Biotech Daily

Friday June 25, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 9%, CATHRX DOWN 17%**

*** AVEXA DIRECTORS HIT BACK AT PRO-ATC LETTER**

*** R&D TAX CREDIT ALIVE AND WELL, AWAITING SENATE SITTING**

*** CELLESTIS HAILS US GUIDELINES ON TB TESTING**

*** DR BRUCE GRAY ORDERED TO PAY SIRTEX $2.6m**

*** US AMA GIVES IMPEDIMED REIMBURSEMENT CATEGORY III CODE**

*** RAY LARKIN JNR REPLACES HEARTWARE CHAIRMAN ROB THOMAS**

*** PRIMA'S CEO MARTIN ROGERS DEPARTS BOARD**

*** KARMELSONIX US REGULATORY TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.5 percent on Friday June 25, 2010 with the S&P ASX 200 down 66.7 points to 4413.0 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and four were untraded.

Living Cell was best, up two cents or 9.1 percent to 24 cents with 192,500 shares traded, followed by Pharmaxis up 17 cents or 8.1 percent to $2.27 with 1.2 million shares traded.

Novogen climbed 6.1 percent; Benitec and Starpharma were up more than three percent; with Cellestis, Chemgenex and Cochlear, Mesoblast and Optiscan up more than one percent.

Cathrx led the falls, down five cents or 16.7 percent to 25 cents with 6,000 shares traded, followed by Bionomics down 11.9 percent to 26 cents with 218,451 shares traded.

Bone and Cellmid both lost 9.1 percent; Impedimed, Prana and Viralytics were down more than six percent; Virax fell 5.3 percent; Heartware was down three percent; Acrux, CSL, Sirtex and Tissue Therapies shed more than two percent; with Alchemia, Biota and Phylogica down more than one percent.

AVEXA

Avexa's directors have urged shareholders to oppose resolutions to the July 6, 2010 extraordinary general meeting and have criticized a letter sent supporting the votes.

Avexa told the ASX that the parties who requisitioned the meeting requiring a vote to remove chairman Nathan Drona and recently appointed director Uri Ratner had "not formally stated their strategy for your company and have not disclosed what they intend to do with the cash assets of the business".

Avexa said an anonymous and undated letter was recently sent to shareholders signed by "Shareholders that invested in Avexa for ATC" recommending shareholders vote in favor of the resolutions to remove Mr Drona and Mr Ratner and replace them with Bruce Hewett and Steven Crowley (BD: May 26, 2010).

Avexa said the letter provided biographies of Mr Hewett and Mr Crowley and enclosed a blank proxy form.

Avexa's directors said the letter "argues strongly in favor of a strategy to relaunch the development of apricitabine (ATC)".

Last week, Biotech Daily reported on European and US AIDS groups also calling for the continuation of the apricitabine program (BD: Jun 18, 2010).

The Avexa directors claimed the letter contained "inaccurate and misleading statements" and criticized several points in the letter relating to comparative drugs and claims relating to the action of apricitabine.

In particular Avexa said the letter cited the success of the drug Isentress as evidence that there was a market for a drug like ATC but responded that "approval of Isentress and drugs like it actually raised the hurdle and shrunk the market for a drug like ATC during its development".

"Isentress is the first drug approved in an entirely new class of antiretroviral agents called integrase inhibitors," Avexa said. "By definition of being first in class, there is no competition and therefore these drugs tend to generate higher sales."

"On the contrary, ATC's mechanism of action is NOT [Avexa's emphasis] an integrase inhibitor but rather a nucleoside reverse transcriptase inhibitor," the directors said.

"ATC would have to compete against well established drugs on the markets such as AZT, ddI, ddC, D4t, 3TC, FTC and Abacavir and a closely related class of drug called nucleotide reverse transcriptase inhibitors which include Tenofovir," the directors said.

Avexa said there were "many key factors one needs to consider when investing substantial shareholder capital in a program such as ATC".

Issues around marketing, patent life, partnership landscape, funding requirements and the market in general play an important role in the evaluation process, the company said.

"Yes, ATC has positive phase II and III data, but it takes competitive data to be successful," the Avexa directors said.

"Ultimately, ATC required an HIV focused commercial partner willing to fund its final development, gain the necessary approvals and market the drug globally," they said.

"Your board can confirm that every major global pharmaceutical company with an HIV franchise has been contacted and presented all clinical findings in relation to ATC under confidentiality agreements as part of the process to extract any and all value for ATC during the past 12 months," the directors said.

"In the end, none of these parties submitted a term sheet proposal to license ATC for the board's consideration," they said.

The directors said it was continuing their search for the best available merger, acquisition, in-licensing opportunity, or other corporate initiative for the $23 million in net cash expected to be available at June 30, 2010.

Avexa was up 0.2 cents or 6.7 percent to 3.2 cents with 9.2 million shares traded.

R&D TAX CREDIT BILL

A spokeswoman for Innovation Minister Senator Kim Carr says the R&D Tax Credit Bill has passed the House of Representatives and is awaiting Senate debate.

The spokeswoman said the Bill has not been shelved and was “still on the agenda”.

Biotech Daily understands that speculation in the biotechnology sector on the tax credit start date of July 1, 2010 has caused at least one deal to be cancelled.

Through a spokeswoman, Senator Carr told Biotech Daily: “The Liberal Party’s deliberate filibustering and obstruction in the Senate has deprived small and medium sized businesses from doubling their cash benefits and large business from having their benefits increases by one third.”

“I remain resolute in pursuit in having these reforms adopted by the Parliament upon our return,” Senator Carr said.

“The legislation was not debated in the Senate by the end of the sitting period and therefore the legislation will not be passed by July 1, 2010,” Senator Carr said.

“The Government maintains its support for this important reform and it is the Government’s intention to make these changes law,” Senator Carr said.

IMPEDIMED

Impedimed says the granting of an American Medical Association category III CPT code will improve access to reimbursement for its post-breast cancer lymphoedema test.

Impedimed said the current procedural terminology (CPT) code for the use of bioimpedance spectroscopy in the measurement of extracellular fluid differences of the limbs would cover the use of the L-Dex U400 for its US Food and Drug Administration cleared indication for aiding in the clinical assessment of unilateral lymphoedema of the arm in women.

The company said the code would become effective on January 1, 2011, following a six month implementation period beginning from its release on July 1, 2010.

Impedimed chief executive officer Greg Brown said the code covered the use of the technology in measuring extracellular fluid differences between the limbs and “such a definition for the code allows for both the present cleared claim and a future potential clearance for other limbs”.

“The company recently announced to the Australian market that it had filed with the FDA an expanded claim for aiding in the clinical assessment of lymphoedema of the limbs,” Mr Brown said (BD: Apr 7, 2010).

“The company will continue to work towards expanding the coverage for the L-Dex U400 with this new category III code by educating health insurance providers within the United States as to the potential health economic benefit of a pre-emptive model of care with respect to breast cancer patients,” Mr Brown said.

Impedimed said that category III codes were recognized as emerging technologies and had “the advantage of not having a specific payment amount associated with them”.

Health insurance providers make individual decisions regarding payment for healthcare services based on, among other things, both economic and available clinical data to demonstrate the benefits of the procedure, the company said.

Impedimed said that patients who developed lymphoedema had significantly higher medical costs than patients who don’t and early detection reduced suffering and costs.

Impedimed fell four cents or 6.45 percent to 58 cents.

CELLESTIS

Cellestis says the US Centers for Disease Control and Prevention has issued guidelines supportive of its Quantiferon for the detection of Mycobacterium tuberculosis infections.
Cellestis said the Centers for Disease Control advised that interferon gamma release assay (IGRA) blood tests were now preferred over the century-old tuberculin skin test for diagnosing tuberculosis infection in certain populations.
Cellestis said it was pleased to see the preferential adoption of interferon gamma release assay, of which Quantiferon "was the leading test, in a number of significant circumstances, which we believe recognizes the medical value of the superior result provided by [Quantiferon]".
Cellestis director and medicine professor at the University of California San Diego Prof Antonino Catanzaro said that in the US, "up to 14 million Americans may be infected with TB bacteria and are at risk of developing full-blown, highly contagious TB".
"These guidelines encapsulate the enormous body of clinical evidence on the performance of the QFT test and reflect the significant benefits this test is bringing to TB control worldwide," Prof Catanzaro said.
The guideline is available at the CDC's Morbidity and Mortality Weekly Report website: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_w.
The CDC report 'Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection - United States, 2010' along with a companion implementation guide, appeared in the June 25, 2010, Volume 59, No. RR-5 issue of the CDC's Mortality & Morbidity Report.
Cellestis said that tuberculin skin test drawbacks included a higher risk for false positives, especially in people who have been BCG-vaccinated; irritating TB-extract that must be injected under the skin; and the need for a second doctor's visit were evaluated by the CDC and factored into their recommendations.
Cellestis chief executive officer chief executive officer Dr Tony Radford said that "with a specificity of more than 99 percent, QFT virtually eliminates false positive results and is simple to administer".
Cellestis said that interferon gamma release assays (IGRA) were preferred over the tuberculin skin test (TST) for testing persons who have received BCG (as a vaccine or for cancer therapy) as well as for diagnosing TB infection for persons from groups that historically have low rates of returning to have TSTs read.
The company said the report concluded that interferon gamma release assays could be used in place of, not in addition to, tuberculin skin tests in all situations in which CDC recommended testing and was considered acceptable medical and public health practice.
Cellestis quoted the guidelines saying interferon gamma release assays could be used in place of tuberculin skin test, without preference, to test recent contacts of persons with infectious tuberculosis and for periodic screening to address occupational exposure to TB.
The tuberculin skin test was preferred for testing children under the age of five years, but the use of interferon gamma release assays in conjunction with of tuberculin skin tests was advocated by some experts to increase diagnostic sensitivity in this age group.
Cellestis was up five cents or 1.7 percent to $2.95.

SIRTEX MEDICAL

Sirtex says former chairman Dr Bruce Gray has been ordered by the Federal Court to pay the company $2,575,185.83 in costs and damages for the long-running legal battle.
The company said Dr Gray had until July 22, 2010 to file an appeal (BD: Jun 11, 2010).
Sirtex fell 12 cents or 2.4 percent to $4.96.

HEARTWARE INTERNATIONAL

Heartware says that C Ray Larkin Junior will replace chairman Robert B Thomas form July 1, 2010 and Mr Thomas will continue as a director.

Heartware said Mr Larkin joined the board in October 2008 and Mr Thomas had been chairman since November 2004.

The company's president and chief executive officer Doug Godshall said that with Heartware domiciled in the US "and our common stock successfully listed on Nasdaq, it is an appropriate time to transition board leadership to the US".

Mr Thomas said that Mr Larkin had "more than 30 years of medical device experience" and his "deep operational knowledge of the medical device industry combined with his extensive public company experience have provided an insightful perspective for our board".

Heartware's other directors are Timothy Barberich, Dr Christine Bennett, Doug Godshall, Dr Seth Harrison, Robert Stockman and Dr Denis Wade.

Heartware said Mr Larkin was chairman of Align Technology and Novasys Medical, a director of Neuropace and Therox as well as a venture partner at Cutlass Capital and an executive committee member at Synecor.

Mr Larkin joined critical care device company Nellcor as vice-president of sales and marketing in 1983 rising to president and chief executive officer.

Mr Larkin is a graduate of LaSalle University and a former captain in the US Marine Corps.

Heartware said Mr Thomas was a director of Virgin Blue Holdings and Tower and was on the advisory board of Nomura Australia.

The company said Mr Thomas held a Bachelor of Economics degree from Monash University and was chairman of the Stockbrokers Association of Australia.

Heartware fell seven cents or three percent to $2.23.

PRIMA BIOMED

Prima's former executive director Martin Rogers has departed the board and will continue as chief executive officer, from today.

Prima said the change would allow it "to better focus on its operational activities" during the implementation of late stage clinical trials of its CVac ovarian cancer therapy vaccine.

The company said Mr Rogers would be able to focus his time exclusively on the clinical outcomes of the CVac trials and developing the product for the global oncology market.

Prima said it would "seek to add additional members to its board in due course to complement the skill sets of its existing directors".

Prima was unchanged at 11.5 cents with 3.5 million shares traded.

KARMELSONIX

Karmelsonix has requested a trading halt pending as announcement "in relation to an important update regarding regulatory matter for its devices in the US market".

Trading will resume on June 29, 2010 or on an earlier announcement.

Karmelsonix last traded at 1.9 cents.