Biotech Daily

Monday July 23, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ELLEX UP 10%, CELLMID DOWN 12.5%**

*** ELLEX EXPECTS TURNAROUND 2011-'12 PROFIT**

*** ATCOR APPLIES FOR US CLEARANCE FOR SPHYGMOCOR XCEL**

*** BIODIEM RODENT DATA BACKS BDM-E FOR RETINITIS PIGMENTOSA**

*** EMA APPROVAL OF UNIQURE'S GLYBERA 'GOOD FOR BENITEC'**

*** BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**

*** CELLMID HAS LESS THAN TWO QUARTERS CASH - MORE COMING**

MARKET REPORT

The Australian stock market fell 1.7 percent on Monday July 23, 2012 with the S&P ASX 200 down 70.2 points to 4,128.9 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and six were untraded.

Ellex was the best, up two cents or 10.3 percent to 21.5 cents, with 34,360 shares traded.

Psivida climbed 9.5 percent; Sirtex and Tissue Therapies rose more than two percent; with Cochlear up 0.4 percent.

Cellmid led the falls, fell 0.2 cents or 12.5 percent to 1.4 cents with 215,000 shares traded.

Genetic Technologies lost 9.1 percent; Antisense, Impedimed, Mesoblast and Optiscan were down more than five percent; Sunshine Heart fell 4.65 percent; Bionomics, Clinuvel, Phosphagenics, Reva and Viralytics were down more than three percent; Acrux, Anteo, Nanosonics, Phylogica and Resmed shed more than two percent; with Compumedics, CSL, Heartware, Pharmaxis, Starpharma and Universal Biosensors down more than one percent.

ELLEX MEDICAL LASERS

Ellex says it expect a net profit before tax of $1.1 million for the year ended June 30, 2012, on revenue up 10 percent to $47.5 million.
Ellex said the upgrade was due to “improved bottom line focus, coupled with improved sales in the US and Australia”.
Ellex chief executive officer Tom Spurling said it was “very pleasing to see our continued efforts to exercise tight cost control, reduce working capital, improve operating efficiencies and drive greater market penetration have contributed positively to our cash flow and good operating result during the period”.
The company said it expected to release its full-year results by August 31, 2012.
Ellex was up two cents or 10.3 percent to 21.5 cents.

ATCOR MEDICAL

Atcor says it has filed a 510k marketing clearance application with the US Food and Drug Administration for the Sphygmocor Xcel.
Atcor said it expected FDA clearance for the non-invasive central blood pressure diagnostic, designed specifically for the clinical practice and pharmaceutical research market, by the end of 2012.
The company said that the Sphygmocor Xcel was launched in May at the European Society of Hypertension Congress in London.
Atcor chief executive officer Duncan Ross said the company was “pleased with our customers’ enthusiasm and new orders placed for the Xcel”.
Atcor said the Excel was available for sale in Europe, Australia and four Asian markets.
The company said it planned to file applications for approval to sell into additional markets beyond the US.
Atcor was untraded at six cents.

BIODIEM

Biodiem says mouse and rat data shows that its BDM-E reduces abnormal blood vessel growth, damage typical to retinitis pigmentosa and improves retina function.
Biodiem said the BDM-E results were presented at the International Society for Eye Research meeting in Berlin, Germany July 21 and 22, 2012.
The company said BDM-E had US Food and Drug Administration orphan drug designation for the treatment of the inherited degenerative eye disorder, retinitis pigmentosa.
Biodiem said it had a research agreement with the US Foundation Fighting Blindness to test BDM-E in a pre-clinical model of retinitis pigmentosa and the Australian research presented in Berlin was conducted under Monash University retinal disease specialist Prof Jennifer Wilkinson-Berka and University of Melbourne Prof Erica Fletcher.
The poster concluded that “BDM-E effectively reduces vascular injury and neuronal and glial damage in a variety of retinal pathologies [and] BDM-E may have potential as a retino-protective agent”.
Biodiem said the research results confirmed the potential of BDM-E to reduce formation of abnormal blood vessel growth; reduce the signs of damage typical to retinitis pigmentosa; and improved the function of the retina and inhibit the death of cells imperative for sight.
The company said the results added momentum to its plan to outlicence BDM-E.
Biodiem chief executive officer Julie Phillips said the results “contribute to the strong and growing preclinical evidence showing BDM-E‘s positive effect in models of eye disease”.
Biodiem was untraded at 6.1 cents.

BENITEC BIOPHARMA

Benitec chief executive officer Dr Peter French says the European Medicines Agency approval of Uniqure's gene therapy breaks ground for all gene therapy companies.
Benitec said that when formally approved, Uniqure's Glybera, for lipoprotein lipase deficiency, would be "the first gene therapy product to be approved in the EU or United States".
The company said that Gybera was developed by Uniqure, formerly Amsterdam Molecular Therapeutics to treat the disease that affected several hundred people in the European Union and a similar number in North America.
"The implications of this decision for Benitec Biopharma's technology and programs [are] enormous," Dr French said.
"I believe that a major reason why big pharmaceutical companies have been slow to invest in the gene therapy field is because, until now, there have been no approved products in the major markets," Dr French said.
"Now there is a precedent for approaches using gene therapy delivery to gain marketing approval, meaning that they can be used to treat patients, and enter the standard revenue/reimbursement model of pharmaceuticals," Dr French said.
"This takes the valuation of our programs out of the theoretical arena and into a realistic scenario of market size and penetration," Dr French said.
"Our shareholders, along with current and potential licencing partners can now be confident that, should our programs pass the clinical stage testing in terms of safety and efficacy, they have a realistic probability of reaching the market," he said.
"We are now no longer seen as ground-breakers and therefore high risk," Dr French said. "We have a precedent to follow."
Benitec said that although the Uniqure therapy did not use its gene silencing technology, it used a similar viral delivery method to take the gene silencing DNA to target cells and tissues and was regarded as a form of gene therapy by the regulators.
The company said that Dr French had an "encouraging" preliminary meeting with the EMA in May regarding the design of the pain drug program and the Uniqure decision validated the focus on the European market as the first jurisdiction to enter.
Benitec said it was in early stage discussions regarding potential collaborative approaches with Uniqure.
Benitec was unchanged at 1.7 cents with 8.1 million shares traded.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.
Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.
When companies clearly explain that they have equity draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.
Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported, as will maiden revenues or profits.
Companies reporting after the close of business will be dealt with in the following edition.

David Langsam
Editor

CELLMID

Cellmid says its net operating cash burn for the three months to June 30, 2012 was $647,000 with cash at the end of the quarter of $1,051,000.

Cellmid chief executive officer Maria Halasz told Biotech Daily that the company had a further $500,000 “committed but not yet received from the last $1.5 million raising” as well as revenue from Evolis hair growth products sales to pharmacies expected this month (BD: Apr 26, 2012).

Cellmid fell 0.2 cents or 12.5 percent to 1.4 cents.