Biotech Daily

Tuesday October 18, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 10%; MESOBLAST DOWN 7%**

*** GENETIC TECHNOLOGIES SELLS 600 BREAST CANCER TESTS**

*** CBIO FINAL CLINICAL STUDY REPORT; NOVO NORDISK 60-DAY OPTION**

*** COCHLEAR RECALL COSTS UP TO $150m; DIRECTORS FEES FROZEN**

*** BIOMÉRIEUX PAYS LBT $274k; $274k MORE BY YEAR-END**

*** PHARMAUST'S EPICHEM WINS WA EXPORT GONG**

*** CHARGES AGAINST UBNZ'S MAY WONG END GENESIS FINANCE TALKS**

*** TWO ACTINOGEN DIRECTORS TAKE 43% OF COMPANY**

*** CATHRX HAS ONE QUARTER CASH; $2m COMING**

*** BENITEC VOTES ON 70m DIRECTOR OPTIONS, SMALL NAME CHANGE**

MARKET REPORT

The Australian stock market fell 2.07 percent on Tuesday October 18, 2011 with the S&P ASX 200 down 88.5 points to 4,186.9 points.

Five of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and 14 were untraded. All three Big Caps were down.

Prana was the best, up 1.5 cents or 9.7 percent to 17 cents with 6,000 shares traded, followed by Genetic Technologies up 6.7 percent; QRX up 5.4 percent; Universal Biosensors up 4.65 percent and Viralytics up 3.3 percent.

Mesoblast led the falls, down 71 cents or 7.15 percent to $9.22 with 1.1 million shares traded, followed by LBT down 6.7 percent to 4.2 cents with 5,000 shares traded.

Benitec and Cellmid lost five percent or more; Biota fell 4.1 percent; Alchemia, Clinuvel, Impedimed and Tissue Therapies were down more than three percent; Allied Health, Living Cell, Resmed and Starpharma shed more than two percent; with Cochlear, CSL and Sirtex down one percent or more.

GENETIC TECHNOLOGIES

Genetic Technologies says its US subsidiary Phenogen Sciences has begun its roll-out of the Brevagen breast cancer test to obstetricians and gynecologists.

Genetic Technologies said the test was being marketed in eight metropolitan areas, with territory expansion expected in the coming months.

The company said the Brevagen test was “the first clinically validated breast cancer predictive risk assessment tool that combines a woman’s genetic information with clinical data to assist physicians in developing personalized risk management plans”.

Genetic Technologies said that in the first 90 days, the Phenogen sales team made more than 2,800 sales calls, reaching 800 physicians, representing good presentation into its initial tier one targets.

The company said 600 test kits were placed in targeted accounts, resulting in early adopter Brevagen use within two weeks of launch and processing re-imbursements on initial sales had begun.

Genetic Technologies said Phenogen had begun the credentialing process with the US top-10 preferred provider organizations (PPO), which represent more than 60 percent of covered lives in the US.

The company said the first contract had been finalized with additional contracts expected anticipated to be completed by January 2012.

Phenogen’s president Lewis Stuart said the early response “has been positive, particularly in those practices with a strong orientation toward breast cancer prevention”.

“We are adjusting the way physicians think about breast cancer risk and how it relates to all women, not just those with known high-risk genes,” Mr Stuart said.

“Experience from the initial roll-out has allowed us to validate and refine our marketing strategy and proceed into the broader market with greater certainty,” Mr Stuart said.

Genetic Technologies said the Brevagen risk test was administered in a physician’s office using a cheek-swab and following analysis in a certified laboratory, doctors received a predictive risk assessment report for the patient.

The company said the patient’s risk of breast cancer was calculated by combining their relative risk score from seven genetic markers, called single nucleotide polymorphisms, with their Gail score of factors that comprise the patient’s clinical make-up including current age, age at menarche, age at live first birth, race and ethnicity.

Genetic Technologies said the test provided five-year and lifetime predictive risk assessments to more accurately evaluate the patient’s risk for developing breast cancer, regardless of family history or previous indeterminate test results.

The company said that in a US Women’s Health Initiative clinical trial, 3,300 women were assessed for breast cancer using the Brevagen test, which was validated to reclassify about 64 percent of women in the intermediate Gail breast cancer risk group, those with a 1.5-2.0 percent five-year risk, with about 28 percent reclassified as higher risk candidates for breast cancer.

Genetic Technologies said a preventive treatment plan based on this would prevent about 50 percent of cancers in this group.

The company said that more than 36 percent in the intermediate Gail breast cancer risk group would be re-classified down, avoiding unnecessary treatment, side effects and costs and indicating that a total of one in two patients in the intermediate group would have their standard of care changed for the better.

Genetic Technologies was up one cent or 6.7 percent to 16 cents.

CBIO

CBio says the final report on its phase IIa clinical trial of XToll for rheumatoid arthritis will be sent to Novo Nordisk triggering an option decision within 60 days.

In August the company said the 155-patient trial showed XToll did not meet is primary endpoint (BD: Aug 1, 2011)

CBio said delivery of the final report and completed workplan to Novo Nordisk would trigger a change to its balance sheet with an already received $US3 million option fee being counted as income in the current financial year, instead of a liability.

The company said the option agreement included up-front fees, $US111 million in milestone payments and double-digit royalties on sales.

CBio said XToll's efficacy was assessed by the American College of Rheumatology standardized measure of improvement and concluded that although a numerically higher number of patients in the XToll treatment groups achieved at least 20 percent improvement in their symptoms (ACR20), statistical significance was not reached and the primary endpoint of the trial was not met.

CBio said that the mean values for the ACR20 response at the end of week 12 were 42 percent in patients receiving 75mg, 35 percent in patients receiving 25mg, and 30 percent in those receiving placebo.

The company said that a statistically significant XToll treatment effect was demonstrated in several secondary efficacy parameters including ACR-N which was a measure of disease activity tracking worsening as well as improvement across a range of signs and symptoms, along with swollen joint count, tender joint count and erythrocyte sedimentation rate at week-16 and week-24, a marker of inflammation in the blood.

CBio said that interleukin-6 (IL-6) was a marker of inflammation, significantly reduced in the blood of XToll treated patients.

The company said that circulating serum IL-6 levels were elevated in rheumatoid arthritis patients, however the reduction in circulating IL-6 observed in the 75mg patient group approached the normal range reported for healthy subjects.

CBio said that clinically meaningful signals of efficacy were demonstrated in the health assessment questionnaire and "trends to improvement heading towards low disease activity" were demonstrated in DAS28, a composite score across a range of disease measures, at week-24, but the trends did not reach statistical significance.

The company said that the longer patients received XToll treatment the greater their improvement and the drug was safe and well-tolerated.

CBio said that the pharmacokinetic results suggested that subjects were not optimally dosed.

The company said that there was significant variability in the amount of XToll measured in the blood of patients and it was "apparent that the existing formulation is not optimal for injection under the skin" with reformulation required before any large-scale trial.

CBio chairman Stephen Jones said the final data supported the view that XToll was a potential new therapy for autoimmune and inflammatory diseases.

"We have demonstrated improvement in a number of disease activity areas and we have identified a number of interesting trends. The board's view is that further studies of XToll in autoimmune disorders are appropriate," Mr Jones said.

"The Board believes this a potential first-in-class drug with a novel mechanism of action," he said.

"In addition to Novo Nordisk, the final report will be presented to a number of major pharmaceutical companies who have continued to express their interest in XToll," Mr Jones said.

CBio was unchanged at 21.5 cents.

COCHLEAR

Cochlear chairman Rick Holliday-Smith says the estimated cost of the Nucleus 5 recall was in the range of $130 million to $150 million.

Last month Cochlear recalled the CI-512 mainstay of the Nucleus 5 range of implants following an increase in CI-512 failures (BD: Sep 12, 2011).

At that time Cochlear chief financial officer Neville Mitchell told Biotech Daily the CI-512 had grown to 70 percent of implant revenue and more than 50 percent of total revenue.

In his address to the annual general meeting today Mr Holliday-Smith said the company had made provision for "many items, including costs relating to the recall, stock write offs, other related write offs or impairments and relevant costs that may be incurred over time".

Mr Holliday-Smith said the provision would be finalized in the results for the six months to December 231, 2011, but "based on current information, our view for this provision item or 'recall cost' is that the financial impact will be in the range of $130 million to $150 million.

He said the provision included "a number of non-cash items and we expect the after tax cash cost impact of this provision to be in the range of $20 million to $30 million".

Mr Holliday-Smith said the company was expected "to generate strong cash flows and that we will be successful in dealing with the current issues: and the dividend pattern would continue.

"We will increase your first half dividend to $1.20 per share, the same amount as the final dividend for [2010-'11]," Mr Holliday-Smith said.

"In the absence of further information, we will continue to pay dividends at this level. We will only reconsider this view if we see unfolding performance significantly below what we expect."

Mr Holliday-Smith said the company was asking for a 33 percent increase in the total remuneration cap for director remuneration to $2 million.

"This is the first increase we have sought since 2007 and the main intention was to give room for the addition of a further director if we felt someone with unique skills and experience was identified," Mr Holliday-Smith said.

"We understand this is a sensitive issue at this time and note there may [be] a degree of negative sentiment, at the same time we need to proceed with these matters and obtain your support," he said.

Mr Holliday-Smith said the remuneration for 2011-'12 was set to increase four percent from July 1, 2011 in line with inflation, and at the time the increase was seen to be fair and could be met within the existing cap.

"In light of the recall and its impact we have decided to leave the director's fees at the 2010 level," Mr Holliday-Smith said. "It is an action we feel is appropriate at this time."

All resolutions to the annual general meeting were passed overwhelmingly, with about five percent of proxy votes cast opposing both the increase in the directors' remuneration pool and the re-election of Mr Holiday-Smith.

The total number of votes cast was about half the total number of shares on issue.

Cochlear fell as much as 5.5 percent, closing down 96 cents or 1.76 percent at $53.54.

LBT INNOVATIONS

LBT says Biomérieux has paid $US300,000 ($A273,873) in royalties for its Previ-Isola plate streaking system as the first half of the minimum due for the 2011 calendar year.

In its Appendix 4C Quarterly Report LBT said it spent $61,105 on research and development of its automated plate assessment system.

The company said it had $3.15 million in cash at September 30, 2011.

LBT fell 0.3 cents or 6.7 percent to 4.2 cents.

PHARMAUST

Pharmaust says wholly-owned subsidiary Epichem has won the Small to Medium Service Provider category of the 2011 Western Australian Industry and Export Awards program.
Pharmaust said the award was coordinated by the Western Australian Department of Commerce and recognizes the State's best export businesses.
The company said State winners progressed as national finalists to the National Export Awards to be announced in Brisbane on December 8, 2011.
Pharmaust said it was Epichem's second Western Australian export award after winning the Small Business Export Award in 2010 and the subsidiary won the Australian Exporter of the Year for achievements in international business.
Epichem managing director Dr Wayne Best said his company's profile within the biotechnology sector and the broader business community had "increased significantly in the last couple of years".
"I believe this, combined with our maturing intellectual property from R&D-007 [for diabetes] and R&D-013 [for cryptosporidium] will provide some good opportunities for Epichem to grow in the near future," Dr Best said.
Pharmaust said Epichem had provided synthetic and medicinal chemistry services to the drug discovery and pharmaceutical industries for seven years, with pharmaceutical clients and others in 18 countries using the services on a regular basis.
Pharmaust was untraded at 1.8 cents

GENESIS RESEARCH AND DEVELOPMENT CORPORATION

Genesis says that it has ended discussions with UBNZ following charges being laid against principal May Wang in Hong Kong.
Genesis said the Hong Kong Independent Commission Against Corruption had charged Ms Wang with giving bribes of HK$73 million ($A9.2 million).
The company said it previously had been in talks about UBNZ investing in the company (BD: Jun 29, 2010).
Genesis said a warrant had been issued for the arrest of Jack Chen on related charges.
The company said it did not intend to proceed with any further business dealings with UBNZ.
Genesis chief executive Stephen Hall said that the company had been "reviewing a number of opportunities for the development and marketing of [New Zealand] food and derivatives".
"At this stage none of these opportunities have any certainty of proceeding," Mr Hall said.
Genesis was untraded at three cents.

ACTINOGEN

Actinogen directors Prof David Keast and David Zohar have increased their holding in their company to 17.07 percent and 25.94 percent, respectively.
Executive director Mr Zohar and associates increased their holding from 7,827,982 shares (15.83%) to 20,875,449 shares (25.94%).
Scientific director Prof Keast increased his holding from 3,733,333 shares (7.55%) to 13,733,333 shares (17.07%).
The substantial shareholder notice said the shares were in consideration for the acquisition of Celgenics (BD: Sep 26, Oct 4, 2011).
Actinogen was untraded at 2.5 cents.

CATHRX

Cathrx says its net operating cash burn for the three months to September 30, 2011 was $2,044,000 with cash at the end of the quarter of $3,114,000.
Last week Cathrx announced a fully-underwritten rights issue to raise up to $2 million (BD: Oct 14, 2011).
The company is also in talks with a potential European development and commercialization partner (BD: Sep 29, 2011).
Cathrx was untraded at 14 cents.

BENITEC

Benitec shareholders will vote to issue 70 million options to its four directors and change the company name to Benitec Biopharma.
The Benitec annual general meeting notice proposed the issue of 40 million options to chairman Peter Francis, with 10 million options each to directors Mel Bridges, Dr John Chiplin and Iain Ross.
The notice said the options were exercisable at five cents each by September 26, 2016.
Benitec said shareholders would also vote on the re-election of Mr Bridges.
The meeting will be held at Grant Thornton, Level 17, 383 Kent Street, Sydney on November 17, 2011 at 10am (AEDT).
Benitec fell 0.1 cents or 5.3 percent to 1.8 cents with 2.7 million shares traded.