Biotech Daily

Wednesday May 6, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 13%**
- BIOTRON DOWN 8%

*** EU APPROVES MEDICAL DEVELOPMENTS PENTHROX, $850k MILESTONE**

*** AUSBIOTECH CHINA MEDICAL TECHNOLOGIES GUIDE**

*** ELLEX CHALLENGES OPHTHALMIC LASER MARKET LEADER**

*** GI DYNAMICS TO RESTART US TRIAL BY JULY, RESTRICTOR UNVEILED**

*** ANTEO RELEASES MIX&GO 200nm MAGNETIC PARTICLES COUPLING KIT**

MARKET REPORT

The Australian stock market lost 2.3 percent on Wednesday May 6, 2015 with the S&P ASX 200 following international markets down 134.3 points to 5,692.2 points.

Eight of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Medical Developments was the best, up 27 cents or 12.7 percent to $2.40 with 387,289 shares traded.

Ellex climbed 5.9 percent; GI Dynamics and Starpharma were up four percent or more; Antisense and Viralytics were up more than three percent; Compumedics rose 2.3 percent; with Mesoblast up half a percent.

Yesterday's best, Biotron, led the falls, down one cent or 7.7 percent to 12 cents with 161,800 shares traded.

Optiscan lost six percent; Genetic Technologies and Pharmaxis fell more than five percent; Atcor, Impedimed, Oncosil, Prima, Sirtex and Uscom fell more than four percent; IDT, Nanosonics, Neuren, Osprey and Tissue Therapies were down three percent or more; Acrux, Actinogen, Benitec, Clinuvel and Resmed shed more than two percent; Admedus, Anteo, Avita and CSL were down more than one percent; with Cochlear down 0.6 percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the UK, supported by France, Belgium and Ireland, has assessed the Penthrox methoxyflurane inhaled analgesic as approvable.

Medical Developments said that the UK Medicine and Healthcare Products Regulatory Agency had issued the final assessment report noting that "all outstanding issues pursuant to the decentralized procedure have been successfully resolved".

The company said that the approval process moved to the national phase which was "purely administrative" and should take 30 days before marketing authorization was issued and Penthrox would be available for sale.

Medical Developments said that UK distribution partner Galen expected sales to begin within three months and on approval the company would receive a second milestone payment of about $850,000 dollars, with sales-based milestone payments to follow.

Medical Developments chief executive officer John Sharman said that the approval was "the most significant event in the company's history".

"In these four countries there are more than 50 million accident and emergency hospital attendances each year and we estimate these markets for Penthrox to be worth circa $100 million per annum," Mr Sharman said.

"Penthrox has a number of very significant competitive and clinical advantages over its competitor products and we believe the market for trauma pain in Europe for an inhaled, fast acting, non-narcotic analgesic like Penthrox is very large," Mr Sharman said.

Medical Developments chairman David Williams said that it would be "fantastic to see Australia's first choice, front line analgesic being used by foreign doctors, hospitals and ambulance".

"Our drug helps trauma patients relieve their pain quickly and also makes minor surgical procedures more comfortable," Mr Williams said. "We are now well on our way in terms of delivering our globalization strategy for Penthrox."

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AUSBIOTECH

Ausbiotech says it has launched the 'Guide for Australian medical technology companies seeking to engage in China' to companies seeking to engage with and in China.

Ausbiotech said that the China Guide was part of a larger project "to facilitate medical devices and diagnostics trade and partnership with China by breaking down the information barriers for Australian companies".

The industry organization said that the Guide and the broader project were supported with funds from the Australian Trade Commission as part of the Asian Business Engagement Plan and would provide information about intellectual property management and the types of business structures suitable for Australian companies in China.

Ausbiotech said that the Australian medical technology industry consisted of an estimated 500 to 800 companies, which were seeking opportunities in global markets and were increasingly seeking support to enter Asian markets, specifically China, but most were micro or small enterprises with a turnover of less than $2 million, with limited capability to assess overseas markets independently.

The industry organization said the China Guide provided information about intellectual property management, information on business structures, the business, cultural and regulatory context and other information that a medical technology company may consider when developing their business plan for China.

The Guide is at: www.ausbiotech.org or request hard copies from admin@ausbiotech.org.

ELLEX MEDICAL LASERS

Ellex says that with 14.2 percent of the $US412 million a year global ophthalmic laser market it is just 0.3 percentage points behind the market leader Lumenis.

In February, Ellex reported revenue of $30,691,000 for the six months to December 31, 2014 (BD: Feb 27, 2015).

Today, the company said that an independent assessment of the global ophthalmic laser industry by Market Scope LLC entitled '2015 Comprehensive Report on the Global Ophthalmic Laser Market' and released last month reported that the global ophthalmic laser market was valued at US$412million a year and forecast to grow at a compounded rate of 4.5% per annum from 2015 to 2020.

Ellex said that according to the Market Scope analysis its global market share increased from 12.7 percent to 14.2 percent, 0.3 percentage points of market share behind the market leader compared with 4.1 percentage points behind 12 months earlier.

Ellex chief executive officer Tom Spurling said the company was "pleased to have our position as a leading market participant independently verified".

"The positive momentum of our business is demonstrated by our growing share of a growing global market," Mr Spurling said. "It is also encouraging to note that the market for our products and services continues to grow at a strong rate, offering significant opportunity for the continued expansion of the Ellex business."

Ellex said that Market Scope report detailed its improved result in the sub-market of glaucoma treatment lasers, with Ellex ranked first in the world at 50 percent, up from 41 percent 12 months earlier and growth in market share to first in the world for photo-disruptor YAG lasers, from 15.3 percent to 18.7 percent of market share.

Ellex was up two cents or 5.9 percent to 36 cents.

ANTEO DIAGNOSTICS

Anteo says its Mix&Go 200nm Magnetic Particles Coupling Kit gives researchers the ability to bind a range of bio-molecules onto small magnetic particles"

Anteo said that the 200 nanometre (nm) kit had been developed to expand the line of Mix&Go enabled products.

The company said the kit had advantages over traditional methods with the smaller particles providing benefits when used in immunoassay applications, including lateral flow assays and when used for bio-molecular separations including cell separation applications.

Anteo said the product would deliver scientists greater control and accuracy in less time.

Anteo chief executive officer Dr Geoff Cumming said the Coupling Kit "effectively increases the surface area per unit mass available for protein binding [which] can lead to a number of improvements including increased assay sensitivity".

"Normally, the handling complexity increases disproportionately with reducing size," Dr Cumming said. "Using Mix&Go, we have overcome the tendency for smaller sized particles to aggregate and fall out of solution," Dr Cumming said.

Anteo said that the particles in the Coupling Kit were provided fully activated with Mix&Go and were ready to use, with general buffer solutions known to work for a majority of applications, allowing users to immediately couple with their protein of choice.

The company said that the kit was suitable for coupling a broad range of bio-molecules for diverse applications, such as magnetic, fluorescent and chemi-luminescent detection in immunoassays and purification applications using bio-molecules including proteins, peptides, antigens and antibodies.

Anteo fell 0.1 cents or 1.1 percent to nine cents.

GI DYNAMICS

GI Dynamics says it expects to restart its US Food and Drug Administration-halted Endobarrier trial by July 2015 and has unveiled its Restrictor product.

In a teleconference, GI Dynamics chief executive officer Mike Dale said that a fifth patient of the 325 enrolled in the 500-patient trial had developed a bacterial liver infection, the cause of the FDA halt to the trial earlier this year (BD: Mar 6, 2015).

Mr Dale said that the company had undertaken a "strategic review" and among its outcomes was the "enhancement of the current platform" with a device called the Restrictor which had a small aperture, effectively part-plugging the stomach outlet to the small intestine and making the patient feel satiated.

Mr Dale provided slides of reductions of weight and blood glucose (HbA1c) levels in a small trial of 18 patients showing that the Restrictor in combination with the Endobarrier reduced both weight and HbA1c levels.

He said that the Restrictor was being developed to be used on its own or in combination with the Endobarrier.

Mr Dale said that the strategic review had concluded that large randomized controlled trial data was increasingly necessary for reimbursement and said that the Endobarrier trial was expected to complete enrollment by the end of 2016 with data analysis by the end of 2017 and the FDA pre-market approval application to be filed by July 2018.

Mr Dale said that the company had spent $US32 million on the Endobarrier trial so far and expected to spend a further $US35 million to complete the trial.

He said the company had about $US40 million in cash which would take it to March 2016.

Mr Dale said that the company had reviewed its quality systems which were subject to a European Union suspension of Endobarrier shipments (BD: Oct 6, Dec 1, 2014).

Mr Dale said that distribution models needed to be adapted to encourage traditional partnering and cost sharing and to establish clear lines of responsibility and leverage local market knowledge.

He said that direct investment in distribution would continue in Australia and Germany but all prior distribution arrangements would be cancelled and be replaced with "traditional, independent distributor arrangements".

Mr Dale said that Endobarrier procedural complexity would be reduced, thereby lowering the cost of increased adoption.

Asked about annual general meeting proposals to issue him and six directors stock equal to 1,943,500 Australian shares and 1,868,150 options, following the regulatory setbacks and the fall in market capitalization from a high of $328 million to the current $71 million, Mr Dale said that the provision of equity incentives was a standard procedure for US companies (BD: May 1, 2015).

GI Dynamics was up half a cent or four percent to 13 cents.