Biotech Daily

Monday August 26, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRANA UP 13.5%, PHARMAXIS DOWN 7%**

*** CE MARK FIRST APPROVAL FOR ALLIED HEALTH CARDIOCEL**

*** NUSEP SHARE PLAN RAISES $1.2m**

*** ANTEO FILES 2 NEW AUSTRALIAN MIX&GO PATENT APPLICATIONS**

*** QRX REQUESTS 'FDA REVIEW' TRADING HALT**

*** BENITEC PROMOTES CEO DR PETER FRENCH TO M-D**

*** PRANA PLEADS SCHULTZ TO ASX 14% QUERY**

MARKET REPORT

The Australian stock market climbed 0.23 percent on Monday August 26, 2013 with the S&P ASX 200 up 12.0 points to 5,135.4 points.

Nine of the Biotech Daily Top 40 were up, 16 fell, seven traded unchanged and eight were untraded.

Prana was the best, up 7.5 cents or 13.5 percent to 63 cents with two million shares traded.

Allied Health climbed 5.3 percent; Genetic Technologies, Prima and Tissue Therapies were up more than three percent; Alchemia rose 2.4 percent; Benitec, CSL and Nanosonics were up more than one percent; with Mesoblast up 0.7 percent.

Pharmaxis led the falls, down one cent or 6.7 percent to 14 cents with 5.1 million shares traded.

Phosphagenics and Reva lost more than five percent; both Medical Developments and Neuren fell 4.8 percent; Avita, Impedimed and Sirtex were down more than three percent; Osprey shed 2.9 percent; Anteo, QRX, Resmed, Starpharma and Viralytics fell one percent or more; with Acrux, Bionomics, Cochlear and GI Dynamics down by less than one percent.

ALLIED HEALTHCARE GROUP

Allied Health says it has Conformité Européenne (CE) mark for its Cardiocel bovine patch for cardiac repair and expects first sales by the end of the year.

Allied chief operating officer Dr Julian Chick told Biotech Daily that the CE mark was the first full market approval for the product, although it was available under the Australian Authorised Prescriber Scheme in Victoria and Queensland.

The company said that the first approval for the Adapt process-treated tissue was for cardiac diseases and defects, but the tissue had potential uses for vascular reconstruction, hernia repair and pelvic floor reconstruction

The Cardiocel was originally developed at Biomd, which later merged with Allied Health, (BD: Feb 19, 2009).

Allied said that the Adapt tissue engineering process produced animal-derived tissues for implantable tissue patches compatible with the human body for soft tissue repair applications and for the production of replacement tissue heart valves.

The company said the Adapt technology had advantages over current tissue treatment processes on the market, notably the reduction of calcification (BD: Mar 6, 2013).

Allied lodged its CE mark application in June last year and the then Cardiocel chief executive officer Bob Atwill said the CE mark submission was “a key value driver for the Allied Healthcare Group” (BD: Jun 5, 2012).

Today, Allied chief executive officer Lee Rodne said the CE mark approval was “a key milestone for Allied”.

“As we continue to roll-out Cardiocel in different markets, we can look forward to increased revenue streams and we expect to see a significant lift in company revenue over the coming years,” Mr Rodne said.

Allied said it would launch and start selling the product throughout Europe for the repair and reconstruction of heart defects including treating congenital heart disease and repairing heart valves in both children and adults.

The company said that the approval provided commercial and scientific validation and was a platform to launch additional cardiovascular products, as well as regenerative tissue products for the repair and reconstruction of other defects and diseases.

“Cardiocel’s approval in Europe provides the surgeons with an important addition to their treatment in the repair of cardiac defects and offers children and adults suffering from cardiac defects and disease a promising new technology that displays strong levels of regeneration and long term benefits,” Mr Rodne said.

Allied said that Cardiocel had benefits for patients and surgeons including strong levels of regeneration of self-tissue without needing external stem cells or growth factors and no cytotoxicity at the site of repair, thereby reducing the issue of calcification which could lead patients to have repeat surgeries.

The company said that Cardiocel was ready to use, off the shelf, saving time during surgery.

In April, Allied filed a US Food and Drug Administration 510 k pre-market approval application and said it expected US approval for Cardiocel in 2014 (BD: Apr 2, 2013).

Allied was up 0.4 cents or 5.3 percent to 7.9 cents with 57.2 million shares traded.

NUSEP

Nusep says its share purchase plan at 4.5 cents a share has raised $1,193,120.

Nusep said that the funds were for its Sydney membrane manufacturing facility, for working capital and paying down existing liabilities.

Nusep was up half a cent or 11.6 percent to 4.8 cents.

ANTEO DIAGNOSTICS

Anteo says it has filed two new Australian patent applications relating to and extending the company's Mix&Go molecule binding or 'bio-glue' technology.

Anteo said that if the Australian Patent Office granted the patents entitled 'Conjugating Molecules to Particles' filed on August 13 and 'Coating of Particles' filed on August 20, along with additional jurisdictions in which they were expected to filed, they would provide protection in novel biological fields and broaden the fields of use of existing patent portfolio.

The company said the patent applications expanded and build on its existing patent portfolio and broaden the field of use to new areas such as the commercially valuable market sector of bio-separations.

Anteo said that there was potential for further patentable material to emerge as it worked "to further exemplify the existing filings".

Anteo chief executive officer Dr Geoff Cumming said that protecting the Mix&Go technology and its potential uses was" an ongoing priority for Anteo and the developments announced today are pleasing".

Anteo fell 0.1 cents or 1.7 percent to 5.9 cents.

QRX PHARMA

QRX has requested a trading halt pending an announcement "in relation to the results of the new drug application review of Moxduo by the US Food and Drug Administration".

Last year, QRX fell 71 percent on the FDA complete response letter rejecting its application for Moxduo IR and requiring further data (BD: Jun 27, 2012).

In June 2013, QRX said that data for 64 of the 375 subjects at a single trial site in Study 022 comparing Moxduo to equi-analgesic doses of morphine or oxycodone had incorrect time codings that needed to be corrected (BD: Jun 27, 2013).

QRX chief executive officer Dr John Holaday said at that time the adjusted data would be filed "in the next several weeks" and the Prescription Drug User Fee Act date would be delayed from August 26 to November 2013.

The equi-analgesic dose study Study 022 provided mixed results when Moxduo (12mg morphine and 8mg oxycodone) was compared to either 24mg morphine or 16mg oxycodone alone (BD: Jun 14, 2012).

Trading will resume on August 29, 2013 or on an earlier announcement.

Prior to the announcement, QRX fell 1.5 cents or 1.3 percent to $1.085.

BENITEC BIOPHARMA

Benitec says that chief executive officer Dr Peter French has been appointed to the board as managing director.

Benitec said that Dr French joined the company in 2009 as its chief scientific officer and was appointed chief executive officer in June 2010.

The company said that Dr French was responsible for driving its clinical development strategy, with lead programs in hepatitis C and lung cancer preparing to enter clinical trials.

Benitec chairman Peter Francis said that Dr French's "achievements as [chief executive officer] in building the company's portfolio of programs and directing its emergence as a clinical stage company make it highly appropriate that he join the board and the directors are delighted with this outcome".

Benitec was up half a cent or 1.75 percent to 29 cents.

PRANA BIOTECHNOLOGY

Prana 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 13.9 percent from 50.5 cents on August 22 to 57.5 cents on August 23, 2013, but did not note an increase in trading volume.

ASX data shows that Prana has climbed 238.2 percent from 17 cents on August 27, 2012.

Prana said that it had "no direct explanation for the increase in price of the securities other than": anticipated results of the Reach2 trial for Huntington's disease in the coming weeks, and as previously announced that PBT434 showed potential as a treatment for Parkinson's disease, approval of an open label extension study in Alzheimer's disease; completion of a phase II PBT2 Huntington disease trial; dosing the first patient in the PBT2 Alzheimer's disease extension study; and an announcement earlier this month that it was preparing for the next steps in the PBT2 development path.

Prana climbed 7.5 cents or 13.5 percent to 63 cents with two million shares traded.