



# Biotech Daily

Thursday, May 12, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: VIRALYTICS UP 10%; MESOBLAST DOWN 5%**
- \* **START-UP SELLS 60,000,000 BIONOMICS SHARES; TRADING HALT**
- \* **CEPHALON TAKES 72% OF CHEMGENEX**
- \* **SUNSHINE HEART: 750k US PATIENT MARKET; ASX 29% QUERY**
- \* **CBIO RAISES \$5.1m**
- \* **GENETIC TECHNOLOGIES PLEADS GOOD NEWS TO ASX 285% QUERY**
- \* **CLINUVEL READY FOR SCENESSE EUROPEAN SUBMISSION**
- \* **INAVIR EARNS BIOTA \$1.6m**
- \* **BIOMD EGM TO BECOME ALLIED HEALTHCARE**
- \* **PRANA 139m SHARE ISSUE, PLACEMENT EGM**
- \* **CENTAURUS TAKES 6.5% OF CELLESTIS WITH DERIVATIVES**
- \* **OMI REQUESTS ACQUISITION, CAPITAL RAISING SUSPENSION**

## MARKET REPORT

The Australian stock market fell 1.76 percent on Thursday, May 12, 2011 with the S&P ASX 200 down 84.1 points to 4696.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and nine were untraded. All three Big Caps fell.

Viralytics was best, up 0.7 cents or 10 percent to 7.7 cents with 16.1 million shares traded, followed by LBT and Sunshine Heart both up 9.1 percent to six cents. Biota and Universal Biosensors climbed more than five percent; Prana was up 4.8 percent; Clinuvel was up 3.3 percent; Impedimed rose 2.3 percent; with Genetic Technologies, Pharmaxis and QRX up more than one percent.

Mesoblast led the falls, down 49 cents or 5.05 percent to \$9.22 with one million shares traded. Optiscan, Phylogica, Prima and Tissue Therapies fell more than four percent; Alchemia, Phosphagenics and Starpharma were down more than three percent; Living Cell and Nanosonics shed more than two percent; with Acrux, Cochlear and CSL down more than one percent.

## BIONOMICS

Start-up Australia has sold 60,000,000 of its 88,364,866 Bionomics shares to institutions in Australia and overseas at 57 cents a share.

Managing-director Dr George Jessup told Biotech Daily the overhang was believed to be suppressing the share price.

Dr Jessup said he acquired the most recent tranche of Bionomics shares at 24 cents a share about 18 months ago.

Dr Jessup said Start-up first invested in Bionomics predecessor company Iliad in April 2003 and had acquired several more tranches of shares following the initial acquisition. He said that the sale was to a number of institutions including some that had not previously been known for investing in biotechnology.

Last year, Start-up Australia announced the potential sale of its 27.76 percent stake in Bionomics saying that despite reaching significant developmental milestones the company's share price of about 31 cents did not reflect its value (BD: Nov 11, 2010). If one buyer had acquired the shares the sale would have triggered a take-over of the company, but the invitation to tender closed on March 31, 2011.

Biotech Daily believes efforts were made to find multiple buyers so that the sale would not exceed the 20 percent compulsory takeover provisions of the Corporations Act.

In a letter to Bionomics chairman Chris Fullerton, Dr Jessup said that following the release of clinical trial results for Bionomics' anxiety drug, BNC210, on March 30, 2011, Start-up received "numerous approaches from investors seeking to become shareholders in Bionomics".

"We have been pleased to work closely with Bionomics and its advisers in responding to that demand and believe that today's orderly sale represents a significant milestone in the maturing of the Bionomics' register," Dr Jessup said.

He said the 57 cent a share price was "in line with the volume weighted average price of Bionomics shares since the BNC210 results were released".

"We are pleased to see that Bionomics' share register will be strengthened with the introduction of major Australian and international investors," Dr Jessup said.

"We intend to continue to work with Bionomics and Southern Cross Equities to ensure any future liquidity events for our shares take place in an orderly manner," Dr Jessup said.

He said that near-term value adding milestones, including phase II clinical trial results for cancer drug BNC105 and partnering negotiations would add significant value for shareholders.

Separately, Bionomics has requested a capital raising trading halt.

Trading will resume on May 16, 2011 or on the release of an earlier announcement.

Bionomics last traded at 72 cents.

## CHEMGENEX

Cephalon says it has increased its acceptances for its Chemgenex takeover bid from 212,488,838 shares (67.77%) to 224,574,961 shares (71.62%).

Cephalon said it had received acceptances for 9,382,573 options or 85.69 percent of the listed options.

The bid is conditional on receiving 90 percent of shares and options and trading over the past fortnight appeared to be from one buyer acquiring or attempting to acquire more than 10 percent of the listed options.

Cephalon can remove conditions at any time.

The listed options, exercisable at 68 cents, expire in February 2012.

Chemgenex was unchanged at 69 cents.

## SUNSHINE HEART

Sunshine Heart's C-Pulse aorta cuff pump could have a target market of more than 750,000 patients in the US.

The director of mechanical circulatory support at Saint Luke's Mid America Heart and Vascular Institute in Kansas City Missouri Dr Sanjeev Aggarwal told an investor briefing in Melbourne that the C-Pulse device was suitable for at least 50 percent of the 1,500,000 Americans with class III heart failure.

At a lunch hosted by RBS Morgans, Dr Aggarwal said that class II patients were generally treated with drug therapies and the 200,000 to 300,000 patients in class IV heart failure generally required left ventricular assist devices or heart transplants, but there was a large group of ambulatory patients with significant functional limitations in class III heart failure that could benefit from the Sunshine Heart device.

Dr Aggarwal said his 600-bed hospital performed a full range of cardiac procedures including the implantation of left ventricular assist devices.

"Heart failure is becoming an epidemic in the US," Dr Aggarwal said.

Dr Aggarwal was one of the cardiac surgeons performing the minimally invasive implantation of the C-Pulse device and showed an edited video of a live procedure.

He said the ability to implant the device without cutting through the sternum was "a game changer" and that repeated interventions through the sternum increased the risk of cutting into the heart itself.

Dr Aggarwal said that the C-Pulse device, through its pacemaker-like incision could buy patients two to five years before they might require a left ventricular assist device.

He said that heart disease was progressive and, in general, patients did continue from one stage of heart failure to the next stage.

But Sunshine Heart chief executive officer Dave Rosa said one of the endpoints for the recently completed pilot trial was to see whether or not stage III patients with the C-Pulse device improved to the point that they could be reclassified as stage II.

Mr Rosa said the results of the trial were expected to be completed and released at the Heart Failure Society of America meeting in Boston in September 2011 .

Dr Aggarwal said take-up of the C-Pulse device by cardiologists would be "data-driven" and they would pay great attention to the safety and efficacy results presented in Boston.

Mr Rosa said that should the results prove to be positive, he expected a much faster take-up rate for pivotal trial centres than the two years it took to complete the pilot trial.

Sunshine Heart has permission from the US Food and Drug Administration to implant a further 20 C-Pulse devices and is preparing its submission for a 270-patient randomized pivotal trial for registration (BD: Apr 4, 11, 2011).

The company has previously said it will require up to \$35 million to fund the pivotal trial.

Sunshine Heart was up 0.5 cents or 9.1 percent to six cents with 2,016,139 shares traded.

## SUNSHINE HEART

Sunshine Heart 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 from 4.9 cents on May 10, 2011 to 6.3 cents on May 12, 2011, a 28.6 percent increase and noted an increase in trading volume. Sunshine Heart said it had been "conducting an education roadshow ... for institutional investors and members of the medical profession" (see above).

"One aim of the road show has been to help professional investors better understand the heart failure market in the US and issues involved in the available treatment of heart failure," Sunshine Heart said.

## CBIO

CBio says it has raised \$5,100,000 through the issue of 11.6 million shares at 44 cents a share to professional and sophisticated investors.

CBio said the funds were for the manufacturing scale-up for the phase IIb trial of its XToll drug candidate for rheumatoid arthritis along with the discovery of a successor drug among the 48 variants of XToll, regulatory filings, planning a clinical trial "in another disease indication such as Lupus" and for general working capital.

CBio fell three cents or 5.45 percent to 52 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies 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 from 10 cents on April 27, 2011 to 28.5 cents on April 13, 2011, a 285 percent increase and noted an increase in trading volume. Genetic Technologies said on April 27, 2011 its Australian laboratory was certified under the US Clinical Laboratories Improvements Amendments (BD: Apr 28, 2011).

While the announcement had no immediate impact on the Australian share price, the following night saw an increased level of trading of the company's American depository receipts on the Nasdaq by US investors "who are more familiar with the significance of such certification", Genetic Technologies said.

The company said that drove an increase in both the volume and price of its ASX shares. Genetic Technologies was up half a cent or 1.8 percent to 28 cents with 2.1 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it held "a constructive pre-submission meeting" with the European Medicines Agency on the registration dossier for afamelanotide for erythropoietic protoporphyria.

Clinuvel said the EMEA acknowledged the company would meet all filing requirements for afamelanotide (Scenesse) and agreed with the tentative dossier submission period of the last quarter of 2011 for the orphan designated disease.

The company said the meeting was "the penultimate step of the European drug approval process prior to filing under the EMA's centralized procedure.

Clinuvel said that all relevant EMA departments had the opportunity to comment on the documentation prior to formal evaluation of the marketing authorization application.

Clinuvel said a paediatric investigational plan for the use of afamelanotide in children with erythropoietic protoporphyria (EPP) would be submitted this month.

The company said the EMA recommended that a good manufacturing practice audit be initiated to facilitate the review process and confirmed that, since erythropoietic protoporphyria was an orphan indication, no application fees would be payable.

Clinuvel said that approval through the centralized procedure would allow it to market afamelanotide under the brand name Scenesse in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

Clinuvel chief executive officer Dr Philippe Wolgen said that "to arrive at this crucial stage within five years of starting the program in EPP is a truly exceptional achievement".

"Subject to positive results in the CUV029 and CUV030 trials, we will be able to submit efficacy data for 250 EPP patients and safety data for 450 additional photodermatoses patients evaluated across the clinical program," Dr Wolgen said.

Clinuvel was up six cents or 3.28 percent to \$1.89.

### BIOTA

Biota says Daiichi Sankyo sales of Inavir for the three months to March 31, 2011 amounted to YEN3.9 billion (\$45.3 million) and its royalty would be \$1.6 million. Biota said the royalties were after allowance for specified selling costs and Japanese withholding tax.

Biota said it expected to receive the funds by the end of May 2011.

Biota was up six cents or 5.1 percent to \$1.24.

### BIOMD

Biomd shareholders will vote to acquire Allied Medical, issue 13,440,000 shares to Avexa, issue a further 67,000,000 options and change its name to Allied Healthcare Group.

Biomd said the options comprised 43,200,000 options to the proposed directors or their nominees; 8,500,000 "transaction options" to existing directors or the nominees; 10,400,000 options to employees and consultants of Allied Medical; and 4,900,000 transaction options to Biomd employees, advisers and consultants.

Biomd formally lodged its bid for Allied last week (BD: May 4, 2011).

The meeting will be held in the board room at 589 Stirling Highway, Cottesloe, Western Australia on June 10, 2011 at 8am (AWST).

Biomd was untraded at five cents.

### PRANA BIOTECHNOLOGY

Prana shareholders will vote to ratify the placement and issue of 139,200,000 shares and 10,089,000 options to a range of investors.

Prana said resolutions called for ratification of the prior placement of 27,200,000 shares at 22.5 cents each along with 6,800,000 attaching options exercisable at 22.5 cents by March 24, 2015; the issue of 12,000,000 shares and 3,000,000 options to Peregrine Corporate on the same terms; and 289,000 options to Rodman and Renshaw on the same terms.

The company said shareholders would be asked to vote on the issue of 100,000,000 shares at no less than 80 percent of the five-day volume weighted average price at the time of issue to professional and sophisticated investors.

The meeting will be held at Suite 1, 1233 High Street, Armadale, Victoria on June 10, 2011 at 10.30am (AEST).

Prana was up one cent or 4.8 percent to 22 cents.

### CELLESTIS

Centaurus Capital says it has increased its interest in Cellestis from 5,223,145 shares (5.43%) to 6,221,890 shares (6.47%).

Centuarus said 2,006,537 shares were held "contracts for difference" acquired at \$3.42 a share on May 2, 2011.

Cellestis was unchanged at \$3.38.

### OMI HOLDINGS

OMI has requested a voluntary suspension to follow the trading halt it requested on May 10, 2011, "pending the release of an announcement in relation to a proposed acquisition and capital raising".

OMI last traded at 0.6 cents.