Biotech Daily

Wednesday February 29, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PSIVIDA UP 86%, OPTISCAN DOWN 21%**

*** ANTISENSE-CHINA JV FOR ATL1102 FOR MS, CANCER, ASTHMA**

*** PSIVIDA UP 80% ON PROBABLE EUROPEAN ILUVIEN APPROVAL**

*** 2nd US PROCESS PATENT FOR ALCHEMIA'S FONDAPARINUX**

*** SIRTEX H1 REVENUE UP 8% TO $37m, PROFIT UP 70% TO $6m**

*** MAYNE H1 REVENUE FLAT AT $27m, PROFIT UP 242% TO $4m**

*** CYCLOPHARM REVENUE UP 8% TO $10m, PROFIT TO $1.7m**

*** SCIGEN REVENUE UP 29% TO $US16m, LOSS UP 72% TO $17m**

*** RESONANCE H1 REVENUE UP 11% TO $898k, LOSS DOWN 37% TO $241k**

*** COMPUMEDICS H1 REVENUE DOWN TO $15m, RETURN TO $403k PROFIT**

*** BIODIEM H1 REVENUE UP 118% TO $550k, LOSS DOWN 49% TO $689k**

*** GI DYNAMICS CLAIMS 1st ENDOBARRIER REVENUE**

MARKET REPORT

The Australian stock market climbed 0.84 percent on Wednesday February 29, 2012 with the S&P ASX 200 up 35.8 points to 4298.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and five were untraded.

Psivida was best, up $1.07 or 85.6 percent to $2.32, with 31,456 shares traded, followed by Antisense up 15 percent to 2.3 cents with 46.9 million shares traded. Bioniche climbed 10 percent; Allied Health was up 6.45 percent; Living Cell was up 4.4 percent; Reva was up 3.8 percent; Acrux, Anteo, Avita, Circadian, Phylogica and QRX rose two percent or more; with Cochlear, Sirtex and Universal Biosensors up more than one percent.

Optiscan led the falls on news of an 80 percent fall in half year revenue, down 3.5 cents or 20.6 percent to 13.5 cents, with 500,665 shares traded, followed by Cathrx down 16.7 percent to four cents with 42,142 shares traded. Benitec and Clinuvel lost more than five percent; Genetic Technologies and Neuren fell four percent or more; Patrys shed 2.7 percent; with Alchemia, CSL, Nanosonics and Viralytics down more than one percent.

ANTISENSE THERAPEUTICS

Antisense will form a joint venture with Tianjin International Joint Academy of Biotechnology and Medicine to develop and commercialize ATL1102 for multiple sclerosis, stem cell mobilization and asthma.

Antisense previously licenced ATL1102 to Israel's Teva following statistically significant phase II trial results for multiple sclerosis, but Teva later returned the drug (BD: Jun 30, 2008; Mar 24, 2010).

Antisense said the Tianjin International Joint Academy of Biotechnology and Medicine Therapeutics was established as part of an initiative of the Chinese Government and State Food and Drug Administration to accelerate economic growth and develop China's biotech industry and opened in June, 2009, receiving an investment of RMB1.1 billion ($A162 million) to install specialized devices and apparatus in a new technology facility.

Antisense said that the Academy had completed deals with Genzyme Corp and Johnson & Johnson.

Antisense managing director Mark Diamond told Biotech Daily that the value of the joint venture and the two parties' percentage interest had not been disclosed.

The company said the parties would establish a strategic alliance and joint venture with Antisense providing access and appropriate licences to the ATL1102 patents and patent applications and related know-how for ATL1102 research and development and commercialization purposes, including data previously generated up to and including the phase II stage of development.

The company said the Academy and its investment partners would fund all the agreed development activities.

Antisense said that the initial development activities proposed to be undertaken in China to international development standards included a phase I/II stem cell mobilization study in cancer patients, the conduct of a chronic toxicology study in one species to be followed by a phase IIb study in multiple sclerosis patients and a potential phase II study in asthma patients.

Antisense said that based on study outcomes, the Academy would be responsible for commercialization of ATL1102 for China and Antisense for its commercialization for the rest of the world.

The company said that the parties would share income derived from commercialization of ATL1102 on agreed splits depending on the level of investment made by the Academy and in what countries the commercialization benefits were generated.

Antisense said that the definitive agreement would be executed by July 1, 2012, but the parties were hopeful of earlier agreement and the ATL1102 development activities would begin immediately thereafter.

Tianjin International Joint Academy senior vice-president Prof Yao-Zhou Zhang said the Academy was "very keen to develop a significant competency in the antisense technology field".

"I personally have spent many years in research on gene silencing and RNA targeting approaches, and accordingly am excited by the prospects of working with the second generation antisense technology via our proposed alliance with [Antisense]," Prof Zhang said. "We view ATL1102 as the first of what we hope may be a broader group of initiatives or projects to come from the proposed alliance."

Mr Diamond said that his company believed the academy would "make an excellent development and commercialization partner for ATL1102 and we are excited about the prospect of moving back into development with ATL1102, a compound that we have long believed to have significant commercial value".

Antisense was up 0.3 cents or 15 percent to 2.3 cents with 46.9 million shares traded.

PSIVIDA

Psivida climbed as much as $1 or 80 percent to $2.25 on a “positive outcome of the decentralized procedure for the approval of Iluvien in Europe”.

Last year, Psivida fell 48.5 percent on the Nasdaq following the US Food and Drug Administration refusal to approve Iluvien for diabetic macula oedema (BD: Nov14, 2011).

Today, Psivida said the UK Medicines and Healthcare Products Regulatory Agency issued to licencee, Alimera Sciences a final assessment report along with the agreement of the concerned member states that Iluvien was approvable.

The company said the regulatory process would enter the national phase in which the reference member state and each concerned member state including Austria, France, Germany, Italy, Portugal and Spain granted a national licence.

Psivida said that Iluvien would be indicated for the treatment of vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies.

The company said that the International Diabetes Federation estimated that, in these seven countries alone, 22.1 million people were currently living with diabetes and the US Centers for Disease Control and Prevention estimated that there were 25.8 million Americans with diabetes. Psivida said that Alimera estimated that within the seven concerned member states 1.2 million people had diabetic macular oedema.

Psivida chief executive officer Dr Paul Ashton said he was “very pleased about this favorable outcome of the EU regulatory process for Iluvien”.

The company said Iluvien was an injectable, sustained-release intravitreal insert that released fluocinolone acetonide for up to 36 months.

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

On the Nasdaq on February 24, Psivida was up 48.7 percent to $US1.74 with 450,286 shares traded. On Monday, Psivida climbed a further 22.9 percent on Nasdaq and last night the company was up 12.6 percent to $US2.42 with 913,348 shares traded, a total movement of 106.8 percent since February 24.

Psivida was up $1.07 or 85.6 percent to $2.32, with 31,456 shares traded.

ALCHEMIA

Alchemia says it has been granted a US patent further protecting its fondaparinux sodium manufacturing process.

Alchemia said fondaparinux was approved for sale in the US for the prevention and treatment of venous blood clots in July 2011.

The company said the patent, entitled ‘Synthetic Heparin Monosaccharides’ broadly protected critical building blocks used in the manufacturing process.

Alchemia said that monosaccharide building blocks enable the efficient synthesis of fondaparinux which is a pentasaccharide or five sugar molecule.

Alchemia’s head of intellectual property Michael West said the granted patent was the second of four US patent applications in for the process that had proceeded to grant.

The company said that the branded version of fondaparinux Arixtra had been off-patent since 2002 in the US meaning that the process originally developed for its manufacture had been open for anyone to use for nearly a decade.

Alchemia chief executive officer Dr Pete smith said that the lack of any other abbreviated new drug application (ANDA) approved generic competitors was “testament to the complexity of the original synthetic process used for fondaparinux”.

Alchemia fell half a cent or 1.1 percent to 44 cents.

SIRTEX

Sirtex says revenue for the six months to December 31, 2011, was up 8.1 percent to $36,800,000 with the net profit after tax up 69.7 percent to $6,097,000.
Sirtex said that dose sales of its SIR-Spheres microspheres for inoperable liver cancer were up 16.1 percent to 2,698 units for the six months to December 31, 2011, with US sales up 25 percent to 1,702 doses, Asia-Pacific sales were up 27 percent to 258 doses, while European sales fell 2.9 percent to 738 doses.
Sirtex said that a fully-franked dividend of seven cents a share was paid in October 2011 for the year to June 30, 2011 and no interim dividend would be paid.
The company said that net tangible asset backing per share was up 4.1 percent to 93.1 cents and diluted earnings per share was up 68.75 percent to 10.8 cents.
Sirtex said that cash and cash equivalents at December 31, 2011 was $39,701,000 compared to $41,156,000 at December 31, 2010.
Sirtex was up six cents or 1.2 percent to $5.04.

MAYNE PHARMA

Mayne Pharma says revenue for the six months to December 31, 2011, was up 0.07 percent to $27,128,000 with the net profit after tax up 242 percent to $5,429,000.
Mayne chief executive officer Scott Richards said the improved result “was driven by a return to more normalized ordering patterns by the company’s US marketing and distribution partner Warner Chilcott and the operational restructure which was undertaken in 2011 to drive efficiencies and decrease operating expenses”.
“We are pleased that the 150mg Doryx product has been able to maintain marketing exclusivity in the US to date despite the attempts of several generics companies to enter the market,” Mr Richards said. “Doryx revenue for the period was well up on the previous six months to June 30, 2011 but down on [the previous corresponding period] driven by the stronger Australian dollar,” Mr Richards said.
“Sales of other products were up 8.3 percent … driven by the proprietary pharmaceutical products Astrix, Kadian and Eryc and contract manufacturing,” Mr Richards said.
“The business is now debt free … and cash has grown over the half,” Mr Richards said.
The company said that net tangible asset per share was up 63.6 percent to 14.4 cents and diluted earnings per share was up 234.7 percent to 2.51 cents.
Mayne said that cash and cash equivalents at December 31, 2011 was $6,076,000 compared to $13,400,000 at December 31, 2010.
Mayne was unchanged at 28 cents.

CYCLOPHARM

Cyclopharm says revenue for the 12 months to December 31, 2011 was up 8.4 percent to $10,331,808, but the company had a net loss after tax of $956,220.
Cyclopharm posted a net profit after tax for the year to December 31, 2010 of $450,106 and said today that a “slower than expected ramp up at its molecular imaging division at Macquarie University had negatively impacted the results, but the company said it expected a growth in patient volumes thought the department.
Cyclopharm said cash and cash equivalents at December 31, 2011 was $2,043,814 compared to the previous year’s $1,541,644.
The company said that diluted loss per share was 0.55 cents compared to the previous year’s diluted earning per share of 0.26 cents.
Cyclopharm was unchanged at 3.6 cents.

SCIGEN

Scigen says its revenue for the 12 months to December 31, 2011 was up 29.1 percent to $US15,763,000, with the net loss after tax up 72.4 percent to $US16,810,000.
Scigen said the revenues excluded the sale of its Israel operation.
Scigen said that basic loss per share was 3.044 US cents compared to the previous year's 1.766 US cents.
Scigen was untraded at 4.5 cents.

RESONANCE HEALTH

Resonance says its revenue for the six months to December 31, 2011 was up 11 percent to $898,000, with the net loss after tax down 37 percent to $241,000.
Resonance said that net tangible assets per share was up 6,733 percent to 41 cents, with basic loss per share 0.07 cents for the six months to December 31, 2011, compared to 0.11 cents per in the six months to December 31, 2010.
The company said that cash and cash equivalents were $1,299,434 at December 31, 2011, compared to $1,674,334 at December 31, 2010.
Resonance was untraded at 1.4 cents

COMPUMEDICS

Compumedics says its revenue for the six months to December 31, 2011 was down 1.5 percent to $14,785,000, posting a net profit after tax of $152,000, compare to the previous corresponding period's loss of $1,140,000.
Compumedics said that diluted earnings per share was 0.001 cents for the six months to December 31, 2011, compared to a diluted loss per share of 0.01 cents per in the six months to December 31, 2010.
Compumedics was untraded at 8.1 cents

BIODIEM

Biodiem says its revenue for the six months to December 31, 2011 was up 118 percent to $550,000, with the net loss after tax down 49 percent to $689,000.
Biodiem said that net tangible assets per share fell 28.2 percent to 1.76 cents
Biodiem said that there was a 20 percent boost to revenue from a licencing milestone payment from the Serum Institute of India.
Biodiem was untraded at nine cents

GI DYNAMICS

GI Dynamics says its revenue for the 12 months to December 31, 2011 was $US234,000 and included the first revenue from sales of its Endobarrier obesity and diabetes device.
GI Dynamics said that net loss after tax increased 80 percent to $US26,358,000 ($A24,392,000).
GI Dynamics was up 1.5 cents or 1.4 percent to $1.055.