Biotech Daily

Thursday April 26, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENERA UP 13%, SUNSHINE HEART DOWN 10%**

*** FDA PANEL VOTES FOR HEARTWARE'S PUMP**

*** SWISS INSURANCE FOR CLINUVEL'S SCENESSE**

*** AUSTRIA FIRST PSIVIDA ILUVIEN APPROVAL FOR DME**

*** GSK Q3 BIOTA RELENZA ROYALTY $1.5m**

*** CELLMID PLACEMENT RAISES $1.5m**

*** ACRUX SMALL REVENUE FORECAST REDUCTION**

*** QRX: WATSON ACTAVIS TAKEOVER 'GOOD FOR MOXDUO IR'**

*** NUSEP ABS NOVACELL AGREEMENT FOR SINGAPORE BLOOD PLANT**

*** AUSTRALIAN PATENT FOR PHYLOGICA PHYLOMER LIBRARY SCREENING**

*** US PATENT FOR NOVOGEN, MARSHALL EDWARDS ME-143 FOR CANCER**

MARKET REPORT

The Australian stock market was up 0.34 percent on Thursday April 26, 2012 with the S&P ASX 200 up 14.8 points to 4,375.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged, two traded one share each and three were untraded.

Genera was the best for the second trading day in a row, up three cents or 12.5 percent to 27 cents with 121,144 shares traded, followed by Psivida up 11.6 percent on small volumes, with Neuren up 11.1 percent and Prima up 10.3 percent on strong volumes. Clinuvel climbed 6.6 percent; Heartware was up 4.1 percent; Alchemia, Circadian, CSL, Nanosonics and Resmed rose two percent or more; with Acrux and Biota up by less than one percent.

Sunshine Heart led the falls, down 0.3 cents or 9.7 percent to 2.8 cents with 247,419 shares traded, followed by Cellmid down 9.5 percent to 1.9 cents with 19.4 million shares traded. Bionomics lost 7.6 percent; Benitec and Reva were down more than five percent; both Avita and Optiscan fell four percent; Prana was down 3.45 percent; Living Cell, Mesoblast, Phosphagenics and Phylogica shed two percent or more; with Anteo and Pharmaxis down more than one percent.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration's Circulatory System Devices Panel voted to approve its ventricular assist system for bridge-to-transplant.

The Panel meeting with Heartware last night was one of the final steps in the approval process and considered trial data as well as the FDA specified safety and efficacy questions.

Heartware said the Panel voted clearly in favor of the two safety and efficacy questions with a nine-to-two vote in favor of "Do the benefits of the Heartware system … outweigh the risks for use in patients who meet the criteria specified in the proposed indication?"

Heartware chief executive officer Doug Godshall said that the company was "pleased with the panel's strong recommendation".

"The Advisory Committee meeting outcome represents an important step toward approval of the Heartware ventricular assist system in the United States and we look forward to continuing our dialogue with the FDA as it finalizes its review of our [pre-market application]," Mr Godshall said.

"Heartware remains committed to optimizing outcomes for patients with end-stage heart failure and looks forward to expanding the clinical experience for the device in the future," Mr Godshall said

Heartware said that the Advisory Committee's recommendation was not binding but would be considered by the FDA in its review of the pre-market approval application.

Heartware was up eight cents or 4.1 percent to $2.05.

CLINUVEL PHARMACEUTICALS

Clinuvel says two Swiss health insurers have provided coverage for Scenesse, or afamelanotide 16mg implant, for erythropoietic protoporphyria.

Clinuvel said that like Italy, Switzerland had allowed supply of the drug under specific laws prior to formal European approval.

The company said that Scenesse to be used for the rare genetic disease erythropoietic protoporphyria which caused extreme skin intolerance to light, could be supplied immediately to physicians who treated about 50 patients in Switzerland and the costs would be covered in full by the insurance companies.

Clinuvel said that Scenesse had been available on prescription in Italy since 2010.

The company said that earlier this year it filed a marketing authorization application with the European Medicines Agency for erythropoietic protoporphyria (BD: Feb 7, 2012) and approval would allow marketing in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

The company said it would begin a US phase III trial "shortly" and last month said it had in-principle agreement with the US Food and Drug Administration on the erythropoietic protoporphyria (EPP) trial protocols (BD: Mar 15, 2012).

Clinuvel chief scientific officer Dr Hank Agersborg said the Swiss insurance coverage was "excellent news for the Swiss EPP patients, who have proven to be very motivated and compliant during the past six years of continuous treatment in trials and under compassionate use schemes".

"The reimbursement will enable the collection of further long term patient data adding to our scientific dossier," Dr Agersborg said.

Clinuvel chief executive officer Dr Philippe Wolgen said that following the 2010 Italian reimbursement, "this welcome decision by Swiss insurers confirms the need to treat these patients who currently do not receive any pharmaceutical or medical assistance".

Clinuvel was up 11 cents or 6.6 percent to $1.78.

PSIVIDA

Psivida says Austria is the first European country to approve the marketing of Iluvien for vision impairment associated with chronic diabetic macular oedema.

Psivida said the Austrian Agency for Health and Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit) granted marketing authorization to Iluvien for the treatment of diabetic macular oedema considered insufficiently responsive to available therapies.

The company said the marketing authorization followed the completion of the decentralized regulatory procedure, in which the UK Medicines and Healthcare products Regulatory Agency was the reference member state and gave a positive outcome for Iluvien along with the six concerned members states, which included Austria, France, Germany, Italy, Spain and Portugal (BD: Feb 29,2012).

Psivida said that additional concerned members state marketing authorizations were expected in the coming months and licencee Alimera reported it expected Iluvien to be available in the EU by the end of 2012.

Psivida chief executive officer Dr Paul Ashton said the company was “very pleased Iluvien has received this marketing authorization and will soon be available to patients in Austria”. “We look forward to Iluvien receiving the additional expected EU approvals,” Dr Ashton said.

Psivida said the International Diabetes Federation estimated that about 750,000 people were living with diabetes in Austria and Alimera estimated more than 40,000 people suffer from diabetic macular oedema.

The company said that Iluvien was an injectable, sustained-release intravitreal insert that released sub-microgram levels of fluocinolone acetonide for up to 36 months for the treatment of chronic diabetic macular oedema.

Psivida said it was developing an insert of the same design for the treatment of uveitis affecting the posterior of the eye.

Psivida climbed 25 cents or 11.6 percent to $2.40.

BIOTA

Biota said it expects to receive a $1,500,000 Glaxosmithkline royalty payment for sales of Relenza in the three months to March 31, 2012.

Biota said the payment represented sales of Relenza of $17 million for the three months and compare to a royalty of $500,000 million for $7.0 million in Relenza sales for the three months to December 31, 2011 and $1.0 million from Glaxosmithkline for $14.1 million in Relenza sales in the three months to March 31, 2011

Biota was up half a cent or 0.6 percent to 81.5 cents.

CELLMID

Cellmid says it has raised $1.5 million through the placement of 90,909,088 shares at 1.65 cents a share.

Cellmid said that 17,475,473 shares would be issued under the remaining 15 percent capacity rule on May 3, 2012 and pending shareholder approval 73,433,615 shares would be issued following an extraordinary general meeting expected to be held on or before June 8, 2012.

Cellmid said the funds would assist the pharmacy launch of its Évolis hair growth lotions, as well as continue diagnostic and therapeutic antibody product development programs.

Cellmid fell 0.2 cents or 9.5 percent to 1.9 cents with 19.4 million shares traded.

ACRUX

Acrux says revenue from its Axiron testosterone replacement therapy for the year to June 30, 2012 was likely to be 12.5 percent to 14.3 percent lower that previously forecast.
Acrux said that it expected revenue to be between $US6 million and $US7 million compared to previous advice of $US7 million and $US8 million, or 14.3 percent and 12.5 percent lower, respectively.
Acrux said it reaffirmed its forecast of $40 million in Axiron revenue for the 2012-'13 financial year.
The company said that the US testosterone therapy market was increasing at more than 25 percent a year, with year-on-year growth in total prescriptions for transdermal testosterone therapies of 28 percent for the three months to March 31, 2012.
Acrux said that at April 13, 2012, Axiron's share of the total transdermal prescription market was 12 percent and Axiron's share of new-to-brand prescriptions was 22 percent and sales in countries outside the US were expected to begin from July 1, 2012.
Acrux said that Lilly had marketing authorization for Axiron in Canada and regulatory decisions on marketing applications in Australia and select European countries were expected during 2012, with a marketing application also filed in Brazil.
Acrux said it earned royalties and milestone payments from Eli Lilly on worldwide net sales of Axiron, which in the first year had been impacted by rebates to patients under the co-payment card assistance offered by Lilly since the launch of Axiron in 2011.
The company said the rebates were expected to reduce during 2012 as Lilly expanded the coverage of Axiron on payer drug formularies.
Acrux said that Eli Lilly's financial results for the three months to March 31, 2012 reported net sales of Axiron of $US16.2 million, with a slower reduction in the level of rebates.
The company said that net sales of Axiron in the nine months to March 31, 2012 were $US37 million, leading Acrux to revise its forecast revenue from Axiron in the year to June 30, 2012 between $US6 million and $US7 million compared to the previous forecast of $US7 million to $US8 million.
Acrux was up one cent or 0.25 percent to $4.05 with 1.9 million shares traded.

QRX PHARMA

QRX says that the Watson Pharmaceuticals acquisition of its US commercialization partner for Moxduo immediate release, Actavis, would be positive for sales.
QRX said that preparations for the product launch of Moxduo IR by October, 2012 were on track and there were no changes to the strategic partnership agreement with Actavis.
QRX chief executive officer Dr John Holaday said that Actavis had "already invested considerable resources and increased their branded opioid sales force from 60 to 120".
"We believe the acquisition is a very positive move that strengthens opportunities for Moxduo both in the US and abroad and we look forward to continuing progress with the Actavis-Watson team," Dr Holaday said.
QRX cited public records saying that Watson was "among the top five pharmaceutical companies in the United States and among the top four generic companies in the world, based on total prescriptions".
The company said that in November 2011, Watson launched its generic version of Kadian, a long-lasting morphine formulation for the treatment of chronic pain and Kadian was previously solely marketed as a branded product by Actavis, bringing them more than $US275 million in sales over the past year.
QRX said that both companies were marketing generic versions of Kadian in the US.
QRX was unchanged at $1.79.

NUSEP

Nusep says it has an agreement to establish a 50-50 joint venture fractionation facility in Singapore with the India based ABS Novacell Biopharmaceuticals.
Nusep said the initial therapeutic plasma facility in Singapore would use its patented Prime technology and manufacture both currently unprocessable plasma and normal therapeutic plasma products.
The company said that initially it would fractionate normal plasma for the Singapore clinical trials which it had to undertake and the next step would be to manufacture currently unprocessable plasma (CUP) sourced from India for sale into India via ABS.
Nusep managing director Dr Hari Nair said the joint venture would validate Nusep's Prime technology for the production of plasma-derived therapeutic products.
Nusep executive chairman John Manusu said the joint venture opened the $US1 billion Asian therapeutic plasma market.
Nusep said that ABS would provide $US20 million in cash within three months of executing agreement and Nusep would contribute $US5 million to the joint venture, which it expected to raise in 2013, and transfer its intellectual property relating to plasma fractionation using the Prime technology.
The company said that other than increased sales, the venture would not have an impact on its revenue, although the investment might result in a one-off accounting impact.
Nusep said the partners agreed the enterprise valuation of Prime to be $US50 million and the agreement was expected to be finalized by the end of May 2012.
The company said that it had received a further $32,000 from Goh Thee Woon and was owed a further $258,000 (BD: Apr 2, 2012) but that no money had been received from Samuel Chai who owed $1.2 million.
Nusep was unchanged at 3.5 cents.

PHYLOGICA

Phylogica says IP Australia has granted a new patent entitled 'Method of constructing and screening libraries of peptide structures'.
Phylogica said the patent covered methods of producing designed, synthetic libraries of peptides, which were predicted to be rich in structure and more likely to be drug-like than conventional random peptides.
Phylogica said there were numerous applications of the patented technology, including the rational design of Phylomer libraries in parallel formats on solid surfaces, such as peptide arrays or beads.
The company said that array formats enabled tens of thousands of peptides to be screened against multiple targets on a single miniature chip, significantly reducing the time and cost of identifying relevant drug candidates.
Phylogica said the technology was "highly amenable to scaling using multiple chips to screen hundreds of thousands to millions of peptides at a time" and enhanced various value-added uses of its platform, including direct phenotypic screening of Phylomer libraries for the discovery of novel antivirals, antibiotics or anticancer agents.
The company said that array formats facilitated the construction of a range of high-density Phylomer libraries, which could be used for new applications of the platform, such as the identification of disease biomarkers for the development of novel diagnostic products.
Phylogica chief executive officer Dr Paul Watt said the patent added "another powerful component to Phylogica's Phylomer platform and opens up new opportunities in the emerging field of synthetic biology".
Phylogica fell 0.1 cents or two percent to 4.9 cents.

NOVOGEN

Novogen says the US Patent and Trademark Office has issued a patent to 57 percent subsidiary Marshall Edwards covering ME-143 for use in treating cancer.

The patent entitled 'Chroman derivatives, medicaments and use in therapy' was described on the US PTO website as covering "novel chroman derivatives and intermediate compounds, compositions containing same, methods for their preparation and uses thereof as therapeutic agents particularly as anti-cancer and chemotherapeutic selective agents are described".

Novogen said the patent was expected to provide protection until September 2025 and Marshall Edwards had received notices of allowance from the Japanese Patent Office for two patents that cover the ME-143 and ME-344 compositions of matter, respectively, and their use in treating cancer.

Marshall Edwards chief executive officer Dr Daniel Gold said the "key US patent for ME-143 follows on the heels of a related patent for ME-344 as well as a composition patent for both compounds, solidifying the intellectual property position surrounding our two lead oncology drug candidates".

"As we prepare for our upcoming phase II clinical trials, we believe our strong patent estate will help to facilitate our partnering efforts both in the US and in high growth markets abroad," Dr Gold said.

Novogen fell 0.8 cents or 8.1 percent to 9.1 cents.