Biotech Daily

Thursday October 17, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 20%, NEUREN DOWN 7%**

*** PHARMAXIS PREPARES FOR US BRONCHITOL CF TRIAL IN 2014**

*** IDT COMPLETES $3.1m PLACEMENT**

*** ALLIED PHASE I HERPES VACCINE TRIAL 'SAFE SO FAR'**

*** CIRCADIAN PHASE IA VGX-100 SOLID TUMOR TRIAL ENROLLED**

*** ANTISENSE EXPECTS EARLY LOOK AT ALT1103 ACROMEGALY DATA**

*** BENITEC PLEADS SCHULTZ, ROADSHOWS TO ASX 45% QUERY**

*** CYCLOPHARM CHAIRMAN VANDA GOULD CHARGED ON TAX SCHEMES**

MARKET REPORT

The Australian stock market was up 0.38 percent on Thursday October 17, 2013 with the S&P ASX 200 up 20.2 points to 5,283.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Antisense was the best, up 0.2 cents or 20 percent to 1.2 cents with 4.8 million shares traded, followed by Prima up 13.3 percent with 3.8 million shares traded, Benitec up 13.1 percent to 56 cents and Atcor up 10.5 percent to 21 cents, with 4.5 million shares traded.

Viralytics climbed 7.1 percent; Uscom was up 5.9 percent; Allied, Avita and Starpharma were up more than four percent; Medical Developments, Osprey and Phosphagenics rose more than two percent; Acrux, Clinuvel, Cochlear, CSL, GI Dynamics, Mesoblast and Reva were up more than one percent; with Resmed up 0.2 percent.

Neuren led the falls, down one cent or 7.4 percent to 12.5 cents with 18.3 million shares traded.

Bionomics lost 5.4 percent; Optiscan fell 4.9 percent; Patrys and Pharmaxis were down more than three percent; Living Cell shed 2.4 percent; with Alchemia, Anteo, Nanosonics, Sirtex and Tissue Therapies down by more than one percent.

PHARMAXIS

Pharmaxis expects to dose the first of about 350 patients in its pivotal US trial of Bronchitol for cystic fibrosis and by July 2014.

In a teleconference for its first quarter results, Pharmaxis chief executive officer Gray Phillips said that the company expected to sign a US distribution partner by April 2014.

Mr Phillips said the adult trial, known as CF303, would cost about $15 million and he expected a trial regulatory response from the US Food and Drug Administration by the end of this year.

He said the trial was expected to take about two years.

Mr Phillips said that sales of Bronchitol for cystic fibrosis were “heading in the right direction” and detailed the regional increases in sales (BD: Oct 16, 2013).

Mr Phillips said that Bronchitol required approval in Russia and Turkey with distributors in the final stages of negotiations in those countries while the company was also targeting the rest of Eastern Europe.

Mr Phillips said that patients in Germany were continue to cycle on and off the drug and the company was working with clinics to encourage better compliance, which would lead to greater sales.

He said that the uptake by clinics in the UK was 87 percent with better compliance and a low drop-out rate and the company was hoping to reach a 100 percent uptake.

Mr Phillips said the US ban on Aridol had not affected sales so far but a stock shortage was developing and the company as working with the FDA to confirm the contractor proposed remedy.

In June, Pharmaxis said it believed the listing could relate to issues outstanding from a 2012 scheduled FDA audit of a third party contract packer and the company continued to work with the packer in its response to the audit to have Aridol removed from the Import Alert as soon as possible (BD: Jun 3, 2013).

Mr Phillips said that Pharmaxis had received interest in the external funding of its research and development pipeline.

“We are in very detailed scientific discussions with government, pharmaceutical companies and venture capital companies,” Mr Phillips said.

In May, following the failure of its phase III trial of Bronchitol 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 to reduce the annualized cash burn 37.5 percent from about $32 million to $20 million. (BD: Apr 24, May 21, 28, 2013),

Mr Phillips said in May that by the end of 2013 the company would cease funding the ASM8 and PXS2200 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.

Pharmaxis fell half a cent or 3.85 percent to 12.5 cents with 260,327 shares traded.

IDT AUSTRALIA

IDT says it has completed its fully-underwritten placement raising about $3.1 million through the issue of 11,481,482 shares at 27 cents a share.

Last month, IDT raised $2,037,380 of a hoped-for $2,883,508 in a rights issue and said the shortfall of 3,133,808 shares would be placed through the underwriter, Wilson HTM Corporate Finance (BD: Sep 27, 2013).

Today, IDT managing director Dr Paul MacLeman said the funds would be used to implement the company’s new strategies.

IDT was unchanged at 37 cents.

ALLIED HEALTHCARE GROUP

Allied Health says that all 20 patients in its phase I trial of a herpes simplex virus 2 therapeutic vaccine have received two of three doses with “no safety issues to date”.
Allied said the trial had five cohorts of four participants each.
Allied chief executive officer Lee Rodne said the company expected the trial, being undertaken by Prof Ian Frazer and his Coridon team in Brisbane, would provide “important safety data, as well as the first indication of the vaccine’s protective and therapeutic effect in humans”.
In September Allied announced a fully-underwritten rights issue to raise $10 million, closing tomorrow October 18, of which $3 million was earmarked to increase its Coridon holding from 52 percent to 60 percent (BD: Sep 23, 2013).
Allied said that the therapeutic vaccine was based on technology developed by Prof Frazer and was designed as both a preventative and a therapeutic effect against herpes simplex virus 2.
The company said the primary focus of the study was safety but all participants had been screened to exclude previous exposure to herpes simplex virus 1 associated with oral cold sores or herpes simplex virus 2 associated with genital herpes, so the results would provide an early indicator of the vaccine’s ability to generate an effective immune response.
“The core technology has already shown very positive results in pre-clinical studies and we believe the phase I study will provide further validation of Prof Frazer’s immunotherapeutic vaccine technology,” Mr Rodne said.
Allied said that there was no cure for herpes simplex virus 2 and the US Centres for Disease Control estimated that one in six people in the US between the age of 14 and 49 had contracted the infection.
Allied was up half a cent or 4.8 percent to 11 cents with 17.4 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says subsidiary Ceres Oncology has completed enrolment of 19 patients in the phase Ia stage of its US trial of VGX-100 for solid tumors.
Circadian said that the wholly-owned subsidiary was developing the human monoclonal antibody VGX-100 targeting vascular endothelial growth factor-C (VEGF-C) as a treatment for patients with solid tumors including recurrent glioblastoma multiforme as well as breast cancer related lymphoedema.
The company said the trial with patients with advanced or metastatic solid tumors was a two-part dose escalation study of VGX-100 alone in the phase Ia stage and in combination with bevacizumab, marketed as Avastin in the phase Ib trial.
Circadian said that the primary objective of the study was to establish the safety profile of VGX-100, with secondary objectives including the determination of anti-tumor activity, biomarker levels and pharmacokinetics of VGX-100.
The company said that a further 23 patients would be enrolled in the phase Ib combination dose escalation study of VGX-100 with bevacizumab, giving a total of 42 patients.
Circadian said that preliminary efficacy data indicated that about a third of patients had a best tumor response of stable disease, with some showing durable responses of their disease not progressing for more than 15 weeks while on therapy.
The company said that detailed evaluation of VGX-100 alone or in combination with Avastin in the higher dose level patient cohorts was ongoing with an interim analysis of all patient data expected by the end of 2013 and final results in early 2014.
Circadian was unchanged at 25 cents.

ANTISENSE THERAPEUTICS

Antisense says it will conduct an interim analysis of a sub-set of data from its 24-patient phase II clinical trial of ATL1103 in patients with acromegaly by the end of 2013.

Antisense began dosing in April at 11 sites in the UK, Spain and France with more sites proposed for Central Europe and Australia (BD: April 10, Aug 2, 2013)

Today, Antisense said it expected that by the end of November 2013 eight patients would complete the full three months dosing at both of the dose levels and an interim analysis was expected to be available by the end of 2013.

The company said that the interim analysis would assess the percentage reduction from each patient's baseline at the start of the study for serum insulin-like growth factor-I (IGF-I) levels to their levels after the completion of dosing.

Antisense said that the effect of ATL1103 on reducing IGF-I levels was the primary marker of drug activity being assessed in the trial as acromegaly patients had elevated serum IGF-I levels compared to the normal population.

The company said the interim analysis was not powered for statistical significance but would provide "important and timely indicative data on the efficacy of ATL1103" which could be useful in planning the development of ATL1103 beyond the phase II trial.

Antisense said that the interim analysis could provide sufficient information to expedite discussions with prospective pharmaceutical and development partners ahead of the final trial results expected by July 2014.

Antisense was up 0.2 cents or 20 percent to 1.2 cents with 4.8 million shares traded.

CYCLOPHARM

Cyclopharm chairman Vanda Gould has been charged with tax and money laundering offences along with two other people and has been released on $5 million bail.

A spokesman for the Australian Federal Police told Biotech Daily that the three men, Gould, Peter Borgas and John Leaver appeared in the Sydney Central Local Court yesterday and Mr Gould had been released on bail of $5 million.

A Federal Police media release said that the three were charged with "tax and money laundering offences relating to the transfer of $30 million into Australia".

The media release said the matter related to the use of tax havens.

The Federal Police said the three men were each charged with: conspiracy to dishonestly cause a loss, or to dishonestly cause a risk of loss, to a third person, namely the Commonwealth, contrary to subsection 135.4(5) of the Criminal Code1995; and conspiracy to deal with property intending that the property, namely $30,000,000, would become an instrument of crime, contrary to section 400.3(1) and section 11.5 of the Criminal Code1995".

The Federal Police said the two offences carried maximum penalties of 10 and 25 years imprisonment respectively.

Cyclopharm said the matter was "an ongoing taxation dispute which is not connected to the company's business".

"In the absence of Mr Gould, directors have considered available information and are not aware of any impact on the company's business as a result of the allegations against Mr Gould," Cyclopharm said.

Cyclopharm managing director James McBrayer told Biotech Daily that the matter had been on-going for several years.

Mr McBrayer said that Mr Gould continued as the company's chairman and was a taxation accountant.

Cyclopharm was unchanged at 20 cents.

BENITEC BIOPHARMA

Benitec 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 45.2 percent from 36.5 cents on October 3 to 53 cents today, October 17, 2013 and noted an increase in trading volume.

Benitec said there has been "a steady increase in the stock price since the commencement of an investor roadshow" on September 12, 2013 in Melbourne, which was extended to a number of presentations in Sydney, Brisbane and Perth over the last four weeks, with the roadshow presentation posted on the ASX on September 12, 2013 (BD: Oct 8, 2013).

Benitec climbed 6.5 cents or 13.1 percent to 56 cents.