

Biotech Daily

Thursday January 24, 2013

Daily news on ASX-listed biotechnology companies

* ASX UP, BIOTECH DOWN: PSIVIDA UP 8%, BENITEC DOWN 6%

* WEHI LINKS IMMUNE CELL DEATH DEFECTS TO AUTOIMMUNE DISEASE

- * PHARMAXIS Q4 REVENUE, SALES DOUBLE
- * PSIVIDA'S ALIMERA HOPES FOR ILUVIEN DME PATIENT ACCESS SCHEME
- * NUSEP SELLS SOFTWARE BUSINESS TO CALIFORNIA'S PREMIER

* PRIMA CEO MATTHEW LEHMAN'S INVESTOR ROADSHOW

* VIRALYTICS CEO DR MALCOLM MCCOLL STARTS ON \$357k

MARKET REPORT

The Australian stock market climbed 0.47 percent on Thursday January 24, 2013, with the S&P ASX 200 up 22.4 points to 4,810.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 14 traded unchanged and four were untraded.

Psivida was the best, up 10 cents or 7.7 percent to \$1.40 with 9,000 shares traded, followed by Antisense up 7.1 percent to 1.5 cents with 2.5 million shares traded.

Living Cell climbed 6.4 percent; both Genetic Technologies and Optiscan were up five percent; Avita climbed 4.55 percent; QRX and Universal Biosensors rose more than two percent; Pharmaxis and Resmed were up more than one percent; with CSL up 0.2 percent.

Benitec led the falls, down 0.1 cents or 5.9 percent to 1.6 cents with 632,300 shares traded, followed by Bionomics down 5.7 percent to 41.5 cents with 192,021 shares traded.

Prana lost 4.65 percent; Alchemia and Medical Developments were down more than three percent; Clinuvel, GI Dynamics and Mesoblast shed more that two percent; Anteo and Starpharma were down more than one percent; with Acrux, Cochlear, Heartware and Nanosonics down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the death of immune system cells is important to prevent diseases such as type 1 diabetes, rheumatoid arthritis and lupus.

The Institute said that its researchers had found that the autoimmune diseases could be treated with existing medications that forced long-lived immune system cells to die.

The Institute said that in the development of the immune system, some cells were produced that had the potential to attack the body's own tissues, causing autoimmune disease and the death of these self-reactive immune cells through apoptosis, or

programmed cell death, was an important safeguard against autoimmune disease. WEHI said that Dr Kylie Mason, Dr Lorraine O'Reilly, Dr Daniel Gray, Prof Andreas Strasser and Prof David Huang, with the University of Melbourne's Prof Paul Waring discovered that when immune cells lack the two related proteins, Bax and Bak, the cells could attack healthy tissues, causing severe autoimmune disease.

WEHI said Bax and Bak were members of the Bcl-2 protein family, a large group of proteins that controlled cell death.

Dr O'Reilly said it was thought that Bax and Bak acted like an irreversible switch in cells, determining when cells die by apoptosis.

Dr O'Reilly said that in healthy cells, Bax and Bak were in an inactive form, but when cells were under stress or received external signals instructing them to die, Bax and Bak switched into an active form that started the destruction of the cell.

Dr O'Reilly said that without Bax and Bak, cells were highly protected against apoptosis and some immune cells that lacked the proteins Bax and Bak were able to attack healthy tissues in many organs of the body.

"Normally, these self-reactive immune cells are deleted during development," Dr O'reilly said.

"In the absence of Bax and Bak, enough self-reactive cells survive development to persist in the body and cause autoimmune disease in organs such as the kidneys

(glomerulonephritis), similar to what is seen in the most severe form of lupus," Dr O'Reilly said.

"Our findings confirm that defective apoptosis of immune cells can cause autoimmune disease, and that Bax and Bak are important determinants of immune cell death," Dr O'Reilly said.

"We were also interested to see that, in our model, loss of Bak on its own was sufficient to cause autoimmune disease, albeit to a lesser extent than losing both Bak and Bax," Dr O'Reilly said.

"This supports a recent discovery that humans with mutations in the Bak gene are predisposed to certain autoimmune diseases," Dr O'Reilly said.

"The research provides hope for people with autoimmune diseases as Bax and Bak activity can be triggered by a new class of potential anti-cancer agents, called BH3mimetics, which are currently in clinical trials for certain types of leukaemia in Melbourne," Dr O'Reilly said.

"Our findings suggest that BH3-mimetics might be an exciting new option for treatment for autoimmune conditions, by activating Bax and Bak and making the self-reactive immune cells which are causing the autoimmune disease to die," she said.

WEHI said that the research article, entitled 'Proapoptotic Bak and Bax guard against fatal systemic and organ-specific autoimmune disease' was expected to be published online in the journal Proceedings of the National Academy of Sciences by January 28, 2013.

PHARMAXIS

Pharmaxis has posted total revenue for the three months to December 31, 2012 of \$1,002,000 a 186.9 percent increase over the previous three months' revenue. In a teleconference, Pharmaxis chief executive officer Dr Alan Robertson said the revenue was primarily from the sales of Bronchitol for cystic fibrosis in Europe and Australia as well as sales of Aridol, with total sales increasing 145.7 percent from \$341,000 for the three months to December 31, 2011 to \$838,000 for the three months to December 31, 2011. Dr Robertson said that sales of Bronchitol for cystic fibrosis, primarily in Germany and Australia, were up from \$218,000 for the three months to September 30, 2012 to \$450,000 for the three months to December 31, 2012.

Dr Robertson said that 10 percent of potential cystic fibrosis patients in German had tried Bronchitol and that all but one centre in Australia had patients using Bronchitol. Dr Robertson said that first revenue had been received from Denmark and sales would be

Dr Robertson said that first revenue had been received from Denmark and sales would be expected from France, Italy and Spain, in the next few months.

Dr Robertson said the reimbursement process in the UK had been slowed down by the regulatory process that concluded in October 2012, but Bronchitol was in use in the largest centre at London's Brompton Hospital.

The teleconference was told that the 150-patient European trial for Bronchitol for under-18 year olds would begin dosing "in the next few months" with results expected in 2014.

Dr Robertson said that there would be a public US Food and Drug Administration advisory meeting on January 30, 2013 with a review date for approval of Bronchitol for cystic fibrosis for adults and children over the age of six years, on March 18, 2013.

He said the company had the strong support from cystic fibrosis organization in the US. Dr Robertson said that there were 30,000 people with cystic fibrosis in the US, but there were 195,000 people with bronchiectasis and the 485-patient, phase III European and US trial for that indication was expected to close by April with results by July 2013.

He said that the Pharmaxis pipeline included the phase II ASM8 for severe asthma, as well as the company's internally developed PXS4728A, a small molecule inhibitor of the SSAO protein implicated in driving inflammatory processes.

Dr Robertson said he expected the PXS4728A once-a-day tablet to begin a phase I clinical trial this year with potential use in multiple inflammation-related respiratory diseases including asthma and chronic obstructive pulmonary disease.

He said that research and development work continued on PXS64 for idiopathic pulmonary fibrosis and the Pharmaxis-discovered lysyl oxidase like-2 inhibitors, potentially for pulmonary fibrosis and cancer.

Pharmaxis said it had \$65 million in cash at December 31, 2012.

Pharmaxis was up 1.5 cents or 1.2 percent to \$1.28.

<u>PSIVIDA</u>

Psivida says its licensee for Iluvien for diabetic macular oedema, Alimera Sciences, will pursue a patient access scheme for the injectible drug.

Psivida said that the UK's National Institute for Health and Clinical Excellence had published final guidance indicating that Iluvien was not cost effective for the treatment of chronic diabetic macular oedema considered insufficiently responsive to available therapies, consistent with the final draft guidance issued in November (BD: Dec 3, 2012). Psivida said that the patient access scheme was intended to allow treatment decisions to be based on patient need, rather than cost and the scheme was under review by the National Institute for Health and Clinical Excellence.

Psivida was up 10 cents or 7.7 percent to \$1.40.

NUSEP

Nusep says it will sell its non-core asset, the Proteoiq software business, to the Palo Alto, California-based Premier Biosoft.

Nusep chairman John Manusu told Bitoech Daily that half of the undisclosed cash payment had been received as a deposit, with the transaction expected to be completed by March 2013.

Nusep said the offer was unsolicited from Premier, which was a leading provider of software for the life science market.

Nusep managing director Prakash Patel said the transaction "frees up cash-flow from the non-core software division and allows the company to apply these funds on its core consumables and Prime-related businesses including Spermgen".

Premier chief executive officer Arun Apte said that in the proteomics market, Proteoiq was a strategic fit with his company's existing product offering and helped consolidate its position "as a leader for providing informatics tools for mass spectrometry". Nusep was untraded at 7.8 cents.

PRIMA BIOMED

Prima says that chief executive officer Matthew Lehman will host investor days across Australia in February.

Prima said that Mr Lehman would provide a company update and take questions from investors at the meetings in Sydney, Melbourne, Brisbane and Perth.

Mr Lehman will present in Perth on February 4, at the Parmelia Hilton Hotel, 14 Mill Street, Perth from 10am (AWST); at the Westin Melbourne Hotel, 205 Collins St, Melbourne; on February 5, from 10.30am (AEDT); in Brisbane at the Hilton Hotel, 190 Elizabeth Street, Brisbane on February 6, from 10am (AEST) and at the Radisson Blu Hotel, 27 O'Connell Street, Sydney, on February 7, from 10.30am (AEDT).

Prima was unchanged at 10.5 cents with 2.8 million shares traded.

VIRALYTICS

Viralytics says that recently appointed chief executive officer Dr Malcolm McColl's base salary will be \$357,000 a year, including superannuation.

Viralytics said that Dr McColl would be entitled to a performance related short-term incentive bonus of up to 30 percent of the salary.

The company said that Dr McColl had not been appointed a director of the company and if he was appointed he would not receive any additional remuneration.

Viralytics said that Dr McColl would receive 1,200,000 free options exercisable at the 30day volume weighted average price to the commencement date of January 21, 2013, vesting in tranches of 400,000 options at 12 monthly intervals from that date.

Viralytics was unchanged at 30 cents.