

# Biotech Daily

Wednesday January 28, 2009

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: ALCHEMIA UP 27%, SUNSHINE HEART DOWN 21%
- \* CYTOPIA MAKES UNCAPPED BID FOR PROGEN'S CASH
- \* BIOGUDE BRIEF: CYTOPIA COULD CREATE A BETTER PROGEN PARTY
- \* COGSTATE CASH FLOW POSITIVE; 6 MONTHS PROFIT
- \* QRX TO BEGIN KNEE RECONSTRUCTION PAIN TRIAL
- \* ATCOR SIGNS \$1.3m TRIAL CONTRACTS
- \* FLUOROTECHNICS EXPECTS POSITIVE CASH BALANCE IN 2009
- \* TISSUE THERAPIES HAS ONE QUARTER CASH; \$3.4 m RIGHTS ISSUE
- \* ENTRUST INCREASES TO 6% OF PROGEN

#### MARKET REPORT

The Australian stock market climbed 1.5 percent on Wednesday January 28, 2009 with the S&P ASX 200 up 51.5 points to 3,495.5 points.

Nine of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and 12 were untraded. All three Big Caps were up.

Alchemia was best, up three cents or 27.27 percent to 14 cents with 67,000 shares traded, followed by Impedimed up six cents or 9.09 percent to 72 cents.

Psivida climbed 4.17 percent; Biota, Circadian, Pharmaxis, Resmed, Ventracor and Viralytics rose more than two percent; with Avexa, CSL and Cochlear up more than one percent.

Sunshine Heart led the falls, down 1.5 cents or 21.43 percent to 5.5 cents with 6,000 shares traded, followed by Novogen down 15.48 percent to 71 cents and Universal Biosensors down 15 percent to 51 cents.

Benitec and Phosphagenics both lost 9.52 percent; Chemgenex was down 6.98 percent; Acrux and Clinuvel fell more than four percent; with Progen down 2.35 percent.

## CYTOPIA, PROGEN, AVEXA

Cytopia has made a bid for Progen's estimated \$70 million in cash offering an uncapped share buy-back and claiming greater synergies than the proposed merger with Avexa. Progen raised the funds primarily for its phase III PI-88 liver cancer trial which was discontinued (BD: Jul 23, 2008).

In November a group of Progen investors including the Taiwan-based Medigen attempted to spill the board and replace it with directors including former EG Capital executive Alison Coutts and Antisense chairman Bob Moses (BD: Nov 10, 2008).

The coup attempt, included a plan to build a major cancer compound company, but failed earlier this month. Investors holding about 50 percent of Progen's 60 million shares voted and the existing board was supported by about 20 million votes to 10 million votes (BD: Jan 16, 2009).

Meanwhile, the proposed merger with Avexa was announced (BD: Dec 22, 2008) offering a return of capital at \$1.10 a share to shareholders capped at \$20 million, providing the remaining funds to the merged entity to continue developing Avexa's phase III HIV compound, apricitabine or ATC. Shareholder meetings of the two companies to support that merger are expected in March.

Cytopia said today that a meeting has been requisitioned to replace the board with independent directors Robert Collins, Dr Damian Pethica and Tom Williams.

In a media conference Cytopia's chief executive officer Andrew Macdonald said his company held less than one percent of Progen but he had the required five percent to requisition a meeting.

Mr Macdonald said he had spoken to a range of Progen investors and there was "not strong support for the merger" with Avexa.

Cytopia is developing early stage anti-cancer compounds

Mr Macdonald said the institutions primarily wanted their money back.

Biotech Daily has been told that institutional shareholders including Entrust, Manifest Capital and Northcape among others are believed to primarily want their cash back and would back whichever proposal returned the greatest amount of money.

Mr Macdonald said that Cytopia was not only interested in the remaining cash that would come from a merger, but that Progen had early stage anti-cancer compounds that would be of benefit to Cytopia's pipeline, including Progen's 500 series. He also said there could be value to be unlocked in PI-88 and that the Progen team had "some excellent clinical capabilities".

Mr Macdonald said the three independent directors would review the merger proposals which have not been detailed at this stage.

He said Progen should hold the meeting to consider his company's resolutions at the same time as the meeting to consider the Avexa merger to give shareholders the greatest choice.

The key resolutions are an uncapped offer of \$1.10 per share; replacement of the board with three independent directors elected on a platform of exploring a merger between Cytopia and Progen.

Progen chief executive officer Justus Homburg told Biotech Daily the company would evaluate the Cytopia proposal, but said "the merger with Avexa provides the greatest opportunity to shareholders" of the proposals evaluated so far.

Avexa's chief executive officer Dr Julian Chick told Biotech Daily he had no comment to make and documentation for investor meetings would be provided in the near future. Cytopia was unchanged at 11 cents.

Progen fell two cents or 2.35 percent to 83 cents.

Avexa was up 0.1 cents or 1.45 percent to seven cents.

## MARC SINATRA'S BIOGUIDE BRIEF: PROGEN-AVEXA MERGER

Although not explicitly stated, Cytopia has announced what, I guess, comes down to a hostile merger with Progen.

After about a minute of consideration, I was able to come to the firm conclusion that Cytopia's proposal was vastly superior to Progen's current proposed merger with Avexa. The simple reason is that I think Progen's shareholders will do better to spend their cash on Cytopia than on Avexa.

Avexa essentially has one main project in apricitabine, which is closer to market than any of Cytopia's project's, but negative signals having been dripping off apricitabine for a while a now (BD: Dec 22, 2008) and Progen's cash still won't get apricitabine to market.

In contrast, Cytopia has a compound in a phase II trial for glioblastoma multiforme, an inhibitor of Janus kinase (JAK) 2 for which an investigational new drug application is about to be lodged and a licencing and research and development collaboration with Novartis covering JAK 3. The only real negative signal coming from these projects is a delay in Novartis' milestone payment, which was due in the second quarter of last year.

Another factor in Cytopia's favor is that merging two small molecule cancer companies is likely to create an awful lot more synergies than merging a cancer company with an infectious diseases company.

From a Cytopia shareholder's point view, the potential merger appears to be a no brainer pending the fine detail. But, even if applications for the share buy-back are dramatically higher than expected, a merged Progen and Cytopia should still have plenty of cash to accelerate Cytopia's very promising development projects while the vast majority of companies are scaling back their activities.

There is a lot of water to pass under the bridge before a Progen-Cytopia merger becomes a reality, but I think inclusion of the resolution allowing Progen shareholders unlimited participation in the share buy-back probably tips the scales in favor of a merger with Cytopia.

If I were a Progen shareholder, I wouldn't be selling any of my shares into the buy-back.

Marc Sinatra

## COGSTATE

Cogstate has reported its second profitable quarter in a row with receipts from customers for the three months to December 31, 2008 of \$2,473,874.

Cogstate chief executive officer Brad O'Connor told Biotech Daily that it was the second consecutive profitable quarter and the company was cash flow positive and ex[pected to remain so.

Cogstate has announced a series of significant contracts by major pharmaceutical companies to use its cognitive testing system.

Mr O'Connor said the company would release a profit guidance statement to the market in February.

Cogstate posted total operating and investing cash flows for the quarter of \$691,088 with cash in the bank of \$2,776,674.

Cogstate was up five cents or 33 percent to 20 cents with 314,500 shares traded.

#### **QRX PHARMA**

QRX Pharma says a pilot study to determine the clinical profile of its dual opiod Moxduo IR (intra rectal) for pain following total knee replacement will begin next month.

QRX said data collected from this study would be used to support final phase III trials required for new drug approval submission to the US Food and Drug Administration.

The study is targeted to enroll 45 patients and is being conducted at three US clinical research sites.

The company said it expected to complete dosing prior to July 2009.

QTX said that "to mitigate approval risk" associated with the two remaining phase III study protocols for Moxduo IR, it had decided to submit requests for special protocol assessment with the FDA.

The special protocol assessment process provides a mechanism for the company to achieve a binding agreement with the FDA regarding the acceptability of the study design and proposed statistical analysis plan prior to implementation of the clinical trial.

In December 2008 QRX submitted its "combination rule" phase III study protocol to the FDA for special protocol assessment approval.

The double-blind study is intended to compare Moxduo IR 6mg/4mg to its components (to 6mg morphine and to 4mg oxycodone) in patients with moderate to severe post-surgical pain following bunionectomy.

QRX said it expected a response from the FDA no later than March 2009 and expected to file in mid-2009, after completion of the 45 patient pilot comparator study, the special protocol assessment for the other phase III study, a placebo controlled study in patients following total knee replacement.

QRX said it had made progress with its other clinical pipeline candidates and preclinical stage drugs including a clinical trial designed to evaluate the safety and efficacy of the intravenous formulation Moxduo IV (intravenous) for the immediate post-surgical treatment of hospital-based pain, comparing up to 48 hours of dosing of morphine plus oxycodone to that of intravenous morphine alone is scheduled to begin in Germany in March 2009, comparing the two treatment regimens for pain management in 40 patients with moderate to severe pain following hip replacement surgery.

Moxduo CR (continuous release) is a formulation designed to provide 12 hours of pain relief in patients with moderate to severe pain and continues on track to begin phase I studies in 2009, QRX said.

This formulation will encompass not only sustained delivery technology, but also technologies to deter abuse and tampering.

QRX said its Dystonia and Parkinson's disease development program (Torsin) with a family of small molecules was making progress under a collaborative research agreement at the University of Alabama (Caldwell Labs) to confirm the preclinical efficacy of its lead molecules.

In October 2008 the University announced the award of an undisclosed amount of grant funding from the Michael J Fox Foundation to its Centre for Neurodegeneration and Experimental Therapeutics to validate Torsin A in mammalian models as a therapeutic target for Parkinson's disease.

QRX said business development efforts continued with its venomics platform to secure strategic relationships for development of venom-derived coagulants.

QRX was up one cent or four percent to 26 cents.

# ATCOR MEDICAL

Atcor has signed agreements valued at \$US860,000 (\$A1.3 million) to supply Sphygmocor systems to a US biotechnology company and a pharmaceutical company. Atcor said Sphygmocor was a central blood pressure measuring systems and the deals included clinical trial support services. t

The company said the minimum total value of the contracts was \$US650,000 for the US biotechnology company and \$US210,000 for the large pharmaceutical company. Atcor said the new orders brought the minimum total value of pharmaceutical trial contracts secured in the past eight months to more than \$US6.5 million.

Atcor chief executive officer Duncan Ross said the company was "producing strong growth despite a tough macro-economic environment".

Mr Ross said the contracts showed the importance of Sphygmocor as a tool for understanding drug efficacy and mechanisms of action in clinical trials. Atcor climbed 1.5 cents or 9.09 percent to 18 cents.

#### **FLUOROTECHNICS**

Fluorotechnics says that despite appearing to have one quarter cash in its Appendix 4C quarterly report it expects positive cash flow for the rest of 2009.

In the quarterly report to the ASX, Fluorotechnics said it had a net operating cash burn of \$1,732,407 for the three months to December 31, 2008 and cash at the end of the quarter of \$1,378,698.

Company chairman Rick Taylor told Biotech Daily that funds from the initial public offer were used to fund the acquisition of The Gel Company, meet one-off costs and fund expanding production capacities and other expansion operating costs.

Mr Taylor said the cash flow for the last quarter was "not a reliable indicator of future cash outgoings and receipts".

He said the company updated its sales projections on December 18, 2008 and projected forward its cash position.

"This projected that the Fluorotechnics group should have positive cash balances throughout the remainder of the 2009 financial year and expects to have increasing monthly cash balances starting early in the 2010 financial year," Mr Taylor said. Fluorotechnics fell five cents or 5.26 percent to 90 cents.

## **TISSUE THERAPIES**

Tissue Therapies has enough cash to continue operations for three months and has announced a rights issue to raise \$3.4 million.

Tissue Therapies said in its Appendix 4C quarterly report that it had a total operating and investing cash burn of \$469,700 for the three months to December 31, 2008 and cash at the end of the quarter of \$324,000.

The company's chief executive officer Dr Steven Mercer said costs had been reduced and the amount would cover the costs for one quarter.

At the same time the company announced a one-for-two rights issue at 12 cents a share a 33.3 percent discount to last night's 18 cents close

The funds are to continue its Vitrogro wound therapy treatment trial in Canada and Australia, as well as funding the commercial scale manufacturing of Vitrogro.

The record date is February 10, 2009 with a closing date of February 27, 2009.

Tissue Therapies said ABN Amro Morgans Corporate was lead manager for the offer.

Tissue Therapies fell two cents or 11.11 percent to 16 cents.

PROGEN Entrust Funds Management increased its substantial shareholding in Progen from 3,053,871 shares (5.05%) to 3,691,127 shares (6.1%) on January 27, 2009.