Biotech Daily

Monday May 14, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ELLEX UP 6%, UNIVERSAL BIO DOWN 7%**

*** ALCHEMIA'S FONDAPARINUX TAKES 22.5% OF US MARKET**

*** DESPITE RESULTS, TRANSGENE TG4001 PROVES VIRAX CO-X-GENE**

*** IMMURON APPOINTS ZIWELL FOR MORE SE ASIA SALES**

*** JAPAN GRANTS AGENIX THROMBOVIEW PATENT**

*** DRILL INVESTMENTS REDUCES, DILUTED TO 5.6% OF IMMURON**

*** CBIO PLEADS SCHULTZ TO ASX 29% QUERY**

MARKET REPORT

The Australian stock market was up 0.28 percent on Monday May 14, 2012 with the S&P ASX 200 up 11.9 points to 4,297.0 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and five were untraded.

Ellex was the best, up one cent or 5.6 percent to 19 cents with 15,726 shares traded, followed by Heartware up five percent to $2.30 with 206,736 shares traded.

Genetic Technologies climbed 3.6 percent; Anteo and Bionomics rose more than two percent; CSL, Nanosonics and QRX were up more than one percent; with Acrux, Cochlear and Sirtex up by less than one percent.

Universal Biosensors led the falls, down 4.5 cents or seven percent to 60 cents with 153,607 shares traded, followed by Patrys down 6.7 percent to 2.8 cents with 30,000 shares traded.

Benitec lost 5.3 percent; Alchemia and Bioniche fell more than four percent; Viralytics was down 3.3 percent; Impedimed and Tissue Therapies shed more than two percent; with Biota, Clinuvel, Mesoblast, Pharmaxis and Reva down more than one percent.

ALCHEMIA

Alchemia chief executive officer Dr Pete Smith has told Biotech Daily that its generic fondaparinux synthetic heparin has taken 22.5 percent of the US prescription market.

In a media release to the ASX Alchemia said that sales of fondaparinux were reported to be $US20 million for the three months to March 31, 2012 a 120 percent increase over the three months to December 31, 2011.

In February Alchemia said that the drug had taken 18 percent of the US prescription market with sales of more than $1.4 million a week following the US launch in July 2011 by Dr Reddy's Laboratories. (BD: Feb 6, 2012).

At that time, Alchemia said that the non-hospital retail segment of the market was known to be relatively higher priced and profitable compared with the hospital or non-retail segment and Dr Reddy's had achieved a dollar market share of more than 30 percent in the retail segment.

Dr Smith told Biotech Daily that the latest data he had seen showed the total US market share was 22.5 percent or $1.67 million a week and 37 percent of the retail market.

Alchemia fell two cents or 4.3 percent to 45 cents.

VIRAX HOLDINGS

Virax says Transgene's TG4001 human papillomavirus therapeutic vaccine using its Co-X-Gene technology has shown to be safe with some, but less-than-expected efficacy.

Virax has licenced its Co-X-Gene technology to the France-based Transgene and chief executive officer Dr Larry ward told Biotech Daily that the intellectual property effectively covered any use of an antigen and a cytokine in the same viral vector.

Dr Ward said that in this case the viral vector was modified vaccinia Ankara with a combination of the antigen from human papillomavirus (HPV) and the interleukin-2 (IL-2) cytokine.

Virax said that Transgene announced the six month headline results of its randomized phase IIb study of TG4001 in women with cervical intraepithelial neoplasia of grades two and three (CIN2 and CIN3) resulting from infection with human papillomavirus.

The company said that histological resolution and viral clearance were significantly higher for TG4001 treated groups relative to placebo groups, with highly significant statistical values, but the histological clearance was not comparable to surgical treatment.

Virax reported Transgene saying that despite the strong proof-of-concept for the activity of TG4001 it was not planning to take TG4001 into phase III for this indication.

Transgene outlined alternate clinical development plans for TG4001 that, through partnerships, would involve a focus on other HPV induced malignancies with higher unmet clinical needs such as head and neck cancer, or cervical cancer particularly when TG4001 was used in combination with chemotherapy.

Virax said it had also licenced the Co-X-Gene technology for the lung cancer vaccine TG4010, which had successfully completed phase IIb testing and Transgene had an option agreement with Novartis based on that result.

Virax said that a TG4010 phase IIb/III trial was scheduled to commence imminently with data release from the phase IIb component of the trial expected by July. 2013.

The company said that Transgene could receive up to EUR700 million ($A902 million) plus royalties if an option with Novartis was exercised, which would result in a licence payment to Virax.

Virax said that the measured clinical activity of both products to date provided clinical validation of the Co-X-Gene technology.

Virax was untraded at 0.9 cents.

IMMURON

Immuron has appointed the Singapore-based Ziwell Medical (S) Pte Ltd to distribute Travelan for travelers' diarrhoea in Singapore, Malaysia and Brunei.

Immuron said that the cow colostrum derived Travelan was "clinically-proven to prevent with 90 percent efficacy the main cause of travelers' diarrhea" an illness endemic in each of these countries which according to the World Tourism Organization, hosted about 34 million travelers in 2010 and had a local resident population of 33 million people.

Last week, the company appointed Integramed Asia (Thailand) Co to sell Travelan in Thailand, Hong Kong, Cambodia, Vietnam and Laos (BD: May 10, 2012), which also had endemic travelers' diarrhoea and had more than 44 million travelers in 2010, in addition to the local resident population of about 190 million people.

Today, Immuron said that Ziwell Medical was required to gain regulatory approval for the sale of Travelan and sell specified minimum volumes, with an agreed timetable for the launch and sales.

Immuron said it was "determined to capture the full value of our extremely effective Travelan product in Asia and elsewhere".

Immuron was up 0.2 cents or 12.5 percent to 1.8 cents with 1.8 million shares traded.

AGENIX

Agenix says Japan's Patent Office had granted a key patent covering the manufacturing process of its Thromboview imaging agent for the detection of blood clots in humans.

Agenix executive chairman Nicholas Weston said the patent protection in Japan "confers further certainty and significantly increases the commercial value of the Thromboview diagnostic technology globally".

"In conjunction with the other patents covering the use and production of Thromboview, this new patent delivers a major commercial advantage to Agenix in one of the world's leading markets for diagnostic imaging and manufacturing," Mr Weston said.

Agenix said the patent covered humanized antibodies derived from DD-3B6/22 specific for the D-dimer fragment of fibrin and provided long-term protection for the company's technology through broad claims over methods of manufacture and use.

The company said that the patent was a major asset in the commercialization of Thromboview and establishing strategic business partnerships with pharmaceutical and medical diagnostic companies.

Agenix said that Thromboview was protected by multiple patents in Japan, the US, Europe, Singapore, Australia and New Zealand, with the granting of patents for China and Canada pending, providing protection to 2022 with possible Hatch-Waxman term extension to 2027.

The company said that legislation in the EU, US and Japan granted biologics a period of 10, 12 and six years of data exclusivity, respectively, from the time of registration and this was likely to considerable enhance Thromboview's protection in those markets.

Agenix said that Thromboview would potentially provide medical professionals with a new way to accurately detect live blood clots and pulmonary embolisms in the human body without exposure to high chest radiation and toxic chemicals currently used for imaging.

The company said that Thromboview had completed two phase II human clinical trials in the US and there was a large body of independent clinical evidence that showed the diagnostic was safe and effective.

Agenix said it was in discussions with potential partners in multiple geographies to partner or licence the technology to complete a phase III clinical study ahead of a market launch.

Agenix was up 0.2 cents or 33.3 percent to 0.8 cents with 7.2 million shares traded.

IMMURON

Drill Investments has reduced its substantial holding in Immuron and has been diluted through a placement and share rights issue.

Drill Investments said in its substantial shareholding that it had reduced and been diluted from 22,000,000 shares (6.6%) to 20,710,000 shares (5.56%).

The notice, signed by director James Barry Drill, said the dilution was in August 2011 when Immuron had a placement and rights issue at seven cents a share raising $1,050,000 of a hoped for $5 million (BD: Aug 17, 25, Nov 4, 2011).

Drill said that the 1,290,000 shares were sold for $22,147 or 1.7 cents a share.

CBIO

CBio has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from seven cents on May 8 to nine cents on May 11, 2012, a 28.6 percent increase and noted an increase in trading volume.

CBio fell half a cent or 5.6 percent to 8.5 cents.