Biotech Daily

Wednesday July 9, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 17%, IDT DOWN 12%**

*** ALL CHANGE AT QRX:**
- TREAGUS, HANCOX REPLACE FARRELL, PACE, CAMPBELL, QUINN

*** PROGEN, MEDIGEN PI-88 INTERIM ANALYSIS THIS MONTH**

*** RHINOMED, FITNESS FIRST PARTNER ON TURBINE NASAL PLUGS**

*** PHOSPHAGENICS REQUESTS 'FUNDING EVENT' TRADING HALT**

*** PERPETUAL TAKES PROFIT, AGAIN, DOWN TO 5.6% OF SIRTEX**

MARKET REPORT

The Australian stock market fell 1.06 percent on Wednesday July 9, 2014 with the S&P ASX 200 down 58.4 points to 5,452.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and five were untraded. All three Big Caps fell.

Prana was the best, up four cents or 16.7 percent to 28 cents with 1.4 million shares traded, followed by Avita up 11.1 percent to 10 cents with 670,624 shares traded.

Neuren climbed 9.2 percent; Oncosil rose 2.1 percent; Atcor, Living Cell, Pharmaxis, Starpharma and Tissue Therapies were up more than one percent; with Alchemia up 0.9 percent.

IDT led the falls, down three cents or 12.0 percent to 22 cents with 10,000 shares traded.

Circadian lost 7.1 percent; Acrux was down 6.6 percent; Bionomics, Ellex and Medical Developments fell more than four percent; Patrys was down three percent; Benitec, GI Dynamics, Prima, Sirtex and Universal Biosensors shed more than two percent; Cochlear, CSL, Mesoblast, Nanosonics and Viralytics were down more than one percent; with Resmed down 0.6 percent.

QRX PHARMA

QRX chairman Dr Peter Farrell and directors Dr Gary Pace, Peter Campbell and Michael Quinn resigned prior to the Walker Group requisitioned extraordinary general meeting.

QRX said that the resignations of Dr Farrell and Dr Pace were effective from 9.50am today ahead of the 10am meeting in Sydney, while Mr Campbell and Mr Quinn would retire from the close of business on July 11, 2014 “to facilitate an orderly transition”.

In a later announcement, QRX said that Mr Hancox was elected with 51,922,786 proxy votes (63.3%) in favor and 30,077,611 proxy votes (36.7%) against, with Dr Treagus elected by a slightly larger majority.

The company’s most recent Appendix 3B announcement said there were 164,190,969 shares on issue meaning the votes against Mr Hancox amounted to 18.3 percent of the company, sufficient to call extraordinary general meetings.

The new board will have to appoint a third director following the resignation of all four existing directors.

The Walker Group holds 16,443,120 shares or 10.0 percent of QRX and called the board spill following 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).

Today, the meeting chairman Peter Campbell said the outgoing directors were “devastated by the recent turn of events”.

“Throughout the clinical trials for Moxduo, the company followed FDA guidance to meet the combination rule,” Mr Campbell said. “The company was encouraged by its interactions with the FDA leading up to June 2012 and was very disappointed at not receiving approval as a consequence of the revised interpretation in June 2012 by the FDA of the combination rule and its applicability to Moxduo,” Mr Campbell said.

“Despite the existing regulation that equivalence in efficacy and safety was required for approval, the FDA elected to ask for a clinical benefit for some particular patient population,” Mr Campbell said. “They then agreed that Study 022 and post hoc analyses could satisfy their requirements.”

“That review took over 12 months during which time the FDA was under intense and controversial political pressure regarding opioid approvals,” Mr Campbell said.

“Unfortunately, at the April 2014 advisory committee meeting, the committee rejected Study 022’s post hoc analyses and preferred pre-specified outcomes and statistical metrics instead,” Mr Campbell said.

Following this feedback, the FDA declined to approve Moxduo,” Mr Campbell said.

“Given this history, the focus now turns to feedback from the FDA in the meeting later tonight, and what that means for the future of Moxduo and QRX Pharma,” he said.

In April, FDA background notes to the advisory committee were critical of the QRX trial design and endpoints and said that “throughout clinical drug development, the Division [of Anesthesia, Analgesia, and Addiction Products] has held milestone meetings with the applicant, including a pre-IND, end-of-phase II and pre-NDA meeting,” the notes said.

“Additionally, the Division evaluated the phase III protocol, Q8003-008, under special protocol assessment but did not agree with the proposed primary efficacy endpoint and statistical approach and issued a ‘no agreement letter’,” the FDA notes said.

Then QRX chief executive officer Dr John Holaday said he could not recall receiving that letter.

At March 31, 2014, QRX had a cash burn of $2,673,000 and cash of $14,259,000.

According to ASX data from Commonwealth Securities the QRX market capitalization as of last night was $14 million.

QRX climbed 0.2 cents or 2.3 percent to nine cents.

PROGEN PHARMACEUTICALS

Progen says that an independent committee will conduct an interim analysis of Taiwan licencee Medigen Biotechnology Corp's phase III trial of PI-88 for liver cancer.
Progen said that Medigen had scheduled a July 27, 2014 meeting for the independent committee of medical and statistical experts to un-blind and analyze the 131 patient data.
The company said that Medigen was completing the phase III trial in Taiwan, South Korea, China and Hong Kong to confirm the safety and efficacy of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection.
Progen said that recruitment of 500 patients for the phase III trial had been completed and if the interim results from this clinical trial were in line with expectations, Medigen expected to lodge the accelerated new drug application with the Taiwan Food and Drug Administration this year.
Progen was untraded at 83 cents.

RHINOMED

Rhinomed says it will partner with the Fitness First chain to promote its Breatheassist Turbine nasal plug technology this month.
Rhinomed said that with Fitness First it would use, demonstrate and promote the technology, which enabled improved airflow and easier breathing.
The company said the Turbine plugs showed a 38 percent average improved airflow and minimized shortness of breath resulting from strenuous exercise, improving performance.
Rhinomed said the Turbine technology would be provided to fitness class instructors at 40 Fitness First locations and displayed in more than 70 facilities, featured in the Fitness First magazine and was designed to coincide with the Tour de France cycling event.
Rhinomed chief executive officer Michael Johnson said the deal was an "outstanding commercial opportunity".
"This is a real coup for our company," Mr Johnson said.
Rhinomed was up 0.8 cents or 21.05 percent to 4.6 cents with 13.2 million shares traded.

PHOSPHAGENICS

Phosphagenics has requested a trading halt pending an announcement "regarding a significant event relating to funding".
Trading will resume on July 11, 2014 or on an earlier announcement.
Phosphagenics last traded at nine cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have again reduced their substantial shareholding in Sirtex from 3,868,684 shares (6.90%) to 3,122,165 shares (5.56%).
Perpetual said it sold the 746,519 shares from May 20 to July 4, 2014 at prices ranging from $16.66 to $18.58.
Perpetual has been taking profit on its Sirtex holding this year, having bought founder Dr Bruce Gray's shares in 2013 (BD: Aug 12, 2013; Feb 5, 18, 19, 21, Apr 4, May 16, 2014).
Sirtex fell 40 cents or 2.1 percent to $18.67 with 175,366 shares traded.