Biotech Daily

Thursday December 17, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 17%; CELLMID DOWN 7%**

*** BIOTECH DAILY EDITORIAL: THE YEAR IN REVIEW**

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MARKET REPORT

The Australian stock market was up 0.18 percent on Thursday December 17, 2009 with the S&P ASX 200 up 8.4 points to 4670.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, eight fell, six traded unchanged and 10 were untraded.

Prima was best on no news, up 2.5 cents or 16.7 percent to 17.5 cents with 26.2 million shares traded, followed by Patrys up 12.5 percent to 13.5 cents with 200,000 shares traded. Acrux climbed 6.4 percent; Alchemia and Living Cell were both up 5.9 percent; Heartware, Phosphagenics, Prana and Tissue Therapies were up more than three percent; Mesoblast rose 2.2 percent; with Bionomics, Biota, Cochlear, Psivida and Sirtex up more than one percent.

Cellmid led the falls, down 0.2 cents or 6.7 percent to 2.8 cents with 1.3 million shares traded, followed by Novogen down 5.2 percent; Clinuvel fell 3.5 percent; Sunshine Heart and Viralytics shed more than two percent; with Nanosonics down 1.7 percent.

BIOTECH DAILY EDITORIAL: THE YEAR IN REVIEW

We lost a few companies in 2009, but it was **Apollo Life Sciences** that claimed the status of the first casualty of the recession that passed us by.

The departures were not Darwinian in the sense that some companies that are not the best in terms of board, management and technologies have survived the law of the economic jungle, while others that may have been "better" companies have failed.

On October 24, 2008 Apollo went into administration and was lost to biotech. More significant was the failure of **Ventracor** to sprint the last 100 metres of its FDA registration marathon in March 2009.

Dia-B reported its own death prematurely, with two companies claiming to be Pallane Medical squeezing each other out through the back door listing, with the loser the one with Peter King, the Winteray gang, no $12 million and a virus test and the winner was Peter Stafford hoping to take the original diabetes technologies forward.

Biosignal was attacked and eaten by Dr Paul D'Sylva and his Perth-based Empire entrepreneurs metamorphosing from anti-microbial film to actors on film.

Narhex Life Sciences was on life-support itself until its supporting pillar **Dr Michael Cohen** died suddenly in November. Biotechnology also lost Living Cell founder **David Collinson** - tragically - as the type 1 diabetes technology gained New Zealand approval and has begun trials. Living Cell is in good shape, but the future of Narhex is uncertain.

The folly of **Fermiscan** directors focusing on inventor Prof Veronica James instead of developing her breast cancer technology cost the company everything and dragged **Polartechnics** down with it. Polartechnics is very unwell, but is not dead, yet.

Agenix, once the great $100 million Agen, has been in a suspension since September 2008, but this is all to do with its management and nothing to do with any global recession. The company's former chief financial officer and chief executive officer Neil Leggett has been facing charges in the Queensland criminal justice system. The Chinese biopharmaceutical companies Agenix thought it bought are proving to be as viral as their remedies.

Companies we thought would have died by now, but have surprised by surviving are **Norwood Abbey**, **OBJ** and **Rockeby Biomed**.

Solagran remains the only quasi-biotechnology company with a dedicated cheerleader contingent despite giving nearly half the company to **Opes Prime**. We continue to be amazed by the company's announcements, despite the unexpected departure of director Denis Kilroy and the sudden death of company secretary Peter Stedwell, replaced by his son Justyn in that role. The links to Bioprospect, which boasts Elias Leo 'The Gun' Khouri and Snr Sgt Anthony Langdon of Victoria's Water Police Unit are worthy of attention. Similarly, **Stirling** has former career policeman, Peter Boonen, marketing forest-based products from Kiev, except unlike Solagran's over-the-counter cure-all for liver cancer, alcoholism and Alzheimer's, it appears that Stirling is merely a distributor rather than owner of the over-the-counter cure-all for influenza, tuberculosis and HIV.

In a merger more like a distressed auction, **Cytopia** will become part of Toronto's YM Biosciences, just as **Stem Cell Sciences** was given up for a song to Stemcells Inc.

Portland Orthopaedics and **Advanced Ocular** were two more biotechnology losses and **Nusep** almost became the bigger better longer sex company Nxgen for a prematurely shorter smaller time than most and has returned as a normal ordinary sperm separator.

In good news departures, **Arana** and **Peplin** both accepted offers they could not refuse from Cephalon and Leo Pharma, respectively, making most but not all investors very happy.

Big winners improving their market capitalizations by more than 5-fold in the 12 months to November 30, 2009 included **Acrux, Avita, Biopharmica, Biota, Genera, Halcygen, Healthlinx, Nanosonics, Prima** and**, Unilife**, with many others more than doubling their share prices and market capitalizations during the year.

At last count, biotechnology companies raised more than $426 million in the year to November 30, 2009, while the total raised, including biotechnology institutions, was more than $600 million - or an average of $50 million a month.

Biotech Daily has taken an activist role on several issues in 2009, strongly advocating that the **Federal Government** begin to comprehend that the sector was worthy of significant investment. So far we have not been successful in winning the hearts and minds of the Federal Government and its advisers. The efforts have continued since unveiling of the less-than-radical **Commercialisation Australia** and will be redoubled in 2010. Biotech Daily has also written submissions on taxation policy, corporate governance and the roles of the **ASX** and the **Australian Securities and Investments Commission**.

Biotech Daily's last edition for the year will be published tomorrow and we return on January 18, 2010. There will be a modest subscription price increase in the New Year.

We wish all our subscribers and readers a very relaxing Summer holiday break, Happy Chanukah, Merry Christmas and Summer Solstice.

David Langsam, Editor
Marc Sinatra, Analyst

CHEMGENEX PHARMACEUTICALS

Chemgenex says the US Food and Drug Administration will hold a public advisory meeting on February 10, 2010 to review its Omapro application.
Chemgenex said the meeting would be held by the FDA's Oncologic Drugs Advisory Committee to review omacetaxine mepesuccinate (Omapro) for the treatment of adults with chronic myeloid leukemia who have failed prior therapy with imatinib and who have developed the Bcr-Abl T315I mutation.
The company said the Committee provided advice and recommendations to the FDA on regulatory issues.
Chemgenex was up half a cent or 0.5 percent to 98.5 cents.

PHARMAXIS

Pharmaxis has applied to the Australian Therapeutic Goods Administration for the right to market Bronchitol in Australia for the treatment of cystic fibrosis.

Pharmaxis said the marketing application followed the filing of an application to market Bronchitol for the treatment of cystic fibrosis with the European Medicines Agency in October.

The company said both applications were based on a successful phase III clinical trial reported in May with headline results showing a 6.5 percent improvement in the lung function of patients treated with Bronchitol (BD: May 4; Jun 16, 2009).

Pharmaxis chief executive officer Dr Alan Robertson said it had been “an important year for Pharmaxis and I am delighted that 2009 is ending with another step towards bringing Bronchitol to the cystic fibrosis community in Australia”.

“Pharmaxis has prepared a comprehensive brief for the TGA based on a well-designed global study carried out across 40 centres, including Australia,” Dr Robertson said.

“Bronchitol is designed to hydrate the airway surface of the lungs and promote normal lung mucus clearance in people with cystic fibrosis, Dr Robertson said.

“We believe that Bronchitol has the capacity to modify the course of the disease and are looking forward to working with the TGA over the coming months,” he said.

Pharmaxis said Bronchitol had orphan drug designation and fast track status from the US Food and Drug Administration and orphan drug designation from the European Medicines Agency.

The company said the TGA would advise by mid-February 2010 if the marketing application was accepted for evaluation.

A final decision on the application is expected in the first half of 2011.

Pharmaxis was unchanged at $2.74.

NEW SOUTH WALES SUPREME COURT, LEON CARR

Former Fermiscan director and major shareholder Leon Carr has told Biotech Daily that he will appeal the findings of New South Wales Supreme Court Justice Robert McDougall.

On December 15, 2009 Justice McDougall said Mr Carr “committed numerous breaches of the law” and referred the matter to the Australian Securities and Investments Commission for further action. Mr Carr and others were ordered to pay or compensate Resource Equities Limited more than $2.3 million (BD: Dec 16, 2009).

FLUOROTECHNICS

Fluorotechnics expects to raise $1,819,311 in a fully underwritten one-for-five non-renounceable pro rata rights issue at 30 cents a share.

Fluorotechnics said the rights issue was underwritten by major shareholder Hunter Hall and the funds would be used for sales and marketing as well as working capital.

The company said sales expectations for the 2010 financial year was $7 million to $10 million.

The record date is December 30, 2009 and the offer closes on January 18, 2010.

Fluorotechnics was untraded at 35 cents.

BIOTRON

Biotron says its BIT225 has reduced HIV viral loads in vitro by 99 percent and has stopped the virus transferring to uninfected T cells.

Biotron said the study of BIT225 tested on blood samples form 18 HIV positive patients at Sydney's St Vincent's Hospital was announced last week at the Fourth International Workshop on HIV Persistence During Therapy in St Martin, West Indies.

The workshop was told BIT225 was able to inhibit replication of the HIV virus in monocyte cells isolated from the HIV-infected patients, where until now, it had been able to hide from current drug treatments.

Biotron said monocytes collected from the patients were treated with BIT225 to see the effect of the drug on virus within the cells.

Biotron's senior virologist Dr John Wilkinson told delegates at the convention that BIT225 was able to stop the virus replicating in these storage cells by up to 99 percent and it was also able to stop the virus transferring to uninfected T cells.

"In people infected with HIV there is an ongoing cycle of infection of T cells with HIV from reservoir cells and, at present, there is no drug that can target this process," Dr Wilkinson said. "Treatment and elimination of this reservoir remains a major therapeutic challenge."

"Even patients who have been treated with highly active anti-retroviral therapy can experience rapid virus rebound because of these virus reserves in reservoir cells," he said. "By specifically targeting HIV in reservoir cells, Biotron's BIT225 offers the potential to stop this on-going cycle of infection."

Biotron said a paper describing BIT225's ability to inhibit HIV replication in reservoir cells was published in the American Society for Microbiology's journal 'Antimicrobial Agents and Chemotherapy'.

The paper entitled 'The Antiviral Efficacy of the Novel Compound BIT225 Against HIV-1 Release from Human Macrophages' was co-authored by Dr Wilkinson and Biotron chief executive officer Dr Michelle Miller and others.

The abstract says the study "suggests that BIT225 is a late-phase inhibitor of the viral life cycle, targeting Vpu and a drug capable of significantly inhibiting HIV-1 release from both acute and chronically infected macrophages".

The abstract is at http://aac.asm.org/cgi/content/abstract/AAC.01308-09v1.

Biotron said it was preparing protocols for a phase Ib/IIa trial of BIT225 in HIV patients in addition to the proposed phase II trial of BIT225 in patients with hepatitis C virus.

Dr Wilkinson said the market potential of any drug capable of treating HIV infection is very large with the disease costing the $US3.3 billion every year.

Biotron was up 1.3 cents or 13.4 percent to 11 cents with 5.1 million shares traded.

ELLEX MEDICAL LASERS

Ellex says sales of its ophthalmic laser and ultrasound systems "softened in the second quarter" and budget targets will not be met for the half year ending December 31, 2009.

Ellex said group sales were expected to be 20 percent below budget "and hence the profit for the half is expected to be materially lower than for the previous corresponding period".

In February, Ellex posted record first half revenues of $30.4 million but said that after a write off for goodwill the company made a loss for the period (BD: Feb 26, 2009).

Prior to the write-off, the earnings before interest tax and depreciation was $2.5 million.

Ellex said Australian and Japanese sales were expected to be close to budget.

Ellex was untraded at 18.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has granted orphan drug designation to afamelanotide for the management of solar urticaria.

Clinuvel said it was the second orphan drug designation granted to afamelanotide which also has the designation for erythropoietic porphyrias.

The company said FDA orphan drug designation was reserved for new drugs or therapies being developed to treat rare diseases or conditions that affect smaller populations and allowed for an accelerated review process, seven-year market exclusivity in the US on obtaining marketing authorization, tax benefits and exemption from user fees.

Clinuvel chief executive officer Dr Philippe Wolgen said the additional award for afamelanotide "boosts our confidence in the choices we have made for this development program, for which we identified that our drug would provide the optimum medical utility and benefit for patients affected by [ultra-violet] and light".

"After more than a decade of development, a critical factor to the commercial success of the drug will hinge on market protection and exclusivity," Dr Wolgen said.

"Today's FDA verdict provides us precisely this," he said.

Clinuvel said solar urticaria was a skin disorder characterized by an acute mast cell (allergic) response to the photo antigen UV or light.

Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches and immediate localized reactions vary from wheal formation and erupting flares on exposed skin sites to swelling of soft tissues, the company said.

Clinuvel said more than 5,000 people were diagnosed with solar urticaria worldwide.

Clinuvel said that a pilot phase II study of solar urticaria, showed patients' tolerance to light increased following the administration of afamelanotide (BD: Jul 15, 2009).

Afamelanotide was granted orphan medicinal product status by the European Medicines Agency for solar urticaria in June 2009.

Clinuvel is preparing final phase III trials to begin in the northern hemisphere in 2010.

Clinuvel fell one cent or 3.5 percent to 27.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has taken an option to evaluate the Brevagen breast cancer diagnostic product from California's Perlegen Sciences Inc.

Genetic Technologies said the Brevagen test was a diagnostic product providing information about individual, non-familial, sporadic risk of breast cancer for women who have undergone biopsies where the outcome was indeterminate.

The company said about 1.6 million women undergo breast biopsies each year in the US and 65 percent or one million of these were indeterminate.

Genetic Technologies chief executive officer Dr Paul MacLeman said Brevagen would, if acquired, "build further upon Genetic Technologies' strategy to provide the most advanced and comprehensive products in the cancer management area".

"This test is complementary and provides information that extends to a larger patient group than those women needing our existing BRCA test, which provides information on familial breast cancer risks," Dr MacLeman said.

The company said it was undertaking due diligence which would result, should it proceed, in an asset purchase rather than a corporate acquisition.

Genetic Technologies said the rights to be acquired would be global and include the purchase of laboratory equipment, intellectual property, certifications, sales and marketing material and other trade secrets and know-how.

Genetic Technologies was untraded at 3.4 cents.

PHYLOGICA

Phylogica has requested a trading halt pending an announcement regarding the “signing of formal documentation shortly with a large pharmaceutical and biotechnology group”.
Phylogica said the partnership would use its library of phylomers or protein fragments (BD: Aug 26, 2009).
Phylogica last traded at 13 cents.

NANOSONICS

Wilson HTM says that yesterday’s notice of initial substantial holder for Nanosonics was not correct in that its 10,568,609 shares are less than five percent and Wilson HTM is not “substantial” in Nanosonics.
Nanosonics fell one cent or 1.72 percent to 57 cents.

PHOSPHAGENICS

Phosphagenics says its tocopheryl phosphate mixture or TPM insulin project is on track to return to the clinic for human trials in the first half of 2010.
Phosphagenics said it had adapted the TPM patch technology for the oxycodone program.
The company said its scientists had completed dose optimization of the insulin formulation, substantially reducing the amount of insulin required to achieve therapeutic dose and had completed and tested the matrix insulin patch on animals demonstrating that blood glucose levels were lowered for the duration of the studies.
Phosphagenics said it had renamed TPM as a “targeted penetration matrix” delivery system and said it was capable of topically delivering large molecules, such as insulin, into the blood circulation in a non-invasive manner using its patch.
Phosphagenics chief operating officer Dr Esra Ogru said the technology could deliver large proteins, such as insulin, through the skin and into the blood stream and had the “potential to reduce the number of invasive injections per day”.
Phosphagenics was up 0.2 cents or 3.1 percent to 6.6 cents.