over baseline and 23.1 percent of the low dose patients had an improvement … of 15 letters or greater over baseline,” Dr Ashton said.

“Previously published results from a clinical study of Retisert in [diabetic macular oedema] patients, showed similar efficacy,” Dr Ashton said.

“In the Retisert trial in 197 patients, 17 percent had an improvement … of 15 letters or greater over baseline at 12 months,” Dr Ashton said. “The safety and efficacy results to date in this study continue to be consistent with our expectations regarding Iluvien and we look forward to reporting future results as they become available,” he said.

Psivida said data would be evaluated with interim analyses at months 18, 24, 30 and 36.

The last patient was enrolled in this study at the end of February 2008.

Psivida was up nine cents or 9.78 percent to $1.01.

PSIVIDA

Psivida says its vice-president of finance and chief financial officer Michael Soja will resign “to pursue other interests” effective from March 20, 2009.

The company said its corporate controller, Len Ross, would become the principal financial and accounting officer.

TISSUE THERAPIES

Tissue Therapies has "with great pleasure announced today the appointment of Mr Mel Bridges as a director of the company".

Tissue Therapies said Mr Bridges had spent the majority of his career in the biotechnology and healthcare industry, with more than 30 years experience building successful companies and commercializing a wide range of Australian technology.

The company said Mr Bridges was co-founder of Panbio and Impedimed and is the chairman of Alchemia, Impedimed and Incitive as well as a director of Benitec and Genera Biosystems.

Mr Bridges is also the chairman of private biotechnology companies based in Brisbane, Sydney and Melbourne.

As chairman, he was lead negotiator on the trade sale to Pfizer of the Four Hats Capital-backed, Catapult Genetics.

Tissue Therapies said Mr Bridges had "an exceptional track record in founding, as well as assisting, a variety of technology companies to high-end exits".

During his career Mr Bridges has raised more than $300 million in biotechnology investment capital, the company said.

Tissue Therapies was unchanged at 12.5 cents.

VIRALYTICS

Viralytics has issued 3,000,000 shares at four cents a share to the commercial arm of the University of Newcastle, Newcastle Innovation, as part payment for contractual research.

Viralytics said the share price was the same as for shares issued in the December 2008 share purchase plan.

The company said the share issue was in lieu of a cash payment to Newcastle Innovation.

After the issue of the shares Newcastle Innovation will hold 14.2 million shares (4.8%).

Viralytics was up 0.1 cents or 2.56 percent to four cents.

IMPEDIMED

Impedimed says 14,370,317 shares held in voluntary escrow will be released on March 30, 2009.

With the release of the escrowed shares the company's total share issue will be 82,535,126 shares, with a further 7,510,126 shares under mandatory escrow.

The largest parcel of escrowed shares, 6,395,783 shares, is held by Starfish Technology Fund whose principal Dr Michael Panaccio is a director of Impedimed.

US venture investor Versant Ventures holds 4,832,081 escrowed shares, with Impedimed chief executive officer Greg Brown holding 1,212,025 escrowed shares.

Statewide Superannuation and Westscheme, each own 916,546 escrowed shares, with director Mel Bridges holding an indirect interest in 97,336 escrowed shares.

Impedimed said those holders or controllers who comprise members of the board "have confirmed they have no near term plans to dispose of any of the shares on market as a result of their release from escrow".

Impedimed was unchanged at 70 cents.

IM MEDICAL

IM Medical shareholders were divided over resolutions on three share placements to Fortrend Securities and other investors.
IM Medical approved all resolutions with opposition ranging up to 22.5 percent of proxy votes with 62.2 percent in favor for the third resolution.
Two resolutions relating to the US-based Fortrend were supported by 74.9 percent of proxy votes with 9.8 percent opposed and 62.8 percent in support and 21.8 percent against respectively.
IM Medical was unchanged at 0.2 cents with 4.7 million shares traded.

NUSEP

Nusep has been suspended from ASX quotation, pending the company's compliance with Chapters 1 and 2 of the Listing Rules.
The suspension relates to Nusep's change in nature and scale of activities, following shareholder approval of the acquisition of 100 percent of the issued capital of Nxgen Pharmaceuticals.
The acquisition is effectively a back-door listing for Nxgen, purveyors of widely-advertised male sex performance drugs.
Nusep last traded at five cents.