# Biotech Daily

Wednesday February 18, 2009

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: POLARTECHNICS UP 16%, PHYLOGICA DOWN 30%**

*** RNAi REGENERATES GENESIS**

*** VENTRACOR REGRETS DEATHS, REBUTTS NON-DISCLOSURE ARTICLE**

*** PROGEN CITES $500k AVEXA BREAK FEE; BLOCKS SINGLE MEETING**

*** POLARTECHNICS EXPANDS CERVISCREEN HOME USE**

*** CSL H1 PROFIT UP 44% TO $502m**

*** GSK'S $20m PUSHES BIOTA $12.8M H1 LOSS TO $7.2m PROFIT**

*** PROBIOTEC POSTS H1 PROFIT UP 73% TO $4.3m**

*** MEDICAL THERAPIES CONVERTS 17¢ NOTES FOR 6.8¢, SHARES**

*** COGSTATE, UNITED BIOSOURCE PART COMPANY**

## MARKET REPORT

The Australian stock market fell 1.48 percent on Wednesday February 18, 2009 with the S&P ASX 200 down 51.1 points to 3,413.2 points. Nine of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and 10 were untraded.

Polartechnics was best, up two cents or 16 percent to 14.5 cents with 921,642 shares traded, followed by Universal Biosensors up 5.78 percent to 48 cents.

Bionomics climbed 5.3 percent; Antisense and Novogen were up more than three percent; Clinuvel rose 2.27 percent; with Cochlear, Phosphagenics and Resmed up more than one percent; and Heartware and Mesoblast up by less than one percent.

Phylogica led the falls, down 1.7 cents or 29.8 percent to four cents with 140,000 shares traded, followed by Peplin down 22.22 percent to 42 cents and Living Cell down 16.7 percent to 10 cents.

Genera lost 9.1 percent; Sirtex fell 7.69 percent; Acrux and Cytopia were down five percent or more; Viralytics fell 4.76 percent; Alchemia and Cellestis were down more than three percent; CSL and Starpharma shed more than two percent; with Avexa and Biota down more than one percent.

## GENESIS R&D

New-Zealand-based Genesis R&D is hoping to raise $NZ4-6 million ($A3.2-4.8 million) to further develop two RNA interference (RNAi) technologies.

In Melbourne to meet investors, potential investors and the media, Genesis chief executive officer Stephen Hall told Biotech Daily that Genesis started as a therapeutics developer became a bio-agriculture company from 1996 to 2004 and has returned to therapeutics.

Mr Hall said he was appointed chief executive officer in December 2004 and the company has sold or licenced its agricultural products, “retaining some royalty streams [which are] economic assets without any funding requirements”.

Mr Hall said the company had $NZ900,000 in cash with a further payment of $NZ700,000 expected from New Zealand’s Inland Revenue Department.

He said Genesis was burning $NZ300,000 a month.

Mr Hall said the company was owed $NZ2 million by the Hong Kong and Singapore-based Pure Power Global since August 2008, as payment for the sale of shares in Biojoule.

Separately, the company has sold its royalty rights to bio-information technology in return for a 10 percent stake in Real Time Genomics, a US-based entity backed by San Francisco venture capital firm Catamount Ventures.

Genesis said in a media release that the Slim Search software was “seeing significant market interest based on its ability to rapidly assemble and query genomic datasets”.

Having licenced or sold off non-core assets, Mr Hall said the company was clearly focused on RNAi therapies.

“We have a preclinical RNAi candidate with in vivo delivery data for intra-tumoral head and neck cancers in mice,” Mr Hall said.

He said the RNAi lead candidate, RRM1, was a small interfering RNA (siRNA) compound.

But he said the company was also pursuing a new technology called single-strand RNA (ssRNA) “which is expected to have better in vivo intracellular delivery compared to siRNA”.

He said the single separate strands of complementary RNA were introduced into the cell like administering a small molecule.

Mr Hall said the data on ssRNA was achieved through fluorescence studies using flow cytometry “showing the single strand RNA cannot anneal outside the cell but can anneal inside the cell”.

He said ssRNA in vivo data was “probably 12 months away”.

Mr Hall said ssRNA degraded over time, unlike short hairpin RNA (shRNA) “which remains in the cell continuing to produce RNA interference for a long period and potentially integrating into the genome potentially affecting future generations”.

Mr Hall said regulators were very concerned with the implications of genome changes.

“Most of the world is chasing siRNA and our single strand RNA is in the same conceptual space,” Mr Hall said.

He said that Genesis had “kept ssRNA under the radar” while completing patenting work, but there had been interest for both technologies from other major players in the area of gene silencing, all from the US.

Mr Hall said that through attending bio-conferences in the US and Europe and taking advantage of the intense partnering sessions, all the major companies were aware of the work Genesis was doing.

Apart from the capital raising, Mr Hall said Genesis expected to sign trade collaboration deals to further develop its technologies.

Genesis has the ASX code of GEN and was untraded at six cents.

VENTRACOR

Ventracor says an article in The Australian newspaper “makes incorrect and misleading allegations regarding the company and its Ventrassist left ventricular assist device”.

The article by Rebecca Urban in yesterday’s Australian focused on Ventracor’s reporting of the deaths of three patients deaths implanted with its heart pump and problems with the percutaneous or through-the-skin-lead (BD: Feb 10,2009).

Today, Ventracor said the February 10 urgent field safety notice regarding the model LVA4 Ventrassist left ventricular assist device (LVAD), catalogue number VA166 was “voluntary and precautionary action” advising physicians not to implant the VA166 until further analysis had been undertaken.

Ventracor said it took this action “as the company always has, and always will, put the safety of patients first”.

“The company denies the allegation made in the article that 11 cases of conductor fracture involved ‘product faults’,” Ventracor said.

“Conductor fracture has been caused in three cases by accidental trauma, such as cutting implements.

“In all the other eight cases, it has now been confirmed that the patients did not wear a lead support belt in accordance with instructions for use.

“The lead support belt is provided to support and protect the lead.

“The company has received no reports of conductor fracture in cases where it is established that patients have fully complied with instructions, including the use of the lead support belt.

“The company is continuing its investigation in close consultation with the Australian Therapeutic Goods Administration,” Ventracor said.

The company said it was “in full compliance with its obligation to make continuous disclosure pursuant to ASX Listing Rule 3.1 [and] takes its obligations under ASX requirements very seriously and requested a trading halt immediately upon the decision to issue the field safety notice”.

Ventracor said it did not have any obligation to disclose the three deaths mentioned in its announcement of February 10 at the time of those individual deaths.

“After informing medical device regulatory authorities, there was no requirement to suspend implants or its clinical trials and, consequently, the company considers that there was no material announcement to be made at the time,” Ventracor said.

“Patients may ultimately die from diverse causes, including their general medical condition.

“Although the company recognizes that such events are distressing for those involved, it does not consider individual deaths disclosable unless they have a material impact on the company’s clinical trials or sales of its product.

“The Ventrassist LVAD is used as a therapy for the treatment of seriously ill patients with end stage heart failure with the purpose of prolonging and improving their quality of life.

“The company’s clinical trial results to date have been outstanding, and met the performance goal specified in the US [bridge-to-transplant] clinical trial,” Ventracor said.

Ventracor said the article in The Australian “incorrectly states that no Ventrassist devices may be used in Australia”.

The company said the field safety notice on the VA166 has not affected its other products such as the LVA3 Ventrassist LVAD, catalogue number VA016, which has been implanted in more than 220 patients worldwide and remains available for sale in Australia and overseas.

Physicians worldwide are continuing to implant the Ventrassist LVAD, Ventracor said.

Ventracor was in a voluntary suspension and last traded at 8.3 cents.

PROGEN, AVEXA, CYTOPIA

Progen has acquiesced to Cytopia's requisitioned general meeting but has restricted resolutions to the replacement of the board, excluding a share buy-back scheme.

The requisitioned meeting will be held on March 27, 2009 and Progen has urged shareholders to oppose the resolutions.

Progen's Avexa merger meeting, scheduled for March 11, was announced last year (BD: Dec 22, 2008) and was followed with a hostile proposal from Cytopia (BD: Jan 28, 2009).

Progen said it was "not satisfied with respect to certain technical matters related to the authority of the signatories to the requisition as submitted to Progen and released to the market by Cytopia" but following subsequently executed documentation and information supplied by the lawyers acting on behalf of the Cytopia shareholder group, Progen concluded it was possible to act on the requisition.

Progen said the resolutions on the share buy back and rescinding previous shareholder approvals were not valid and not competent to be considered by shareholders.

Progen said the Cytopia shareholder group's lawyers "agreed to the buy back resolution not being put and has no objections to the exclusion of the members' explanatory note, as it is now inaccurate".

The only resolutions to be considered at the general meeting are those relating to the removal and appointment of directors, Progen said.

Progen said Cytopia's proposed '100 percent buy back' could not be implemented and a return of all capital could be made through a winding up of the company, but the amounts and timing of any return was "highly uncertain and may be materially less than $1.10".

Progen said the Cytopia shareholder group has said the new directors would consider a merger between Progen and Cytopia but no information has been provided on the merger terms and strategy of the combined group.

Progen said there would be significant legal risks if the new directors, if appointed, took steps which resulted in a breach of the merger implementation agreement with Avexa, such as any attempt to terminate the merger that is not in accordance with the terms of the agreement, including a potential claim for damages substantially in excess of the $500,000 break fee which would be payable to Avexa.

Progen said these Cytopia group proposals were "ill-conceived, ill-defined, highly uncertain and cannot be compared to the potential value which would be created by the Avexa merger".

Progen said it considered a request to hold the Cytopia requisitioned meeting on the same day as the Avexa merger meeting and said "this was not considered legally or practically possible due to the requirement for new directors to give at least 35 business days notice of their nomination and consent under Progen's constitution and the legal issues associated with the original requisitions put forward by the Cytopia Shareholder Group.

Progen said that delaying the merger meeting as requested by the Cytopia group was "not in the best interests of the company".

"All issues relating to a decision on the resolutions ... are before shareholders and there is no reason why that meeting should not proceed as scheduled," Progen said.

Progen said the merger proposal with Avexa had "the potential to deliver value in excess of $1.35 a share" and was in the best interests of shareholders as a whole.

Cytopia's chief executive officer Andrew Macdonald told Biotech Daily that he believes Progen shareholders will defeat the Avexa merger and support the new resolutions spilling the board.

Progen was unchanged at 84 cents.

Cytopia fell half a cent or five percent to 9.5 cents.

Avexa fell 0.1 cents or 1.43 percent to 6.9 cents.

## POLARTECHNICS

Polartechnics self-sampling device, Cerviscreen, has been adapted to test for sexually transmitted diseases.
Polartechnics said the diagnostic could be used to test for Chlamydia, gonorrhoea and trichomoniasis in both men and women and is targeted at sexually active people aged 15 to 50 year.
The company said it provided an opportunity to self-sample for sexually transmitted infections without the need for a prior medical consultation or an invasive physical exam.
Polartechnics said the flocked nylon fibre swab could be uses as to take vaginal, anal or oral swabs or could be uses with urine samples.
The company said Cerviscreen was the world's first commercially available self-sampling device and it would "play a major role" in reducing sexually transmitted infections (STIs) in Australia and worldwide.
Polartechnics said that globally there are more than 340 million new cases of curable STIs in men and women a year with a global market potential of more than 75 million tests a annum, valued at more than $3 billion.
Polartechnics has contracted to sell the device to Gribbles Pathology which is part of the Healthscope group for distribution through Australian.
The company said the results from its device were "identical with those using physician obtained samples" as the same pathology services were used.
The Polartechnics device will be distributed in China and the ASEAN region directly to the public from pharmacies, enabling home based self-sampling.
The STI self-sampling device has been approved for clinical use in Europe, Australia and the US.
Polartechnics is in the process of developing both pathology and distribution contracts in Europe and the US.
Polartechnics said the STI self-sampling device was not technically complicated and high volume production contracts were in existence.
Polartechnics climbed two cents or 16 percent to 14.5 cents.

## CSL

CSL's says its net profit after tax for the six months to December 31, 2008 was up 44 percent to $502 million on revenue up 25 percent to $2.35 billion.
CSL said that after adjusting for currency benefits and non-operational items totaling $44 million net profit after tax was up 24 percent.
Research and development was $153 million or 6.5 percent of revenue.
CSL said diluted earnings per share was up 35 percent to 85.4 cents.
An unfranked interim dividend of 30 cents per share will be paid with a record date of April 9, 2009.
CSL chief executive officer Dr Brian McNamee said that he expected a net profit after tax for the full year to June 30, 2009 between $1.02 billion and $1.06 billion.
"Using fiscal year 2007-'08 constant currency and excluding the benefit of a number of non-operational items this equates to $810 million to $850 million, consistent with guidance at the company's annual general meeting in October last year," Dr McNamee said.
"We continue to believe the result will be toward the high end of this guidance, despite additional research and development investment and a reduction in expectations for Gardasil royalties," Dr McNamee said.
CSL was down 80 cents or 2.14 percent to $36.60 with 2.4 million shares traded.

## BIOTA

Biota says it has had profit after tax for the six months to December 31, 2008 up 31 percent to $7,214,000 but this includes the $20 million payout from Glaxosmithkline.
Biota and Glaxosmithkline settled the case last year (BD Jul 21, Oct 29, 2008) with the lower than expected payment, which took revenue for the six months to $33,561,000 up 10.5 percent on the previous corresponding period.
Discounting the one-off $20 million payment, Biota had an underlying loss of $12,786,000 on underlying revenue of $13,561,000.
Relenza royalties fell from $16,483,000 in the six months to December 31, 2007 to $3,819,000 in the half year to December 31, 2008.
Biota had cash and cash equivalents of $55.4 million at December 31, 2008.
Biota fell half a cent or 1.08 percent to 46 cents.

## PROBIOTEC

Probiotec says its net profit after tax for the six months to December 31, 2008 was up 73.5 percent to $4,267,637 million on revenue up 41 percent to $46.5 million.
Probiotec said diluted earnings per share was 9.01 cents.
A fully franked interim dividend of 1.25 cents per share will be paid with a record date of March 4, 2009.
The company said it had material growth in revenue and earnings in the first half of the 2008-'09 financial year, benefitting from increasing its portfolio of own-branded products.
Growth was achieved in the company's branded products, especially the Celebrity Slim weight loss products and pharmaceutical products provided contributions including the Lomotil, Lofenoxal and Vermox brands.
Probiotec was down eight cents or 5.8 percent to $1.30.

## MEDICAL THERAPIES

Medical Therapies convertible note-holders will be issued 2.55 shares and be paid 6.8 cents for each note, instead of receiving 17 cents per note.
Medical Therapies said it would raise $510,000 through the issue of shares at three cents each and converting notes to fund the cash component of the payment.
The converting notes will be issued at a zero coupon rate and automatically convert into ordinary shares at three cents a share once shareholder approval has been received.
Medical Therapies will call an extraordinary general meeting to seek approval for the conversion in relation to the converting notes.
Medical Therapies has $1.1 million of convertible notes on issue which matured on December 31, 2008 when the company was required to repay the face value of the notes together with any outstanding interest to those note-holders that would not convert.
The notes were issued in December 2006 with a face value of 17 cents and the right to convert to one ordinary share each. Conversion was not an attractive option at the prevailing share prices, and Medical Therapies expected that most of the notes would be redeemed and their face value had to be repaid.
Medical Therapies said holders of 77.2 percent of the notes have accepted the company's proposal, the convertible note deed poll has been amended and the liability will be removed when the ordinary shares are issued and payments are made.
Medical Therapies chief executive officer Maria Halasz said the company would have "a very simple capital structure, which is important … to raise future development funding".
Medical Therapies was untraded at three cents.

## COGSTATE

Cogstate and United Biosource Corp will not renew the strategic relationship initiated in 2008 to co-market and deliver Cogstate's clinical trials software.

Cogstate said it and United Biosource were "committed to supporting cognitive assessment in clinical trials".

Cogstate said the companies recognized that "optimal client service requires the seamless integration of technology, operations, and science delivered as a comprehensive solution".

To meet increased demand, Cogstate will increase resources in both the US and Britain.

United Biosource will continue to support customers in the US, Europe and Japan, providing a full suite of specialty clinical services to ensure measurement precision and data quality within clinical studies, Cogstate said.

Cogstate said it did not expect revenue or profitability for the 2009 financial year would be materially impacted by the decision not to renew the agreement.

For the half year ended December 31, 2008, Cogstate maintained its maiden profit guidance of $1.2 million to $1.3 million net profit after tax, which it expected to confirm on February 25, 2009.

Cogstate fell two cents or 9.3 percent to 19.5 cents.