Biotech Daily

Tuesday September 15, 2009

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market edged up 0.2 percent on Tuesday September 15, 2009 with the S&P ASX 200 up 9.2 points to 4540.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and six were untraded. All three Big Caps were up.

Living Cell was best, climbing 3.5 cents or 21.9 percent to 19.5 cents with 1.6 million shares traded, followed by Biota up 13.5 percent to $2.52 with 2.45 million shares traded.

Viralytics climbed eight percent; Alchemia and Psivida were up seven percent or more; Cytopia was up four percent; Benitec, Cochlear, Genera and Progen rose more than two percent; with Chemgenex, Nanosonics and Resmed up more than one percent.

Genetic Technologies led the falls, down 0.9 cents or 15.25 percent to five cents with 40,000 shares traded, followed by Prana down 2.5 cents or 11.9 percent to 18.5 cents.

Antisense lost 8.9 percent; Sunshine Heart was down seven percent; Phylogica, Sirtex and Tyrian fell more than four percent; Universal Biosensors was down 3.85 percent; Tissue Therapies shed 2.3 percent; with Acrux, Heartware, Novogen and Starpharma down by more than one percent.

MARC SINATRA'S BIOGUIDE: GENERA BIOSYSTEMS

Overview: Genera Biosystems was one of the few life sciences company floats to get up in 2008 and, with its share price 60 percent above the offer price, Genera investors should be happy in a difficult market.

While not the only application for its technologies, Genera is firmly focused on the human papilloma virus (HPV) testing segment of the cervical cancer screening market.

This is a potential multi-billion dollar market segment that is developing quickly, but a significant number of players are already out there.

What does Genera need to do to succeed?

Financials: Market cap: $48 million; cash: $3.3 million; last quarter cash burn: $726,000.

Directors: Non-executive chairman, Fernando Careri; chief executive officer, Dr Allen Bollands; non-executive directors Mel Bridges, Mr David Symons William Tapp; executive director, Dr Karl Poetter.

Genera's board is solid, without being spectacular. Mel Bridges is the shining light, but given his other commitments may be spread a bit thin.

Products in Development:

1. Paptype: a diagnostic for the simultaneous detection and genotyping of HPV in cervical smear samples based on Genera's Ampasand Bead technology (described below). Paptype identifies the 14 high risk and two low risk HPV genotypes. A recently completed retrospective study involving 894 abnormal Pap smear samples found a nine percent false negative rate for Paptype compared to 21 percent for the market leading test, Qiagen's Hybrid Capture 2, results consistent with an earlier pilot study.

Genera expects to complete three further clinical studies of Paptype during 2009, including one in a true screening population. The company also hopes to obtain Australian and EU marketing approval and complete a worldwide or regional licensing deal by the end of 2009. US FDA approval is penciled in for 2011-'12, but is likely to be the responsibility of a licencee.

2. Ampasand Bead Technology: this technology employs a standard flow cytometer to sort color and size-coded micro-beads that are coated with probes to specific analytes, so that a combination of beads mixed with a single sample can be used to test for multiple analytes at one time. After Paptype, Genera intends to develop a test for the sexually transmitted diseases Chlamydia trachomatis and Neisseria gonorrhoea.

3. QSand: an optical detection system based on whispering gallery modes, whereby changes in the emission spectrum of probe coated translucent beads upon binding of an agent can be used to identify the agent. An important feature of this technology is that signal amplification is not required.

Significant Product Markets: The American Cancer Society estimates that there will be 11,270 new cases and 4,070 deaths from cervical cancer in the US this year. Worldwide these numbers are thought to be 473,000 and 253,500, respectively, 85 percent of which are in developing countries.

The National Cancer Institute estimates that 55 million Pap tests are performed per year in the US, with 3.5 million (6%) returning an abnormal result. Worldwide, it is thought about 120 million pap tests are done each year.

It is difficult to ascertain the current size of the HPV testing marketing, with global estimates ranging around $US250-$350 million.

There are several HPV tests already on the market. The most notable are Qiagen's Hybrid Capture 2 and Hologic's Cervista HPV HR. Both are FDA-approved for certain cervical cancer screenings. The Hybrid Capture 2 test garnered sales of $US135 million for the first nine months of the 2007 financial year.

Opinion: Given the nature of the diagnostics industry, it seems likely that for Genera to be successful, Paptype must be successful.

On that note, there is an air of inevitability that HPV testing will continue to play an increasingly larger role in cervical cancer screening in years to come. HPV testing alone, however, is not a perfect screening tool and the area and how HPV testing is used in it, will continue to evolve.

If it evolves such that precise genotyping information is of major importance in cervical cancer screening, Genera's prospects would seem extremely good.

Given the present situation, however, I think it will be the quality of the partner that Genera attracts for Paptype that will be the biggest determinant of its success, rather than the relative advantages or disadvantages of Paptype compared to competitors.

A quality partner is required to give Paptype a foothold in what is likely to become an increasingly competitive environment, where no company has a knockout technology and marketing is a key.

Such a partner would also bode well for Genera, because once the market has accepted one product based on the Ampasand technology, acceptance of following products should be much easier.

Paptype is worthy of a licencing deal with a major player and the signing of any such deal would be a major value uplift point for the company.

For now, I see the company as pretty good buying and have given it a valuation of $1.05 per share based on comparables.

Genera was up two cents or 2.5 percent to 82 cents.

Marc Sinatra's Bioguide
marc@biotechdaily.com.au

PHOSPHAGENICS

Phosphagenics says a phase I trial of its transdermal oxycodone patch delivered the pain drug into the blood stream “in a reproducible, consistent and sustained manner”.

Phosphagenics said the transdermal delivery of oxycodone was a world’s first and the drug continued to be released from the skin to the bloodstream for four days after the patch was removed.

Earlier this year Acrux discontinued its transdermal Fentanyl trial citing regulatory hurdles as too high to be commercially viable (BD: Feb 2, 2009).

Phosphagenics said oxycodone was a leading opioid for pain management, which was “more potent than morphine [but] produces less adverse side effects”.

The company said that oxycodone could only be administered orally or intravenously and it intended to become the first company to offer chronic pain sufferers, such as cancer patients, an oxycodone gel or patch that would provide sustained pain relief.

Phosphagenics said the global market for oxycodone was $US1.5 billion a year.

Phosphagenics said the eight patient trial showed that the patch delivered about 40mg of oxycodone into the body over a seven-day period.

The company said subjects were given a single dose of the drug using the company’s matrix patch which was removed three days after application.

Phosphagenics said, that at that point, the oxycodone plasma concentrations were still increasing, suggesting that they had not peaked at the time of patch removal. The company said oxycodone delivery into the blood continued for four days after the patch was removed, showing the depot effect of its patented carrier system within the skin.

Phosphagenics said the trial was designed to assess the absorption profile of oxycodone in a matrix patch following a single administration, to acquire information necessary to obtain ethics approval for the repeat dose study.

The company said that only one of its proprietary patches was used and the planned repeat dose study would be conducted on both the matrix and reservoir patch systems to determine the best patch for the phase II and III clinical trials.

Phosphagenics research and development vice-president Dr Paul Gavin told Biotech Daily, the trials were expected later this year and the matrix was a scaffolding system into which the ingredients could be combined including Phosphagenics’ tocopheryl phosphate mixture or TPM and the active pharmaceutical ingredient - in this trial, oxycodone.

Phosphagenics said the open label, single centre study was conducted at the Royal Adelaide Hospital with University of Adelaide’s anaesthesia professor Prof Guy Ludbrook as principal investigator.

Prof Ludbrook said the results were “exciting” and the patch appeared “potentially very suitable for chronic pain management”.

He said oral oxycontin gave pain relief for “a matter of hours” but the oxycodone patch might “provide sustained drug delivery for a matter of days, thus removing some of the peaks and troughs of pain relief associated with oral treatment”.

Phosphagenics chief operating officer Dr Esra Ogru said “the results are a world first and represent the potential of a significant breakthrough in the treatment of chronic pain”.

“Our next trial, scheduled to be completed before the end of this year will involve a repeat daily dosing study and will examine oxycodone blood levels over a longer period.”

Dr Ogru said that all opioids had similar molecular structures and it was “possible that a successful oxycodone program could be applied to many other opioids in a market whose sales exceed US$6 billion annually”.

“We are also in the final stages of submitting our US [investigational new drug application] for our formulated oxycodone,” Dr Ogru said.

Phosphagenics was unchanged at 11 cents with two million shares traded.

AVITA MEDICAL

Avita chairman Dalton Gooding and chief executive officer Dr William Dolphin are on a roadshow to rehabilitate the company's image, not to raise funds.

In Melbourne, Mr Gooding and Dr Dolphin told Biotech Daily that the company had sufficient funds for its programs and had "made tremendous progress" but needed to get the message through to investors that the company required re-rating.

In May Avita won a $US1.45 million ($A2 million) grant from the US Armed Forces Institute of Regenerative Medicine for its Recell wound treatment and in July announced a $5 million Fortrend draw-down facility (BD: Jul 20, 2009).

"The company has made tremendous progress," Dr Dolphin said.

"We've had a major clean-up of the company. The manufacturing operations had too many layers and we have had major infrastructure cost savings," Dr Dolphin said.

He said the manufacturing of the profitable Breath-A-Tech asthma mask and spacer division had been moved to Malaysia, while the Recell wound treatment kit was being manufactured by Ventrix in Southern California.

"Sales are moving well on both Recell and Breath-A-Tech," he said.

Dr Dolphin said European sales of Recell were up significantly from a low base and the company was focused on key thought-leaders for Recell.

He said Respironics provided $US350,000 ($A406,441) in royalties from sales of Breath-A-Tech products in the 12 months to June 30, 2009.

Dr Dolphin said that seven of the 160 presentations at the European Burns Association were on Recell's efficacy in wound treatment and six of the seven presentations were from independent, arms-length, wound-care professionals.

He said the company would follow up about 20 serious leads from that one conference.

"We're not after finance," Dr Dolphin said. "We're looking for support in the market."

"This is not a broken down disaster," he said.

"We are delivering on our promises and looking for a re-rating," Dr Dolphin said.

Mr Gooding said that the company had changed entirely since it was formed through the merger of Visiomed and Clinical Cell Culture (BD: Oct 10, 2007; Feb 12, 2008).

"Weve gone through the rebuilding," Mr Gooding said.

"Now it's the growth phase and we're about two years to yield," Mr Gooding said.

Avita was one of the 21 biotechnology companies posting increased revenue from sales of products for the year to June 30, 2009.

The company increased revenue by 67 percent to $3.27 million and reduced its loss by 58 percent to $5.13 million.

Last month, Avita jumped as much as 143.5 percent to a high of 27.5 cents on news of Chinese regulatory approval for its Recell wound-care product (BD: Aug 17, 2009), closing up 8.5 cents at 20 cents with 7.1 million shares traded.

Today, Avita was up 1.5 cents or 9.4 percent to 17.4 cents.

PROGEN PHARMACEUTICALS

Progen says the Supreme Court of Queensland has provisionally allocated a trial date for early February 2010 for a legal battle with interests associated with Taiwan's Medigen.

In August Progen began proceedings alleging that the respondents acted in concert to control or influence the company's board (BD: Aug 4, 2009).

Progen said it had taken action against Medigen Biotechnology Corporation, Tzu Liang Huang also known as James Huang, CCH Investment Corp and 14 others alleging the respondents contravened section 606 of the Corporations Act 2001.

Progen was up 1.5 cents or 2.4 percent to 64 cents.

CSL

The US based Capital Group Companies has become a substantial shareholder in CSL with 32,199,306 shares or 5.43 percent.
Capital Group said it became substantial on September 11, 2009 acquiring 18,964,263 shares at an average price of $32.33 between May 25, 2009 and September 11.
The Capital Group said it did not own shares in CSL but held them on account for Capital Research and Management Company.
CSL climbed six cents or 0.18 percent to $33.74 with 3.1 million shares traded.

COCHLEAR

The US based Capital Group Companies increased its substantial shareholding in Cochlear from 6,718,374 shares (11.99%) to 7,322,475 shares (13.03%) on September 11, 2009.
Capital Group has been increasing its holding since November 3, 2008 when it had 8.80 percent of the company.
Capital Group said it did not own shares in Cochlear but held them on account for Capital Research and Management Company.
The shares were acquired at an average price of $59.057.
Cochlear climbed $1.79 or 2.9 percent to $63.80.

PRANA BIOTECHNOLOGY

Bam Opportunity Fund and associated companies have become substantial shareholders in Prana with a holding of 30,000,000 shares or 12.88 percent.
The New York-based Bam Opportunity Fund said it was associated with Hal Mintz and Ross Berman as well as Bam Capital, Bam Management and Bam Opportunity Offshore Fund.
Prana fell 2.5 cents or 11.9 percent to 18.5 cents.

ITL LTD

ITL has appointed Angelo Tsagarakis as chief financial officer replacing Greg Lewis from November 30, 2009 and Jennine McClure as company secretary from today.
ITL said Mr Tsagarakis held an economics degree from Monash University and most recently was Melbourne IT's finance general manager, responsible for the group's financial management and reporting function and was involved in a number of major acquisitions.
Ms McClure joined ITL in March 2009, from Eyecare Partners, where she was responsible for acquisition integration and management of services and was company secretary.
ITL was up 0.2 cents or 2.41 percent to 8.5 cents.