Biotech Daily

Tuesday April 28, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP:**
ALCHEMIA UP 12.5%, PHOSPHAGENICS DOWN 12%

*** FERMISCAN, INVENTOR PROF VERONICA JAMES BACK IN COURT**

*** BIOTECH DAILY EDITORIAL: WHO BREAKS A BUTTERFLY ON A WHEEL?**

*** MESOBLAST BEGINS CERVICAL SPINE FUSION PROGRAM**

*** BIOSIGNAL RAISES $120k, SWAPS ONE DIRECTOR FOR THREE**

*** PRIMA A MONTH FROM PIVOTAL US OVARIAN CANCER TRIAL**

*** ROCKEBY TELLS ASX: SWINE FLU PUSHED SHARE PRICE 147%**

*** HEALTHLINX HAS ONE QUARTER CASH, $3m FUNDING FACILITY**

*** SELECT VACCINES SAYS $200k SHOULD LAST TWO QUARTERS**

MARKET REPORT

The Australian stock market fell 0.62 percent on Tuesday April 28, 2009 with the S&P ASX 200 down 23.2 points to 3,708.4 points.

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

Alchemia was best, climbing four cents or 12.5 percent to 36 cents with 139,577 shares traded followed by Clinuvel up 5.08 percent to 31 cents.

CSL and Genetic Technologies climbed more than four percent; Acrux, Benitec, Genera and Labtech were up more than three percent; Antisense and Mesoblast rose more than two percent; Avexa, Chemgenex, Cochlear, Impedimed and Psivida were up more than one percent; with Pharmaxis and Resmed up by less than one percent.

Phosphagenics led the falls, down two cents or 12.12 percent to 14.5 cents with 1.6 million shares traded, followed by Novogen down 6.12 percent to 46 cents. Biota eased 8.5 cents from yesterday's 90 percent leap, down 8.5 cents or 5.38 percent to $1.495 with 20.5 million shares traded.

Nanosonics lost 5.9 percent; Sirtex fell 4.4 percent; Starpharma was down 3.45 percent; Progen shed 2.22 percent; with Cellestis down 0.6 percent.

FERMISCAN

Fermiscan is suing the inventor of its x-ray diffraction hair test Prof Veronica James claiming a new test using finger nails and skin is an improvement on their patent.

Prof James sold the 1998 hair x-ray diffraction patent to Fermiscan in 2004 and has been the subject of legal action brought against her by Fermiscan - including an Anton Piller order allowing the company to search and seize her private property.

Following the initial court action, the company and Prof James reached a settlement which included an agreement that Prof James would not disparage the company, which has been interpreted as a silencing order against the scientist.

Middleton's intellectual property partner Jane Owen is not bound by the settlement and told Biotech Daily there would be a hearing at the New South Wales Supreme Court on May 25, 2009.

Ms Owen said Fermiscan alleges that Prof James has breached the settlement clause preventing her from disparaging the company and that Fermiscan alleged that work Prof James had undertaken on x-ray diffraction of finger nails and skin was "an improvement" to the original patent they acquired from Prof James in 2004.

On January 3, 2008 Prof James filed international patent application PCT/AU2008/000005 entitled 'Biometrics Diagnosis' with the Australian Patent Office.

On July 17, 2008 the World Intellectual Property Organisation published the application on its website with the description: "The invention provides a method of detecting neoplastic or neurological disorders comprising exposing skin or nails to X-ray diffraction and detecting changes in the ultrastructure of the skin or nails, and also provides an instrument when used in the method of detection."

An adjunct professor at the Australian National University's Research School of Chemistry, Prof James article entitled 'Fiber diffraction of skin and nails provides an accurate diagnosis of malignancies' was published online in the International Journal of Cancer on February 3, 2009 by Wiley Interscience (www.interscience.wiley.com).

The article says that an early diagnosis of malignancies correlates directly with a better prognosis, but for many malignancies there are no readily available, noninvasive, cost-effective diagnostic tests with patients often presenting too late for effective treatment.

"This article describes for the first time the use of fiber diffraction patterns of skin or fingernails, using X-ray sources, as a biometric diagnostic method for detecting neoplastic disorders including but not limited to melanoma, breast, colon and prostate cancers.

"With suitable further development, an early low-cost, totally non-invasive yet reliable diagnostic test could be conducted on a regular basis in local radiology facilities, as a confirmatory test for other diagnostic procedures or as a mass screening test using suitable small angle X-ray beam-lines at synchrotrons."

The abstract is at http://www3.interscience.wiley.com/journal/121664971/abstract.

Fermiscan alleges that x-ray diffraction of skin and nails is merely "an improvement" on Prof James's original patent for x-ray diffraction of hair to detect breast cancer.

Fermiscan managing director David Young told Biotech Daily that he was "prohibited from talking about it".

"We are not talking about it until it's resolved," Mr Young said.

"We hope one day she will win a Nobel Prize for the technology and [it will] make her very rich," Mr Young said. "She has a royalty stream for the product," he said.

Asked whether the matter could not be resolved without legal action, Mr Young said he wished it could be.

Prof James' solicitor Jane Owen said the skin and nail test was "absolutely a new invention".

“The diffraction process has been used since the 1930s to examine biological materials,” Ms Owen said. “The difference is the use of different biological materials to test for cancers and different cancers to those in the 1998 Fermiscan patent.”
“It’s a complete over-simplification to think you can substitute a nail for a hair and then expect to automatically predict the results will be the same. The new patent application is for different biological materials for the detection of different and further types of cancer.”
“If Fermiscan’s claim was valid, it would be tantamount to saying that they own all x-ray diffraction processes for all biological material.
“Their patent simply doesn’t go that far,” Ms Owen said.
Prof James has an Order of Australia Medal for her services to the deaf and there is an annual two day camp called the Veronica James Science Challenge for Hearing Impaired Children supported by the University of Sydney’s Faculty of Medicine through its department of pathology. Prof James has worked on breast cancer since the 1980s.
Fermiscan was down 1.5 cents or 7.89 percent to 17.5 cents.

BIOTECH DAILY EDITORIAL

Whatever the merits of the case Fermiscan is mounting against Prof Veronica James, it is simply bad for the biotechnology sector when a scientist is hounded by a company.
Fermiscan is spending its investors’ money to take the most drastic action possible against the inventor of its technology and soon it will be requiring Polartechnics shareholders to follow suit.
It is not credible that the company cannot find a creative role for Prof James assisting in this most interesting method of non-invasively detecting very early cancer.
Together they could be saving women’s lives.
It is most poignant when the circumstances of the plaintiff Fermiscan are compared with those of the defendant Prof Veronica James
Prof James is receiving legal assistance on a no-win, no-pay basis and is supported by women concerned with the high incidence of breast cancer. She should be allowed to retire in dignity and comfort, instead of facing endless court cases because she continues to research her life’s passion. When she could not find suitable equipment, she designed and engineered it herself. She should be celebrated as a great pioneering scientist.
Fermiscan is spending investors’ money, for what purpose?
If Prof James disparages their test, originally based on her work, so what?
This is science. Evidence rules.
The company has not explained why legal action is necessary.
And to the best of Biotech Daily’s knowledge neither Prof James nor Fermiscan have been able to clearly demonstrate superior results with the x-ray diffraction of hair process above the standard of care of mammography and biopsy.
If Prof James’s skin and nail test does prove superior, Fermiscan could apologize, waive all previous agreements, pay a suitable fee and hire Prof James as a consultant.
Regardless of any facts and argument to be played out in court, one thing is clear, this case should never have begun and Biotech Daily strongly opposes the silencing of scientists with anything other than scientific evidence.
Biotech Daily believes that regardless of subsequent events, originating scientists should be celebrated by those who seek to capitalize on their creativity.
The Fermiscan Polartechnics merger will give the new company, Novus Diagnostics, an opportunity to reappraise the relationship with Prof James.

David Langsam
Editor

MESOBLAST

Melbourne's Epworth Hospital has approval Mesoblast's phase II trial of its allogeneic, or off-the-shelf, cell therapy for fusion of the cervical spine.

Mesoblast said the 24-patient randomized, controlled trial would compare the safety and effectiveness of its Neofuse against an autograft procedure using a patient's own hipbone.

The company said that in preclinical trials at Melbourne's Monash University, Mesoblast's allogeneic cells "resulted in earlier and more robust fusion of the cervical spine than autograft, without any adverse events".

Mesoblast said that as many as 200,000 spinal fusion procedures of the cervical spine were performed each year in the US alone for irreversible, end-stage degenerative disc disease.

The company said the limited options available to patients in need of cervical fusion made the Neofuse cell therapy "a major commercial opportunity for Mesoblast and one that may represent an accelerated path to market entry".

Mesoblast said the "excellent safety profile" in preclinical studies was important in view of the recent notification to surgeons by the US Food and Drug Administration concerning life threatening complications associated with the use of an alternative therapy for cervical fusion, recombinant human bone morphogenetic protein.

Mesoblast executive director Prof Silviu Itescu said that cervical fusion was a major, new market opportunity within a broader strategy of building a franchise for treatment of spinal diseases, including spinal fusion of the lumbar and cervical vertebrae for end-stage degenerative inter-vertebral disc disease, and repair and regeneration of the discs for patients with earlier stage disease.

Mesoblast was up two cents or 2.6 percent to 79 cents.

BIOSIGNAL

Biosignal says it has raised $120,000 through a placement of 12,000,000 shares, at 1.0 cent a share to Empire Investments.

The placement includes 300,000 options exercisable at 1.0 cent within two years.

Biosignal said the capital raised would be used "to position the company for a major strategic business transaction later in 2009".

Biosignal chief executive officer Prof Peter Steinberg said that in the current environment, "a number of business opportunities exist that may not be available at other times".

"The new capital raised will allow Biosignal to actively evaluate opportunities to acquire or merge with complementary businesses," Prof Steinberg said.

"These transactions have the potential to improve shareholder value by significantly boosting the company's financial condition and scale of operations," he said.

Biosignal said that following the placement three new directors had been appointed, BNP Paribas investment banker Russell Baines, Ausbiotech director and former Phylogica and Xceed Capital chief executive officer Dr Stewart Washer and Nick Hagan

Dr John Keniry continues as Biosignal chairman but director Bruce Foy resigned on April 27, 2009.

Biosignal was up 1.1 cents or 68.75 percent to 2.7 cents with 2.1 million shares traded.

PRIMA

Prima says it has completed protocol design and is awaiting manufacturing specifications for its pivotal phase IIb/III US trial of its CVac ovarian cancer therapy vaccine.

Prima said it had begun the final regulatory submission process of its US Food and Drug Administration investigational new drug application.

The company said the application would be managed by former FDA director of cell and gene therapy Dr Joyce Frey-Vasconcells.

Prima said the protocol design for the selection of patients for the phase IIb/III pivotal trial has been completed and was managed by gynecological oncologist Dr Heidi Grey at the Fred Hutchinson Cancer Centre in Seattle, which would host the US section of the trial.

Prima executive director Martin Rogers told Biotech Daily the last part of the application was the manufacturing specifications for the mannan fuse protein which was expected next week with the submission to the FDA completed by the end of May.

Mr Rogers said the trial was expected to start immediately after filing.

Mr Rogers said that news from Dendreon that its Provenge had completed a successful phase III trial was important to Prima because the Nasdaq-listed company was developing a cancer immune-therapy and the FDA had had doubts over cancer vaccines.

Prima said the Dendreon treatment was targeted at prostate cancer and earlier this month it concluded its pivotal trial.

The company noted that Dendreon's market capitalization had grown from $US600 million to more than $US2 billion over the last month.

Its share price rose sharply in recent weeks in anticipation of the successful completion of its pivotal trial, which paves the way for it to achieve commercialization and become the world's first FDA-approved cancer vaccine immuno-therapy.

Prima said it was "delighted with the recent progress and achievements of Prima and in the coming weeks will offer the opportunity for eligible shareholders to subscribe for new shares … through a further share purchase plan".

Shareholders issued shares in the December 4 2008 share plan would be limited from investing further funds to the extent that the aggregate amount by any one shareholder would exceed $5,000.

Prima said Laurence Freedman had become a substantial shareholder, investing $1.5 million in a placement at 2.6 cents a share.

Prima said Mr Freedman was a former Channel 10 director and major shareholder and founder of fund management group Equitilink.

The company said an extraordinary general meeting would be held to approve the share plan and the placement to Mr Freedman's companies.

Prima fell half a cent or 6.85 percent to 6.8 cents with 33.5 million shares traded.

ROCKEBY BIOMED

Rockeby has told the ASX that the swine flow outbreak could explain recent trading in its securities.

The ASX said the company's share price rose from 1.9 cents on April 24, 2009 to 4.7 cents on April 27, 2009, a rise of 147.4 percent, along with an increase in trading volume.

Rockeby said the World Health Organisation had "issued laboratory guidelines which states that rapid influenza tests designed for testing influenza A can be used for testing swine influenza".

"The company's human influenza A rapid test can be used for the testing of swine influenza," Rockeby said.

Rockeby was up 1.9 cents or 42.22 percent to 6.4 cents with 13.5 million shares traded.

HEALTHLINX

In its Appendix 4C quarterly report Healthlinx said it that it had a total operating and investing cash burn of $536,000 for the three months to March 31, 2009 and cash at the end of the quarter of $354,000.

But Healthlinx said it had announced a $3 million funding facility “which has not yet been drawn down”.

“Documents have been executed and the funds are available when required,” Healthlinx said.

Healthlinx was untraded at 4.9 cents.

SELECT VACCINES

Select Vaccines says it had a total operating and investing cash burn of $262,000 for the three months to March 31, 2009 and cash at the end of the quarter of $200,000.

Select Vaccines did not disclose any other available funds.

Select Vaccines chief financial officer Richard Wadley said the company had cut back on expenditure and he expected the cash available would last more than two quarters.

Select Vaccines fell 0.1 cents or 12.5 percent to 0.7 cents. With 2.0 million shares traded.