# Biotech Daily

Thursday November 13, 2008

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECHS DOWN: LABTECH UP 29%, POLARTECHNICS DOWN 16%**

*** PROGEN TO GIVE HALF ITS CASH TO SHAREHOLDERS**

*** FIVE PATRYS PRODUCTS SHOW CANCER THERAPEUTIC POTENTIAL**

*** INDEPENDENT COMMITTEE BACKS NOVOGEN'S CANCER TRIAL**

*** 42% OF CLINUVEL OPPOSE DIRECTOR L JACK WOOD'S 350k OPTIONS**

*** AVEXA PRESENTS PAPERS ON HIV, ANTIBACTERIAL PROGRAMS**

*** ARANA LOSS UP ON REVENUE UP 14% TO $39.5m**

*** ARANA'S US PRESIDENT PROMOTED TO ACTING CEO**

*** 42% OF PROTEOME OPPOSE CEO'S PERFORMANCE RIGHTS**

*** STEM CELL'S 2nd ASX CASH FLOW QUERY: FUNDS EXPECTED**

## MARKET REPORT

The Australian stock market tumbled 5.4 percent on Thursday November 13, 2008 with the All Ordinaries down 211.2 points to 3,672.4 points.

Five of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and 11 were untraded.

Labtech was best, up 3.5 cents or 29.17 percent to 15.5 cents with 99,800 shares traded, followed by Genetic Technologies up 23.33 percent to 7.4 cents and Novogen up 22.5 percent to 98 cents. Progen climbed 4.13 percent with 1.3 million shares traded; Chemgenex was up 0.92 percent with 1.1 million shares traded; and CSL was up 0.14 percent.

Yesterday's best, Polartechnics, led the falls, down 1.4 cents or 15.73 percent to 7.5 cents with 100,000 shares traded, followed by Optiscan down 9.09 percent to six cents.

Living Cell lost 8.11 percent; Avexa, Cathrx and Impedimed fell more than seven percent; Acrux, Circadian, Clinuvel, Pharmaxis, Stem Cell and Viralytics were down five percent or more; Universal Biosensors and Ventracor fell more than four percent; Biota, Cellestis and Cochlear were down more than three percent; Psivida and Resmed shed more than two percent; with Arana down 1.27 percent.

PROGEN

Progen will return 50 cents a share (currently trading at 63 cents), will consider an acquisition or merger and further review its pipeline of oncology compounds.

Progen said its board was “acutely aware that there has been considerable shareholder disquiet about the future direction of the company since we discontinued the PI-88 phase III trial (see Biotech Daily; July 23, 2008).

Progen released a summary of a review of the company by the Sydney-based corporate advisory firm Beerworth & Partners saying the board agreed the measures would be “fundamental in accomplishing … the restoration of Progen in the market” and supported the outcomes of the review.

Progen said it had received proposals from different companies including potential merger proposals or expressions of interest.

“All of the proposals received were incomplete and are not in sufficient detail to warrant disclosure of specific terms,” Progen said. “Some were, in the opinion of the board, not capable of proper consideration or implementation.”

With the review completed, Progen said it would give further consideration to the proposals and investigate whether there is potential for a transaction which is in shareholders' interests.

“In the absence of any alternative proposal being in the interests of shareholders, the following is endorsed by your board as the way forward for Progen to restore its position in the market,” Progen said.

Progen said it raised about $100 million primarily to support PI-88 development and its phase III trial. Progen's cash reserves will be about $70 million by February 2009.

Beerworth & Partners recommended a capital return of 50 cents a share equating to $30.2 million or 43percnet of estimated cash reserves at February 2009.

Shareholder approval will be required for this capital return.

This would up to three years of the estimated capital and operational funding requirements for delivering the remainder of the strategy, below.

The capital return realizes some value for shareholders, but if there is greater value in alternative proposals, then the board will recommend that path.

Beerworth & Partners said Progen had a strong pipeline of oncology compounds and projects and an excellent technical team and recommended independent assistance in prioritizing the development of this pipeline.

An independent and commercially experienced life sciences expert will assist Progen’s management to review the inventory of compounds and projects to determine which should be developed, terminated or sold.

Progen said financial and economic events greatly reduced market prices and this is an “opportune environment” to consider a synergistic acquisition or merger.

Progen's business model has focused on the registration and commercialization of a single compound, PI-88. Progen's future emphasis would be on the development of a balanced portfolio of compounds and projects and licencing an appropriate partner before commencing any future phase III trial.

Progen said Beerworth & Partners found that the market restoration of Progen would involve an assurance that it has appropriate board, management and technical teams and recommended that an external organization with appropriate expertise help ensure this.

A “task force” including external advisers will review Progen’s corporate governance and risk management systems to ensure best practice protocols and procedures.

Progen will hold its annual general meeting at the Indooroopilly Golf Club in Brisbane on November 24, 2008.

Progen was up 2.5 cents or 4.13 percent to 63 cents with 1.3 million shares traded.

PATRYS

Patrys says five of its lead natural human antibody products “effectively prevented the spread of cancer in preclinical studies”.

Patrys said independent researchers at Germany’s University of Wurzburg’s division of surgical oncology found that in preclinical studies designed to test the ability to prevent the spread of colon cancer to the animal’s liver, 35 percent of the 20 animals treated with lead product PAT-LM1 developed metastases, whereas 85 percent of the 20 animals in the control group developed metastases.

The company said PAT-LM1 was scheduled to enter human clinical trials in 2009.

Patrys said the researchers evaluated four additional Patrys lead products in studies designed to evaluate a product’s ability to prevent the spread of gastric cancer to an animal’s bone marrow and blood, referred to as “recurrence” or “minimal residual disease”.

Patrys said in aggregate, 38 percent of the 47 animals treated in these studies with Patrys products developed minimal residual disease, whereas 73 percent of the 48 animals in the control group developed minimal residual disease.

Patrys said its PAT-SM6 was scheduled to start human clinical trials in 2009 and was “one of the most potent antibodies tested in the gastric cancer studies”.

Surgical oncologist at the University of Wurzburg Dr Bertram Illert, one of the lead investigators for the studies, said the consistency of the results over a significant number of animal experiments “points to the great promise of natural human antibody-based therapies to prevent metastases and recurrence, where products on the market offer little promise.”

“The anti-cancer benefits of natural human antibodies were also seen in the results obtained from a human clinical trial that we conducted with another product developed by Patrys technology, PAT-SC1, where 35 gastric cancer patients treated with a small dose of PAT-SC1 obtained a survival benefit relative to a historic control group of untreated patients,” Dr Illert said.

“In fact, we have just seen one of those treated patients who lived seven years cancer-free, with no recurrence, where without treatment his life expectancy was 15 months,” Dr. Illert said.

Dr Illert also conducted the PAT-SC1 human clinical trial.

Patrys said PAT-SC1 was one of several products generated using Patrys’ natural human antibody technologies that are being developed by larger industry companies, in this case Astrazeneca, the success of which would bring returns to the company.

Patrys head of research Dr H Peter Vollmers said effective treatments could be established by identifying and developing antibodies made by the human immune system that effectively attack and kill cancer cells – as a supplement to cancer patients’ own natural anticancer immunity.

“The positive results from this series of studies provide broad support for this approach,” Dr Vollmers said.

Patrys’s vice-president of research and development Dr Frank Hensel said that all five of the products “demonstrated the ability to prevent the spread of cancer in these preclinical studies” and each product did so through distinct mechanisms, meaning each product kills cancer cells in a unique way.

“Our team and collaborators will continue to study those differences to determine the best clinical uses for each product,” Dr Vollmers said.

Patrys was unchanged at 10 cents.

## NOVOGEN

Novogen says an independent committee has recommended continuing US 72 percent subsidiary, Marshall Edwards' phase III ovarian tumor trial.

Novogen said independent data monitoring committee overseeing the conduct of the phase III ovarian tumor response (Ovature) trial, has recommended continuation of the multi-center trial of orally-administered phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs.

The trial intends to determine phenoxodiol's safety and effectiveness when used in combination with carboplatin.

The committee is responsible to ensure that patients recruited to the study are not exposed to unnecessary safety risks, that the study continues to meet its clinical objectives, that it is run according to the required standards and that recruitment progress is satisfactory.

Novogen said that following yesterday's review of recruitment progress, as well as safety and efficacy data, the committee recommended that the study remains open and continue as planned towards its accrual target of 340 patients.

Novogen's group director of research Prof Alan Husband said that at the time of the committee meeting, 78 patients had completed the study and "a substantial data set was made available for review".

"While site recruitment was slower than expected in the early stages of the study, we now have 75 sites involved and the pace of recruitment has increased significantly," Prof Husband said.

"We will continue to apply all possible strategies to ensure the study continues towards its interim and final analysis endpoints," Prof Husband said.

The trial is recruiting ovarian cancer patients whose cancer initially responded to chemotherapy, but has since become resistant or refractory to traditional platinum treatments.

Patients are being recruited at clinical sites in the US, Europe and Australia.

Novogen said the trial has been approved by the US Food and Drug Administration under a special protocol assessment program, indicating that the study's design, clinical endpoints and statistical analyses are acceptable to the FDA.

The protocol provides for an interim analysis of the data, which, if statistically significant, can be used to support a request for accelerated marketing approval.

An analysis of interim results will be possible after the targeted patient recruitment to this study is completed and 95 patients have disease progression.

More information about the trial is at www.ovaturetrial.com.

Novogen climbed 18 cents or 22.5 percent to 98 cents.

## CLINUVEL

A large minority of shareholders have opposed the issue of 350,000 options to director L Jack Wood.

While other resolutions were passed more easily, Clinuvel received 17,608,441 proxy votes opposing the options issue with 14,477,035 proxy votes in favor.

Following a poll of votes the resolution was passed by 24,670,565 votes (58.3%) to 17,646,865 votes (41.7%).

The remuneration report was opposed by 5,892,657 proxy votes with 25,701,790 proxy votes in favor.

The reelection of directors Dr Roger Aston and Mr Wood were passed overwhelmingly.

Clinuvel fell 1.5 cents or 5.88 percent to 24 cents.

## AVEXA

Avexa says peer-reviewed detailed results from its phase IIb trial of apricitabine have been presented at an HIV conference in Glasgow.

Avexa chief executive officer Dr Julian Chick told Biotech Daily the poster and presentation at the Ninth International Congress on Drug Therapy in HIV Infection provided peer-reviewed detailed results from the trial (see Biotech Daily; March 12, 2008) held in Glasgow, November 9-13, 2008.

Avexa said in its media release it also presented data on its antibacterial program at the Interscience Conference on Antimicrobial Agents and Chemotherapy and the Infectious Diseases Society of America meeting in Washington, DC, October 25-28, 2008.

The apricitabine data demonstrated the drug "provided significant and durable antiviral activity over the 48-week treatment period, with a favorable safety profile and no evidence of resistance development".

Avexa said sustained and improved responses in viral load and CD4 cells were seen from week 24 to week 48 and the greatest improvements were seen in patients switching from 3TC (lamivudine) to apricitabine (ATC) at week 24 nearly, doubling their CD4 cell increase from week 24 to 48, but they still lagged behind those receiving ATC for the full 48 weeks.

Dr Chick told Biotech Daily that ATC would be useful to patients resistant to 3TC as well as having the capacity to be a stand alone drug or used in combination with generic AZT (zidovudine) as 3TC is.

Avexa said in its media release that data from its antibacterial program showed "the potent in vivo antibacterial activity" of its lead antibacterial candidate AVX13616, particularly against drug-resistant Staphylococcus pathogens.

AVX13616 was as active as mupirocin in a nasal decolonization model but required only a single application.

Avexa said the compounds were being developed for topical indications and/or wound infection/catheter-related infections.

"The data demonstrate that this class of compounds, represented by our lead compound AVX13616, possesses strong bactericidal activity in particular against gram-positive pathogens such as Staphylococcus aureus," Dr Chick said.

Avexa said a single application of 5% AVX13616 (about equimolar to 2% mupirocin) was as effective as 2% mupirocin administered twice a day for five days in nasal decolonisation of methicillin-resistant Staphylococcus aureus in mice.

Avexa fell one cent or 7.41 percent to 12.5 cents.

## ARANA

Arana has reported an increased loss for the 12 months to September 30, 2008 on revenue from continuing operations up 14.2 percent to $39,491,000.

Arana's preliminary final report is complicated by the previous year's sale of Domantis for $136.1 million as well as the Evogenix acquisition.

The bottom line loss attributable to member for the year to September 30, 2008 of $4,092,000 is compared to a profit the previous year of $133,414,000 which includes the $136.1 million. Discounting the Domantis sale would have given Arana a loss in the previous year of $2.7 million.

The 2008 loss figure also includes $488,000 received from the sale of the animal health business.

Revenue from sales licencing and royalties increased from $24,745,000 to $25,699,000 with interest up $4 million.

Arana fell one cent or 1.27 percent to 77.5 cents.

## ARANA

Arana Therapeutics has appointed its head of US operations Dr Steffen Nock as acting chief executive officer.

Last week Arana announced the unexpected resignation of chief executive officer Dr John Chiplin saying he wanted to return to the US (see Biotech Daily; November 6, 2008).

Arana said Dr Nock was president of Arana Therapeutics Inc based in San Francisco.

Dr Nock holds a PhD in biochemistry from Bayreuth University, Germany.

Prior to joining Arana he held senior positions with Evogenix, Absalus and Zyomyx as well as a research position at Stanford University.

Arana chairman Robin Beaumont said Dr Nock would relocate to Australia for six months and the company would commission "an international search for a permanent CEO".

## PROTEOME

Proteome's annual general meeting saw strong division over 1.1 million performance rights to chief executive officer Dr Jenny Harry and the company remuneration report.

The performance rights resolution was passed by 72,700,814 proxy votes (57.8%) to 53,132,993 proxy votes (42.2%).

The remuneration report was opposed by 49,600,783 proxy votes with 73,350,416 proxy votes in favor.

The reelection of directors Dr Caroline Popper and a prior approval of shares were passed overwhelmingly, but a proposed name change to Tyrian Diagnostics and constitution amendment was passed by 110.5 million proxy votes in favor and 15.5 million against.

Proteome was untraded at six cents.

## STEM CELL SCIENCES

Stem Cell Sciences has told the ASX that it expects sufficient funds from fee-generating research, licence fees and the sale of its media business to continue operations.

The ASX noted a cash burn of $2,174,000 for the quarter ending September 30, 2008 with cash of $1,636,000 at the end of the quarter and total receipts of $102,000.

Stem Cell said its restructure had been completed and the company had announced "the first of what it is anticipated to be a number of such announcements" that it had an agreement with the CHDI Foundation to support the standardization of CHDI's novel mouse embryonic stem cell lines (see Biotech Daily; November 10, 2008).

Stem Cell said it had also announced the creation the first authentic rat embryonic stem cells "which led to immediate commercial interest from a number of organizations".

"It is expected that at least one of these should lead to cash generating licence deals before the end of the year," the company told the ASX.

The company said it was pursuing infringers of its intellectual property and had secured a licence deal worth $US750,000 over six years (see Biotech Daily; November 12, 2008).

Stem Cell said it intended to complete the sale of its SC Proven media business by the end of the year "which would ensure the company has sufficient funds to continue to trade at the current level of operating expenses even without any additional sales".

Stem Cell Sciences fell one cent or five percent to 19 cents.