Biotech Daily

Friday July 15, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: FACTOR THERA UP 8%; ANTISENSE DOWN 9%**

*** PSIVIDA: 'MEDIDUR PREVENTS UVEITIS RETURN, IMPROVES ACUITY'**

*** COO GLENN CROSS TO REPLACE AUSBIOTECH CEO DR ANNA LAVELLE**

*** PHARMAXIS US BRONCHITOL CYSTIC FIBROSIS TRIAL RECRUITED**

*** US PATENT FOR ANALYTICA AUTOSTART BURETTE**

*** BOTANIX OPENS UP 35%, CLOSES UP 50%**

*** INVERAREY SELLS, BUYS DOWN TO 6% OF IMMURON**

MARKET REPORT

The Australian stock market was up 0.33 percent on Friday July 15, 2016 with the ASX200 up 18.0 points to 5,429.6 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell and six traded unchanged.

Factor Therapeutics was the best, up 0.3 cents or 8.1 percent to four cents with 400,800 shares traded.

Anteo and Opthea climbed more than seven percent; Biotron was up 6.8 percent; Compumedics, Genetic Technologies, Pharmaxis, Psivida and Uscom were up more than five percent; Benitec was up 4.3 percent; Admedus, Atcor and Cellmid were up more than three percent; IDT and Impedimed rose two percent or more; Bionomics, Ellex, Polynovo and Sirtex were up more than one percent; with Clinuvel, CSL, Medical Developments and Reva up by less than one percent.

Antisense led the falls, down 0.3 cents or 8.6 percent to 3.2 cents, with 20,000 shares traded.

Living Cell and Prana fell more than four percent; Osprey, Universal Biosensors and Viralytics were down more than three percent; Airxpanders shed 2.1 percent; Actinogen Cochlear, Mesoblast, Neuren and Orthocell fell more than one percent; with Pro Medicus and Resmed down by less than one percent.

PSIVIDA CORP

Psivida says a phase II study of Medidur for uveitis shows the injected fluocinolone acetonide drug improves visual acuity and prevented recurrence of the disease.

Psivida says that an investigator-sponsored phase II study of Medidur showed no recurrence of uveitis in 11 Medidur-treated eyes treated after two years, while six of 10 fellow eyes with standard of care including steroid eye drops, but without Medidur, experienced recurrence.

The company said that visual acuity typically declined over time in uveitis patients, but all Medidur-treated eyes had a significant improvement in mean visual acuity compared to baseline throughout the two years, and mean visual acuity showed successive improvement at two years over one year.

Psivida said that at one year, the improvement in mean visual acuity from baseline was 17 letters on the early treatment diabetic retinopathy study chart ($p = 0.041$), while at two years, the improvement from baseline had increased to 22 letters ($p = 0.016$).

The company said that the Durham, North Carolina-based Duke University School of Medicine professor of ophthalmology Dr Glenn Jaffe was the principal investigator on its phase III trial of Medidur for posterior uveitis and was the lead investigator for the phase II study.

Psivida chief executive officer Paul Ashton “Medidur’s performance in these two-year results continued to exceed our expectations”.

“Arresting and preventing recurrence of disease over a two-year period coupled with continued improvement in visual acuity are extremely encouraging and point to Medidur’s potential to provide an effective, well-tolerated treatment in an area where there is significant unmet medical need,” Dr Ashton said.

Psivida said that other safety results were also positive, with the most common adverse event elevated intraocular pressure in 18 percent of Medidur-treated eyes after implantation and was managed “by standard means”.

The company said that two eyes were treated with filtration procedures during the two years.

Psivida said that research was reported in a paper entitled ‘Injectable Fluocinolone Acetonide Long-Acting Implant for Noninfectious Intermediate Uveitis, Posterior Uveitis, and Panuveitis’ to be published in in the journal Ophthalmology, with an abstract available at: http://www.aaojournal.org/article/S0161-6420(16)30330-X/abstract.

The abstract concluded that fluocinolone acetonide “effectively controlled intraocular inflammation in all eyes in the study and at the last follow-up all implanted eyes demonstrated an improvement in visual acuity … [and the] implant is a promising approach for patients with non-infectious intermediate uveitis, posterior uveitis, or panuveitis who do not respond to, or are intolerant to, conventional therapy”.

The company said that 11 participants with recurrent non-infectious intermediate, posterior or pan uveitis were randomized to receive a masked low or a high dose of Medidur.

Psivida said that fellow eyes with uveitis were treated with standard of care, which included steroid eye drops and the patients were assessed throughout the 24- month follow-up period of the study.

The company said that its phase III trial was studying the low dose of Medidur.

Psivida said that Medidur was an injectable micro-insert designed to treat posterior uveitis and provided sustained release of the corticosteroid fluocinolone acetonide for three years.

The company said that Dr Jaffe would present the study results at the American Society of Retinal Specialists meeting, to be held in San Francisco, August 9 to14, 2016.

Psivida climbed 23 cents or 5.5 percent to $4.40.

AUSBIOTECH

Ausbiotech says that chief operating officer Glenn Cross will replace Dr Anna Lavelle as chief executive officer the industry organization on September 1, 2016.
Ausbiotech said that Dr Lavelle had been the organizations chief executive officer for more than 11 years with.
The organization said that Dr Lavelle would continue as principle advisor to the board.
Ausbiotech said that Dr Lavelle was named among the 100 most influential people in global life sciences, as determined through nominations and selections from an international panel of experts and peers and reported in Scientific American Worldview: A Global Biotechnology Perspective .
Ausbiotech chair Julie Phillips said that Dr Lavelle was “respected, visionary and eminent, as well as talented, tenacious and a dedicated advocate for our industry and we have been very fortunate to have her expertize”.
“Ausbiotech has gone from strength-to-strength under Anna’s leadership,” Ms Phillips said.
Ms Phillips said that Dr Lavelle’s landmark reform, the Research and Development Tax Incentive was a highlight achievement.
Ausbiotech said that national communications manager and chief industry affairs officer Lorraine Chiroiu would be appointed deputy chief executive officer.
Biotech Daily salutes Dr Lavelle’s excellent leadership in our decade of working together.

PHARMAXIS

Pharmaxis says it has completed recruitment of its US approval-directed, 420-patient phase III trial of Bronchitol (mannitol) in adults with cystic fibrosis.
Pharmaxis said that trial results were expected by July 2017 and pending a positive outcome it would submit a response to the US Food and Drug Administration, with a decision expected by the end of 2018.
The company said that the FDA-guided trial was a 26-week randomized, double-blind parallel group investigation of Bronchitol twice daily in cystic fibrosis patients aged 18 and over to assess improvements in lung function, pulmonary exacerbations and safety.
Pharmaxis said that 424 patients had been recruited and subject to randomization, the final enrolment was expected to be 420 adult patients.
The company said that US development of Bronchitol was partnered with the Parma, Italy-based Chiesi Farmaceutici SpA which was responsible for the new drug application and funding up to $US22 million of the $US26 million trial costs (BD: Jan 18, May 8, 2015).
Pharmaxis said that milestones payments up to $US25 million would be payable including $US10 million on the launch of Bronchitol.
Pharmaxis chief executive officer Gary Phillips said the company was “pleased to have attained this significant milestone in such a large undertaking securing more than 400 study participants at 126 sites in 21 countries”.
“The US is the largest [cystic fibrosis] market and we now have greater certainty around when the study will report and, subject to that report being positive, when the FDA will complete its consideration of our new drug application,” Mr Phillips said.
Mr Phillips said that the study protocol followed the design of two complete trials, in which a post hoc analysis of the subgroups of adult patients showed a significant improvement in forced expiratory volume over one second.
Pharmaxis said Bronchitol was approved for cystic fibrosis in patients older than six years in Australia and for patients aged 18 years and older in the European Union and Israel.
Pharmaxis was up 1.5 cents or 5.7 percent to 28 cents with one million shares traded.

ANALYTICA

Analytica says it has been granted a US patent for its Autostart burette system, providing patent until January 17, 2031.
Analytica chief executive officer and co-inventor Geoff Daly said that “obtaining patent protection in the world’s largest medical device market is a major milestone and an important step in the commercialisation of the Autostart infusion system”.
“The patent process is lengthy and complex, with this national phase patent taking more than 10 years from the priority date,” Mr Daly said.
“Demonstrating that a product can achieve this level of intellectual property protection is valuable to licencees and may encourage licence deals from one of the larger infusion system manufacturers,” Mr Daly said.
Analytica said that the burette was sold under licence in Australia and New Zealand by Medical Australia under their Tuta Firstflow brand name.
Analytica fell 0.1 cents or 11.1 percent to 0.8 cents with 9.2 million shares traded.

BOTANIX PHARMACEUTICALS (FORMERLY BONE MEDICAL)

Botanix opened under the code BOT at 2.7 cents, climbing as high as 3.4 cents before closing at three cents, a 50 percent premium to its initial public offer price of two cents.
Botanix raised $3.5 million to backdoor into Bone Medical to develop cannabidiol dermatology products (Mar 21, Jun 14, 2016).
The June general meeting passed resolutions including the 3,333 for 1,000 consolidation, approval of the change in nature and scale of activities, the name change and the election of directors Matthew Callahan, Graham Griffiths and Dr William Bosch, with Mr Griffiths replacing chairman Robert Towner who would continue as a director.
The company said the Philadelphia, Pennsylvania-based Botanix was developing products for skin diseases including acne, psoriasis and atopic dermatitis.
Mr Callahan said the company’s “first product, BTX1503, targeting moderate to severe acne presents a compelling investment opportunity in a space where there has been little innovation for a decade” with human trials to begin by the end 2017.
Botanix closed at three cents with 24 million shares traded.

IMMURON

The Melbourne-based Inverarey as trustee for Kilchurn Trust says it has reduced its holding in Immuron from 71,250,000 shares (6.88%) to 5,875,567 shares (5.79%).
In 2013, Inverarey as trustee for Kilchurn Trust become substantial Immuron and said that Inverarey held 70,000,000 shares and Ian Pattison and Katherine Forrest held 1,250,000 shares with Chimaera Capital as registered holder (BD: Oct 24, 2013).
Today Inverarey said it sold 4,750,000 shares between October 29 and November 12, 2013, acquiring shares in rights issues on March 3, 2014 prior to the company’s November 2014 one-for-40 consolidation (BD: Nov 20, 2014).
Immuron raised $284,000 in a rights issue at 0.3 cents a share (BD: May 1, 2013).
The Inverarey notice said it acquired 1,203,393 shares in the rights issue at 25 cents a share which raised $5,330,245 on July 7, 2016 (BD: Jul 5, 2016).
Immuron was unchanged at 23 cents.