Biotech Daily

Friday February 5, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH TUMBLE: BENITEC UP 36%; OPTISCAN DOWN 25%**

*** BIOGUIDE BRIEF: TOUGH ROAD AHEAD FOR AVEXA'S APRICITABINE**

*** RESMED RECORD QUARTER, H1 REVENUE, PROFIT**

*** BIOTA'S RECORD $32.6m RELENZA ROYALTY**

*** TAIWAN APPROVES CELLESTIS'S QUANTIFERON-TB GOLD IN-TUBE**

*** BENITEC BENEFITS 131% FROM PFIZER OPTION ON TACERE**

*** CIRCADIAN COMPANIES REDUCE 5% IN ANTISENSE**

*** HEALTHLINX WINS BIOSPECTRUM ASIA PRODUCT OF THE YEAR GONG**

*** MEDICAL DEVELOPMENTS LOSES CEO CHRIS ROSSIDIS**

*** FULLERTON TAKES 10% OF INCITIVE**

*** SOLAGRAN TELLS ASX: EXPECT $17m SALES BY YEAR END**

MARKET REPORT

The Australian stock market fell 2.3 percent on Friday February 5, 2010 with the S&P ASX 200 down 107.5 points to 4514.1 points. Just two of the Biotech Daily Top 40 stocks were up, 28 fell, six traded unchanged and four were untraded.

Benitec was best climbing as much as 130.8 percent to nine cents before closing up 1.4 cents or 35.9 percent at 5.3 cents with 22.7 million shares traded.

Resmed was up 5.8 percent; Novogen climbed 4.9 percent; with CSL up 1.4 percent.

Optiscan led the falls, down two cents or 25 percent to six cents with 825,714 shares traded, followed by Cathrx down 18.9 percent to 30 cents and Sunshine Heart down 13.5 percent to 3.2 cents.

Antisense, Patrys and Tissue Therapies fell more than nine percent; Bionomics, Genetic Technologies, Living Cell and Universal Biosensors were down more than seven percent; Avexa and Prana lost more than six percent; Alchemia, Impedimed and Mesoblast fell five percent or more; Biota and Nanosonics fell more than four percent; with Circadian, Psivida and Sirtex down more than three percent.

MARC SINATRA'S BIOGUIDE BRIEF: AVEXA

Avexa announced the results of its truncated phase III trial of apricitabine in HIV patients with nucleoside reverse transcriptase inhibitor resistance yesterday (BD: Feb 4, 2010).

While it seems clear that apricitabine (ATC) works, the main issue is that it wasn't shown to work significantly better than lamivudine (3TC) in terms of the primary outcome measure of HIV viral load suppression at 24 weeks.

The issue for Avexa is finding a partner willing to commit the tens of millions of dollars it is likely to take to bring apricitabine to market when it has, at best, modest benefits over 3TC.

Compounding the difficulty of the task facing Avexa is that 3TC will go off patent in the US and Europe very soon and generic versions of the drug are ready to hit the market. Consequently, if apricitabine were to make it to market it will be competing not only with an exceedingly well established drug, but one that is almost certain to become as cheap as chips.

What worries me most, however, is that I haven't, as yet, found any truly significant evidence from Avexa's phase IIb trial of ATC versus 3TC to suggest overwhelmingly that ATC would out-perform 3TC in the phase III trial.

This makes Avexa's phase III trial more of long kick to a large pack, rather than a stab pass to a full-forward metres in the clear.

Avexa has to put on a brave face despite its phase III trial results if it is to have any chance of finding a partner for ATC, but they will need to be able to put a flawless business case together to justify throwing any more money at the compound.

Avexa fell one cent or 6.9 percent to 13.5 cents with 4.7 million shares traded.

Marc Sinatra
Analyst

RESMED

Resmed has posted record revenue of $US522.1 million and profit up 42 percent to $US88,085,000 for the six months to December 31, 2009.
Remed said revenue was up 18 percent for the six months compared to the previous corresponding period.
Diluted earnings per share was $US1.15, an 44 percent increase over the six months ended December 31, 2008.
The company said revenue for the three months to December 31, 2009 quarter was up 23 percent to $US275.1 million compared to the quarter to December 31, 2008, with net profit after tax up 36 percent $US46.0 million.
Resmed said research and development expenditure for the quarter was $19.1 million, about seven percent of revenue.
The company said research and development expenses increased by 28 percent, compared to the quarter ended December 31, 2008.
Resmed rose 35 cents or 5.8 percent to $6.34 with 9.4 million shares traded.

BIOTA

Biota expects to receive a royalty payment of $32.6 million from Glaxosmithkline for $462 million sales of Relenza in the three months to December 31, 2009.
The royalty payment follows the previous quarter to September 30, 2009 indicative royalty of $24.1 million and $8.9 million for the three months to June 30, 2009.
Biota said the figures were calculated on an exchange rate of $A1.8182 to one British pound, but the final payment would be calculated on exchange rates at April 30, 2010.
Biota said it would report indicative Relenza royalty income of $56.7 million for the six months to December 31, 2009 in its interim report on February 17, 2010.
Biota fell nine cents or 4.25 percent to $2.03 with 2.8 million shares traded.

CELLESTIS

Cellestis says Taiwan's Department of Health has approved the sale of the Quantiferon-TB Gold In-Tube tuberculosis test.
Cellestis said the approval came after examination of the regulatory submission, including analysis of Quantiferon-TB Gold In-Tube's clinical performance and quality compliance.
Cellestis said it would market the test in Taiwan through its commercial partner Holy Stone Healthcare which was "instrumental in developing the market … and in obtaining regulatory approval in Taiwan".
The company said the prevalence of tuberculosis in Taiwan was more than 60 cases per 100,000 population and BCG vaccination was mandatory at birth.
Unlike the tuberculin test, Quantiferon-TB Gold In-Tube does not interact with the BCG vaccination, so the test is widely applicable to all populations in Taiwan, Cellestis said.
Cellestis chief executive officer Dr Tony Radford said the company was "very grateful for the assistance provided by Holy Stone Healthcare in navigating the intricacies of the regulatory process".
Cellestis fell nine cents or 2.5 percent to $3.49.

ANTISENSE, CIRCADIAN

Two Circadian related companies have reduced their substantial holding in Antisense from 157,153,297 shares (29.46%) to 142,165,909 shares (24.12%).
The companies selling Antisense shares were Circadian's wholly-owned subsidiary Polychip Pharmaceuticals and Polychip's 42.38 percent subsidiary Syngene.
Circadian chief executive officer Robert Klupacs and company secretary Natalie Korchev told Biotech Daily that the Packer family-owned Consolidated Press Holdings held 19.9 percent of Syngene and the Howard Florey Institute also owned about 20 percent, with the remainder owned by about 40 other holders.
Mr Klupacs said Syngene was effectively an investment company with one investment, the Antisense shares.
Polychip was diluted from 102,739,830 shares (19.26%) to 106,906,497 shares (18.14%) while Syngene reduced from 54,413,467 shares (10.2%) to 35,259,412 shares (5.98%).
Syngene sold 12,944,939 shares for $1,047,245.57 or 8.1 cents a share on February 3, 2010, when Antisense climbed 300 percent on the news of a journal article and a patent (BD: Feb 3, 2010) and a further 2,600,000 shares at 7.05 cents a share on February 4, 2010.
Antisense fell 0.6 cents or 9.5 percent to 5.7 cents with 6.2 million shares traded.
Circadian fell 2.5 cents or 3.8 percent to 63.5 cents.

BENITEC

Benitec says it will benefit from milestone and royalty payments relating to Pfizer exercising an option with Tacere Therapeutics to develop hepatitis C virus compounds.
The company's share price jumped 131 percent to nine cents on the news.
Benitec chief executive officer Sue MacLeman told Biotech Daily that Tacere was created by former Benitec staff who then licenced two patents for hepatitis C from the company as well as a non-exclusive licence to the core RNA-interference Graham '099 patent.
Benitec owns 4.2 percent of Tacere and is entitled to milestone payments and royalties.
Ms MacLeman said that Pfizer had declared the development of a DNA-directed RNA interference (ddRNAi) treatment for hepatitis C "a Pfizer project of interest" further validating her company's approach to drug development.
Ms MacLeman said the Pfizer option deal with Tacere was worth $145 million and Benitec's 2006 deal with Tacere was "multi-million dollar".
In a media release to the ASX, Benitec said Pfizer had exercised the option in a January 2008 agreement to further develop and commercialize Tacere's hepatitis C virus compounds.
Benitec said the lead clinical candidate was "a new class of agent containing three separate RNAi elements, simultaneously targeting three different sites of the hepatitis C virus and encapsulated in an adeno-associated virus protein coat.
The company said that in preclinical animal studies Tacere demonstrated that a single intravenous injection of the agent resulted in penetration of hepatocytes, the site of hepatitis C virus replication at sufficiently high levels to potentially eradicate the virus.
Benitec said Tacere had been collaborating with Pfizer for two years to demonstrate that the agent had "an excellent safety profile in both mice and non-human primates".
"The triggering of this option by Pfizer is a validation of the Benitec ddRNAi-expressed approach to treating chronic diseases from the world's biggest pharmaceutical company," Ms MacLeman said.
Benitec said Tacere and Pfizer would work together for at least 12 months to complete regulatory toxicology studies, with Pfizer paying for all aspects of the collaboration.
Benitec said it had its own active development program with products in development in the infectious diseases and cancer space.
Benitec jumped as much as 130.8 percent to nine cents before closing up 1.4 cents or 35.9 percent at 5.3 cents with 22.7 million shares traded.

HEALTHLINX

Healthlinx says its ovarian cancer diagnostic Ovplex was the joint winner of the Biospectrum Asia product of the year award along with the Shancol cholera vaccine.
In a media release Healthlinx said the award was judged by an independent jury of international life sciences experts compiled by the Singapore-based Biospectrum Asia magazine, including Burrill & Co chairman Dr Steven Burrill and Bionomics chief executive officer Dr Deborah Rathjen.
The company said Ovplex used "a simple blood test and provides a superior performing alternative to the use of CA125 alone to aid in the diagnosis of ovarian cancer with a proven diagnostic efficiency of 92 percent".
Healthlinx chief executive officer Nick Gatsios told Biotech Daily that he was not aware the Ovplex test had been nominated for the award.
He said he was pleased with the independent validation of his company's test by the panel of judges.
Healthlinx was up 0.9 cents or 12.9 percent to 7.9 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments chairman David Williams said chief executive officer Chris Rossidis had resigned.
Medical Developments said Mr Williams would act as executive chairman while the company undertakes a search for a new chief executive officer.
Medical Developments was up one cent or 6.7 percent to 16 cents.

INCITIVE

Fullerton Private Capital has become a substantial shareholder in Incitive with a holding of 50,000,000 shares or 9.8 percent.
The notice said the shares were bought in a placement on December 14, 2009 for $250,000 or 0.5 cents a share.
The Perth-based Fullerton filed its substantial shareholder notice from Greendale Corporate with the document signed by director Evan Cross.
Mr Cross has been involved in a number of biotechnology companies including Resonance Health and Advanced Ocular, either as a director or company secretary.
Incitive was untraded at 0.5 cents.

SOLAGRAN

Replying to an ASX Appendix 4C quarterly cash statement query Solagran said it expected revenue of $US15 million ($A17.3 million) by December 2010.
Solagran said last week that its net operating cash burn for the three months to December 31, 2009 was $2,296,000 with cash at the end of the quarter of $2,456,000 (BD: Jan 29, 2010).
Solagran said it would begin sales of Ropren, a Russian-registered pharmaceutical in February 2010 with monthly sales expected "to rapidly increase".
The company said it was forecasting $US15 million in retail sales of Ropren by December 2010.
Solagran told the ASX it was forecasting negative operating cash flows for the March 2010 quarter in line with the December 2009 quarter, with initial material cash inflows from Ropren sales in Russia to occur in the June 2010 quarter.
Solagran told the ASX that it had "shown the ability to raise funds as necessary to fund its operations".
Separately, Solagran said the Russian Health Control Authority had approved the issue of a pharmaceutical wholesale distribution licence to its appointed distribution company for the Russian market, Biophar LLC.
The company said the rights to produce the Bioeffectives R substance and the finished pharmaceutical Ropren had been transferred from Galenopharm to Solagran Son.
Solagran said it would announce initial Russian sales results on March 10, 2010.
Solagran fell 1.5 cents or 5.7 percent to 25 cents.