Biotech Daily

Monday November 14, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: ANTISENSE UP 23%; PSIVIDA DOWN 49%**

*** PSIVIDA FALLS 49% ON FDA ILUVIEN REJECTION**

*** PRANA: 'PBT2 REVERSES LOSS OF SYNAPTIC ACTIVITY' IN MICE**

*** USPTO ALLOWS CELLMID MIDKINE CARDIAC ISCHEMIA PATENT**

*** PHOSPHAGENICS 'OVER-SUBSCRIBED' PLAN RAISES $3m**

*** CATHRX UNDERWRITTEN 1-FOR-7 RIGHTS ISSUE RAISES $2m**

*** AUSTRALIAN ETHICAL SELLS 2m TISSUE THERAPIES SHARES**

*** ANTISENSE PLEADS SCHULTZ TO ASX 77% QUERY**

*** STARPHARMA REQUESTS CAPITAL RAISING TRADING HALT**

*** ISONEA REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.19 percent on Monday November 14, 2011 with the S&P ASX 200 up 8.1 points to 4,304.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and eight were untraded.

Antisense was the best, up 0.3 cents or 23.1 percent to 1.6 cents with 133.6 million shares traded.

Cellmid and Compumedics climbed more than six percent; Impedimed was up 5.4 percent; Phosphagenics, Prana and Viralytics were up more than three percent; Circadian, Mesoblast and Tissue Therapies rose more than two percent; Sirtex was up 1.1 percent; with Cochlear, CSL and Pharmaxis up by less that one percent.

Psivida led the falls, down $2.00 or 48.78 percent to $2.10 with 14,761 shares traded.

Alchemia, Heartware and Sunshine Heart lost five percent or more; Clinuvel, Genetic Technologies, Living Cell and Neuren were down three percent or more; Acrux, Bionomics, Biota and Phylogica shed more than one percent; with Resmed down 0.4 percent.

PSIVIDA

Psivida fell 48.5 percent on the Nasdaq on Friday following the US Food and Drug Administration refusal to approve licencee Alimera's Iluvien for diabetic macula oedema.
Psivida fell by a similar amount on the ASX today, but on small volumes.
In a media release to the ASX Psivida chief executive officer Dr Paul Ashton said: "We are obviously surprised and disappointed with the FDA's decision".
Psivida's head of investor relations Brian Leedman told Biotech Daily that European Union approval for Iluvien for diabetic macular oedema (DME) was "still possible and we have other products in the pipeline and $21 million in the bank".
Alimera reported the FDA complete response letter, saying "it was unable to approve the Iluvien [new drug application] because the NDA did not provide sufficient data to support that Iluvien is safe and effective in the treatment of patients with DME".
In February, Psivida said the phase III Iluvien trial showed the drug was statistically significant at 33-months but not at 36-months.
Psivida said its partner Alimera Sciences presented the 24-month, top-line results and had submitted the FDA new drug application on the basis of the lower of two doses being trialed (BD: Feb 4, May 5, 16, 2011).
In December 2010, the FDA asked Alimera to provide 36-month data (BD: Jan 16, 2011).
Mr Leedman told Biotech Daily in February that the endpoint for the FDA-approved pivotal trial was significance at 24 months, the best result was achieved at 30-months with the lower dose of the steroid flucocinolone acetonide delivered in a 'eyelash' sized insert injected into the eye and the treatment retained statistical significance at 33-months.
On Friday, Alimera quoted the FDA saying that "the risks of adverse reactions shown for Iluvien … were significant and were not offset by the benefits demonstrated by Iluvien in these clinical trials".
The company said the FDA wanted it to conduct two additional clinical trials to demonstrate that the product was safe and effective for the proposed indication.
Alimera reported that it will be requesting a meeting with the FDA to clarify next steps.
Alimera said it expected to submit its formal response to the preliminary assessment report to the European Medicines and Healthcare Products Regulatory Agency (MHRA) later this month.
Alimera said that based on the submission, the MHRA was expected to make a recommendation on the approvability of Iluvien for DME by the end of this year, with a decision regarding approval by July 2012.
Dr Ashton said the company would discuss the complete response letter in a teleconference at 9am US Eastern Standard Time (4am, AEDT).
"We will also discuss our product pipeline outside of Iluvien, including our other two clinical stage product candidates: one we are independently developing to treat uveitis affecting the posterior segment of the eye using the same insert as Iluvien and the other we are developing in collaboration with Pfizer to treat glaucoma and ocular hypertension," Dr Ashton said (BD: Jun 15, Sep 13, 2011).
"We also continue to advance our Biosilicon research and development," Dr Ashton said.
"Although we will not be due the $25 million milestone payment for FDA approval of Iluvien, we continue to believe that our $21.3 million of cash resources at September 30, 2011 is sufficient to support our current and planned operations into at least calendar year 2013," Dr Ashton said.
In the US on Friday, Psivida fell $US1.905 or 48.47 percent to $US2.025 with 1,331,020 Nasdaq shares traded.
On the ASX, Psivida was down $2.00 or 48.78 percent to $2.10 with 14,761 shares traded.

PRANA BIOTECHNOLOGY

Prana says Merz Pharmaceuticals GmbH and Max Planck Institute scientists have shown that its PBT2 improves synaptic activity in neurons used for memory in mice.

Prana said the data was presented at The Society for Neuroscience meeting in Washington DC, November 12-16, 2011.

The company said that in a poster entitled 'Aggregation inhibitors reverse beta-amyloid-induced inhibition of long term potentiation in murine hippocampal slices'.

Prana said the experiments reported that PBT2 was able to prevent synapatic toxicity or loss of signal conductivity, caused by the formation of toxic amyloid beta oligomers.

The company said the data indicated that it might be beneficial for neuro-protective agents such as PBT2 that could interrupt amyloid beta self-assembly into aggregates, to be administered to early stage patients to best maintain synaptic plasticity and function as an effective treatment for Alzheimer's disease.

Prana's head of research Prof Robert Cherny said that the "independent data help us to understand how PBT2 can help the brain create new memories by preventing the formation and toxicity of soluble beta-amyloid oligomers".

"Whilst these findings confirm our belief that Alzheimer's disease patients will most benefit from early intervention in the disease process, we believe that PBT2's benefits will include but not be limited to helping early patients," Prof Cherny said.

Prana said that PBT2 was in development for Alzheimer's and Huntington's disease, both of which affect a patient's memory and ability to plan and execute tasks.

The company said that both diseases were associated with the formation of toxic oligomers of a protein and PBT2 was able to prevent the oligomers from forming and could also disaggregate many existing oligomers.

Prana said that PBT2 resulted in significant cognitive improvement in a clinical trial with Alzheimer's disease patients and the next trials in Alzheimer's and Huntington's diseases, would further PBT2's potential as a therapy for the diseases.

Prana was up half a cent or 3.2 percent to 16 cents.

CELLMID

Cellmid says the US Patent and Trademark Office has allowed its patent application relating to a midkine treatment for ischemic heart disease.

Cellmid said the patent application (number 10/371,030) was entitled 'Pharmaceutical composition for preventing or treating ischemic disease' and was "a key patent in [its] ischemia patent family", which in turn was fundamental to the Cellmid acute myocardia infarction (CAMI) 103 program for the treatment of cardiac arrest and strengthened the company's intellectual property position in the midkine space.

The company said the patent was part of the global patent family owned by Cellmid that covered the use of midkine as a therapeutic agent in ischemic diseases such as stroke and heart attack and patents had been granted in Europe, Australia and South Korea.

The company said the ischemia family patents complemented and reinforced its Horiba patent family, which gave global coverage for the use of midkine in treating myocardial disorders and heart failure.

Cellmid chief executive officer Maria Halasz said the allowance in the US was "a significant addition to Cellmid's [intellectual property] assets and is especially important as it provides extra patent protection around our current program in heart ischemia".

Ms Halasz said that Cellmid also gained protection under this patent family for the use of midkine for stroke.

Cellmid was up 0.1 cents or 6.25 percent to 1.7 cents with 7.6 million shares traded.

PHOSPHAGENICS

Phosphagenics says its “four-times oversubscribed” share plan raised $3 million through the issue of 21,433,226 shares at 14 cents a share.
Last month, a Phosphagenics placement was also over-subscribed raising $24.1 million (BD: Oct 21, 2011).
Today, the company said that $14 million in application funds were received and that all applicants would receive at least 1,000 shares with a maximum of 71,429 shares, worth $10,000.
Phosphagenics said the funds would go to accelerating development of its transdermal tocopheryl phosphate mixture (TPM) oxycodone patch.
Phosphagenics was up 0.5 cents or 3.0 percent to 17 cents with 5.1 million shares traded.

CATHRX

Cathrx says it has raised $2,046,883 through its fully underwritten one-for-seven share entitlement issue at 10 cents a share.
The company said it received applications for 5,806,329 shares and the shortfall of 14,662,496 shares would be issued to the underwriter the Malaysia-based Cybotel Industries.
Cathrx said the funds would go to working capital and continued development and testing of its cardiac catheters.
Cathrx was unchanged at 10.5 cents.

TISSUE THERAPIES

Australian Ethical’s Smaller Companies trust has reduced its substantial holding in Tissue Therapies from 13,030,850 shares (7.72%) to 11,148,450 shares (6.61%).
Tissue Therapies said it sold the 1,882,400 shares for $2,914,968 or an average price of 51.3 cents a share.
Tissue Therapies acquired 5,829,935 shares for $2,914,968 or an average price of 50 cents a share in a rights issue and placement (BD: May 25, 2011).
Tissue Therapies was up 1.5 cents or 2.75 percent to 56 cents.

ANTISENSE

Antisense has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose from 0.9 cents on November 8, 2011 to 1.6 cents today, November 14, 2011, a 77.7 percent increase and noted an increase in trading volume.
Antisense said that it expected clinical trial results for its growth hormone receptor targeting drug ATL1103 by the end of this year and reaffirmed the timeline at its annual general meeting on November 8, 2011.
Antisense closed up 0.3 cents or 23.1 percent to 1.6 cents with 133.6 million shares traded.

STARPHARMA

Starpharma has requested a trading halt “pending an announcement to the market regarding an equity capital raising”.
Trading will resume on November 16, 2011 or on an earlier announcement.
Starpharma last traded at $1.075.

ISONEA

Isonea has requested a trading halt pending “an announcement to the market in relation to a capital raising”.
Trading will resume on November 16, 2011 or on an earlier announcement.
Isonea last traded at 0.8 cents.