Biotech Daily

Wednesday February 27, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CELLMID UP 17%, PSIVIDA DOWN 5%**

*** INVION EXPECTS THREE PHASE II RESULTS IN 2013**

*** ALCHEMIA H1 REVENUE UP 3320% TO $9m, LOSS DOWN 2% TO $6m**

*** MAYNE H1 REVENUE UP 1% TO $27m, PROFIT TO $2.5m LOSS**

*** CRYOSITE H1 REVENUE UP 16% TO $4.6m, PROFIT UP 60%, DIVIDEND**

*** LIVING CELL H1 REVENUE UP 253% TO $3m, PROFIT DOWN 98% TO $172k**

*** CLINUVEL H1 REVENUE UP 222% TO $1m, LOSS DOWN 30% TO $4m**

*** LBT H1 REVENUE DOWN 6% TO $451k, LOSS UP 40% TO $916k**

*** CIRCADIAN TO SELL VEGF REAGENTS**

*** GI DYNAMICS LAUNCHES ENDOBARRIER IN ISRAEL**

*** CELLMID PLEADS SCHULTZ TO ASX 29% QUERY**

*** BENITEC TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** MEDICAL DEVELOPMENTS DIRECTOR IAIN KIRKWOOD RESIGNS**

MARKET REPORT

The Australian stock market was up 0.66 percent on Wednesday February 27, 2013 with the S&P ASX 200 up 33.0 points to 5,036.6 points. Eighteen Biotech Daily Top 40 stocks were up, seven fell, nine traded unchanged and six were untraded. All Big Caps rose.

Cellmid was the best, climbing 29.2 percent to 3.1 cents, on no news, before closing up 0.4 cents or 17.4 percent at 2.7 cents with 44.0 million shares traded. Patrys and Tissue Therapies climbed more than 14 percent; Antisense and Phylogica were up eight percent or more; Allied Health was up 7.1 percent; Sunshine Heart climbed 6.9 percent; Clinuvel and Pharmaxis were up more than four percent; Viralytics was up 3.45 percent; Cochlear, Living Cell, Mesoblast, Neuren and Prana rose more than two percent; with CSL, GI Dynamics, Resmed, Sirtex and Starpharma up one percent or more.

Psivida led the falls, down 10 cents or 5.2 percent to $1.83 with 1,500 shares traded. Both Ellex and Prima fell 4.55 percent; Alchemia and Bionomics lost more than three percent; Medical Developments shed two percent; with Nanosonics down one percent.

INVION (FORMERLY CBIO)

Invion chief executive officer Dr William Garner says he expects results from three separate phase II trials this year.

Dr Garner said the company's 120-patient, randomized, controlled, phase II trial of INV102, an oral beta adrenergic inverse agonist (beta blocker) also known as Nadolol, for smoking cessation, was about to begin "imminently" to be followed by a trial of the same drug for asthma and a trial of chaperonin-10 for lupus.

As CBio's XToll, chaperonin-10 failed to meet its endpoints for rheumatoid arthritis, but Dr Garner said there were indications that it could be useful for lupus and possibly other inflammatory blood diseases (BD: Aug 1, 2011).

Dr Garner told an investors meeting, hosted by Macquarie Bank in Melbourne, that the phase II asthma trial was fully funded by a grant from the US National Institutes for Health, but asthma would be a long and expensive indication to pursue.

Dr Garner said that 15 percent of all people who attempt to give up cigarettes and failed, cited coughing of phlegm as the reason for failure.

He said that INV102 was able to repair epithelial lung cells so that when smokers stopped, there was a significant reduction in mucous-producing cells, reducing the cough.

Dr Garner said that the company needed to demonstrate that the patients on the active drug in the trial had a better tobacco quit rate than the controls.

Dr Garner said that with about 750,000 US smokers failing to quit due to coughing, the addressable market would be worth about $600 million a year.

"If we get approval for smoking cessation it could generate interest from existing players [in the asthma market]," Dr Garner said.

Dr Garner said that INV102 would be a course of tablets for about five months for smoking cessation, but asthma and other respiratory diseases would require indefinite use.

Dr Garner said that although Nadolol was off-patent there was intellectual property protection for the routes and doses to be used for Invion's specific indications.

Dr Garner said that Invion was spending about $5 million a year and had $3.4 million in cash at December 31, 2012.

He said that the company would have to raise more cash.

Invion fell 0.2 cents or 2.9 percent to 6.7 cents.

ALCHEMIA

Alchemia says revenue for the six months to December 31, 2012 was up 3319.6 percent to $9,438,000 with a net loss after tax down 1.7 percent to $5,895,000.

Alchemia said the revenue included $4.5 million from the fondaparinux profit share with partner Dr Reddy's and $4.4 million in research and development tax refund.

The company said that the operating expenditure of $15.5 million was higher than the previous corresponding period's $6.5 million, with increased of spending on the phase III HA-irinotecan clinical trial of $6.9 million and $3.9 million spent on Nasdaq listing expenses and demerger costs.

Last year, Alchemia failed to list on the Nasdaq when a capital raising of up to $60 million did not meet its minimum (BD: Dec 21, 2012).

The company said its diluted loss per share fell 27.6 percent to 2.1 cents at December 31, 2012 and net tangible asset backing per share was down 81.4 percent to 1.1 cents.

Alchemia said it had cash and cash equivalents of $6,135,000 at December 31, 2012 compared to $12,346,000 at June 30, 2012.

Alchemia fell one cent or 3.1 percent to 31 cents.

MAYNE PHARMA

Mayne says revenue for the six months to December 31, 2012, was up 0.9 percent to $27,375,000 with the previous profit after tax turned to a loss of $2,546,000.
Mayne chief executive officer Scott Richards told a teleconference that the six months to December 31, 2012 “was nothing less than transformational”.
Mr Richards said Mayne had two products: Doryx which faced and lost a patent suit; and Subacap which faced regulatory challenges in Europe.
“We needed a new pipeline,” Mr Richards said. “I’m pleased to say we have a much stronger business … and earnings outlook.”
“We now have 17 products in development, with four products filed to the [US Food and Drug Administration] including two from Metrics,” Mr Richards said.
Mr Richards said that Metrics had only been included in the data since November 14, 2012, but contributed 30 percent of sales and had performed either at or above guidance.
Mr Richards said the company had received UK approval for Subacap for fungal infections, with further marketing authorizations expected this year and was in discussion with the FDA for approval in the US.
The company said that net tangible asset per share fell 49.3 percent to 7.3 cents and diluted earnings per share fell from 2.51 cents at December 31, 2011 to a loss of 1.0 cents at December 31, 2012.
Mayne said that cash and cash equivalents at December 31, 2012 was $30,381,000 compared to $11,596,000 at June 30, 2012.
Mayne fell one cent or 2.6 percent to 37.5 cents with 1.7 million shares traded.

CRYOSITE

Cryosite says revenue for the six months to December 31, 2012, was up 15.8 percent to $4,510,000 with net profit after tax up 60.2 percent to $559,000.
Cryosite said that a dividend of 0.5 cents a share would be paid on April 5, for shareholders at the record date of March 22, 2013.
Cryosite said revenue came from its cord blood banking services, bio-repository management, adult stem cell storage, warehousing and distribution services.
The company said that net tangible assets per share was up 15.7 percent to 12.5 cents and diluted earnings per share was up 57.3 percent to 1.18 cents.
Cryosite said that cash and cash equivalents at December 31, 2012 was $5,226,169 compared to $4,524,750 at June 30, 2012.
Cryosite was up 1.5 cents or 3.1 percent to 50 cents.

LIVING CELL TECHNOLOGIES

Living Cell says revenue for the six months to December 31, 2012, was up 252.8 percent to $3,334,000 with the net profit after tax down 97.8 percent to $172,000.
Living Cell said that the previous corresponding period included an $11.1 million payment for the sale of Diabecell to joint venture Diatranz Otsuka and in the six months to December 31, 2012 it received service fees from Diatranz Otsukaof $3.3 million.
The company said that net tangible asset per share was up 1.2 percent from 4.02 cents at June 30, 2012 to 4.07 cents at December 31, 2012, while diluted earnings per share was down from 2.40 cents to a loss of 0.07 cents.
Living Cell said that cash and cash equivalents was $2,354,000 at December 31, 2012 compared to $3,170,000 at June 30, 2012.
Living Cell was up 0.1 cents or 2.1 percent to 4.9 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2012 was up 221.7 percent to $1,249,626 with a net loss after tax down 31.8 percent to $4,253,359.
Clinuvel said that the supply of Scenesse, or afamelanotide, under reimbursement schemes in Italy and Switzerland generated $531,273 in revenue for the six months to December 31, 2013 compared to $43,218 in the previous corresponding period.
The company said its diluted loss per share fell 38.6 percent to 12.4 cents at December 31, 2012 and net tangible asset backing per share was down 22.2 percent to 28 cents.
Clinuvel said it had cash and cash equivalents of $9,929,436 at December 31, 2012 compared to $12,719,025 at June 30, 2012.
Clinuvel was up 10 cents or 4.35 percent to $2.40.

LBT INNOVATIONS

LBT says revenue for the six months to December 31, 2012 was down 6.4 percent to $450,760, with a net loss after tax up 40.4 percent to $916,469.
LBT said that $284,000 of the revenue came from royalties from sales of Biomérieux's Previ Isola laboratory dish streaking machine.
LBT said its net tangible assets per share fell 64.0 percent to 0.41 cents and diluted loss per share was up 39.4 percent to 0.92 cents..
The company said it had cash and cash equivalent of $2,422,000 at December 31, 2012 compared to $2,932,000 at June 30, 2012.
LBT was untraded at 4.5 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it has launched a range of vascular endothelial growth factor-C (VEGF-C) and VEGF-D Vegenics-branded products as research reagents
Circadian said it would initially offer versions of recombinant human VEGF-D and VEGF-C that have been developed as part of its therapeutic development programs.
The company said its products had "improved and complementary properties to available VEGF-C and VEGF-D research reagents" and would expand the range of reagents currently available to investigators researching angiogenesis and lymphangiogenesis.
Circadian said it expected to add further VEGF-C and VEGF-D Vegenics-branded products to its catalogue in the next six months.
Circadian chief executive officer Robert Klupacs said the company wanted "to further enhance scientific research by providing high quality, unique and specialized reagents".
Mr Klupacs said that he expected the launch of the reagents to be "the first of many to become available to the research community from the portfolio of products in development by Circadian and our partners".
"Direct marketing of research reagents is an important part of our ongoing strategy to increase revenues into the company," Mr Klupacs said.
"Given the ever-increasing number of laboratories studying angiogenesis and lymphangiogenesis worldwide and the need to provide investigators with highly specialized reagents, we anticipate that our research reagents will become an important ongoing revenue source which we will utilize to support our ongoing drug development activities," Mr Klupacs said.
Circadian said that products could be ordered directly through www.vegenics.com.
Circadian was untraded at 29 cents.

GI DYNAMICS

GI Dynamics says Israel's Sheba Medical Center in Ramat-Gan, Tel Aviv is offering its Endobarrier treatment for obesity and type 2 diabetes.
GI Dynamics said the Center was the first in the country to treat patients with the duodenal insert device that reduced both blood sugar and body weight.
Sheba Medical Center Institute of Endocrinology's head of obesity clinic Dr Gabriella Lieberman said the diabetes center was "at the forefront of innovative advances in managing type 2 diabetes and obesity and we are pleased to offer Endobarrier therapy to our patients".
"Our first groups of patients responded well to this brief, endoscopic procedure and are achieving control of their diabetes while losing weight," Dr Lieberman said.
GI Dynamics said it had an agreement with Lavi Medical Agencies as the exclusive distributor for Endobarrier in Israel.
The company said that Endobarrier received approval from the Israeli Ministry of Health in February 2012 for type 2 diabetes and obesity treatment for up to 12 months.
Lavi chief executive officer Dani Shaham said that Endobarrier therapy enabled "diabetes control along with weight loss without the risks associated with bariatric surgery".
GI Dynamics chief commercial officer Mark Twyman said the first Israeli patients were "yet another milestone in the global commercialization of Endobarrier therapy" and the company would add more centers in Israel and work with the distributor to provide Endobarrier to patients living with uncontrolled type 2 diabetes and obesity.
GI Dynamics was up one cent or 1.3 percent to 78 cents.

CELLMID

Cellmid 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 29.2 percent from 2.4 cents to 3.1 cents, today, and noted an increase in trading volume.
Cellmid closed up 0.4 cents or 17.4 percent at 2.7 cents with 44.0 million shares traded.

BENITEC BIOPHARMA

Benitec has requested a voluntary suspension to follow the trading halt requested on February 25, "regarding a proposed capital raising" (BD: Feb 25, 2013).
Benitec last traded at 1.3 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that director of 10 years, Iain Kirkwood has resigned, with effect from February 26, 2013 to "spend more time on Avexa and some of his other directorships".
The company said it was looking for a replacement with respiratory medicine and/or finance experience.
Medical Developments fell four cents or two percent to $1.96.