



Biotech Daily

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Daily news on ASX-listed biotechnology companies

LATE BREAKING NEWS: According to Bob Moses of the group seeking to depose the Progen board, Dr Stanley Chang has accepted that he would have a conflict of interest in any negotiations over PI-88 and has withdrawn his candidacy for election as a Progen director. See lead article.

- * **ASX UP, BIOTECHS DOWN: TYRIAN UP 33%, LIVING CELL DOWN 47%**
- * **PROGEN, MEDIGEN, \$70m IN CASH & A \$2m MILESTONE PAYMENT**
- * **OPTISCAN IN ROBOTIC PROSTATE SURGERY TRIAL**
- * **FDA CLEARS SUNSHINE HEART US TRIAL**
- * **2 ALCHEMIA DIRECTORS QUIT; AGM OPPOSITION TO OPTIONS**
- * **BENITEC'S LAWYERS REVIEW USPTO 'FINAL OFFICE ACTION'**
- * **PSIVIDA AGM BACKS DIRECTORS BUT NOT THEIR OPTIONS**
- * **HALCYGEN COMPLETES PIVOTAL TRIAL DOSING**
- * **KARMELSONIX' CLOSE VOTES, OUTGOING DIRECTOR APPROVED**
- * **GOLDMAN SACHS AND TYRIAN DIAGNOSTICS**

MARKET REPORT

The Australian stock market climbed 1.6 percent on Friday November 21, 2008 with the All Ordinaries up 54.3 points to 3,386.9 points. Seven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and five were untraded.

Tyrian (Proteome) was best, up one cent or 33.33 percent to four cents with 110,000 shares traded, followed by Polartech up 16.67 percent to seven cents and Viralytics up 12.5 percent to 4.5 cents. Mesoblast climbed 6.25 percent; Genetic Technologies was up 4.0 percent; Cochlear was up 3.68 percent; Biota rose 2.74 percent; with Ventracor up 1.3 percent.

Living Cell led the falls on no news, down 5.2 cents or 37.14 percent to 8.8 cents with 723,311 shares traded, followed by Sunshine Heart down 23.08 percent to five cents and Novogen down 21.11 percent to 71 cents. Neuren lost 18.57 percent; Acrux fell 16 percent; Impedimed shed 15.38 percent; Antisense was down 14.29 percent; Clinuvel fell 12 percent; Benitec lost 9.09 percent; Cellestis, Chemgenex, CSL and Starpharma fell six percent or more; Optiscan and Sirtex were down more than five percent; Bionomics, Labtech, Pharmaxis and Prana fell four percent or more; Resmed and Phosphagenics were down more than three percent; with Universal Biosensors down 1.75 percent.

PROGEN

Progen's annual general meeting on Monday November 24, 2008 will be more interesting than most, with investors hoping to hear details of the story behind the proposed coup. Earlier this month a group of investors holding just under five percent of the company sought to requisition a meeting to oust Progen's existing board including chief executive officer Justus Homburg (see Biotech Daily; November 10, 2008).

The shareholders calling for the meeting were Shu-Hui Hu, Fu-Ying Wang, Fu Mei Wang, and the Lambert Super Fund and proposed the removal of directors Dr Mal Eutick, Robert Williamson, Stephen Jun Chi Chang, Patrick Owen Burns and Justus Homburg.

The coup group called for the replacement of those directors with Antisense chairman Robert (Bob) Moses, former Progen director Dr Stanley Chang and former EG Capital executive Alison Coutts, now with Martin Place Securities and Dr Woei-jia Jiang.

Dr Stanley Chang is a former Progen director, a position that came with Progen's relationship with the Taiwan-based Medigen, which conducted the phase II trial of PI-88 for liver cancer.

Dr Stanley Chang is the chief executive officer of Medigen and not to be confused with Mr Stephen Chang who was a founder of Progen and remains a non-executive director of Progen, but also served as chairman of Medigen.

In 2007, Progen bought back its 15 percent royalty rights to PI-88 held by Medigen so it could have total control of the drug (see Biotech Daily; January 19, 2007).

Earlier this year Progen, having begun a phase III trial and having failed to find a major pharmaceutical company deal to partner PI-88, discontinued research into the compound (see Biotech Daily; July 23, 2008).

Progen said at the time that after expenses it had about \$66 million in cash.

There has been intense speculation in the biotechnology sector and elsewhere about what could be done with that cash.

On November 11, sources close to the coup group detailed their proposals for Progen to Biotech Daily and on November 13, Progen released the key points of the Beerworth and Partners review of its operations.

Both Progen and the coup group proposed the populist policy of returning some of the cash to shareholders, selling or licencing non-core assets and reviewing corporate governance issues.

The only significant point of difference was that apart from a different team running the company, the coup group wanted to proceed with further development of PI-88.

The coup group claimed to have a "term sheet" agreement from a potential licensee for Progen's liver cancer drug, PI-88.

Biotech Daily is intrigued whether Progen's existing management had held or had not held discussions with the third party potential licensee of PI-88.

Biotech Daily finds it most interesting that people separate from the company, such as the coup group, have been able to reach an in-principle agreement.

One matter that has emerged this week is that although the coup group includes Medigen's chief executive officer Dr Stanley Chang as a potential director, Medigen's 2,096,482 share holding (3.47%) was not included in the requisition of meeting notice, meaning that the combined voting strength of the group is more than 8.5 percent.

The other matter that emerged from a series of conversations this week is that Medigen would benefit if PI-88 could be licenced.

According to Progen's 2008 annual report: "There remains \$2,000,000 to be paid on a defined PI-88 commercialization milestone or transaction event being achieved."

The requisitioned meeting is due to be held before January 14, 2008.

Progen was unchanged at 59.5 cents.

OPTISCAN

Optiscan says it has begun a trial using endomicroscopy during minimally invasive robot assisted surgery for prostate cancer.

Optiscan said recruitment was underway at Westlake Medical Center in Austin, Texas after receiving approval for the study from the Austin multi-institutional review board.

The company said prostate cancer was the most common solid tumor in men, with 1 in 11 men at risk of developing prostate cancer in their lifetime.

About 40 percent of patients undergo radical prostatectomy to remove the prostate gland as part of their treatment.

Optiscan said robot assisted prostatectomy provided surgeons with superior visualization of nerves and allowed extremely precise dissection of tissues surrounding the prostate.

The company said that due to the complex nature of the surgical procedure and anatomical structures involved, nerve damage during prostatectomy was possible and could result in undesirable complications such as erectile dysfunction and urinary incontinence.

The need remains for further improvements to tissue identification during surgery, to lower the risk of undesirable post-operative outcomes.

Optiscan said its confocal endomicroscopy allowed real-time microscopy to be performed on living tissue.

The company said it provided high resolution, cellular and sub-cellular imaging and was in use in gastrointestinal endoscopy.

The potential for confocal endomicroscopy to enhance microscopic nerve identification during robot assisted prostatectomy would be evaluated in the 30 patient feasibility study.

The surgery will be performed by Dr Randy Fagin using the Da Vinci surgical robot system.

The study is scheduled for completion in 2009.

Optiscan fell 0.4 cents or 5.97 percent to 6.3 cents.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration has granted full approval to begin the first US clinical trial of C-Pulse for moderate heart failure.

Sunshine Heart said that in September it received conditional approval from the FDA to begin the US clinical trial of its aorta cuff pump (see Biotech Daily; September 12, 2008).

The company said the conditional approval permitted it to start its US clinical trial, but it required several conditions relating to the clinical protocol, patient record keeping and device labeling.

Sunshine Heart said it had addressed the conditions to the satisfaction of the FDA.

The company's chief executive officer Don Rohrbaugh said institutional review board approval was being finalized, along with contractual arrangements with the six approved clinical centers.

"We are still anticipating patient enrollment to commence this year," Mr Rohrbaugh said.

"It should be noted that C-Pulse is the first approved heart assist system to enter into a FDA approved clinical trial for the unmet clinical need of moderate heart failure patients," he said.

Sunshine Heart said the clinical centers for the C-Pulse clinical trial are all university-based teaching hospitals with a heart failure focus.

Sunshine Heart fell 1.5 cents or 23.08 percent to five cents.

[ALCHEMIA](#)

Alchemia says directors Prof Peter Andrews and Dr Julian Clark have resigned as part of its cost-cutting measures effective from today's annual general meeting.

The company cut staff by 60 percent last month (see Biotech Daily; October 28, 2008).

There was strong opposition to the granting of 500,000 options to chief executive officer Dr Pete Smith as well as the cancelled resolution proposing 100,000 options to each director.

Both resolutions received more than 20.7 million proxy votes against with more than 30.5 million proxy votes in favor.

The remuneration report and the re-election of chairman Mel Bridges were clearly passed, but with more than 9.08 million and 7.1 million votes proxy votes against.

Alchemia was unchanged at 14.5 cents.

[BENITEC](#)

Benitec says the US Patent and Trademark Office has provided a 'final office action' on the patent re-examination of the '099 Graham patent.

Benitec said it was reviewing the action in detail.

The company said progress towards allowance had been made with the successful withdrawal of three of the novelty rejections, but two others have been maintained as well as an obviousness rejection.

At this time the full details of this office action are still being reviewed and legal advice is being sought from our advisors, Benitec said.

Benitec said it and the Commonwealth Scientific and Industrial Research Organisation have the right to appeal.

The company said its patents and patent applications in other countries were not directly affected by the action which was based on US patent rules.

Benitec chief executive officer Sue MacLeman said the company was "confident that its gene silencing intellectual property claims will be secured through the reexamination of the '099 patent and these related patents or patent applications."

"This backward-and-forwarding between the patent office and the patent owner is usual in high profile [intellectual property] cases," Ms MacLeman said.

"While this Graham patent is important, it should be remembered that Benitec has 98 patent applications and granted patents in the RNAi space and additional IP that it has licensed," Ms MacLeman said.

"While this patent is under review in the US, we have six other related applications to pursue these claims in the US," she said

Benitec fell 0.3 cents or 9.09 percent to three cents.

[PSIVIDA](#)

Psivida's directors were all elected and re-elected unopposed but significant numbers opposed director's options and an increase in directors' pay.

More than 9.29 million proxy votes supported the election of directors David Mazzo, Dr Paul Ashton, Paul Hopper, Michael Rogers and Peter Savas with no votes against.

But the approvals of options for Dr Ashton and other directors were opposed by more than 1.02 million proxy votes and supported by more than 4.9 million proxy votes.

Increasing the maximum aggregate annual cash to directors was supported by 7.48 million proxy votes and opposed by 1.3 million proxy votes.

Psivida was unchanged at \$1.55.

HALCYGEN

Halcygen has completed recruitment and dosing of the second of three pivotal pharmacokinetic studies of its anti-fungal drug Suba-itraconazole.

The trial is under a US Food and Drug Administration approved investigational new drug application comparing Suba-itraconazole to the market's leading product Sporanox (itraconazole).

Halcygen chief executive officer Dr Roger Aston said the company had completed the recruitment and treatments for the second key study aimed at establishing steady state pharmacokinetics of the drug.

"We remain well on track with our registration program," Dr Aston said.

"We expect to complete the dosing and analysis of the final pharmacokinetic study before Christmas with a view of revisiting the FDA for guidance in the first quarter next year," Dr Aston said.

Halcygen said it had clinically evaluated Suba-itraconazole in five pharmacokinetic studies in Australia, demonstrating demonstrated the Halcygen formulation significantly improved bioavailability or absorption by the gastrointestinal track, compared with the market leader, enabling the use of a lower dose of the drug, the company said.

Halcygen was untraded at 18.5 cents.

KARMELSONIX

Nine of 14 resolutions put to the Karmelsonix annual general meeting were potentially close votes. Two withdraw resolutions would have passed overwhelmingly.

On resolutions relating to the reelection of directors and the issue of options and shares to directors and others, between 7.4 million and 10.4 million proxy votes were against the resolutions with between 13.5 million and 17.1 million proxy votes in favor.

But in all cases more than 60 million proxy votes were cast at the chair's discretion.

The two resolutions withdrawn before the meeting related to the reelection of director Nadaisan Logaraj and the issue of 1,000,000 options to him.

Proxy votes gave an overwhelming vote in favor of Mr Logaraj as a director and with more than 25.0 million proxy votes supporting him and just 56,065 opposed.

Mr Logaraj had the support of 22.9 million proxy votes for his 1,000,000 options.

The opposition was chiefly to the election of Prof Noam Gavriely and Dr Nathan Intrator as directors, along with the issue of stock to IBA Business Consultants, Green Wolf Pty Ltd, Inteq Ltd, Trafalgar Capital, JBCI Holdings and directors Dr Intrator and Dr Henry Pinski. Karmelsonix climbed one cent or 7.69 percent to 1.4 cents.

TYRIAN DIAGNOSTICS

A ceasing substantial notice purporting to be from Goldman Sachs Group Inc says the group sold 11,360,000 Tyrian shares for \$2,726,000 on November 18, 2008.

The notice related to shares allegedly held by Irrewarra Investments but the sale price of 24 cents a share indicated the notice might have been submitted to the ASX in error.

Goldman Sachs was unable to clarify the position on Friday afternoon.

Tyrian was up one cent or 33.33 percent to four cents.