Biotech Daily

Wednesday January 25, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BIONICHE UP 15%, PHYLOGICA DOWN 9.5%**

*** PHARMAXIS ON TRACK FOR BRONCHITOL EU SALES, US APPROVAL**

*** CATHRX HAS TWO QUARTERS CASH, JUST**

*** ACUVAX TO ACQUIRE ISRAELI DIAGNOSTIC**

*** BALAM TAKES 15.5% OF CONSEGNA**

*** SUNSHINE HEART CONSOLIDATES US SHARES 1: 200, NO ASX IMPACT**

MARKET REPORT

The Australian stock market climbed 1.12 percent on Wednesday January 25, 2012 with the S&P ASX 200 up 47.1 points to 4,271.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and six were untraded.

Bioniche was the best, up 10 cents or 15.4 percent to 75 cents with 41,069 shares traded.

Clinuvel climbed 7.8 percent; Allied Health and QRX were up more than three percent; Sirtex, Tissue Therapies and Viralytics rose more than two percent; Alchemia, Anteo, Circadian and CSL were up more than one percent; with Acrux, Biota and Resmed up by less than one percent.

Phylogica led the falls, down 0.4 cents or 9.5 percent to 3.8 cents, with 2.1 million shares traded, followed by Avita down eight percent to 11.5 cents with 211,085 shares traded.

Impedimed lost 7.6 percent; Optiscan was down 6.7 percent; Benitec fell five percent; Antisense, Genetic Technologies and Living Cell were down more than four percent; Phosphagenics, Starpharma and Universal Biosensors shed two percent or more; with Bionomics, Cochlear, Mesoblast, Nanosonics, Pharmaxis and Psivida down one percent or more.

PHARMAXIS

Pharmaxis chief executive officer Dr Alan Robertson says Bronchitol should be on sale in Europe for cystic fibrosis in the next few months and in the US by early 2013.

In a teleconference, Dr Robertson said that the European Medicines Agency was not as strictly bound to timelines as the US Food and Drug Administration and while a formal approval letter was expected this month, timing was a matter for the EMA.

Dr Robertson said Quintiles had been contracted to begin sales in German and then the UK once approval had been formally granted.

Dr Robertson said he expected the new drug application to the FDA for Bronchitol for cystic fibrosis would be filed by April, with a 10 month review period taking approval to the end of 2012 or early 2013.

In its Quarterly Report to Shareholders, Pharmaxis said that the existing label approval from the EMA's Committee for Medicinal Products for Human Use for Bronchitol for cystic fibrosis (BD: Oct 24, 2011) covered adults from the age of 17 years, which was 50 percent of the market.

Pharmaxis said that cystic fibrosis patients aged six to 17 years comprised a further 34 percent of the group.

The report said that "the patients most likely to be the early adopters of Bronchitol will be those patients over the age of 17".

"This patient group has the most rapidly declining lung function and require physiotherapy and medication to prevent further decline in their lungs," Pharmaxis said.

The company said that it had shown that over the 12 months of the clinical trials and taking all patients who participated, regardless of their age, lung function improved by eight percent and "patients between the ages of six and 17 had a larger improvement in lung function than those patients over the age of 17" with no difference in either the frequency, or severity, of adverse events in the younger patient group.

Pharmaxis said there was "a high degree of interest in participating in the trial" in Europe for people under 18 years with pre-trial formalities expected to be completes by the middle of 2012 and, subject to EMA trial design agreement, it could be finished in early 2014.

The company said that its US phase III trial of Bronchitol for bronchiectasis had completed recruitment of 474 subjects with preliminary data due in early 2013.

Pharmaxis said that sales of Aridol as a test for bronchial hyper-responsiveness to assist in asthma diagnosis increased by seven percent for the three months to December 31, 2011, compared to the previous three months.

Dr Robertson said that full reimbursement in the US became effective on January 1, 2012 and was expected to positively impact sales.

Pharmaxis said that following its $80 million capital raising it had $101 million in cash at December 31, 2011 (BD: Dec 13, 2011).

Pharmaxis fell one cent or one percent to $1.015.

CATHRX

Cathrx says its net operating cash burn for the three months to December 31, 2011 was $1,673,000 with cash at the end of the quarter of $3,341,000.

Cathrx provided no further information, but the company has been involved in negotiations to licence its catheters in Europe (BD: Sep 29, 2011).

Cathrx was untraded at eight cents.

ACUVAX

Acuvax says it will acquire an Israeli, non-invasive, early detection diagnostic technology for more than 200 illnesses, disorders and diseases, subject to due diligence,
Acuvax said that “several clinical trials have been completed to date and the medical device product is now ready for full commercialization”.
The company said the diagnostic was “safe, painless, non-invasive, portable, economical and clinical trials to date across numerous areas of patient health have demonstrated a compelling level of accuracy”.
Acuvax said the technology could be used as a point-of-care first-stage screening tool able to identify specific pathologies, prior to confirmative diagnostic tests.
The company said the technology could provide “immediate feedback at the general practitioner level” with the potential to increase population health “by alerting medical practitioners to problems earlier and before major surgery is required”.
Acuvax said there was also the potential to develop derivative screening devices for the alternative medical sectors and revenues could be generated from both upfront device purchases and ongoing ‘per use’ patient tests.
Acuvax said it would benefit from consolidating and controlling all aspects of the technology including: research and development, clinical trials, intellectual property, manufacture, market positioning and pricing and the company would negotiate distribution arrangements for South Africa, Australia and parts of Asia.
Acuvax said it would execute the arrangement through a 100 percent-owned subsidiary which would pay $US20,000 for an option fee with a 90-day due diligence period.
The company said that subject to due diligence a further $US240,000 would be paid through the subsidiary to the Israeli company for all of the technology’s assets and the subsidiary would pay a royalty stream to the Israeli company of less than five percent of revenue to a maximum of $US2,000,000.
Acuvax was formerly known as Avantogen and before that as Australian Cancer Technology and in December 2011, said it had an option for a controlling interest in the unlisted ‘complementary medicine’ company Biohealth Pty Ltd, subject to due diligence and regulatory approvals (BD: Dec 1, 2011).
In February 2011, Acuvax changed its ownership, board and management (BD: Feb 9, 2011) and following the Merck Sharp and Dohme acquisition of the biotechnology assets of 26 percent subsidiary Hawaii Biotech (BD: Jul 23, 2010) and failure of the cancer drug RP101 (BD: Oct 6, 2009), the company saw the departure of majority shareholder Dr Richard Opara (BD: Nov 16, 2010).
Acuvax was up 0.1 cents or 100 percent to 0.2 cents with 8.5 million shares traded.

CONSEGNA GROUP

Balam Global has increased its substantial shareholding in Consegna from 88,636,927 shares (14.33%) to 96,600,000 shares (15.47%).
Balam Global of the British Virgin Islands and Leon Semenenko became substantial shareholders in Consegna on December 16 with the acquisition of 38,388,990 shares or 6.23 percent of the company (BD: Dec 20, 2011).
The initial substantial shareholder notice issued through Western Australia lawyers Clifford Chance said that Balam was based in the British Virgin Islands and Mr Semenenko was based in Geneva Switzerland but did not explain the relationship between the two entities.
Separately, Consegna extended its capital raising trading halt to a voluntary suspension (BD: Jan 23, 2012).
Consegna last traded at 4.4 cents.

SUNSHINE HEART

Sunshine Heart says it will consolidate US common stock at a ratio of 1 for 200., with no impact on its ASX shares.

Sunshine Heart said that ASX clearing house electronic sub-register system (CHESS) depositary instrument (CDI) will be exchanged for 200 US shares.

The company said that it did not expect any change to the underlying value of each CDI.

Sunshine Heart said the last day for trading on the ASX where one share was equivalent to one CDI would be January 27, 2012 and the consolidation would be effected on January 30, 2012.

The company said the consolidation was “to meet certain criteria relating to its minimum listing price on the Nasdaq Capital Market”, which requires a minimum bid of $US1.00.

Sunshine Heart has been trading around three to four cents and the consolidation will value the US shares at about $6 to $8 a share.

The company said it expected the US Securities and Exchange Commission would declare its Form 10 effective and Nasdaq would approve its listing by April 2012.

Sunshine Heart said its CDIs would not be consolidated.

Sunshine Heart was untraded at 3.7 cents.