Biotech Daily

Wednesday March 14, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHARMAXIS UP 9%, SUNSHINE HEART DOWN 7%**

*** PBAC BACKS PHARMAXIS BRONCHITOL FOR CYSTIC FIBROSIS**

*** NEURON SYSTEMS EVALUATES PSIVIDA'S DURASERT FOR DRY AMD**

*** IMPEDIMED PASSES 23m US COVERED LIVES FOR L-DEX TEST**

*** FDA REVIEWS SUNSHINE HEART TRIAL APPLICATION, NO QUESTIONS**

*** ALLIED HEALTH REQUESTS CAPITAL RAISING TRADING HALT**

*** US PATENT FOR ISONEA COUGH COUNTER**

*** PROBIOMICS 1-FOR-20 CONSOLIDATION DATE SET**

*** NUSEP APPOINTS INVESTOR ANDREW GOODALL DIRECTOR**

*** VIRAX APPOINTS JOHN MORRISON DIRECTOR, FILES H1 ACCOUNTS**

MARKET REPORT

The Australian stock market was up 0.93 percent on Wednesday March 14, 2012, with the S&P ASX 200 up 39.6 points to 4287.2 points. Nine of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and eight were untraded.

Pharmaxis was the best, up as much as 14.5 cents or 13.4 percent to $1.23, before closing up 9.5 cents or 8.8 percent to $1.18 with 1.4 million shares traded, followed by Patrys up 8.6 percent to 3.8 cents with 30,000 shares traded.

Psivida climbed 6.3 percent; Prima was up five percent; Clinuvel and Nanosonics were up more than four percent; Cochlear was up 3.1 percent; Bionomics, Phosphagenics and Resmed rose more than two percent; with Mesoblast up 1.2 percent.

Sunshine Heart led the falls, down 0.3 cents or 6.7 percent to 4.2 cents, with 381,337 shares traded.

Avita, Bioniche, Genetic Technologies, Living Cell and Neuren lost more than four percent; Alchemia and Anteo were down more than three percent; Viralytics shed 2.6 percent; with Biota, CSL and Starpharma down by less than one percent.

PHARMAXIS

Pharmaxis says that its cystic fibrosis treatment Bronchitol has been recommended for listing on the Australian Pharmaceutical Benefits Scheme.

Pharmaxis said it was verbally advised of the decision made at the Pharmaceutical Benefits Advisory Committee's March meeting, which will be released via the Committee's website in April.

Bronchitol was rejected by the committee twice last year, but the company resubmitted its application, as well as a "minor resubmission" (BD: Apr 21, Nov 9, 2011; Jan 22, 2012).

Approval for listing on the PBS will provide access to an addressable market of 2,500 cystic fibrosis patients over the age of six years.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that about 3,000 children under the age of six years would not have access to the drug.

Dr Robertson said the existing drug for cystic fibrosis, Roche's Pulmozyme, retailed for about $12,000 or $13,000 a year and Bronchitol would be priced below Pulmozyme.

He allowed Biotech Daily to estimate the addressable market at about $25,000,000 a year.

"We would expect to take a significant part of that market," Dr Robertson said.

Pharmaxis said in its media release that Bronchitol would go to the Australian Pharmaceutical Benefits Pricing Authority to finalize the reimbursement process and the Authority met three times a year, five to six weeks after PBAC meetings.

Dr Robertson said he was "delighted that after a rigorous assessment by one of the world's most demanding reimbursement authorities Pharmaxis has been able to successfully clear this hurdle and demonstrate the economic benefits of Bronchitol".

Bronchitol has orphan drug designation in Europe and has received a positive opinion for marketing from the Committee for Medicinal Products for Human Use (BD: Oct 24, 2011).

Pharmaxis was up 9.5 cents or 8.8 percent to $1.18 with 1.4 million shares traded.

PSIVIDA

Psivida says it has a technology evaluation agreement with Neuron Systems for its bio-erodible Durasert drug delivery technology in ophthalmology.

Psivida said that with the Burlington, Massachusetts-based Neuron Systems it would evaluate Durasert as a delivery system for a treatment for dry age-related macular degeneration, a serious retinal disease that afflicts millions of patients worldwide and can lead to blindness.

Psivida chief executive officer Dr Paul Ashton said that wet age-related macular degeneration affected less than 20 percent of the age-related macular degeneration population and was well treated with products such as Genentech's billion dollar Lucentis or Regeneron's Eylea, but there was no approved treatment for the dominant dry age-related macular degeneration.

"This is the second tech evaluation agreement Psivida has signed for its bio-erodible Durasert technology since Psivida regained the rights to its intellectual property from Pfizer last year," Dr Ashton said.

In November 2011, Psivida announced a technology evaluation agreement with an unnamed pharmaceutical company for Durasert but did not disclose the indications the company was investigating (BD: Nov 23, 2011).

Psivida said it was independently developing a product to treat uveitis affecting the posterior segment of the eye and a product to treat glaucoma and ocular hypertension in collaboration with Pfizer.

Psivida was up 11 cents or 6.3 percent to $1.86.

IMPEDIMED

Impedimed says reimbursement coverage for its L-Dex U400 device for lymphoedema has expanded to up to 23.4 million people in the US.

Impedimed says the additional insurance coverage was through two new plans - one an unnamed 'health maintenance organization' and the other an unnamed 'third party administrator'.

In an investor update released at the same time, Impedimed said it expected to have 50 million covered lives by about July 2012.

Impedimed originally targeted April 2011 for 20 million covered lives and October 2011 for 50 million covered lives (BD: Nov 11, 2010), but adjusted the targets to the end of 2011 and end of 2012, respectively (BD: Apr 1, 2011).

Impedimed had 12 million covered lives in July last year (BD: Jul 11, 2012).

Impedimed chief executive officer Greg Brown said "the 20 million covered lives milestone is a significant achievement for the company".

"The company remains very focused on building coverage for L-Dex readings as part of a total care program for lymphoedema," Mr Brown said.

He said progress with the third party administrator and the adoption of clinical guidelines by a health maintenance organization would help build momentum with other insurers.

Mr Brown said that the health maintenance organization had developed clinical guidelines which aimed at improving breast cancer survivors' quality of life, with breast cancer-related lymphoedema addressed in the guidelines.

He said the guidelines would become active in one centre of the health maintenance organization (HMO) in May 2012, with roll-out to other centres over the coming year.

"The new HMO survivorship clinical guidelines address prospective care for new patients at risk, as well as provide a general guideline for routine surveillance," Mr Brown said.

Impedimed said that the clinical guidelines called for the use of bio-impedance spectroscopy as an aid in the clinical assessment of female patients, in a pre-emptive model of care for newly diagnosed breast cancer patients.

The Impedimed L-Dex is the only US Food and Drug Administration approved bio-impedance spectroscopy device for assessment of lymphoedema.

The company said that supply agreements for the L-Dex U400 devices had not been negotiated with the bio-impedance spectroscopy health maintenance organization.

Impedimed said that the third party administrator had a "unique program covering a fully insured product as well as administering self-funded plans" with customers in Texas, Louisiana, Georgia, Mississippi, Missouri and Indiana.

Impedimed was unchanged at 49 cents.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration has reviewed its application for the C-Pulse feasibility trial and no other information is required at this time.

Sunshine Heart said the FDA's Center for Devices and Radiological Health reviewed the investigation device exemption (IDE) application for the C-Pulse trial and notified the company that it had met the requirements of the relevant FDA regulation.

Sunshine Heart chief executive officer Dave Rosa said the company was "pleased that we have fulfilled the agency's requirements and look forward to working with the FDA regarding the submission of our pivotal trial protocol".

The company said it expected the pivotal US trial would begin by October 2012, as previously forecast.

Sunshine Heart fell 0.3 cents or 6.7 percent to 4.2 cents.

ALLIED HEALTHCARE GROUP

Allied has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on March 16, 2012 or on an earlier announcement.
Allied Health last traded at 3.6 cents.

ISONEA

Isonea says the US Patent and Trademark Office has granted a patent covering its cough count technology in the field of acoustic monitoring of respiratory diseases.
Isonea said that the patent covered the ultrasound-based cough detector that fits against a patient’s neck and automatically detects coughs and counts coughing events.
The company said the sensors could detect high and low frequency mechanical vibrations in the tracheal area and the device sensed coughing events, tracked their severity and duration, and stored the data or sent it wirelessly to a computer or other log.
Isonea said that cough was “an important symptom used in many assessment standards for the diagnosis and treatment of diseases such as asthma, chronic obstructive pulmonary disease, cystic fibrosis and gastroesophageal reflux disease, among others.
Isonea was unchanged at half a cent with 11.9 million shares traded.

PROBIOMICS

Probiomics says that its proposed 1 for 20 share consolidation as part of the back-door listing for Hunter Immunology will occur on March 21, 2012.
Probiomics said that it would soon publish an amended timetable for its re-admission to the ASX (BD: Oct 11, 2011; Feb 7, 2012).
Probiomics was untraded at one cent.

NUSEP

Nusep has appointed Andrew Goodall as a director saying he had been a significant shareholder for a number of years and was the company’s single largest shareholder.
According to ASX data, Mr Goodall held 17,000,000 shares or 18.89 percent at September 26, 2011.
The company said that Mr Goodall brought “a wealth of commercial experience to the board”.
Nusep was untraded at three cents.

VIRAX HOLDINGS

Virax says that company secretary John Morrison has been appointed a director, effective from today and he would join Michael Humphris and Ian Pyman on the board “for the period to completion of the corporate transaction with 4G Vaccines”.
Virax announced the merger with 4G earlier this month (BD: Mar 1, 2012).
Separately, Virax filed its half year accounts, returning to ASX Listing Rules compliance.
The company was suspended on March 1, 2012 for failing to file the accounts.
Virax last traded at 0.9 cents.