Biotech Daily

Thursday July 24, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN: PROGEN UP 12%, AGENIX DOWN 30%**

*** BIOGUIDE: CYTOPIA - FLYING UNDER THE RADAR**

*** BIOTA'S RELENZA ROYALTIES TUMBLE FOR 3 MONTHS TO JUNE 30, 2008**

*** LANDLORD WITH 4% SHANGHAIS AGENIX $16.5 m CHINA DEAL**

*** STEM CELL CASH BURN $3.1m, CASH LEFT $3.7m**

*** ATCOR $1.6m DEAL FOR SPHYGMOCOR IN US & EUROPE**

*** FMR, FIDELITY DROPS ANOTHER 1% OF COCHLEAR**

*** FMR, FIDELITY DROPS 1% OF CSL**

*** USCOM: 'REVENUE UP COSTS DOWN'**

*** ADVANCED SURGICAL IN PATENT BATTLE WITH PORTLAND**

*** SOUTHAM INCREASES TO 18% OF RESONANCE**

*** GENETIC TECHNOLOGIES REFUTES GENE TEST MEDIA REPORTS**

*** ROCKEBY ENDS 6m BIRD FLU TEST DEAL**

MARKET REPORT

The Australian All Ordinaries Index climbed 0.5 percent on Thursday July 24, 2008, up 26.8 points to 5,188.4 points. Nine of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and eight were untraded.

Progen was best, up seven cents or 12.7 percent to 65 cents with 2.0 million shares traded. Neuren climbed 8.33 percent; Redmed rose 6.74 percent; Antisense and Living Cell were up more than five percent; Acrux, Biota and CSL were up more than three percent; with Clinuvel, Novogen and Prana up more than one percent.

Agenix led the falls, down 0.9 cents or 30 percent to 2.1 cents with 8.4 million shares traded, followed by Polartechnics down 10.34 percent to 13 cents and Benitec down 8.57 percent to 6.4 cents. Phosphagenics lost 5.26 percent; Alchemia fell 4.92 percent; Cellestis and Viralytics were down more than three percent; Bionomics, Impedimed and Mesoblast shed more than two percent; with Circadian down 1.73 percent.

MARC SINATRA'S BIOGUIDE: CYTOPIA

Overview: Cytopia is a Melbourne-based drug discovery and development company with core competencies in kinase biology and rational drug design.

With results from a phase II trial for its lead cancer drug due by the end of the year, a drug for several myeloproliferative disorders close to clinical trials and a $274 million deal with Novartis under its belt on an undisclosed project (see below) the fact that Cytopia is trading at a market capitalization of just $7 million above its cash in the bank seems ridiculous. Why does Cytopia continue to fly underneath investors' radar?

Financials: Market cap: $17 million; cash: $11 million; last half year cash burn: $3.8 million.

Directors: Non-executive chairman, Bob Watson; chief executive officer and managing director, Andrew Macdonald; non-executive directors, Dr Kevin Healey, Roderick Lyle, Mark Rowsthorn, Dr Geoffrey Vaughan.

Cytopia's board has done well, but it needs reshaping with more significant industry expertise and international pharmaceutical development experience being a priority.

Products in Development:
1) CYT997: Currently in a phase II trial for multiple myeloma with data analysis to commence in September. A phase II trial in glioblastoma was scheduled to commence last quarter. CYT997 is a vascular disrupting agent and is thought to break down tumor vasculature. It is also thought to have a direct cytotoxic effect. A phase I study of an oral version of CYT997 is underway.

2) CYT387: With animal studies proving positive, Cytopia expects to lodge an investigational new drug application with the US Food and Drug Administration by the end of the 2008. CYT387 is an inhibitor of Janus Kinase 2 (JAK2), which has been shown to be continually active in several myeloproliferative diseases.

3) JAK3 inhibitors: Subject of the 2006 licencing deal with Novartis. As part of the deal, little information can be released by Cytopia, although it is currently being developed for prevention of transplant rejection, with opportunities for rheumatoid arthritis (RA) and other autoimmune diseases. JAK3 is mainly expressed by haematopoietic cells. This is important for targeting inflammatory diseases and lessening side effects.

4) An early JAK2 project for pulmonary hypertension is ready for out-licencing, as is a project targeting the macrophage colony stimulating factor receptor.

Significant Product Markets: Vascular disrupting agents are new drugs, and markets and their sizes are purely theoretical. Sales of Avastin, a drug which inhibits the growth of new tumor vasculature, had worldwide sales of US$2.45 billion in 2007.

Three VDAs are in phase II/III or phase III trials, all combined with other drugs. Oxigene has Zybrestat in a trial for thyroid cancer and Sanofi-Aventis has AVE8062 in a study for soft tissue cancer. Novartis has ASA404, which it licenced from Antisoma in an $890 million deal, in a trial for non-small cell lung cancer.

Initial indications for CYT387 are likely to be polycythemia vera (PV, over production of red cells) and essential thrombocytopenia (ET, over production of platelets). The US prevalence of these diseases in 2003 was 65,243 and 71,078, respectively.

At least two other companies have JAK2 inhibitors in development. Exelixis hopes to start a phase I trial of XL019 later this year, while Incyte's INCB018424 is in a phase I/II trial for PV and ET. Given the nature of PV and ET, JAK2 inhibitors are unlikely to command the price of a $30,000 a year drug like Gleevec, which is also in a phase II PV study.

In regards to JAK3 inhibitors, one percent of the world's population has rheumatoid arthritis (RA), with global organ transplants expected to reach 700,000 a year by 2010. The global market for RA drugs in 2007 was $13 billion and Cytopia says the transplant drug market is $3 billion.

There are at least two other JAK3 inhibitors in development. Notably, Pfizer has CP-690 550 in phase II and III trials for RA, and in phase II trials for the prevention of transplant rejection. Rigel Pharmaceuticals has R348 in phase I trials for RA.

Opinion: Few, if any, ASX listed companies have a pipeline equal to Cytopia's. While Cytopia's compounds are behind those of many of their competitors, the company is operating solely in promising new areas and is close enough to find itself in the box seat should a competitor's older compound fail or prove not as efficacious. Moreover, ample room exists in each area for multiple drugs, lessening risk.

CYT997 and the Novartis collaboration could bear very substantial fruit. However, the biggest potential is in the JAK2 program, where Cytopia has patent protection on its compound and the target. A deep-pocketed partner could use this to rein-in competitors and dictate terms as it sees fit. This is an exceedingly good place to be.

The major reason Cytopia has flown under the radar is that, despite a recent raising through Lodge Partners, it has engaged infrequently in capital raising through Australian brokers. These raisings generate an invariably positive analyst report, broker support and, thus, interest in the company. But they can be of limited use for small companies because they often only provide part of what they need.

While Cytopia's pipeline and management are first rate, to become a major player on the Australian scene it needs to find a considerable amount of cash, additional directors highly experienced in key areas and a network of associations capable of supporting the company as it develops. This would be best achieved if they brought a specialist fund or funds onto the register, which could provide all of these things at once.

Using a mix of comparables and discounted cash flow analysis, I believe Cytopia should be trading at a price of 84 cents a share.

Cytopia was untraded at 21 cents.

Marc Sinatra's Bioguide
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BIOTA

Biota says indicative royalties from Glaxosmithkline's sales of Relenza for the three months to June 30, 2008 were $400,000 on sales worth $6.2 million.

For the full year to June 30, 2008 Biota said indicative royalties totaled $21.3 million on sales worth $304.4 million.

Biota said that adjusting for a previous overpayment the company would receive $20.5 million of the $21.3 million indicative royalty.

For the three months to June 30, 2007 Biota received $11.1 million. Full year Relenza royalties were $39.8 million compared to $5.2 million in the year to June 30, 2006.

Last year Biota chief executive officer Peter Cook said "the fourth quarter figures imply a continuing overall trend of an increase in production capacity" (see Biotech Daily July 26, 2007).

In today's announcement Mr Cook said the most recent quarter's low indicative royalty "reflects the off season in the Northern hemisphere".

"Biota and GSK recently concluded their litigation and we look forward to the normalization of our relationship and developing the Relenza franchise," Mr Cook said.

Biota was up 2.5 cents or 3.73 percent to 69.5 cents.

AGENIX

Agenix is taking measures against the parties representing the vendors of its Shanghai operations, seeking immediate completion of the acquisition agreement.

Last year Agenix Biopharmaceutical (Shanghai) bought the businesses of two associated Chinese companies, Shanghai Rui Guang Bio-Pharma Development (SHRG) and 96 percent of related company, Shanghai Yi Sheng Yuan Pharmaceutical (YSY) (see Biotech Daily June 6, 2007).

When first announced the deal was valued at $16.5 million in cash and shares (see Biotech Daily; February 14, 2007).

At that time Agenix said that for strategic reasons, the Economic Association of Zhou Pu Town, Nanhui District, Shanghai, the township in which YSY's factory and operations are located would remain a four percent shareholder in YSY.

Agenix chief executive officer Dr Stephen Phua told Biotech Daily from Shanghai the problem was failing to receive a waiver for the completion of the share transfer from the four percent shareholder, who is also the landlord.

"The vendors undertook to get the waiver," Dr Phua said.

"We are awaiting a waiver from the four percent shareholders to allow for completion of the share transfer," he said. "The sale of the 96 percent is done; we need the waiver for completion. "We never thought this would be a problem," Dr Phua said.

He said the contract was issued under the law of the Peoples' Republic of China and the next step was to go to the local authorities for arbitration.

Agenix fell 0.9 cents or 30 percent to 2.1 cents with 8.4 million shares traded.

STEM CELL SCIENCES

Stem Cell Sciences says its cash burn for the three months to June 30, 2008 was $3,094,000 and it has cash in the bank of $3,725,000.

Stem Cell's chief executive officer Dr Alastair Riddell told Biotech Daily the extraordinary cash burn included all restructuring and redundancy costs.

He said the company had cash for more than two quarters without revenue.

Stem Cell Sciences was untraded at 35 cents.

ATCOR MEDICAL

Atcor Medical says it has signed two agreements worth $1.6 million to supply its Sphygmocor system to an unnamed pharmaceutical company.

Atcor says the Sphygmocor system non-invasively measures central blood pressures and arterial stiffness. The company said Sphygmocor visibly identified the effects of reflected blood pressure in the central aortic pressure wave which cannot be detected with standard blood pressure monitoring.

Atcor said the new orders brought the minimum total value of pharmaceutical trial contracts to more than $2.8 million in the past 60 days.

Atcor chief executive officer Duncan Ross said the company's pharmaceutical sales had grown and over the past two months it had "executed significant new contracts in the US and Europe".

"This demonstrates the increasing importance of Sphygmocor as a tool for understanding drug efficacy and mechanisms of action," Mr Ross said.

Atcor climbed 2.5 cents or 25 percent to 12.5 cents

COCHLEAR

The US based FMR Corp and Fidelity Investments has again reduced its substantial shareholder in Cochlear from 3,679,963 shares (6.62%) to 3,053,811 shares (5.49%) on July 1, 2008.

FMR Corp and Fidelity reduced its holding in Cochlear by one percent on June 4, June 13, June 25, June 30, 2008.

FMR and Fidelity had been increasing its holding in both Cochlear and CSL.

This is the fifth reduction in Cochlear since Biotech Daily began monitoring the holdings.

For the first time FMR and Fidelity has also reduced its CSL holdings by one percent (see below).

Cochlear fell 18 cents or 0.38 percent to $47.04.

CSL

The US based FMR Corp and Fidelity Investments has reduced its substantial shareholder in CSL from 74,508,665 shares (13.54%) to 68,863,871 shares (12.51%) on July 22, 2008.

CSL climbed $1.13 or 3.31 percent to $35.28.

USCOM

Uscom says its unaudited 2007-'08 financial year result of $960,000 is a 10 percent increase over 2006-'07.

The company said it had a 30 percent decrease in cash burn to less than $1.9 million, leaving a cash balance of $2.5 million.

Uscom said 150 of its ultra sonic cardiac output monitors (Uscom) 1A units had been installed world wide providing "critical mass" in its target markets.

Uscom chief executive officer Paul Butler said the company was "well advanced in marketing partnership discussions to accelerate US market access".

Uscom executive chairman and director of clinical science Rob Phillips said evidence was driving paediatric departments, emergency departments, intensive care units and anesthesia to adopt the technology.

Uscom was untraded at 26 cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE
PORTLAND ORTHOPAEDICS

Advanced Surgical Design & Manufacture and Portland Orthopaedics are in dispute over a claim of patent infringement.

Advanced Surgical said a June standstill agreement with Portland to facilitate negotiations had expired and it would take legal action to protect its Hip Cup patent.

The company said it had been in negotiations to find a commercial outcome to alleged infringements by Portland against Advanced Surgical's Hip Cup patent, granted in May 2008, as well as a related US patent dating back to 2001.

Advanced Surgical's chief executive officer Dr Greg Roger told Biotech Daily that his company's design "allows more even loading around the replacement cup".

He said the product was yet to demonstrate that it worked.

"They developed a similar design," Dr Roger said. "Our patent family dates back to 2001."

Portland Orthopaedics chief executive officer John Brassil told Biotech Daily that the dispute had been ongoing for 18 months involving Portland's previous chief executive officer David Sekel. Mr Brassil said there were no commercial negotiations.

"Our position is very strong that we don't infringe," Mr Brassil said. "Our US patent attorneys have done a significant analysis and there's no merit at all to the claim."

"To suggest we're in commercial negotiations is just nonsense," he said.

"I can't understand what's going on because we can't get any specific details of what has been infringed," Mr Brassil said.

Advanced Surgical said in a media release to the ASX the patent infringement was not material to its operations, but the technology was valuable and the company "must retain the right to deal in intellectual property developed by [it] in any and all markets in which [it] operates".

Advanced Surgical lodged a patent infringement case against Portland in California in June 2008.

The case deals with Portland's Equator Cup and alleged infringements against both of Advanced Surgical's hip cup patents.

Advanced Surgical said it reserved its rights with regard to the patent infringement case but would continue to seek a commercial outcome.

The company said that in addition to the manufacture and sale of medical devices, its business included the potential commercialization of its technologies, such as the Hip Cup, via out-licencing or sale.

Advanced Surgical said the Hip Cup was not one of the eight products which it has in production or development, either directly or in collaboration.

It is one of 16 patent families held by ASDM.

"In the absence of a resolution of the matter, we have commenced this process, and will pursue it, to protect our valuable intellectual property," Advanced Surgical said.

Advanced Surgical climbed five cents or 14.29 percent to 40 cents.

Portland was unchanged at 2.3 cents.

RESONANCE HEALTH

Southam Investments has increased its substantial shareholding in Resonance Health from 23,347,955 shares (6.5%) to 65,014,622 shares (18.1%).

Queensland Investment Corporation ceased its substantial holding in Resonance Health yesterday, selling its 68,000,000 shares or 19.62 percent of the company to existing investors (see Biotech Daily July 23, 2008).

Resonance was untraded at 1.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says enforcement of its intellectual property rights to BRCA1 and BRCA2 gene tests will not restrict research nor increase the price of tests.

Genetic Technologies said earlier this month it would enforce its exclusive intellectual property rights to BRCA1 and BRCA2 genetic tests for hereditary breast and ovarian cancer (see Biotech Daily; July 11, 2008).

The company said it was responding to media reports following its July 11 announcement.

Genetic Technologies said it would offer its own diagnostic service to patients who may have an inherited predisposition to developing breast and ovarian cancers.

The company said its testing service was unrelated to research undertaken in the public sector.

The company said health care providers in Australia and New Zealand had "comparatively low prices compared to other countries".

Genetic Technologies said it was not changing its pricing and was "looking forward to negotiating mutually satisfactory arrangements" with state health authorities.

Genetic Technologies chief executive officer Michael Ohanessian said the company's earlier decision not to enforce patent rights had been at a considerable cost over the last five years.

"The beneficiaries have been laboratories that have been shielded from paying any licence fees," Mr Ohanessian said.

"Genetic Technologies on the other hand continues to carry the financial commitment for its exclusive rights to the patents," Mr Ohanessian said.

"Given that we now offer an excellent service, we believe it is time to revisit that arrangement," he said.

"We are confident that centralizing testing in our Melbourne laboratory will improve the quality and efficiency of testing services," Mr Ohanessian said.

Genetic Technologies said on July 11 that it was delivering a turnaround time "of just four weeks, in stark contrast to certain other laboratories that, according to the Human Genetics Society of Australasia's 2006 Quality Assessment Program for Molecular Genetics, had an average turnaround time of up to 11 months".

Genetic Technologies was untraded at 8.6 cents.

ROCKEBY BIOMED

Rockeby says an agreement to supply six million avian influenza tests to an undisclosed South East Asian country has been withdrawn.

Rockeby said the decision was made on the basis that it had "not received any payments in advance for the first purchase order", as stipulated under the non-binding memorandum of understanding (see Biotech Daily; January 31, 2008).

Rockeby said that it has received more recently orders for its tests from several South East Asian, European, and North African countries worth a total of $US230,000 ($A242,000).

Rockeby chief executive Dr Sze-Wee Tan said the payment for the orders had been received and the tests had been delivered or were in the process of delivery.

Rockeby fell 0.1 cents or 12.5 percent to 0.7 cents.