Biotech Daily

Thursday September 24, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CLINUVEL UP 16%; ANALYTICA DOWN 14%**

*** STARPHARMA VIVAGEL CE 'DEVICE' MARK FOR BACTERIAL VAGINOSIS**

*** PRO MEDICUS SIGNS $11m IMAGING DEAL WITH ALLEGHENY**

*** OBJ PLACEMENT RAISES $6.25m, SHARE PLAN FOR $1.75m MORE**

*** CHINA APPROVES BIODIEM, BCHT LAIV 'FLU VACCINE TRIAL**

*** IDT, MAYNE FINALIZE 2014 TEMOZOLOMIDE DISTRIBUTION**

*** NY LAGODA, FATIMA DICKEY, RICHARD BAYLES TAKE 5% OF CLINUVEL**

*** POIPU 19.5%, TORNEY 12%, CARRARA 19.5% IN STIRLING**

MARKET REPORT

The Australian stock market recovered 1.47 percent on Thursday September 24, 2015 with the ASX200 up 73.6 points to 5,071.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Clinuvel was the best, up 43 cents or 16.4 percent to $3.05 with 15,923 shares traded, followed by Medical Developments up 11.9 percent to $3.48 with 2.9 million shares traded and IDT up 10.8 percent to 41 cents with 845,994 shares traded.

Oncosil climbed 6.9 percent; Cochlear was up 4.25 percent; Anteo, Resmed and Starpharma rose more than two percent; with CSL, Mesoblast and Sirtex up by less than one percent.

Analytica led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 1.4 million shares traded.

Avita and Genetic Technologies lost more than nine percent; Tissue Therapies was down six percent; Compumedics fell 5.3 percent; Antisense and Pharmaxis fell more than four percent; Impedimed, Prima and Universal Biosensors lost more than three percent; Actinogen, Benitec, Bionomics and Biotron shed more than two percent; Acrux, Neuren and Orthocell were down more than one percent; with Viralytics down 0.9 percent.

STARPHARMA HOLDINGS

Starpharma says it has European Union marketing approval for Vivagel BV for the treatment and rapid relief of bacterial vaginosis including symptoms.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that Vivagel had been granted Conformité Européenne (CE) mark approval as a device for the treatment and relief of bacterial vaginosis.

Dr Fairley said that the company had "generated data on the mechanism of action which was more as a device as a physical effect rather than a pharmacological effect".

Dr Fairley said that there were precedents for the device approval including botox and hyaluronic acid and a previous CE mark approval for an anti-microbial.

Dr Fairley said that distribution partnerships were being negotiatied and she expected to have Vivagel available for sale in Europe "in a few months".

Dr Fairley said that the US did not typically use the device method for approval and the company was pursuing trials to demonstrate efficacy for prevention of recurrence of bacterial vaginosis.

In previous phase II and III trials Vivagel showed "clinical" efficacy for prevention of recurrence of bacterial vaginosis but failed to meet efficacy endpoints for "cure" and prevention of recurrence of bacterial vaginosis ((BD: Nov 28, 29, 2012; Apr 3,4, 2013).

In 2014, Starpharma began two 600-patient pivotal phase III trials of Vivagel for the prevention of recurrent bacterial vaginosis in North America, Europe and Asia under a US Food and Drug Administration special protocol assessment (BD: Jul 14, 2014).

The company said at that time that the two double-blind, randomized, placebo-controlled trials would be identical in design and would compare the rate of bacterial vaginosis recurrence in women using Vivagel to placebo gel during a 16 week treatment period.

Today, Starpharma said that those trials were more than 50 percent recruited.

Starpharma said that the CE mark approval allowed Vivagel BV to be marketed in the European Economic Area, which included the 28 countries of the European Union as well as the European Free Trade Association countries, providing access to a population of more than 260 million women.

The company said that European Union approval would be "used as the basis for obtaining what is expected to be relatively rapid regulatory and marketing approvals for Vivagel BV in a number of other countries that formally recognise the EU approval".

Starpharma said that bacterial vaginosis was the most common vaginal infection worldwide, the most common cause of abnormal vaginal discharge and unpleasant vaginal odor in women and was associated with an increased risk of pre-term births, miscarriage, and the transmission and acquisition of sexually transmitted infections, including genital herpes and HIV.

The company said that in clinical trials, Vivagel BV, when used once daily for seven days, "demonstrated significant benefits over a placebo in the treatment of [bacterial vaginosis] in women" with a key benefit "the rapid relief of patients' symptoms … including unpleasant vaginal odor and discharge.

Starpharma said that Vivagel BV helped to normalise vaginal pH and suppress the bacteria that caused the vaginal microflora imbalance that characterised bacterial vaginosis.

The company said that the current market for the management of bacterial vaginosis and associated symptoms was estimated to be more than $US750 million globally.

Dr Fairley said the European approval was "a very significant milestone both for Starpharma and the Vivagel portfolio".

Starpharma closed up 1.5 cents or 2.1 percent to 71.5 cents with 2.4 million shares traded.

PRO MEDICUS

Pro Medicus says that US subsidiary Visage Imaging has signed an $11 million, five-year diagnostic imaging contract with Allegheny Health Network.

Pro Medicus said that Allegheny was subsidiary of the Pittsburgh, Pennsylvania-based Highmark Health, the third largest health care delivery and financing system in America, which was affiliated with Blue Cross Blue Shield.

The company said that its Visage 7 technology would be used for primary diagnosis across Allegheny's network, as well as clinical distribution of diagnostic images to 2,800 physicians throughout the network via a single point of access.

Pro Medicus said that the Allegheny network comprised eight hospitals and the care portfolio had more than 2,000 beds at more than 200 locations.

Allegheny's radiology chair Dr Paul Kiproff said that "Visage 7's prominence in enterprise imaging exemplifies the world class capabilities that we're bringing".

"Visage's proven experience transforming imaging at many of the nation's largest health systems was central to our decision making," Dr Kiproff said.

Pro Medicus said that Allegheny would implement Visage 7 as the key component of a strategy to replace their numerous legacy picture and archiving communication systems.

Pro Medicus chief executive officer Dr Sam Hupert said the deal was "another key milestone for us and is a significant addition to our footprint in the North American market".

Pro Medicus climbed 30 cents or 14.3 percent to $2.40 with 793,412 shares traded.

OBJ

OBJ says it has raised $6.25 million "in an oversubscribed placement" of shares at 5.7 cents a share and proposes to raise a further $1.75 million through a share plan.

OBJ said the placement had "strong support from new institutional and sophisticated investors".

The company said that the record date for the share plan was September 23, it opened today and would close on October 29, 2015.

OBJ said that the funds would be used accelerate its pipeline, service partnered programs, expand partnering and licence agreements and for working capital.

The company said that Baker Young Stockbrokers was lead manager to the placement and Argonaut Securities acted as joint book runners.

OBJ fell 0.1 cents or 1.6 percent to 6.2 cents with five million shares traded.

BIODIEM

Biodiem says China's Food and Drug Administration has approved an investigational new drug application for its live attenuated influenza virus vaccine (LAIV).

Biodiem said that the approval to begin a China trial was given to licencee Changchun BCHT Biotechnology Co (BCHT) and was "an important milestone" in the development the influenza vaccine for BCHT with the trial expected to begin in December, 2015.

The company said that a phase I trial would be conducted in adults aged 18 to 49 years and then enrol people aged between three and 17 years.

Biodiem chief executive officer Julie Phillips said that influenza vaccine sales in China were about 40 million to 50 million doses annually, which corresponds to three to four percent of the population.

"The vaccination rate is very low compared with developed countries and, thus, the 'flu vaccine market has a great growth potential," Ms Phillips said.

Biodiem is a public unlisted company.

IDT AUSTRALIA

IDT says that the agreement with Mayne Pharma to distribute generic temozolomide in the US is “another major commercial milestone”.

In 2013, IDT filed an abbreviated new drug application with the US Food and Drug Administration for six different strengths of temozolomide capsules. Formerly marketed by the US-based Merck Inc as Temodar and indicated for melanoma and glioblastoma multiforme, with a global market in 2013 of about $US996 million (BD: Nov 18, 2013).

Today, IDT said that temozolomide had US sales of about $US220 million in the 12 months to June 30, 2015.

Last year, IDT said that Mayne Pharma’s US division would distribute generic temozolomide for melanoma and glioblastoma multiforme in the US, with definitive documents containing full commercial terms to be finalized, but providing for an initial term of 10 years, with Mayne Pharma the exclusive US distributor, subject to minimum orders (BD: Jul 29, 2014).

Today, IDT said that Mayne would pay “certain upfront payments totalling just over $US1.06 million” on filing of that temozolomide abbreviated new drug application and execution of this agreement, acceptance of the application by the FDA and on IDT’s first commercial supply of temozolomide to Mayne Pharma.

The company said that the agreement contained a product pricing and profit share arrangement based on IDT’s manufacture and Mayne’s US sales of IDT’s temozolomide product, respectively, but the exact terms were confidential.

IDT said the temozolomide application had been accepted by the FDA, was progressing through the review process and it expected to launch the drug in the US by early 2017.

IDT was up four cents or 10.8 percent to 41 cents.

Mayne Pharma was up two cents or two percent to $1.015 with 2.8 million shares traded.

CLINUVEL

Lagoda Investment Manager, Fatima Dickey and Richard Bayles say they have become substantial shareholders in Clinuvel with 2,264,713 shares (5.08%).

The substantial shareholder noticed said that the shareholders included “various clients of Lagoda”, Merrill Edge, Oppenheimer, Fiduciary Trust, US Trust, JP Morgan, State Street, Brown Brothers, Northern Trust, Bank of New York Mellon, Wells Fargo and Fidelity.

The Columbus Circle, New York-based Lagoda said it acquired the 2,264,713 shares for $5,698,287 or $2.516 a share, between July 30, 2014 and September 22, 2015.

Clinuvel was up 43 cents or 16.4 percent to $3.05.

STIRLING PRODUCTS

Directors Peter Dykes, Peter Torney and Timothy Shaw say they have become substantial shareholders (BD: Sep 18, 2015).

In three notices, Mr Dykes as a director of Sydney’s Poipu Bay said the company held 2,000,000 shares (19.5%) acquired for $100,000 or five cents a share, with Mr Shaw’s Carrara Wealth acquiring the same number of shares at the same price and Mr Torney holding 1,200,000 shares (11.7%).

Stirling was suspended at 0.2 cents, or $4.00 following the 2,000-to-one consolidation.