Biotech Daily

Wednesday January 21, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 14%, TISSUE THERAPIES DOWN 13%**

*** PHARMAXIS BEGINS PHASE I PXS4728A INFLAMMATORY DISEASE TRIALS**

*** UNILIFE $6m ABBVIE SYRINGE DEAL**

*** US PATENT FOR CELLMID MIDKINE FOR HEART FAILURE**

*** EMA DELAYS TISSUE THERAPIES VITROGRO APPLICATION, AGAIN**

*** BAILLIE GIFFORD INCREASE TO 13.4% OF COCHLEAR**

*** UBS AG BUYS, SELLS, BORROWS, RETURNS ACRUX SHARES TO 8%**

*** CLINUVEL APPOINTS WILLEM BLIJDORP DIRECTOR**

MARKET REPORT

The Australian stock market climbed 1.61 percent on Wednesday January 21, 2015 with the S&P ASX 200 up 85.7 points to 5,393.4 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and four were untraded. All three Big Caps were up.

Optiscan was the best, up 0.8 cents or 14.3 percent to 6.4 cents with 4.8 million shares traded.

Prima climbed 9.1 percent; Antisense and Cellmid were up eight percent or more; Genetic Technologies was up 7.7 percent; Patrys rose 6.25 percent; Atcor was up 4.2 percent; Cochlear, Ellex, Neuren, Psivida and Viralytics were up more than three percent; Impedimed, Nanosonics, Prana and Universal Biosensors rose more than two percent; CSL and Medical Developments were up more than one percent; with Mesoblast, Resmed and Sirtex up by less than one percent.

Tissue Therapies led the falls, down 4.5 cents or 12.7 percent to 31 cents with 929,078 shares traded, followed by Pharmaxis retreating from yesterday's 25 percent rise before the announcement, down 1.5 cents or 12 percent to 11 cents with 2.9 million shares traded.

Analytica and Phosphagenics lost more than six percent; Oncosil fell five percent; Admedus fell four percent; Bionomics, Biotron and Circadian were down more than three percent; with Acrux, Benitec and Starpharma down one percent or more.

PHARMAXIS

Pharmaxis says it has begun a two-part phase I trial of its semicarbazide-sensitive amine oxidase/vascular adhesion protein-1 inhibitor PXS4728A for inflammatory diseases.

Pharmaxis said that the initial stage was a single ascending dose study in 48 subjects and if the results were positive, it would proceed to a multiple ascending dose study in a separate group of 24 subjects.

The company said that PXS4728A was “a highly selective” small molecule inhibitor of semicarbazide-sensitive amine oxidase (SSAO) that could be administered orally and had demonstrated acceptable drug-like properties in pre-clinical development.

Pharmaxis said that the $2 million trial was expected to report by October 2015.

The company said that the SSAO enzyme had emerged as a target of interest for inflammatory diseases during the last 12 months and a recent peer reviewed publication validated its particular importance in liver diseases such as non-alcoholic steatohepatitis or fatty liver disease.

Pharmaxis said that non-alcoholic steatohepatitis was an area of high unmet clinical need, estimated to reach about $US1.6 billion by 2020 with a number of companies engaged in active research and clinical development.

The company said that the high prevalence of type 2 diabetes and obesity, leading to the disease and other non-alcoholic fatty liver diseases was expected to boost market growth.

Pharmaxis chief executive officer Gary Phillips said the company had been “investing carefully in its early stage pipeline over the past two years”.

“PXS4728A is the first drug candidate from our amine oxidase research platform to have passed all its pre-clinical tests and be cleared to progress to human trials,” Mr Phillips said.

“Having successfully completed the partnering of Bronchitol for the US late last year, it is now appropriate to make a further investment in the SSAO program, an investment that we believe will enhance the company’s partnering negotiations which are continuing to progress to plan,” Mr Phillips said.

Last year, Pharmaxis said that it was “actively seeking development partners” for its SSAO/VAP-1 program and discussions were progressing well (BD: Aug 28, 2014).

In 2013, in the wake of Bronchitol failing its phase III trial for bronchiectasis and the need for a new phase III trial of Bronchitol for cystic fibrosis, Pharmaxis said it would cease funding early stage programs and cut staff (BD: Apr 24, May 21, 2013).

Mr Phillips told a teleconference at that time that by the end of 2013 the company would cease funding the ASM8 and PXS2200 oligonucleotide programs for asthma and chronic obstructive pulmonary disease; the LOXL2 inhibitor for lung and liver fibrosis and cancer; the SSAO inhibitor program for lung inflammation; and the near-term asset the Orbital inhaler for dry powder (BD: May 28, 2013).

Today, Mr Phillips told Biotech Daily that the decision to progress into phase I without a partner was based on the company’s “stronger position having partnered the US Bronchitol business” as well as the wider acknowledgement of SSAO as an attractive target.

Mr Phillips said other reasons for proceeding included “insights from partnering discussions of the increase in asset value achieved by entering into phase I clinical studies” as well as the progress the company was making in partnering discussions and “our assessment of the probability of success of the phase I study”.

Pharmaxis fell 1.5 cents or 12 percent to 11 cents with 2.9 million shares traded.

UNILIFE CORP

Unilife says it has a “definitive global strategic agreement” with the North Chicago, Illinois-based Abbvie Inc for the customization and supply of its injectable drug delivery systems.
Unilife said that Abbvie would pay $US5 million ($A6.1 million) for the exclusive right to form and enter into a mutually-agreeable development and supply agreement for the Unifill Finesse prefilled syringe and the Lisa reusable auto-injector for target therapies within Abbvie’s drug portfolio for the treatment of auto-immune diseases, as well as associated exclusivity fees, but the target therapies and conditions were confidential.
Unilife was up six cents or 7.1 percent to 91 cents with two million shares traded.

CELLMID

Cellmid says that the US Patent Office has granted a patent application entitled ‘Composition for treating or preventing myocardial disorder or heart failure’.
Cellmid said that the granted claims covered the use of midkine as a treatment for heart failure which commonly followed non-fatal heart attacks.
The company said that in published studies using in vivo animal models, midkine treatment following cardiac arrest promoted new blood vessel growth in the affected tissue, limited cardiac dysfuntion, promoted ventricular tissue repair and increased long term survival rates.
Cellmid said that it was significantly that midkine was effective “even where treatment initiation is delayed for weeks after infarct”.
Cellmid chief executive officer Maria Halasz said that the patent reinforced the company’s intellectual property position in using midkine therapeutically.
“Through several global patent families Cellmid’s patent coverage now extends across a number of related mechanisms of action,” Ms Halasz said.
Cellmid head of product development Darren Jones said that midkine “could become an important agent in the treatment of heart failure”.
“In an acute setting [midkine] prevents cardiomyocyte death at the time of the heart attack,” Mr Jones said.
“In the longer term [midkine] promotes beneficial fibrosis and angiogenesis in the cardiac muscle in the weeks following a heart attack,” Mr Jones said.
Cellmid said that equivalent patents had been granted in Europe and Japan.
Cellmid was up 0.2 cents or eight percent to 2.7 cents with 1.1 million shares traded.

TISSUE THERAPIES

Tissue Therapies says the European Medicines Agency has delayed its application, again, for Conformité Européenne (CE) mark for its Vitrogro wound treatment.
Tissue Therapies said that its notified body under the European application process, the British Standards Institute had told it that the EMA had “deferred acceptance of the company’s response to the 180-day review questions for the granting of CE Mark by one month”.
The company said that an opinion from the EMA review committee was expected on March 26 instead of February 26, 2015.
Tissue Therapies said that once the EMA committee had arrived at an opinion, this will be conveyed to Institute which would then inform the company of the opinion.
Last year the EMA delayed the application twice for more questions as well as for the Christmas New Year holidays (BD: Feb 26, Sep 30, Nov 4, 2014).
Tissue Therapies fell 4.5 cents or 12.7 percent to 31 cents.

COCHLEAR

The Edinburgh-based Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 7,058,945 shares (12.38%) to 7,635,693 shares (13.38%).
Baillie Gifford said it bought and sold shares between September 24, 2013 and January 19, 2015 in about 200 separate trades.
Cochlear climbed $2.69 or 3.4 percent to $81.76 with 343,126 shares traded.

ACRUX

The Singapore-based UBS AG and related bodies corporate have reduced their holding in Acrux from 15,742,753 shares (9.45%) to 13,540,409 shares (8.13%).
UBS AG said that between January 6 and January 16, 2015 it bought, sold, borrowed and returned Acrux shares on behalf of a number of institutions, including Citibank, Citigroup, JP Morgan Chase Bank, Macquarie Bank, Morgan Stanley, the Northern Trust Company, Brown Brothers Harriman, BMO Capital Markets Corp and State Street Bank & Trust Co.
UBS AG has previously said that the shares were held for Warbont Nominees and various custodians and were held with the "power to control disposal over shares pursuant to stock borrowing and lending activities" (BD: Dec 19, 2012; Nov 21, 2013).
Acrux has been reported as one of the most heavily 'short-sold' stocks in the Australian biotechnology sector.
Acrux fell 2.5 cents or 1.7 percent to $1.48.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has appointed Willem Blijdorp as a non-executive director.
Clinuvel said that Mr Blijdorp was the founding member, majority shareholder and a current director of B&S International NV, a privately owned Dutch group trading "luxury and fast moving consumer goods and pharmaceutical products" and the appointment came as Clinuvel prepared for the commercial distribution of Scenesse for erythropoietic protoporphyria throughout the European Union.
The company said that Mr Blijdorp managed B&S International for 27 years as chief executive officer and was actively involved in the company's expansion strategy.
Clinuvel said that Mr Blijdorp was awarded the 2014 Ernst & Young Netherlands entrepreneur of the year prize for his expertise in mergers, acquisitions and leadership.
Clinuvel was unchanged at $3.82.