Biotech Daily

Thursday February 28, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 28%, GENERA DOWN 10%**

*** ALCHEMIA PHASE III HA-IRINOTECAN RECRUITMENT CLOSED**

*** ELI LILLY, ACRUX PBS LISTING FOR AXIRON**

*** PRIMA STARTS PHASE II/III CVAC OVARIAN CANCER TRIAL IN EUROPE**

*** QRX RESUBMITS FDA MOXDUO NDA**

*** BIONOMICS REQUESTS CAPITAL RAISING TRADING HALT**

*** HEARTWARE REVENUE UP 34% TO $US111m, LOSS UP 59% TO $US88m**

*** ELLEX H1 REVENUE DOWN 16% TO $22m, PROFIT DOWN 78% TO $144k**

*** OPTISCAN H1 REVENUE UP 223% TO $936k, TURNAROUND PROFIT $136k**

*** IMPEDIMED REVENUE DOWN 7% TO $1.4m, LOSS DOWN 13% TO $5m**

*** AVITA H1 REVENUE DOWN 34% TO $2.4m, LOSS UP 78% TO $4m**

*** USCOM H1 REVENUE DOWN 28% TO $363k, LOSS DOWN 41% TO $671k**

*** GI DYNAMICS REVENUE UP 185% TO $668k, LOSS UP 2% TO $27m**

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

*** CLINUVEL PASSES EMA MANUFACTURING AUDIT**

*** OBJ RIGHTS ISSUE FOR $3.5m**

*** BLUECHIIP APPOINTS ERIC HALL NORTH AMERICA PRODUCT MANAGER**

MARKET REPORT

The Australian stock market was up 1.34 percent on Thursday February 28, 2013 with the S&P ASX 200 up 67.5 points to 5,104.1 points. Thirteen Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and seven were untraded. All Big Caps rose.
Optiscan was the best, up 2.5 cents or 27.8 percent to 11.5 cents with 119,140 shares traded followed by Cellmid up 18.5 percent to 3.2 cents with 44.6 million shares traded.
Prima was up 9.5 percent; Allied Health and Medical Developments were up more than six percent; Nanosonics was up 5.3 percent; Alchemia and Sirtex were up more than four percent; Neuren, Patrys and QRX rose more than two percent; with Acrux, CSL, Mesoblast and Resmed up more than one percent.
Genera led the falls, down one cent or 10 percent to nine cents with 40,000 shares traded.
Circadian fell 8.6 percent; Antisense, Avita and Impedimed lost seven percent or more; and Pharmaxis fell 5.9 percent.

ALCHEMIA

Alchemia says it has completed enrolment of all 415 patients in its pivotal phase III clinical trial of HA-irinotecan for metastatic colorectal cancer.

Alchemia said the total of 415 patients included 71 patients enrolled in an optional pharmaco-kinetic and cardio-toxicity sub-study intended to provide further confirmation of the hyaluronic acid-irinotecan (HA-irinotecan) safety profile.

The company said that the trial was originally planned for 390 patients but "enthusiasm for the clinical trial shown by both investigators and patients resulted in an additional 25 patients being recruited in four weeks" at 76 sites in Australia and Europe.

Alchemia said the additional 25 patients would increase the sub-study to 90 percent of the targeted sample size and increased the statistical power of the whole trial, improving predictability of when the primary endpoint of progression free survival would be met.

Alchemia chief scientific officer Dr Tracey Brown said the rapid recruitment would allow Alchemia "to determine the success of this pivotal trial in the first half of 2014".

"We have been encouraged by the initial statistical review and modeling of the available blinded data, as it suggests that patients as a group are continuing on treatment for longer than anticipated before their disease progresses," Dr Brown said.

"Additionally, we anticipate these further recruitments will provide enhanced validation of the safety and efficacy of the Hyact platform technology," Dr Brown said.

Alchemia said that consultation with both the US Food and Drug Administration and the European Medicines Agency indicated that the successful completion of this single pivotal phase III trial mighty be sufficient for registration in both the US and Europe.

Alchemia was up 1.5 cents or 4.8 percent to 32.5 cents.

ACRUX

Eli Lilly and Co says tomorrow's listing of Acrux's Axiron testosterone replacement therapy on the Australian Pharmaceutical Benefits Scheme is "another important milestone".

A media release from Eli Lilly published on the ASX by Acrux said the listing was expected to be effective from March 1, 2013.

Eli Lilly said the listing was "the latest in a string of achievements for the collaboration" and that Acrux generated export revenue of $55 million in 2010 and $90 million in 2011.

Lilly said that, to date, Acrux had returned about $5 million in royalties to Monash University, contributing to further Australian research and development, and $20 million in corporate tax to the Australian Government.

Lilly said that since 1998, Acrux had raised $96 million in capital and paid $113 million in dividends to shareholders.

Lilly Australia-New Zealand general manager Becki Morison said she was "extremely proud of our collaboration with Acrux, which has seen a treatment that originated in a Monash laboratory exported to benefit men in the United States and now Australia".

Acrux chief financial officer Jon Pilcher said that Government and private investment was essential to the success of research and development in Australia.

"Axiron is the first product developed by Acrux to be made available to Australians via the PBS," Mr Pilcher said.

"The valuable support of the Australian Government and Lilly's contribution to Australian [research and development] has been fundamental in bringing Axiron to market both locally and internationally," Mr Pilcher said.

Acrux was up seven cents or 1.8 percent to $4.05 with 2.3 million shares traded.

PRIMA BIOMED

Prima says it has begun European recruitment for its 1,000 patient phase II/III trial of CVac for ovarian cancer.

Prima said it had authorized several centers in the Ukraine to start enrolling patients and had obtained the requisite ethics and regulatory approvals in Belarus, Belgium, Bulgaria, Germany, Lithuania, Latvia, Poland and Ukraine.

The company said it that expected that the majority of patients would be enrolled in Europe, but the trial was open for recruitment at centers in the US and Australia.

Earlier this month, Prima chief executive officer Mathew Lehman told Biotech Daily that the phase II/III, CANVAS trial was underway with 26 patients screened, 23 randomized and three patients dosed at the 14 active sites of the proposed up to 120 centres in the US, Europe and Australia (BD: Feb 5, 2013).

Today the company said that the cancer vaccine study (CANVAS) would investigate CVac for the maintenance treatment of newly diagnosed, late-stage epithelial ovarian cancer patients who achieved remission after optimal debulking surgery and standard first line chemotherapy.

Mr Lehman said the company was “pleased to open enrollment for the CANVAS trial in Europe”.

Prima was up one cent or 9.5 percent to 11.5 cents with 8.8 million shares traded.

QRX PHARMA

QRX says it has resubmitted its new drug application for Moxduo to the US Food and Drug Administration.

Last year, the FDA rejected the QRX application for the morphine oxycodone combined drug saying it wanted more comparative data (Jun 27, Aug 20, 2012).

QRX chief executive officer Dr John Holaday said he believed the revised documents effectively addressed the FDA’s request for additional data resulting from their review of the initial Moxduo application filed in mid-2011.

“To this end, and as recommended by the FDA, a comprehensive analysis of Study 022 was included as part of the resubmitted NDA,” Dr Holaday said.

“This study demonstrated the lower risks of respiratory depression for Moxduo when compared to either morphine or oxycodone,” Dr Holaday said.

In 2011 QRX said the Study 022 trial showed that Moxduo had a mixed superior safety profile to equi-analgesic doses of either 24mg morphine alone or 16mg oxycodone alone (BD: Jun 14, 2011).

QRX said at that time that the Study 022 primary endpoint of respiratory depression, measured by oxygen desaturation, was less severe and of shorter duration in patients receiving Moxduo IR, but the difference was only significant against 16mg oxycodone and not 24mg morphine.

QRX said it expected to be notified of a new FDA Prescription Drug User Fee Act (PDUFA) date and advisory committee meeting date by March 31, 2013.

QRX was up two cents or two percent to $1.00.

BIONOMICS

Bionomics has requested a trading halt “pending an announcement … regarding a capital raising”.

Trading will resume on March 4, 2013 or on an earlier announcement.

Bionomics last traded at 41 cents.

HEARTWARE INTERNATIONAL

Heartware says that revenue for the 12 months to December 31, 2012 was up 34.0 percent to $US110,922,000 with net loss after tax up 59.3 percent to $US87,718,000.
Heartware said that while gross profit from the reimbursement and payments for its left ventricular assist device increased buy $US30 million, research and development expenses increased $US33 million and sales and administrative costs increased $US11.6 million.
Heartware chief executive officer Doug Godshall said the fourth quarter results “reflect positive initial trends in the commercial launch of the Heartware Ventricular Assist System in the US, following approval from the Food and Drug Administration on November 20, 2012, and continued strong support from our international customers”.
“Today, more than 3,000 advanced heart failure patients globally have received the Heartware System,” Mr Godshall said.
Heartware said that in the three months to December 31, 2012, revenue from non-US markets increased by about 31 percent to $US19.3 million, from $US14.7 million in the fourth quarter of 2011.
The company said that US revenue, was $US13.4 million in the three months to December 31, 2012, an increase of 60 percent from $US8.4 million in the previous corresponding period.
The company said that diluted loss per share was up 56.1 percent to $US6.15, compared to $US3.94 in the year to December 31, 2011.
Heartware said it had $US85,921,000 in cash and cash equivalents at December 31, 2012, compared to $US71,257,000 at December 31, 2011.
Heartware was unchanged at $2.42.

ELLEX MEDICAL LASERS

Ellex says its revenue for the six months to December 31, 2012 fell 16 percent to $22,020,000 taking net profit after tax down 78 percent to $144,000.
Ellex said sales for the six months to December 31, 2011 were high due to significant sales of third-party product into the Australian optometry market and high US sales associated with insurance reimbursement changes.
The company said that in the six months to December 31, 2012 it had improved sales in Asia, particularly in China, and preliminary sales from the limited commercial roll-out of Retinal Rejuvenation Therapy (2RT) following regulatory approval in July for treatment of diabetic eye disease in Europe and Australia.
Ellex chief executive officer Tom Spurling said that “it was disappointing to not achieve the same sales levels as last year, [but] we were pleased to note that sales in the six months to December 31, 2012 were four percent higher than sales in the six months to June 30, 2012”.
“The improved cash from operations was also a pleasing result,” Mr Spurling said.
The company said the net tangible asset backing per share was down 5.0 percent to 19 cents and diluted earnings per share was 0.4 cents compared to the previous corresponding period’s .77 cents.
Ellex said it held cash and cash equivalents of $1,277,000 at December 31, 2012 compared to $1,849,000 at June 30, 2012.
Ellex was untraded at 21 cents.

OPTISCAN

Optiscan says revenue for the six months to December 31, 2012, was up 223.2 percent to $936,025 with a turnaround net profit after tax of $136,302.
Optiscan said that in the six months to December 31, 2012 it shipped the first pre-production systems of the new second generation platform (CIS2) to Zeiss and that "milestone event underscored a 267 percent increase in sales revenue".
The company said that other income also increased, with design and development income of $389,995, as well as an increase in the research and development tax incentive of $157,650.
The company said that net tangible asset per share was up 400 percent from 0.2 cents to 1.0 cents diluted earnings per share was 0.088 cents compared to a loss of 0.64 cents in the previous corresponding period.
Optiscan said that cash and cash equivalents at December 31, 2012 was $753,071 compared to $578,900 at June 30, 2012.
Optiscan was up 2.5 cents or 27.8 percent to 11.5 cents.

IMPEDIMED

Impedimed says revenue for the six months to December 31, 2012 fell 6.6 percent to $1,390,000 with net loss after tax reduced 13.0 percent to $5,165,000.
Impedimed said that lymphoedema test revenue increased by 20 percent with US lymphoedema revenue increasing 39 percent compared to the prior period, while body composition products were down.
The company said its net tangible assets per share fell 33.3 percent to 0.6 cents and diluted loss per share fell 25 percent to 3.0 cents.
Impedimed said it had cash and cash equivalent of $9,649,000 at December 31, 2012 compared to $14,514,000 at June 30 2012.
Impedimed fell 0.7 cents or 7.0 percent to 9.3 cents

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2012 was down 34.0 percent to $2,391,724, with a net loss after tax up 78 percent to $3,798,736.
Avita said that revenue from the sale of goods including the Recell wound treatment and Breath-A-Tech business, as well as US Defense Department trial funding all fell.
Avita said its net tangible assets per share fell 10.0 percent to 4.5 cents and basic loss per share was up 58.2 percent to 1.47 cents.
The company said it had cash and cash equivalent of $14,284,971 at December 31, 2012 compared to $8,230,593 at June 30, 2012.
Avita fell one cent or 7.4 percent to 12.5 cents.

USCOM

Uscom says revenue for the six months to December 31, 2012 fell 27.8 percent to $363,309 with net loss after tax reduced 40.97 percent to $671,217.
The company said its net tangible assets per share fell 17.2 percent to 2.4 cents and diluted loss per share fell 50 percent to 1.1 cents.
Uscom said it had cash and cash equivalents of $896,131 at December 31, 2012 compared to $544,463 at June 30 2012.
Uscom was unchanged at 19 cents.

GI DYNAMICS

GI Dynamics says that revenue for the 12 months to December 31, 2012, was up 185 percent to $668,000, with net loss after tax up 2.0 percent to $26,786,000.
GI Dynamics said it had a 206 percent increase in revenue from sales of its Endobarrier treatment for obesity and type 2 diabetes in Europe and a 131 percent increase in revenue from sales in South America.
GI Dynamics said that net tangible assets per CDI fell 34.7 percent to 15 cents, with diluted loss per share down 63.6 percent to 47 cents.
The company said that it had cash and cash equivalents of $41,481,000 at December 30, 2012 compared to $66,152,000 at December 31, 2011.
GI Dynamics was unchanged at 78 cents.

PROGEN PHARMACEUTICALS

Progen says revenue for the six months to December 31, 2012 was up 46.2 percent to $1,806,400 with a net loss after tax down 23.1 percent to $1,509,608.
Progen said that its Pharmasynth contract manufacturing subsidiary recorded revenue of $1,306,400, an 80 percent increase over the previous corresponding period, primarily due to an increase in the value of manufacturing contracts.
The company said that Pharmasynth recorded a loss of $530,698 for the six months to 31 December 31 2012, compared to a loss of $352,586 for the prior corresponding period.
The company said its diluted loss per share fell 23.0 percent to 6.11 cents at December 31, 2012 and net tangible asset backing per share was down 41.9 percent to 16.81 cents.
Progen said it had cash and cash equivalents of $4,117,477 at December 31, 2012 compared to $1,834,442 at June 30, 2012.
Progen was unchanged at 22.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency has completed a good manufacturing practice audit of the manufacturing facilities for Scenesse or afamelanotide 16mg implant.
Clinuvel said that Scenesse was manufactured at Birmingham Laboratories, part of the Evonik Corp, in Birmingham, Alabama.
The company said that the audit was conducted by the UK's Medicines and Healthcare products Regulatory Agency as part of the EMA's review of a marketing authorization application for Scenesse for the orphan indication erythropoietic protoporphyria (EPP), submitted in February 2012.
Clinuvel's acting chief scientific officer Dr Dennis Wright said that ensuring compliance with manufacturing regulations was "essential for the manufacture of a pharmaceutical and a vital part of the EMA's review process".
"In drug development one must be vigilant that the quality of a novel product like Scenesse is consistently replicated at a commercial scale and manufactured within appropriate controls," Dr Wright said.
Clinuvel chief executive officer Dr Philippe Wolgen said it was "reassuring to learn that the EMA agrees with our assessment that Scenesse is manufactured to the highest industry standards by our manufacturing partner, Evonik Industries".
"In the coming months we expect to learn the full outcome from the EMA's review of our [marketing approval application] and are confident that we will be able to deliver this much needed therapy for EPP patients," Dr Wolgen said.
Clinuvel was unchanged at $2.40.

OBJ

OBJ says it hopes to raise about $3.53 million through a fully underwritten, non-renounceable, one-for-five rights issue at 1.5 cents a share.

OBJ said two free attaching options would come with every five new shares subscribed, exercisable at one cent each by December 31, 2014.

The company said that Novus Capital would be manager and underwriter for the offer.

OBJ fell 0.6 cents or 28.6 percent to 1.5 cents with 20.8 million shares traded.

BLUECHIIP

Bluechiip says it has appointed Eric Hall as its product manager for North America to assist with sales, training, service and support.

Bluechiip said that Mr Hall was based in North Carolina and had more than 15 years experience in life sciences and healthcare, specifically in laboratory design and construction, procurement, logistics, information technology and operational planning.

The company said that Mr Hall held a Bachelor of Science in biology from Campbell University, North Carolina and a Master of Health Administration from the University of North Carolina.

Bluechiip was up half a cent or 2.2 percent to 23.5 cents.