Biotech Daily

Monday March 9, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: POLARTECHNICS UP 20.5%; NOVOGEN DOWN 22%**

*** PROGEN KILLS AVEXA DEAL; CYTOPIA CLOSER TO PROGEN'S CASH**

*** BIO-GUIDE BRIEF: PROGEN BOARD COPS A KICKING**

*** ARANA PHASE II PSORIASIS TRIAL MEETS PRIMARY ENDPOINT**

*** PAKISTAN BUYS 100 POLARTECHNICS' CERVICAL CANCER CONSOLES**

*** MYMETICS BUYS NORWOOD'S VIROSOME ASSETS FOR UP TO $51.25m**

*** ACRUX COMPLETES PHASE III TESTOSTERONE ENROLMENT**

*** CATHRX CUTS COSTS, UNDER ONE ROOF**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Monday March 9, 2009 with the S&P ASX 200 up 8.9 points to 3,154.5 points.

Nine of the Biotech Daily Top 40 stocks were up, eight fell, eight traded unchanged and 15 were untraded.

Polartechnics was best, up 1.7 cents or 20.5 percent to 10 cents with 346,268 shares traded, followed by Prana up 16.7 percent to 17.5 cents and Progen up 13.6 percent to 87.5 cents.

Peplin climbed 6.5 percent; Nanosonics was up 5.4 percent; Phosphagenics was up 4.8 percent; Resmed climbed 3.5 percent; Alchemia and Arana rose more than two percent; with Acrux up 1.16 percent.

Novogen led the falls, down 11 cents or 21.57 percent to 40 cents with 120,202 shares traded, followed by Phylogica down six percent to 4.7 cents.

Avexa, Cathrx and Clinuvel lost five percent or more; Biota, Cellestis, Cochlear and Sirtex shed more than one percent; with CSL down 0.71 percent.

PROGEN, AVEXA, CYTOPIA

Following the receipt of proxy votes, Progen has withdrawn from its proposed merger with Avexa, leaving Cytopia likely to force its merger and take up to $30 million.

Progen said 83 percent of proxy votes opposed the merger with Avexa and the company had cancelled the merger meeting scheduled for March 11, 2009. Progen has informed the Federal Court hearing an injunction to delay the meeting (BD: Mar 6, 2009).

Avexa's meeting scheduled for March 20, 2009 has also been cancelled, but the meeting called by Progen investors associated with Cytopia will proceed on March 27, 2009 with resolutions to replace the board of Dr Mal Eutick, Patrick Burns, Stephen Chang, chief executive officer Justus Homburg, John Lee and Robert Williamson with independent directors Robert Collins, Dr Damian Pethica and Tom Williams (BD: Jan 28, 2009).

Progen said that "with much reluctance" its directors have, by agreement with Avexa, terminated the proposed merger, which was precipitated by a "decisive" shareholder vote with about 83 percent against, 14 percent voting for the merger with three percent open.

Progen will pay a break fee of $500,000 to Avexa.

Progen said about 48 percent of shareholders voted and the merger failed because of "a voting block of shareholders who seemed to be only interested in a larger return of capital than the $20 million [or] 30 percent of shares proposed in the Avexa merger transaction".

Progen said it would satisfy these shareholders through a $40 million share buyback at $1.10 a share representing 60 percent of the Progen share register or 36 million shares.

Progen said it was "advancing discussions for the regional development of PI-88 in Asia" including specific conversations with the Taiwanese Department of Health, which "indicated a high degree of interest in registering PI-88 in Taiwan because of a high unmet medical need [and] indicated that it is prepared to register PI-88 after the successful completion of a confirmatory locally-executed clinical study".

Progen chief executive officer Justus Homburg said the Progen-Avexa merger "had the potential to give shareholders a return on investment in excess of $2.03 to $3.18 per share based on a discounted cash flow valuation of ATC [apricitabine] alone".

"Unfortunately, we have a voting block of shareholders that are not interested in holding biotechnology shares and instead would like to see their investment realized via a cash return as soon as possible," Mr Homburg said.

He said there was another voting block of shareholders that wanted the company's heparin sulfate technology portfolio progressed "and for this reason we have retained sufficient capital for this purpose".

Mr Homburg said some of the shareholders who voted against the merger wanted to remain in a company focused on commercializing PI-88.

He said that less than 15 percent of the Progen register assigned Andrew Macdonald a proxy for the cancelled March 11, 2009 meeting.

Progen said that $40 million buyback would be put to shareholders on April 21, 2009.

Avexa chief executive officer Dr Julian Chick told Biotech Daily the $500,000 break fee would cover costs.

Dr Chick said he was "disappointed" the merger, which could have brought up to $50 million to his company, had been halted, but would push Avexa's programs forward and pursue partnering opportunities.

Cytopia chief executive officer Andrew Macdonald said he was "pleased we can move forward with some clarity".

Progen climbed 10.5 cents or 13.64 percent to 87.5 cents.

Avexa fell 0.4 cents or 5.48 percent to 6.9 cents.

Cytopia was untraded at cents.

MARC SINATRA'S BIO-GUIDE BRIEF: PROGEN

The board of Progen backed out of its deal to merge with Avexa today when it became clear that the merger would be voted down at the meeting scheduled for March 11, 2009.

Well, voted down is somewhat of an understatement. With 83 percent of the vote against and 14 percent for the merger, Progen's board received fewer votes than George W Bush would if he ran for the presidency of North Korea.

Their new plan is to give shareholders back $40 million dollars via a buy-back and concentrate on developing Progen's current non-cash assets. This is despite the fact that the board said late last year that if it could not find a suitable merger partner within 45 days they would wind the company down.

The shareholders have spoken: they did not find a suitable merger partner. And the promise to wind down the company implied the board saw little, if any value, in Progen's non-cash assets on a stand-alone basis.

But all of a sudden, the board seems to see value in Progen's non-cash assets. This is strange since nothing seems to have happened to dramatically alter their value.

All of this makes Progen's buy-back announcement look more designed to keep the current board in power, rather than a well thought-out strategy for Progen's future.

It is time for Progen's current directors to exit, stage left.

The resounding defeat of their Avexa merger proposal shows they really aren't "in-sync" with their shareholders at all and it is time for a new board with fresh ideas and the ability to formulate a workable plan to maximize the value of Progen's assets.

To be frank, given Progen's last 12 months, I would have thought the current directors would have been looking for a way off the board rather than fighting to stay on it.

Marc Sinatra

POLARTECHNICS

Pakistan has ordered 100 Polartechnics' Truscreen cervical cancer test consoles worth more than $500,000.
Polartechnics said the Pakistan Government forecast a demand for the program of up to 180,000 consumable units in the first six months, bringing the value of the program "to nearly $2 million over the first six months".
The company said the first 25 Truscreen consoles were due to be shipped in March 2009, and the entire order satisfied before the end of April 2009.
Polartechnics said more than 85 million women lived in Pakistan and cervical cancer was the fourth most common cancer in the country.
Polartechnics chairman Robert Hunter said the high mortality rate was "attributed to the late presentation of cervical cancers in Pakistan and by making Truscreen available to the broad populations of Pakistani women will lower the rate".
Mr Hunter said the company was negotiating similar programs in other countries.
Polartechnics has signed distribution agreements with medical companies in Indonesia, Thailand, the Philippines and Sri Lanka.
Polartechnics climbed 1.7 cents or 20.48 percent to 10 cents.

ARANA

Arana says its phase II trial of ART621 in patients with stable plaque psoriasis met its primary endpoint with repeat doses of ART621 being well tolerated.

Arana said ART621 exhibited a safety profile consistent with anti-tumor necrosis factor (anti-TNF) activity, the method of administration and the underlying study population.

Arana said it would continue clinical development of ART621 with two ongoing phase II trials for rheumatoid arthritis in combination with methotrexate.

The company said secondary findings from the study provided insight into the efficacy, immunogenicity and pharmacokinetics of ART621.

Arana said the study was not designed to demonstrate efficacy, but evidence of some anti-TNF activity was seen.

Four subjects in the ART621 group achieved a 50 percent reduction in psoriasis area and severity index score at week 12 compared to zero in the placebo group. One of the ART621 subjects also achieved a 90 percent index reduction.

No human anti-ART621 antibody responses were detected for up to four weeks after the last injection, suggesting inherently low immunogenicity of the drug.

Arana chief executive officer Dr Steffen Nock said the phase II study provided “the confidence to continue clinical development of ART621”.

“The data indicate that ART621 possesses anti-TNF activity, was well tolerated and has a competitive half life,” Dr Nock said. “Importantly we did not see any antibody responses against ART621 and this may be an important differentiator commercially, as other anti-TNF products may have their efficacy reduced by such responses.”

Arana was up three cents or 2.15 percent to $1.425.

NORWOOD ABBEY, NORWOOD IMMUNOLOGY

Norwood Abbey says its 21 percent subsidiary Norwood Immunology will sell its Bestiwel Virosome assets to the Nasdaq-listed Mymetics Inc for up to $51.25 million

Norwood Abbey said Bestiwil was the parent entity of the group holding Norwood Immunology’s Virosome assets. Norwood Immunology is an Australia company listed on London's Alternative Investment Market.

The transaction, subject to approval by Norwood Immunology shareholders, provides for an upfront cash payment of EUR5 million and EUR2.5 million (a total of $A14.8 million) in convertible notes in Mymetics and the issue to Norwood Immunology of options in Mymetics to the value of $US9.6 million ($A14.95 million) along with milestone payments to the value of $11.5 million and ongoing royalty entitlements.

Norwood Immunology said it had out-licencing arrangements with Abbott Laboratories and Solvay for two of its core technology platforms and was in a collaboration with Medimmune for its respiratory syncytial virus virosomal vaccine candidate.

Norwood Immunology said its near term aim was “to secure the future of the company through the divestment of its virosomal vaccine development business and thereafter to create shareholder value via the possible development and provision of both veterinary and human stem cell banking and processing services, as well as the possible provision of veterinary and human stem cell (and immunology based) clinical therapies”.

Norwood Immunology said it was evaluating the commercial opportunities flowing from the potential provision of stem cell processing services as well as the provision of stem cell therapies - initially in the veterinary setting.

The company said its aim was “to develop revenue producing stem cell technologies in the near term”.

Norwood Abbey is in a suspension and last traded at 0.6 cents.

ACRUX

Acrux says it has completed enrolment of 150 hypo-gonadal men for its phase III trial of its testosterone metered dose lotion, Axiron.

Acrux said 60 men had finished the treatment and results from the trial were expected by October, 2009.

The company said that feedback from subjects and physicians was “very positive” and the rate of compliance and acceptance with the treatment had been very high.

Acrux said that as its treatment for testosterone deficiency or hypo-gonadism in men moved closer to market the name Testosterone MD-Lotion had been replaced by the commercial brand name Axiron.

Acrux hopes to submit a marketing application to the US Food and Drug Administration in December 2009. If approved, Axiron is expected to enter the testosterone therapy market in early 2011.

Global sales in this market for the year to March 2008 grew by 20 percent to about $900 million, with testosterone gels comprising $600 million.

Last year Acrux published US market research on patients and physicians, in which two thirds of patients said they would prefer Axiron to their existing gel treatment and 87 percent of physicians said that they would offer Axiron to their existing gel patients.

Acrux chief executive officer Dr Richard Treagus said the commercial value of Axiron increased as the company executed each element of its development program.

“We anticipate completing the phase III trial on schedule and in parallel we will continue to engage the FDA as well as prospective marketing partners,” Dr Treagus said.

Acrux said the commercial manufacturing arrangements for Axiron were “a key part of the marketing applications to regulatory authorities”.

In parallel with the phase III trial, Acrux was transferring the manufacturing process to Orion Corp in Europe, which will be the exclusive source of supply for Axiron. The transfer and scale-up of the process has been completed and Orion is preparing for manufacture of registration batches.

Acrux said 27 sites in the US, the UK, Sweden, France, Germany and Australia were participating in the open-label trial.

The primary objective is to demonstrate that Axiron restores average blood levels of testosterone into the normal range and the main trial treatment period is four months, during which blood samples are analyzed.

Acrux said more than 50 men at the US sites were continuing treatment for two months to monitor skin safety with six months continuous treatment.

Axiron has been designed to overcome significant issues with current gel treatments. Large volumes of gel are applied by hand and rubbed on to the upper torso, shoulders or arms. They are considered messy, sticky, slow-drying and may have an unpleasant odor.

One of the biggest drawbacks is the risk of transference to other people through direct skin contact or from residue left on the hands following application.

Axiron is faster-drying and pleasant smelling and is applied to the armpits once daily, using a no-touch applicator designed in Australia.

Acrux climbed half a cent or 1.2 percent to 43.5 cents.

CATHRX

Cathrx will consolidate its manufacturing and production facilities and close its Redfern Technology Park facility.

Cathrx said the move followed European certification of its Homebush manufacturing facility by TUV Rheinland (BD: Mar 2, 2009).

Cathrx chief executive officer Neil Anderson said the TUV certification meant that any approved devices manufactured at Homebush could be sold in Europe.

"The Homebush facility alone has capacity to meet our forecast sales and clinical trial requirements," Mr Anderson said.

Along with the move Cathrx said it was "streamlining its operations to position itself prudently for the current economic conditions".

The company said cost savings and equipment financing benefits would lower the cash break even point by $2.4 million.

Cathrx chairman Denis Hanley told Biotech Daily that 17 of the 65 staff members would not be required at the new facility, but new staff would be appointed as product sales increased.

Mr Anderson said the staff numbers were being adjusted "to meet our needs going forwards".

Mr Hanley and Mr Anderson said the break-even point of 18 months would be through taking a share of the $400 million European market.

They said they hoped Cathrx would eventually build to a five percent to 10 percent share of the European market.

They said they would prefer to be cash-flow positive before going to the US Food and Drug Administration for regulatory approval.

In its media release Cathrx said its current break even point would occur in 18 months time and would require $5 million of new capital.

The company said it intended to raise the capital through a rights issue in the next six months.

Mr Hanley said in the media release that the $5 million requirement "almost exactly equals the value of a grant application that the company had lodged when the Federal Government surprisingly eliminated grants to Australian technology businesses in the first half of 2008".

Cathrx fell two cents or five percent to 38 cents.