

Biotech Daily

Wednesday February 16, 2011

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: BENITEC UP 9%; BIOTA DOWN 16%
- * BIOTA H1 REVENUE DOWN 87% TO \$8m, RETURN TO RED
- * CSL \$500m H1 PROFIT DOWN 19%, ADJUSTED UP 3%
- * RESMED TAKES LOW INTEREST \$US400m CREDIT FACILITY
- * NANOSONICS H1 REVENUE UP 147.5% TO \$2m, LOSS UP 9% TO \$4.5m
- * ITL 500m H1 PROFIT UP 111% TO \$105k; REVENUE UP 2% TO \$21.9m
- * NZ, US CHARITIES GIVE \$280k FOR LIVING CELL'S DIABETES TRIAL
- * ADVANCED SURGICAL THANKS MICHAEL SPOONER FOR REVIEW
- * CSL APPOINTS CHRISTINE O'REILLY DIRECTOR
- * BIOPROSPECT EXPANDS REGEN; RAISES \$3m; APPOINTS JACOB KHOURI
- * KARMELSONIX CONSIDERS SECONDARY LISTING

MARKET REPORT

The Australian stock market slipped 0.02 percent on Wednesday February 16, 2011 with the S&P ASX 200 down 0.8 points to 4930.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and two were untraded.

Benitec was best, up 0.3 cents or 9.4 percent to 3.5 cents with 4.3 million shares traded, followed by Optiscan up 8.8 percent to 6.2 cents with 172,132 shares traded.

Heartware climbed 6.25 percent; Starpharma was up 5.4 percent; Tissue Therapies and Viralytics rose more than four percent; Advanced Surgical and Cellmid were up more than three percent; Phylogica rose 2.6 percent; with Immuron up 1.3 percent.

Biota led the falls, down 24.5 cents or 16 percent to \$1.285 with 5.3 million shares traded, followed by Genera down 13 percent to 40 cents with 30,753 shares traded.

Cathrx lost 9.5 percent; Prana was down 6.7 percent; Alchemia and Chemgenex fell more than four percent; Compumedics was down 3.6 percent; Impedimed, Nanosonics, Prima, Sunshine Heart, Universal Biosensors and Virax shed more than two percent; with Acrux, Cellestis, CSL, Patrys and Pharmaxis down more than one percent.

BIOTA

Biota says its revenue for the six months to December 31, 2010 fell 87 percent \$8,062,000, returning the company to a net loss after tax.

The net loss after tax was \$15,946,000 compared to a half year profit of \$33,485,000 for the six months to December 31, 2009 which included strong Relenza royalty payments from Glaxosmithkline and a full year profit of \$16,235,000 for the 12 months to June 30, 2010.

Biota said its diluted loss per share was 8.8 cents compared to a 19.0 cents diluted earnings per share for the previous corresponding period.

The company said it had \$77,518,000 in cash at December 31, 2010 which was described as "an adequate reserve to manage the variability inherent in the royalty streams".

Research and development costs increased 20.8 percent to \$12,948,000 or 160.6 percent of revenue.

Biota chief executive officer Peter Cook said the launch of Inavir in time for the 2010-'11 influenza season in Japan provided a second royalty generating product in one of the two major global markets.

"Inavir's introductory success, despite the relatively subdued market for influenza antivirals in the immediate post-pandemic environment, further supports our view of laninamivir's value outside Japan," Mr Cook said.

Inavir was launched in Japan during October 2010 by Daiichi Sankyo with sales of YEN2.8 billion (\$A34 million) by December 31, 2010.

Biota said it expected strong royalty income in future years, as Daiichi Sankyo increased production capacity and .the company's chairman Jim Fox and Mr Cook had committed considerable time to meet with US advisors to develop a number of alternative options to maximize the product's value for shareholders.

The company said the options considered were "quite far ranging and include amongst others, alternatives to Biota's traditional early licencing model".

Biota said that Inavir provided a substantially de-risked position for a rest-of-world launch, given its commercial introduction in the Japanese market, but would "require western clinical studies in addition to the Japanese trials and the feasibility of Biota taking the product further into this process to capture greater value is well in hand".

Biota said it "continued to work hard on the option of securing agency funding to complete the majority of the development programs necessary to achieve registration of laninamivir in key western markets".

The company said its phase IIb clinical study of the human rhinovirus antiviral BTA798 in subjects with chronic asthma began in July 2010 and had recruited about half of its intended 400 subjects although recruitment will slow until the peak human rhinovirus season in the US recurs in September.

Biota said a new lead candidate for the prevention and treatment of respiratory syncytial virus had been identified and preclinical studies begun.

The company said that aside from its strategic review, priority would be given to those programs with a near-term pathway to significant commercial returns, notably laninamivir, the human rhinovirus phase IIb study and the new lead candidate for respiratory syncytial virus.

Biota said the value of the influenza market was apparent in the 2009-'10 financial year but revenue was inconsistent.

"This has required some near term prioritization of costs and use of past earnings to maintain the advancement of essential programs," Biota said.

Biota fell 24.5 cents or 16 percent to \$1.285 with 5.3 million shares traded.

CSL

CSL's net profit after tax for the six months to December 31, 2010 fell 18.96 percent from \$617 million to \$500 million but the adjusted figure was up three percent.

CSL said excluding the impact of sales of its H1N1 pandemic influenza vaccine (\$125 million) and compensating for currency movements (\$181 million) the net profit after tax was up three percent from \$531 million in the six months to December 31, 2009 to \$547 million for the six months to December 31, 2010.

The revenue figures were similarly down in raw terms falling 8.7 percent from \$2,317 million to \$2,116 million, but described as increasing seven percent to \$2,300 million after adjustments for the H1N1 vaccine and currency variations.

In a teleconference, CSL chief executive officer Dr Brian McNamee said the unadjusted \$500 million profit was a "pleasing interim result" with the company benefiting from the strength of the Behring business and immunoglobulin sales especially sales of Hizentra for primary immunodeficiency disease and Privigen for a range of immunodeficiency indications, despite the international environment, primarily currency headwinds.

Dr McNamee said the company was increasing its research and development investment, but said it was "lumpy" varying with the initiation of clinical trials.

Research and development expenditure fell 2.16 percent from \$146,924,000 in the six months to December 31, 2009 to \$143,756,000 for the six months to December 31, 2010. As a percentage of total revenue, research and development expenditure increased from 6.3 percent for the half year to December 31, 2009 to 6.8 percent for the six months to December 31, 2010.

CSL said that diluted earnings per share fell 13.9 percent to 91.23 cents and the interim dividend of 35 cents a share was the same as the previous corresponding period. The company said it had \$719,366,000 in cash at December 31, 2010 and Dr McNamee said the share buy back program would continue.

Dr McNamee said that CSL was forecasting 10 percent growth for the full year. CSL fell 49 cents or 1.3 percent to \$37.02 with 2.4 million shares traded.

RESMED

Resmed has taken a credit agreement of up to \$US400 million (\$A400 million) for unspecified purposes.

Resmed said the agreement was with a range of lenders including Union Bank, HSBC Bank US, the Commonwealth Bank of Australia and Wells Fargo Bank for a \$US300 million three year revolving credit facility with an uncommitted option to increase by an additional \$US100 million.

The documents filed to the ASX do not specify any project but one paragraph said the company would "use the proceeds of the credit extensions for general corporate purposes not in contravention of any law or of any loan document (including, without limitation, to finance ongoing working capital, capital expenditures, permitted acquisitions and investments and permitted stock repurchases).

Most of the credit facility is 1.5 to 2.0 percent above the London Interbank Offered Rate (Libor) which in the US is effectively 1.5 to 2.0 percent, as compared to Australian interest rates on cash where Resmed is earning about 6.0 percent on most of its cash reserves. In its half yearly report, Resmed said it had cash and cash equivalents of \$616.2 million at December 31, 2010.

Biotech Daily believes the facility allows Resmed to borrow at low interest rates for any future project rather than reduce higher earning cash reserves.

Resmed was up three cents or 0.9 percent to \$3.27 with four million shares traded.

NANOSONICS

Nanosonics says its revenue increased 147.5 percent to \$2,017,000 for the six months to December 31, 2010, but the net loss after tax increased 8.9 percent to \$4,523,000. Nanosonics said that \$1,371,000 of the revenue came from sales of its Trophon EPR ultrasound transducer disinfection product, with the remainder from interest on cash investments.

Sales of the Trophon EPR were delayed in the six months to June 20, 2010 by a third-party component failure (BD: Feb 26, 2010), with sales re-starting in the six months to December 31, 2010 (BD: Jun 29, 2010).

The company said that net tangible assets per share fell 21.9 percent to 8.42 cents. No dividend will be paid.

Nanosonics fell two cents or 2.3 percent to 85 cents.

<u>ITL</u>

ITL says its net profit after tax for the six months to December 31, 2010 was up 111 percent to \$105,000 on revenue up two percent to \$21,877,000.

ITL said no dividend would be paid and the company had cash and cash equivalents of \$2.69 million at December 31, 2010.

ITL said the small profit was "a major turnaround on the \$900,000 loss reported for the same period last year" achieved by increased control of operating expenses and operational efficiency gains.

ITL was unchanged at 5.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell says two international charities, New Zealand'S Cure Kids and the US Children with Diabetes Foundation will provide \$280,000 in grants for its diabetes program. Living Cell said each charity would provide a \$US140,000 (\$A140,000) grant to directly sponsor each of the two recently added patients in the company's extended New Zealand phase II clinical trial of its Diabecell encapsulated porcine islets of Langerhans treatment for type 1 diabetes (BD: Jan16, 2011).

The company said the New Zealand II trial would conclude after the treatment of these two patients and their subsequent evaluation.

Living Cell's medical director Prof Bob Elliott said the grants would allow the company to complete the dose-finding part to evaluate the dose that provides optimal patient benefit. "Both of these leading charitable foundations are focused on diseases that afflict children," Prof Elliott said. "Having the support of these foundations who understand better than anyone the need for new and improved treatments for type 1 diabetes is very satisfying and a validation of the progress LCT has made with Diabecell."

Living Cell said that so far 12 of the approved New Zealand patients with unstable insulin dependent diabetes had received treatment, which had been shown to safely improve diabetes management and reduce or eliminate episodes of low blood glucose.

Living Cell said that Cure Kids was established more than 30 years ago to address the lack of research into life-threatening childhood illnesses in New Zealand and had invested more than \$25 million in medical research.

Living Cell said the Children with Diabetes Foundation's mission was to find a cure for type 1 diabetes through the funding of human clinical trials which will either prevent diabetes or cure the disease by normalizing blood glucose levels.

Living Cell was unchanged at 12 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says that following the completion of its strategic review, Michael Spooner has resigned as a director "to devote more time to his many other commitments". Mr Spooner is a director of Mesoblast as well as private and public companies.

Advanced Surgical said Mr Spooner assisted with the strategic review over the past four months, resulting in significant investment in new product lines and recruitment of sales personnel.

"The benefits of this investment are evident with core product sales growth of 28 percent for the seven months to January 2011," Advanced Surgical said.

Advanced Surgical chief executive officer Dr Greg Roger said the board "appreciates the efforts of Mr Spooner and wish him well for the future".

"The execution of the initiatives of the strategic review is well underway," Dr Roger said. "Our recent appointment of Ms Jenny Swain as the national sales manager and the growth in sales is delivering on our commitment to make ASDM a large and profitable medical device company," Dr Roger said. "We continue to see traction and new sales channels develop from our recent distributor relationships."

Advanced Surgical was up one cent or 3.6 percent to 29 cents.

CSL

CSL says it has appointed Christine O'Reilly a director, effective from February 16, 2011.

CSL said Ms O'Reilly has been the co-head of unlisted infrastructure investments at Colonial First State Global Asset Management since July 2007 and through the position is a director of the UK Anglian Water Group and UK Electricity North West.

CSL said Ms O'Reilly was a director of Care Australia.

Prior to Colonial First State Ms O'Reilly was the chief executive officer of the Gasnet Australia Group from 2001 until 2006.

CSL said that Ms O'Reilly has a Bachelor of Business degree and was qualified as a chartered accountant.

BIOPROSPECT

Bioprospect says it has raised \$3 million to expand its Regen range and has signed a distribution agreement with Doward International for Australia and New Zealand.

Bioprospect said the products were based on natural ingredients, including emu oil.

The company said it raised \$3 million through the placement of 300,000,000 shares at one cent a share with one attaching option for every one new share.

Bioprospect said it would allot 123,900,000 shares immediately with the balance subject to shareholder approval. The placement was arranged by Novus Capital.

Bioprospect said the funds were for its Regen products, the commercialization of natural skin care and cosmetic ranges as well as general working capital.

Bioprospect managing director Charles Pellegrino said the Regen business had "more than \$100,000 in sales over recent months" and the Doward agreement would ensure "long-lasting benefits to this Australian brand".

The company said that new products included pain management and topical healing treatments were under development as part of an expanded therapeutic range, led by the Regen pain relief spray.

The company appointed the son of major shareholder Gun Capital's Elias Khouri, Jacob Khouri as a non-executive director. Mr Khouri Snr resigned last year (BD: Sep 17, 2010). Bioprospect was up 0.1 cents or 6.7 percent to 1.6 cents with 15 million shares traded.

KARMELSONIX

Karmelsonix says it will seek a listing of its share capital on a secondary stock exchange. Karmelsonix said the process was subject to receipt of regulatory approvals and was expected to be completed within 120 days.

The company said discussions had led it to believe that a secondary listing, with a preference for a North American exchange, such as the Nasdaq over-the-counter stock exchange would provide a greater profile and liquidity as well as ease transaction facilitation and financial confidence given the significant growth program the business was executing across America.

Karmelsonix said it was unable to publicly release the details of ongoing discussions. Karmelsonix was up 0.1 cents or five percent to 2.1 cents with three million shares traded.