Biotech Daily

Thursday March 11, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PSIVIDA UP 7%; GENETIC TECHNO DOWN 7.5%**

*** VIRAX JUMPS 35% ON NOVARTIS $1bn TRANSGENE DEAL**

*** PHARMAXIS COMPLETES ASTHMA DRUG DOSE-PROFILE**

*** CBIO'S 75th PATIENT TRIGGERS $1.1m PAYMENT FROM NOVO NORDISK**

*** MICHAEL QUINN REDUCES, DILUTED 6% IN QRX**

*** ACORN CAPITAL REDUCES 1% IN PHARMAXIS**

MARKET REPORT

The Australian stock market fell 0.12 percent on Thursday March 11, 2010 with the S&P ASX 200 down 5.8 points to 4814.2 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and four were untraded.

Psivida was best, up 29 cents or 7.4 percent to $4.20 with 14,573 shares traded, followed by Benitec up 4.4 percent to 4.7 cents with 97,454 shares traded and Avexa up 4.35 percent to 12 cents with 4.1 million shares traded.

Genera and Living Cell climbed more than three percent; Heartware, Pharmaxis and Starpharma rose more than two percent; with Bionomics, Circadian, CSL, Impedimed, Novogen, Phylogica and Resmed up more than one percent.

Genetic Technologies led the falls, down 0.3 cents or 7.5 percent to 3.7 cents with 159,051 shares traded, followed by Phosphagenics down 6.4 percent to 7.3 cents with 1.1 million shares traded.

Antisense lost 5.8 percent; Clinuvel, Mesoblast, Nanosonics and Optiscan shed two percent or more; with Cellestis, Chemgenex, Sirtex and Universal Biosensors down more than one percent.

VIRAX HOLDINGS

Virax climbed 34.8 percent to 15.5 cents on news that Novartis had a $1 billion option with Virax licencee Transgene for the non-small-cell-lung cancer drug TG4010.

Virax has licenced its Co-X-Gene technology to Transgene SA of Strasbourg, France for use in Transgene's TG4010 as well as TG4001 for pathologies relating to human papilloma virus infection that can lead to cervical cancer.

Last night Transgene announced it had an exclusive option agreement with Novartis for TG4010, in which Novartis would pay a non-refundable fee of $US10 million, with up to EUR700 million ($A1.04 billion) for developmental milestones and sales royalties.

Virax said TG4010 had completed phase IIb testing for the first-line treatment of advanced non-small cell lung cancer in combination with chemotherapy and had potential applications in prostate, breast, kidney, pancreatic and colorectal cancers.

Virax said it would benefit from all milestone and royalty payments upon Transgene achieving relevant development milestones and sale of product.

Virax chief executive officer Dr Larry Ward told Biotech Daily that due to confidentiality agreements with Transgene he could not quantify the value of the Novartis deal to his company, but said "we benefit when they benefit".

Dr Ward confirmed there would be a payment due to Virax following the $US10 million ($A11 million) upfront fee.

"It will certainly extend our runway," Dr Ward said.

"On payment by Transgene we will make an announcement to the ASX," Dr Ward said.

"The exciting thing is the validation of our co-expression technology and therapeutic vaccination," he said.

Dr Ward said that Roche and now Novartis had shown interested in the technology.

In a media release to the ASX Dr Ward said the Novartis agreement with Transgene was "in addition to the previously announced partnership between Roche and Transgene for the HPV therapeutic vaccine, TG4001" (BD: Apr 12, 2007).

"The advancement of both Transgene products into late stage development exemplifies the intrinsic value of the Co-X-Gene technology intellectual property and the Transgene sub-licence," Dr Ward said.

Transgene said it would fund and retain control over the next phase of TG4010 development - a pivotal, phase IIb/III clinical trial of about 1,000 patients with MUC1-positive non-small cell lung cancer, who had normal levels of activated natural killer cells at the time of trial entry, expected to begin this year, with final results in 2013.

Transgene said that results from the phase IIb portion of the trial were expected in the first quarter of 2012 and Novartis would have 90 days to exercise its option.

If Novartis exercised the option it would assume all development, regulatory and commercialization costs related to TG4010 across all indications, Transgene said, including a non-refundable licence fee, milestone payments on development for various indications and longer-term commercialization targets, as well as royalties on global sales.

The company said TG4010 (MVA-MUC1-IL2) used the modified vaccinia Ankara (MVA) virus vector, a poxvirus that combines distinguishing advantages for an optimized systemic vaccination and had been "tested extensively in humans as a smallpox vaccine and is known to strongly stimulate innate and adaptive immune responses to antigens".

MUC1 is a major tumor-associated antigen that provides a viable target for immunotherapy. TG4010 expresses the entire MUC1 gene sequence and has the potential to generate an immune response to all antigenic epitopes of MUC1.

The sequence coding for the cytokine Interleukin 2 (IL2) is included to help stimulate specific T-cell response, Transgene said.

Virax closed unchanged at 11.5 cents with 18.7 million shares traded.

PHARMAXIS

Pharmaxis has completed a phase IIa dose profiling study with the anti-inflammatory agent ASM8 in patients with allergic asthma.

Earlier this year, Pharmaxis acquired ASM8 along with other respiratory technologies from Canada's Topigen Pharmaceuticals (BD: Jan 17; Feb 9, 2010).

Pharmaxis said the study met the pre-defined primary efficacy and safety endpoints and ASM8 was found to be safe at all doses tested and particularly effective at an inhaled dose of 8mg once per day.

The company said that compared to saline control, at the 8mg dose, broncho-constriction following allergen challenge, as assessed by the change in forced expiratory volume in one second (FEV1) was reduced by 32 percent (p=0.03) during the early phase of this response and by 49 percent (p=0.002) during the late phase of this response.

Pharmaxis said that inflammation as measured by sputum eosinophil count, seven hours and 24 hours following allergen challenge was reduced by 49 percent (p=0.02) and by 57 percent (p=0.007) respectively.

[Mosby's Medical Dictionary says an eosinophil is a leukocyte constituting one to three percent of white blood cells and responding to allergies and some parasitic conditions.]

Pharmaxis chief executive officer Dr Alan Robertson said in a media release that the clinical data demonstrated "the potential value of this approach for treating asthma".

"The moderate to severe sector of the asthma market, which is the target of ASM8, represents a significant commercial opportunity and is under-served by current therapies," Dr Robertson said.

Dr Robertson told Biotech Daily that there were specified milestone payments to former share holders of Topigen, paid in Pharmaxis shares

Pharmaxis said the trial was designed to determine the efficacy and safety of ASM8 at a range of doses administered sequentially via inhalation to 12 patients with asthma followed by a controlled allergen challenge.

The company said ASM8 was a combination product of two RNA-silencing oligonucleotides targeted at receptors for mediators of inflammation in asthma.

The chair of the department of medicine at Ontario's McMaster University Prof Paul O'Byrne said that severe allergic asthma was difficult to treat and the results from this trial showed that "the approach of knocking down multiple inflammatory mediators may provide an important clinical option".

Pharmaxis said the prevalence of asthma was estimated at 60 million people in the US, Europe and Japan of which about three million people were classified as having severe, persistent asthma.

Pharmaxis climbed seven cents or 2.8 percent to $2.59.

CBIO

CBio says reaching the half-way mark in recruitment for its 150 patient trial of rheumatoid arthritis drug XToll triggers a $US1 million payment from partner Novo Nordisk AS.

CBio said the clinical trial milestone was triggered by the recruitment of the 75th patient into the phase II clinical trial.

CBio managing director Jason Yeates said his company was "greatly encouraged by progress in the trial and feedback from clinical investigators".

"Many patients are only partial responders to existing therapies and adverse effects from these therapies are a real issue being faced by … patients every day. Safer and more effective treatments are needed," Mr Yeates said.

CBio was up 3.5 cents or 9.6 percent to 40 cents.

QRX PHARMA

Michael Anthony Quinn has reduced his substantial holding and been diluted in QRX from 10,543,090 shares (14.07%) to 7,988,287 shares (7.83%).

In the change in substantial shareholder notice, Mr Quinn, who is also a director of several biotechnology companies including Resmed, said the reduction in shares was through distributions to Innovation Capital Associates QRX Trust I and II, comprising original investors.

Mr Quinn also acquired 5,512 shares in the December rights issue in which 17 million new shares were issued (BD: Dec 18, 2009).

QRX was unchanged at 87 cents.

PHARMAXIS

Melbourne's Acorn Capital has reduced its substantial holding in Pharmaxis from 15,125,283 shares (7.78%) to 14,924,313 shares (6.71%).

Acorn said it sold 200,970 shares for $502,189.14 or $2.50 a share.