Biotech Daily

Friday July 11, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 24%, PSIVIDA DOWN 6%**

*** PHOSPHAGENICS RAISES $16.3m, PLAN FOR $3m MORE**

*** QRX FDA END-OF-REVIEW MEETING, HUNTING FOR A 3rd DIRECTOR**

*** RESONANCE ENDS VUEKLAR ACQUISITION, FOCUS ON HEPAFAT-SCAN**

*** BENITEC EXPECTS 1st TT-034 HEPATITIS TRIAL DATA NEXT WEEK**

*** CORRECTION: BIO-MELBOURNE NETWORK, UNISEED**

MARKET REPORT

The Australian stock market climbed 0.41 percent on Friday July 11, 2014 with the S&P ASX 200 up 22.4 points to 5,486.8 points.

Five of the Biotech Daily Top 40 stocks were up, 19 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Optiscan was the best, up 0.7 cents or 24.1 percent to 3.6 cents with 200,000 shares traded.

Biotron climbed 4.8 percent; Alchemia and Nanosonics rose more than one percent; with Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Psivida led the falls, down 32 cents or 6.4 percent to $4.68 with 1,600 shares traded, followed by Patrys down 6.25 percent to three cents with 478,387 shares traded.

Analytica, Clinuvel and Phosphagenics fell more than five percent; Acrux, Admedus, Antisense, Cellmid, Mesoblast and Pharmaxis were down more than three percent; Atcor, Genetic Technologies and Prima shed more than two percent; GI Dynamics, Neuren and Prana were down one percent or more; with Benitec and Bionomics down by less than one percent.

PHOSPHAGENICS

Phosphagenics says it has raised $16.3 million in a placement at eight cents a share to and hopes to raise a further $3 million through a share plan.

Phosphagenics said that the placement was to institutional and sophisticated investors in Europe, US, Asia and Australia and would be made in two tranches, with the second tranche subject to shareholders' approval at a general meeting to be held on or around August 25, 2014.

The company said that the eight cent share price was a discount of 11 percent to the last sale price of nine cents.

Phosphagenics said that the lead manager of the placement was Bell Potter Securities, assisted by Taylor Collison as co-manager for Australian institutions.

The company said that the record date for the share plan was July 10, the plan would open on July 15 and close on July 29, 2014.

Phosphagenics chief executive officer Harry Rosen said the capital raising "positions us strongly to fulfil our commercialization objectives and fully funds our scheduled TPM-opioid clinical trial programs".

"The capital raised is earmarked for our pivotal TPM-oxymorphone phase II clinical trial in the USA scheduled for the first half of 2015 and our upcoming TPM-oxycodone phase II trial in Australia," Mr Rosen said.

Phosphagenics fell half a cent or 5.6 percent to 8.5 cents with four million shares traded.

QRX PHARMA

QRX provided no details on its end-of-review meeting with the US Food and Drug Administration and says it is searching for a third director.

Earlier this week, Lang Walker director Bruce Hancox and Neuren executive chairman were elected directors of QRX with then chairman Dr Peter Farrell and director Dr Gary Pace resigning ahead of the meeting and directors Peter Campbell and Michael Quinn resigning effective from the close of business today (BD: Jul 9, 2014).

The board spill followed the company's third US Food and Drug Administration rejection of its Moxduo dual opioid and the revelation by QRX of previously unknown FDA criticism of the Moxduo drug application (BD: Apr 23, May 15, 2014).

The resignations have left QRX with two directors and ASX-listed companies are required to have three directors.

Mr Hancox said that there had not been sufficient time to find a third director and a search for a suitable director was underway, but the company could face a fine of $1,000.

In a media release QRX said it "provided feedback" on it July 9, 2014 meeting with the FDA to discuss the feasibility and requirements for approving Moxduo for moderate to severe acute pain, but provided no information about the FDA response.

QRX said it had "outlined several questions to discuss with [the] FDA to ensure the company receives clear direction for the Moxduo program".

"The questions addressed the overall approach for registration of Moxduo, potential study design and the number of clinical studies," the company said.

QRX chief executive officer Dr Edward Rudnic said the company was "encouraged by the extent of engagement on clinical issues by the Food and Drug Administration and we found the meeting to be constructive and helpful".

"We are evaluating the path forward and will utilise this guidance to determine the appropriate next steps," Dr Rudnic said.

QRX fell 0.3 cents or 3.5 percent to 8.3 cents.

RESONANCE HEALTH

Resonance says it has terminated its proposed acquisition of the Dundee, Scotland-based VueKlar Cardiovascular and will focus on its Hepafat-Scan technology.

In June, Resonance said it had a non-binding agreement to acquire Vueklar for scrip for its pipeline of magnetic resonance imaging-related medical devices (BD: Jun 3, 2014).

The company said that it had completed its due diligence and decided not to proceed

Resonance said that the Vueklar technology “appears to present a solid platform for an investor to take forward with an experienced team to support its development ... [but] we have formed the opinion that Resonance Health should prioritize the commercialization of its existing [intellectual property] at this time, specifically following the recent regulatory approvals for Hepafat-Scan”.

Resonance said it was currently undertaking a capital raise and the funds would be used to progress the existing portfolio, including Ferriscan, Hepafat-Scan and the research and development of a magnetic resonance imaging-based fibrosis test.

The company said that Ferriscan was cash flow positive and profitable and commercialization of Hepafat-Scan had begun with a US market assessment, contacting its existing radiology customer base and engaging with pharmaceutical companies planning clinical trials which required a measurement of fatty liver.

Resonance said it was considering a validation study for Hepafat-Scan and ways to automate the large-scale delivery of the technology to the market through an internet ‘cloud’ based product.

The company said that work was continuing on developing methods of using magnetic resonance imaging data to assess liver fibrosis and it was exploring collaboration to continue to work on the project.

Resonance said it had commissioned the Boston, Massachusetts-based Health Business Group for a detailed US market assessment of the opportunities for Hepafat-Scan and the report provided guidance on potential clinical scenarios where Hepafat-Scan could be beneficial, competing approaches, pricing models, reimbursement and distribution alternatives.

The company said it was targetting existing and new customers on the potential role of Hepafat-Scan in various patient management scenarios and had engaged its extensive network of radiology facilities currently using Ferriscan to assess the potential role of Hepafat-Scan within their organizations.

Resonance said that a Japanese study of 3,074 subjects showed that people with non-alcoholic fatty liver disease had nearly three times the risk of developing diabetes than people without the disease and was the first to show a reduction in type 2 diabetes with improvement in fatty liver disease.

The company said that a French study of 5,671 subjects found that non-alcoholic fatty liver disease was an independent predictor of cardio-vascular disease, recommending patients at risk of cardiovascular disease should be screened for the disease, and a third study concluded that fatty liver disease had a strong association with hepatocellular carcinoma, or liver cancer, even in the absence of liver cirrhosis.

Resonance said that as evidence against fatty liver mounted, studies would require the measurement of liver fat accurately and non-invasively, which Hepafat-Scan does.

The company said it was in discussions with pharmaceutical companies planning clinical trials which might require an assessment of liver fat.

Resonance said that discussions were ongoing with a number of companies evaluating the potential use of Hepafat-Scan in their trials.

Resonance was up 0.9 cents or 27.3 percent to 4.2 cents with 4.3 million shares traded.

BENITEC BIOPHARMA

Benitec says it will report on the progress of patients in its phase I/IIa trial of TT-034 for hepatitis C as new cohorts are treated following data safety monitoring board approval.
Benitec said that the first patient dosed at the Durham, North Carolina-based Duke Clinical Research Institute continued to be monitored (BD: May 29, 2014).
The company said that the trial protocol included a data safety monitoring board assessment of the first patient six weeks after dosing to determine whether it was safe to dose the second patient.
Benitec said the assessment was expected to take up to a week to complete.
The first patient was dosed on May 29, 2014 so the assessment should be completed by July 17, 2014.
The company said that a cumulative review of all data would be conducted six weeks after the second patient was dosed to determine if it was safe to proceed onto the second cohort of patients.
Benitec said the TT-034 trial provided for five cohorts, with two patients in cohort 1 and three patients in cohorts 2 to 5, with each cohort having an increasing dose level.
The company said that in cohorts 2 to 5, one patient would be dosed and a review would follow to approve the remaining two patients in that cohort.
Benitec said that patients in cohorts 2 and 3 would be observed for six weeks and patients in cohorts 4 and 5 would be observed for 10 weeks.
The company said the trial's primary end-point was the safety and tolerance of TT-034 in hepatitis C infected patients.
Benitec said it expected to report preliminary assessments of safety data when the second patient was dosed and on the dosing of the first patient in each of the subsequent cohorts or should a material event occur that related to the trial.
Benitec fell half a cent or 0.4 percent to $1.16.

BIO-MELBOURNE NETWORK

Last night's article on the Bio-Melbourne Network July Bio-Briefing on Fibrotech omitted the involvement of Uniseed funding for the private company.
The original media release from Fibrotech said that, along with the Medical Research Commercialization Fund and Brandon Capital, it was supported by Uniseed, a venture fund operating at the University of Melbourne, the University of Queensland and the University of New South Wales with capital provided by the universities and Australian Super (BD: May 2, 2014).
Biotech Daily apologizes for the omission and blames the Palmer United Party as well as the Government for the confusion. No sub-editors will be axed or taxed.
The Bio-Melbourne Briefing will be held at Nexia Australia, Level 18, 530 Collins Street, Melbourne on July 31, 2014 at 3:45pm for a 4pm start.
The Briefing until 5pm will be followed by networking drinks.
For more information and to book go to: http://www.biomelbourne.org/events/view/324.