Biotech Daily

Monday July 21, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: STARPHARMA UP 20%, GENETIC TECHNO DOWN 6%**

*** TGA APPROVES STARPHARMA, ANSELL VIVAGEL-COATED CONDOM**

*** BENITEC 1st HEP C PATIENT SAFETY, MONTH DELAY TO 2nd PATIENT**

*** CE MARK APPROVAL FOR CALZADA, POLYNOVO NOVOPORE**

*** GI DYNAMICS US SEC REPORTING AHEAD OF NASDAQ CO-LISTING**

*** DRAWBRIDGE AUSTRALIA, UK DIVISIONAL ANAESTHETIC PATENTS**

*** EUROPEAN PROGEN FOR PG500 SERIES**

*** BLUECHIIP CLAIMS MORE SALES, US PATENT**

*** GEORGE CAMERON-DOW REPLACES BIOXYNE'S JEREMY CURNOCK COOK**

*** FLEMING TAKES 19.9% OF BIOXYNE, PHILLIP CEASES**

*** VIRAX APPOINTS PROF JOSEPH SPARANO TO ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 0.15 percent on Monday July 21, 2014 with the S&P ASX 200 up 8.2 points to 5,539.9 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, six traded unchanged and eight were untraded. All three Big Caps rose.

Starpharma was the best, up 11.5 cents or 19.7 percent to 70 cents with 1.6 million shares traded.

Admedus climbed eight percent; Impedimed was up 6.7 percent; Benitec and Viralytics rose more than five percent; Oncosil and Neuren rose more than four percent; Antisense, Cellmid, Clinuvel and Nanosonics were up more than three percent; Acrux, Analytica and Circadian climbed more than two percent; Bionomics and Cochlear were up more than one percent; with CSL, Mesoblast, Resmed and Sirtex up less than one percent.

Genetic Technologies led the falls, down 0.2 cents or 5.6 percent to 3.4 cents with 252,465 shares traded. Psivida lost 5.2 percent; Anteo, Prima and Universal Biosensors shed more than two percent; GI Dynamics, Phosphagenics and Tissue Therapies were down more than one percent; with Alchemia down by less than one percent.

STARPHARMA

Starpharma says that the Australian Therapeutic Goods Administration has granted Conformity Assessment Certification for the Vivagel-coated condom.

Starpharma said that the certification was similar to Conformité Européenne (CE) mark certification of devices in Europe.

The company said that marketing partner, Ansell planned to launch the Vivagel condom under the Lifestyles Dual Protect brand, “in the coming months, following listing on the Australian Register of Therapeutic Goods”.

Starpharma said that TGA certification would support “certain regulatory processes in other markets”.

The company said that the Vivagel condom was “a world-first product based on innovative Australian technology [and was] ... the only condom of its type, providing barrier protection and incorporating a proprietary antiviral compound, Vivagel, in the lubricant”.

Starpharma said that Lifestyles Dual Protect condoms would carry the Vivagel brand and the company would receive royalties based on sales.

In 2008, Starpharma signed a licence agreement with SSL International for Vivagel-coated Durex condoms which it said would be worth up to $100 million (BD: Sep 9, 2008).

In 2010, Reckitt Benckiser acquired SSL International and the following year Starpharma said it had terminated the agreement citing “the failure to achieve satisfactory progress” and announced the new licence to Ansell was on terms “as good as the terms with SSL” (BD: Nov, 2010; Aug 18, 2011).

Today, Ansell head of Sexual Wellness Global Business Unit Peter Carroll said the company was looking forward to “rolling out its marketing and sales campaign to support the launch of Lifestyles Dual Protect over the coming months with the first product expected to be available on shelves soon”.

“Our partnership with Starpharma is a great example of two highly innovative Australian businesses working together to bring to market a ground-breaking new sexual health product,” Mr Carroll said.

Starpharma said that Ansell manufactured and marketed condoms across the world and ranked number two globally, with a 70 percent share of the Australian condom market.

Starpharma chief executive officer Dr Jackie Fairley said that certification by the TGA “marks another major milestone for the Vivagel condom and our partnership with Ansell”.

Starpharma said that the Vivagel lubricated contained 0.5 percent astodrimer sodium, previously known as SPL7013 and also referred to as Vivagel.

The company said that Vivagel was intended to help reduce the risk of exposure to viruses that cause sexually-transmitted infections, and had been shown in laboratory studies to inactivate up to 99.9 percent of HIV, herpes simplex virus and human papillomavirus.

Starpharma said that consumer research confirmed “a high level of consumer interest in the Vivagel condom concept with more than 80 percent of participants surveyed rating the product as very interesting and more than 90 percent indicating they would buy it.

The company said that sexually-transmitted infections in Australia continued to rise.

Starpharma said that the licencing agreement with Ansell provided marketing rights for the Vivagel condom in countries outside of Japan, where the product was licenced to Okamoto Industries (BD: May 10, 2011).

The company said that Okamoto was Japan’s leading marketer of condoms with about 60 percent of the Japanese condom market, the second largest global market after the US.

Starpharma said that earlier this year it received regulatory certification of the Vivagel condom in Japan in (BD: March 14, 2014).

Starpharma was up 11.5 cents or 19.7 percent to 70 cents with 1.6 million shares traded.

BENITEC BIOPHARMA

Benitec says that a review of the first patient dosed in its phase I/IIa trial of TT-034 for hepatitis C has approved the study to continue without modification.

Benitec said that the data safety monitoring review board reviewed the patients following a single infusion of the DNA-directed RNA-interference (ddRNAi) drug TT-034 and found that, to date, the patient experienced no treatment-related adverse effects.

The company said that liver biopsy results were encouraging and in line with expectations and that both TT-034 DNA and short hairpin RNA (shRNA) were detected in the biopsy at sub-therapeutic levels, indicating that liver transduction occurred.

The company said that it had expected the second patient to be dosed on July 21, 2014, but the trial site, Duke Clinical Research Unit, advised that the most recent laboratory results from that patient indicated a transient rise in the subject's liver function enzymes.

Benitec said that the trial protocol dictated that the subject could not be dosed until liver function enzyme results were at acceptable levels.

The company said that Duke was preparing to dose the next patient and under the protocol, the procedure to ensure a subject was suitable for dosing took at least 28 days.

Benitec said it had a clinical trial agreement with the University of California San Diego to join Duke to screen and enrol patients for the trial, with screening to begin immediately.

Benitec was up 5.5 cents or five percent to $1.15.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says that wholly-owned subsidiary Polynovo has Conformité Européenne (CE) mark certification for its Novopore topical negative pressure (TNP) foam wound dressing.

Calzada said that Polynovo could market Novopore in the European Union and Canada and received US Food and Drug Administration clearance on March 6, 2014.

The company said that Novopore could be used for the treatment of chronic wounds such as pressure sores.

Calzada said that topical negative pressure was designed to remove wound exudate and promote granulation to regenerate the dermal tissue by applying vacuum through a dressing placed in the wound cavity, sealed using an adhesive film and connected to a vacuum pump via a tube.

Calzada said that current topical negative pressure foam dressings raised concerns from the FDA in respect to complications associated with infection as a result of foam fragments remaining in the wound and bleeding on removal of the dressing.

The company said that Novopore demonstrated in its clinical trial last year (BD: April 17, 2013) that it had the potential to improve outcomes through a reduction in dressing fragmentation, risk of infection, trauma on dressing removal and undesirable dressing retention in the wound.

Calzada said that Polynovo's commercialization strategy included a partnership with an established topical negative pressure product to market and distribute Novopore.

The company said that Polynovo also had received ISO 13485 certification for its quality management system, which showed the company's ability to manufacture medical devices that met regulatory requirements for the European Union, Canada and elsewhere.

Calzada chairman David Williams said the company had the necessary authorizations to market, in the US, Canada and EU, a medical device based on our Novosorb technology.

"This is important regulatory validation for our platform technology and an important commercial building block to generate strategic alliances," Mr Williams said.

Calzada was up 1.5 cents or 14.3 percent to 12 cents.

GI DYNAMICS

GI Dynamics says that as a result of the effectiveness of the Form 10, it is subject to the reporting requirements of the US Securities and Exchange Act of 1934.
GI Dynamics said that it will make US SEC filings ahead of a listing on the Nasdaq.
The company said there was currently no US market for its common stock and it planned to continue its listing on the Australian Stock Exchange.
GI Dynamics fell half a cent or 1.1 percent to 46.5 cents.

DRAWBRIDGE PHARMACEUTICALS

Drawbridge says that divisional patents have been granted in Australia and the UK, relating to a variety of neuro-active steroid anaesthetic and sedative compounds.
Drawbridge said that it had granted in the US, UK, Australia, New Zealand, Hong Kong, Singapore, South Africa and China for its Phaxan anaesthesia and sedation and the newly granted divisional patents extended coverage to the use of a larger group of neuro-active steroids and preparations for sedation and anaesthesia in critical care situations.
Drawbridge chief medical Officer Prof Colin Goodchild said that neuro-active steroids were "compounds that target the central nervous system's natural control circuits normally regulated by hormones progesterone, allopregnanolone and their metabolites".
"Targeting the natural pathways with our compounds offers a variety of useful therapies in critical care situations with compounds that have an inherent high safety profile," Prof Goodchild said.
Drawbridge said that it had completed a proof-of-concept clinical trial comparing the anaesthetic properties of Phaxan with propofol, the agent most commonly used for intravenous anaesthesia (BD: Apr 17, 2014).
The company said that the study results "were extremely positive" confirming that Phaxan was as fast as propofol in onset and offset of anaesthesia with better cardiovascular and respiratory safety.
Drawbridge is a private company.

PROGEN PHARMACEUTICALS

Progen says that the European Patent Office has issued an intention to grant notice for a patent entitled 'Sulfated Oligosaccharide Derivatives'.
Progen said that the patent would protect its PG500 series of small heparan sulfate mimetic molecules and their use in a variety of therapeutic areas predominantly related to oncology, including angiogenesis and metastasis, but also encompassing inflammation and other indications where heparan sulfate mimetic compounds provide important therapeutic options, such as coagulation, thrombosis, raised blood triglyceride levels, HSV-1 infection, or cardiovascular disease.
Progen executive chairman Jitto Arulampalam said that the intention to grant the patent "makes for an important addition to Progen's patent family".
"It complements the patents already granted for this patent family, and includes key jurisdictions such as the United States, Canada, Australia and Japan," Mr Arulampalam, said.
Progen said that lead 500 series compound PG545 was in an open-label, multi-centre phase I study of safety and tolerability by intravenous infusion in patients with advanced solid tumors.
Progen fell two cents or 2.4 percent to 80 cents.

BLUECHIIP

Bluechiip says it has made sales of its tracking tag system to Flinders University, the Florey Institute of Neuroscience and Cell Care Australia.

Bluechiip said that partner Micronic BV had moulded its tag onto a Micronic vial, which include a barcode would have two layers of identification.

The company said the vials were undergoing low temperature testing and validation and Bluechiip and Micronic would collaborate in the sales and marketing of the new product.

Bluechiip said that Bluechiip China was a new entity resulting from the agreement with Eastern Equipment Trading Company in May and it had a 10 percent holding in the entity.

The company said that a patent entitled 'Multi data memory device' was granted by the US Patent and Trademark Office on June 30, 2014 with a term of 20 years June 19, 2009.

Bluechiip was up 0.8 cents or 19.05 percent to five cents.

BIOXYNE

Bioxyne says that George Cameron-Dow has replaced Jeremy Curnock Cook as a non-executive director.

Bioxyne said that Mr Curnock Cook's resignation following his appointment as chief executive officer of the London-based Rex Bionics plc.

The company said that Mr Curnock Cook was appointed a director of Hunter Immunology in March 2010 which became Bioxyne.

Bioxyne said that Mr Cameron-Dow was a founding director of the corporate advisory firm St George Capital and investment fund manager Fleming SG Capital.

The company said that Mr Cameron-Dow had extensive corporate experience including as a director of industrial group Consol and chairman of retirement and health insurance funds.

Bioxyne said that Mr Cameron-Dow was previously the managing director of Xceed Capital and a former director of Calzada and was currently the chairman of Windward Resources and Naracoota Resources.

Bioxyne was up 0.1 cents or 3.85 percent to 2.7 cents with 1.96 million shares traded.

BIOXYNE

The Perth, Western Australia-based Fleming SG Capital Special Opportunities has become a substantial shareholder in Bioxyne with 39,868,277 shares or 19.90 percent.

The Fleming substantial shareholder notice said the company acquired the 39,868,277 shares for $598,024 or 1.5 cents a share.

The Melbourne-based Phillip Asset Management said that on July 18, 2014 it sold 48,688,221 shares for $730,323 or 1.5 cents a share.

Phillip Asset Management said that it acquired 4,732,794 shares at no cost on July 15, 2014 from a related party.

In 2012, Phillip Asset Management as IB Australia Bioscience Fund became Probiomics largest shareholder with 31,355,427 shares or 20.92 percent of the company, following the merger with Hunter Immunology (BD: Mar 28, 2012).

VIRAX HOLDINGS

Virax says it has appointed Prof Joseph Sparano to its scientific advisory board.
Virax said that Prof Sparano would be responsible for leading the phase Ib/II trials of GGTI-2418 for breast cancer, due to begin by April 2015.
The company said that Prof Sparano was the professor of medicine and women's health at New York's Albert Einstein College of Medicine and the associate chairman for clinical research at the Montefiore Medical Center's department of oncology.
Virax said that Prof Sparano was the associate director for clinical research at the Albert Einstein Cancer Center and vice-chair of the Eastern Co-operative Oncology Group, the AIDS Malignancy Consortium and the NCI Breast Cancer Correlative Science Committee.
Virax was unchanged at 0.7 cents with 1.6 million shares traded.