Biotech Daily

Thursday January 29, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT: SIRTEX UP 16%, BENITEC 13%**

*** CLINUVEL: FDA US TRIAL APPROVAL 'A LANDMARK EVENT'**

*** PROGEN RESPONDS TO CYTOPIA OFFER, BACKS AVEXA MERGER**

*** AVEXA CFO ALAN BOYD CHANGES DIRECTION**

*** INTERIM RESULTS GIVE VENTRACOR 79% SUCCESS; H1 REVENUE $13m**

*** PHARMAXIS H1 REVENUE UP 60%; $94m CASH**

*** SIRTEX H1 REVENUE UP 56%, UNAUDITED PROFIT UP 627% TO $16m**

*** CATHRX APPLIES FOR VARIABLE DEFLECTABLE STYLUS EC MARK**

*** JP MORGAN INCREASES TO 8% OF QRX PHARMA; CORRECTION**

*** VICTORIA LAUNCHES NEW CANCER RESEARCH CENTRE**

*** HEALTHLINX HAS UP TO TWO QUARTERS CASH**

*** INCITIVE HAS QUARTER OF ONE QUARTER'S CASH**

*** ACUVAX HAS $74k CASH**

*** GIACONDA HAS $16k CASH**

MARKET REPORT

The Australian stock market climbed 0.9 percent on Thursday January 29, 2009 with the S&P ASX 200 up 30.7 points to 3,526.2. points. Nine of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and 11 were untraded.

Sirtex was best, up 27 cents or 15.88 percent to $1.97, followed by Ventracor up 1.2 cents or 14.46 percent to 9.5 cents with 5.6 million shares traded. Heartware climbed 8.11 percent; Universal Biosensors was up 7.84 percent; Acrux and Phosphagenics were up more than five percent; Genetic Technologies improved 4.44 percent; Antisense and Progen rose more than two percent; with Cochlear up 1.97 percent.

Benitec led the falls, down 0.5 cents or 13.16 percent to 3.3 cents with 190,000 shares traded, followed by Impedimed down 9.72 percent to 65 cents. Polartechnics fell 7.41 percent; Pharmaxis shed 6.77 percent; Starpharma lost 5.56 percent; Psivida fell four percent; Bionomics and Viralytics shed more than two percent; with Biota down 1.12 percent.

CLINUVEL

Clinuvel says the US Food and Drug Administration has granted investigational new drug status for its photo-protective drug afamelanotide.

Clinuvel said it could commence clinical trials in the US, the world's largest pharmaceutical market, extends its clinical program underway in Europe, Australia and Switzerland.

Clinuvel said its first US trial would be a confirmatory pharmacokinetic trial using the final product selected for commercial development, a controlled release formulation.

The company said afamelanotide was granted orphan drug designation for the treatment of erythropoietic protoporphyria by the FDA in July 2008, allowing an accelerated review process, seven-year market exclusivity in the US on marketing authorization, tax benefits, and exemption from filing fees, often in excess of $US1 million.

Last week Clinuvel announced positive interim results from a European phase III erythropoietic protoporphyria trial, due to be completed later this year (BD: Jan 21, 2009).

Clinuvel said the FDA investigational new drug review process involved assessment of quality, safety and clinical data on afamelanotide, generated by the company to date.

Clinuvel is developing afamelanotide as a prophylactic treatment for a range of ultra-violet light and light-related skin disorders as well as cancer related treatments.

The company has identified five UV and light related skin disorders where clinical use of afamelanotide serves the needs of patients who suffer severe and chronic symptoms (see Marc Sinatra's Clinuvel Bio-Guide at the Biotech Daily website www.biotechdaily.com.au).

Clinuvel's chief executive officer Dr Philippe Wolgen said the FDA decision was "a landmark event in Clinuvel's growth".

"Today's progress reflects some of the choices we had to make in our program early on in 2006 when changing the direction of the company," Dr Wolgen said.

"One of those choices resulted in the emphasis on clinical safety of afamelanotide as a new molecule," Dr Wolgen said. "I am thinking of the US patients who have asked us for the drug in the past months. I am also thinking of all the shareholders who have funded the company to date as we enter the world's largest pharmaceutical market."

Clinuvel was unchanged at 24 cents with 1.3 million shares traded.

PROGEN, CYTOPIA, AVEXA

Progen says its directors are "seeking advice" in relation to Cytopia's requisition for a general meeting (BD: Jan 28, 2009).

Progen said that "incomplete and non-binding proposals were received from Cytopia last year before Progen entered into its merger implementation agreement with Avexa" (BD Dec 22, 2008).

Progen said the Cytopia proposals were considered inferior to the current merger proposal with Avexa and no further merger proposal has been received from Cytopia.

Progen said there were no details of the Cytopia proposal referred to in the announcement, so there was uncertainty as to what terms it is offering, what its strategy would be going forward and what cash balance a combined group would have to support operations.

Progen said when its board had an opportunity to consider the information available to it, it will provide a further response to this announcement, but said the board reiterates its support and recommendation of the current merger proposal with Avexa which it believes to be in the best interests of shareholders as a whole," Progen said.

Progen was up two cents or 2.41 percent to 85 cents.

Cytopia was unchanged at 11 cents.

AVEXA

Avexa says chief financial officer Alan Boyd has resigned to accept a position with an industrial company but will remain to prepare his successor.
Avexa said Mr Boyd would assist with the completion of the proposed merger with Progen.
Mr Boyd is expected to remain with the company for several months.
Avexa was unchanged at seven cents.

VENTRACOR

Ventracor says interim results show a 78.6 percent success rate in its Ventrassist left ventricular assist device's US bridge-to-transplant.
Ventracor said that at the time of the interim analysis, the pre-specified performance goal was 75.5 percent.
The company said its clinical trial partner, Inchoir at New York's Mt Sinai School of Medicine is preparing the formal interim analysis for review by the data safety monitoring board.
Ventracor said 138 patients had been enrolled in the trial of the 140 required.
Cardiology principal investigator for the bridge-to-transplant trial Dr Andrew Boyle from the University of Minnesota in Minneapolis, said the enrolment rate was "brisk, which is a reflection of the favorable impression the community has towards the first centrifugal flow pump to reach clinical trials in the US".
Ventracor said 57 patients had enrolled in the separate destination therapy trial.
Ventracor's chief executive officer Peter Crosby told Biotech Daily that his company's trial had been delayed by changes to the destination therapy trial of competitor Thoratec.
The Ventracor pump was being randomized to Thoratec's first generation Heartmate XVE which has regulatory approval for both bridge-to-transplant and destination therapy.
But the approval for clinical trials of the later model, the Heartmate II, meant that it was difficult to find patients prepared to be implanted with the older device.
Ventracor is effectively "caught between devices".
Mr Crosby said the US Food and Drug Administration was aware of the problem and was working with Ventracor to resolve it. He said the development could lead to faster enrolment for the destination therapy trial.
Ventracor also said the 8,000 page second module of the pre-market approval application had been filed with the FDA. The module provides technical explanations of the manufacturing processes used to make the Ventrassist left ventricular assist device.
The company said it had preliminary sales of $12.8 million for the six months to December 31, 2008 and the Ventrassist device had been implanted in 412 patients in 45 hospitals in 10 countries.
Ventracor climbed 1.2 cents or 14.46 percent to 9.5 cents with 5.6 million shares traded.

PHARMAXIS

Pharmaxis' revenue for the six months to December 31, 2008 was up 60.1 percent to $309,000 compared to the first half to December 31, 2007.
In its Appendix 4c quarterly report Pharmaxis said its net operating cash burn for the three months to December 31, 2008 was $6,951,000, its total operating and investing cash burn was $11,608 and the company had $93,970,000 in cash.
Revenue of $281,000 in the December quarter, primarily from sales of Aridol, was a 45.6 percent increase over the $193,000 of the previous quarter.
Pharmaxis fell 10.5 cents or 6.77 percent to $1.445.

SIRTEX

Sirtex says a positive net cash flow of $6,811,000 in the three months to December 31, 2008, has left the company with $14,861,000 in cash.

Sirtex said it “achieved strong growth” with the number of doses of its anti-cancer therapy SIR-spheres sold increasing by 38.1 percent compared to the same period last year, resulting in a 55.8 percent increase in sales revenue to $29,546,000 compared to the previous corresponding period.

The company said that un-audited accounts indicated a half year profit before tax in the vicinity of $16 million, “a significant improvement on the $2.2 million for the same period last year”.

Sirtex said the expected improved profit was partly due to the depreciation of the Australian dollar.

Sirtex said it continued to pursue the recovery of its legal costs of more than $5,500,000 and although the University of Western Australia and former director Dr Bruce Gray were likely to dispute various aspects of the costs and claim, the company expects to recover a significant proportion of the amount.

Sirtex was up 27 cents or 15.88 percent to $1.97.

CATHRX

Cathrx has applied for Conformitée Européenne (CE) Mark approval of its Variable Deflectable Stylet.

Cathrx said the application followed the successful CE Marking of other Cathrx cardiac catheter stylets including a formable stylet and a range of deflectable stylets of various curve sizes over the past year.

The company said its system allowed any of its stylets to be used with any Cathrx catheter, including the Decapolar and Quadrapolar catheters, both of which received approval in March 2008 and are being marketed in Europe.

The stylet can also be used with its Duodecapolar catheter being reviewed by European regulatory authorities for CE marking following an application in October 2008.

Cathrx said that the Variable Deflectable Stylet would offer clinicians several advantages over the fixed curve or deflectable catheters which are on the market, giving clinicians the opportunity to customize, in situ, precise curve sizes and shapes to suit the range of an individual patient’s needs without having to replace either the stylet or the catheter.

Cathrx was untraded at 54 cents.

QRX PHARMA

JPMorgan Chase and affiliates have increased their substantial shareholding in QRX Pharma from 5,338,825 shares (7.12%) to 6,222,588 shares (8.3%).

QRX fell one cent or 3.85 percent to 25 cents.

QRX PHARMA

In yesterday’s edition Biotech Daily described QRX Pharma’s dual opiod Moxduo IR in a trial for pain following total knee replacement as “intra rectal”.

The company has told Biotech Daily that in this case “IR” stood for “immediate release”.

We apologize for the error and won’t comment on the action taken against the sub-editor who wrongly assumed the drug’s delivery route.

VICTORIAN GOVERNMENT

Victoria's Innovation Minister Gavin Jennings and Health Minister Daniel Andrews have launched a $5 million cancer research facility in the Parkville precinct.

Mr Jennings said the Australian Cancer Research Foundation Centre for Therapeutic Target Discovery was "an important link in Victoria's chain of world-class cancer research and treatment facilities".

"This new cancer research facility strengthens Victoria's reputation as a global centre for medical research and healthcare solutions," Mr Jennings said.

"It will play a major part in enabling our outstanding researchers to translate their frontline discoveries into more treatments for cancer, the number one killer of Australians," he said.

He said the Victorian Government welcomed a $5 million investment by the Australia Cancer Research Foundation, a philanthropic organization funded through public and corporate donations, to support researchers in the fight against cancer.

The Australian Cancer Research Foundation funds research and finances facilities to complement those provided by State and Federal governments.

Researchers using the facility, based at the Walter and Eliza Hall Institute of Medical Research will primarily focus on breast and bowel cancer and cancers of the blood.

A media release from the Victorian Government said the grant for the facility was awarded to a Melbourne consortium including the Walter and Eliza Hall Institute, the Royal Melbourne Hospital, the Royal Women's Hospital, the Ludwig Institute for Cancer Research and the University of Melbourne.

The centre aims to identify the key cellular components and processes within tumors and cancer cells that make cancer a potent killer and a major focus of the centre will be identifying ground-breaking new drug targets, the media release said.

HEALTHLINX

Healthlinx has enough cash for up to two quarters.

Healthlinx said in its Appendix 4C quarterly report that it had a total operating and investing cash burn of $299,000 for the three months to December 31, 2008 and cash at the end of the quarter of $486,000.

The company has a loan availabilty of $250,000 and chief executive officer Nick Gatsios told Biotech Daily the company was looking at additional fundraising options

Healthlinx was untraded at 6.3 cents.

INCITIVE

Incitive has about 25 percent of the amount it burnt in the three months to December 31, 2008.

Incitive said in its Appendix 4C quarterly report that it had a total operating and investing cash burn of $442,000 for the three months to December 31, 2008 and cash at the end of the quarter of $111,000.

Incitive was untraded at three cents.

ACUVAX

In its Appendix 4C quarterly report Acuvax (formerly Avantogen) said it that it had a total operating and investing cash burn of $343,000 for the three months to December 31, 2008 and cash at the end of the quarter of $74,000.

Acuvax was untraded at 2.6 cents.

GIACONDA

Giaconda has $16,000 in cash.

Giaconda said in its Appendix 4C quarterly report that it had a net operating cash burn of $63,000 for the three months to December 31, 2008 and cash at the end of the quarter of $16,000.

The company has been attempting to secure funds from a “white knight’ investor, but this had not occurred at the time of publication (BD: Oct 31, 2008).

Giaconda was untraded at 5.5 cents.