Biotech Daily

Wednesday May 23, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC TECH UP 51%, LIVING CELL DOWN 8%**

*** CLINICAL GENOMICS, CSIRO, FLINDERS UNI BOWEL CANCER TEST**

*** CLINUVEL STARTS US SCENESSE EPP PHASE III TRIAL**

*** MEDICAL DEVELOPMENTS LICENCES PENTHROX TO NIPPON ZOKI**

*** US PATENT FOR QRX MOXDUO PAIN RELIEF**

*** PHOSPHAGENICS TURNS TO GERMANY'S LABTEC FOR PATCH PROBLEM**

*** GENETIC TECHNOLOGIES JUMPS 66% ON NASDAQ**

*** BIOXYNE APPOINTS TORREYA PARTNERS ADVISERS**

*** ELLERSTON CAPITAL TAKES 5% OF ACRUX**

*** DAVID ZOHAR ASSOC REDUCES, DILUTED TO 24% OF ACTINOGEN**

*** MAYNE APPOINTS PETER TRUELOVE SALES, MARKETING DIRECTOR**

*** IMPEDIMED L-DEX U400 WINS BIOCOM GONG**

MARKET REPORT

The Australian stock market fell 1.31 percent on Wednesday May 23, 2012 with the S&P ASX 200 down 54.0 points to 4,067.0 points. Six of the Biotech Daily Top 40 stocks were up, 18 fell, 11 traded unchanged and five were untraded.

Genetic Technologies was the best, climbing as much as 62.8 percent to 14 cents, closing up 4.4 cents or 51.2 percent at 13 cents with 12 million shares traded. Universal Biosensors climbed 6.6 percent; Clinuvel was up 5.6 percent; Tissue Therapies rose two percent; Acrux and Sirtex were up more than one percent; with Resmed up 0.3 percent.

Living Cell led the falls, down half a cent or 8.3 percent to 5.5 cents with 45,000 shares traded, followed by Avita down 8.2 percent to 22.5 cents with 559,055 shares traded.

Anteo, Biota, Nanosonics, Phosphagenics and Prana shed two percent or more; Bionomics, Circadian, Impedimed, Mesoblast, Optiscan, Pharmaxis, Reva and Viralytics were down more than one percent; with Cochlear, CSL, Heartware, QRX and Starpharma down by less than one percent.

CLINICAL GENOMICS, THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION, FLINDERS UNIVERSITY

Sydney-based private company Clinical Genomics says a team of scientists has identified genes that show identifiable changes in the blood of people with bowel cancer.

A media release from Clinical Genomics said the discovery had “the potential to underpin a new cost-effective blood test that would signal the early stages of bowel cancer [which] could potentially save thousands of lives by supplementing existing screening programs and encouraging those at risk to have a colonoscopy”.

The company said that research was presented on Sunday May 20, 2012 at the Digestive Diseases Conference in San Diego, California for the collaboration with the Commonwealth Scientific and Industrial Research Organisation and the Flinders Centre for Innovation in Cancer at Flinders University in Adelaide, lead by senior investigator Prof Graeme Young.

Clinical Genomics said that the bowel cancer blood test was under development and being tested with patients from Australia, the US and Europe.

Clinical Genomics chief executive officer Dr Lawrence LaPointe said the group had shown a high detection rate for bowel cancer while also demonstrating a false positive rate of about five percent in samples drawn from a high-risk population.

“These clinical trial results are highly promising but we need to go one step at a time,” Dr LaPointe said.

“The next step is to seek help from other groups and researchers to cast the net more broadly to see what we can achieve with a larger number of tests drawn from a sample of the general population,” Dr LaPointe said.

“There is still some time to go before a blood based test of this nature might be broadly available to a community but the technology is clearly worthy of broader, rigorous testing,” Dr LaPointe said.

“Importantly, a simple blood test like this could significantly improve patient participation with bowel cancer screening programs,” Dr LaPointe said.

CSIRO’s Preventative Health Flagship’s Dr Peter Molloy said the results “are the product of a close alignment of clinical research with advanced genomics, epigenetics and biological statistics viewed through the lenses of clinical need and commercial focus”.

“One new gene identified was particularly sensitive to cancer,” Dr Molloy said.

“This gene is called colon adenocarcinoma hypermethylated or CAHM,” Dr Molloy said.

“In 120 blood samples we observed a high positivity for cancers [of 68 percent], while still being accurate in 97 per centof normal patients,” Dr Molloy said.

“We have also shown that a three gene test including CAHM was able to detect cancer 76 percent of the time with a 93 percent accuracy in normal patients,” Dr Molloy said.

Flinders University’s Prof Young said the prevention of bowel cancer was a major public health priority in Australia and early detection was “clearly the path to better outcomes in the future”.

“One of the key questions is how a test like this might complement existing screening efforts in a cost-effective way to save even more lives in the future,” Prof Young said.

“The breakthrough data presented today is the result of exciting multidisciplinary research between industry, Australia’s national science agency and clinical researchers from one of the nation’s leading teaching hospitals,” Prof Young said.

“The need now is to collaborate more broadly with national and international researchers committed to translation of science innovation to clinical outcomes, to help validate these exciting findings in large scale prospective studies,” Prof Young said.

Clinical Genomics is a private company.

CLINUVEL PHARMACEUTICALS

Clinuvel has begun its US Food and Drug Administration approved phase III study of Scenesse for erythropoietic protoporphyria.

The company previously said the trial of Scenesse (afamelanotide) would be a nearly identical to erythropoietic protoporphyria (EPP) studies in 2011 and would complete the program (BD: Nov, 2011; Mar 15 2102).

Clinuvel said the six-month, randomized, multi-centre, double-blind, placebo-controlled study would recruit up to 100 adult patients in seven specialist centres and treatment of all patients was expected to be completed before the end of 2012.

Clinuvel chief scientific officer Dr Hank Agersborg said the phase III trial protocol had been designed in close consultation with the FDA.

“We anticipate that the results will confirm the safety and efficacy profiles seen in previous trials and enable us to file a new drug application for the drug in the US,” Dr Agersborg said.

“Clinuvel is working with all study sites to facilitate recruitment of patients during early summer,” Dr Agersborg said.

“This period of the year is a particular burden to EPP patients who are prone to incur severe skin reactions when exposed to sunlight,” Dr Agersborg said.

Clinuvel said that erythropoietic protoporphyria was a rare genetic disease found mainly in fair-skinned people and was characterized by severe phototoxicity, or light intolerance, of the skin resulting in intolerable pain, swelling and scarring, usually of exposed areas such as the face, hands and feet.

The company said that symptoms could vary from mild to extreme lasting pain requiring hospitalization and patients often lead an indoor and sheltered life, avoiding light and ultra-violet light exposure to prevent symptoms.

Clinuvel said there was no known effective treatment for EPP, which affected about 10,000 people globally.

Clinuvel was up nine cents or 5.6 percent to $1.70.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it will receive a $100,000 upfront fee from Japan’s Nippon Zoki Pharmaceutical for a licence to its inhaled Penthrox analgesic.

Medical Developments said the licence would facilitate Japanese regulatory approval for the methoxyflurane Penthrox inhaler which was expected to take more than 12 months.

Medical Developments chief executive officer John Sharman said the agreement was “an important step in the development of [the company’s] business in Japan”.

“Whilst there is a lengthy time frame involved before Penthrox may be sold in the Japanese market, the licence agreement with Nippon Zoki is consistent with Penthrox entry into new markets around the world,” Mr Sharman said.

Nippon Zoki president Ryusaku Konishi said the Penthrox analgesic inhaler was “suitable for minor surgery and other treatments requiring short term pain relief and meets the needs of both patients and physicians”.

“Penthrox is an integral part of the current development strategy of Nippon Zoki, a company which excels in the development and marketing of analgesic products,” Mr Konishi said.

“Nippon Zoki will make a concerted effort to develop and make Penthrox available to patients in Japan as soon as possible,” Mr Konishi said.

Medical Developments was up five cents or 6.9 percent to 77 cents.

QRX PHARMA

The US Patent and Trademark Office has issued QRX a patent for a method of pain treatment comprising the administration of Moxduo immediate and controlled release.
QRX said the patent, expiring in 2023, covered the administration of the oral dual opioid compositions of Moxduo immediate release (IR) for the treatment of acute pain as well as Moxduo controlled release (CR) for the treatment of chronic pain.
QRX chief executive officer Dr John Holaday said the patent was “a key component of our intellectual property portfolio that provides long term market exclusivity for QRX Pharma’s Moxduo opioid products for the treatment of acute and chronic pain”.
QRX said that the original US composition of matter patent covered the combination of morphine and oxycodone until 2016 and the new patent was directed to a method of treatment of pain using the defined three-to-two ratio of morphine and oxycodone.
QRX said that patents granted in 2011 extended protection to 2029 and covered a dosing algorithm for converting patients from intravenous opioid administration to Moxduo IR, thereby more effectively and safely managing acute pain following surgery.
QRX said it had completed two phase I studies of Moxduo CR which encompassed sustained delivery technology as well as abuse deterrent and tamper resistant features and was the subject of additional pending global patent applications (BD: Apr 11).
QRX has an FDA Prescription Drug User Fee Act (PDUFA) date of June 25, 2012 for Moxduo IR and with partner Actavis expects to commercialize the product in the US by October 2012 (BD: Mar 19, 2012).
QRX fell half a cent or 0.3 percent to $1.765.

PHOSPHAGENICS

Phosphagenics says it has engaged Germany’s Labtec GmbH for assistance with its tocopheryl phosphate mixture (TPM) oxycodone patch.
Phosphagenics said that it wanted “to enhance the commerciality of the patch and eliminate a minor patch crystallization matter that commonly occurs during development that is normally resolved by optimizing the ratio between solvent and adhesive”.
The company said that it was confident this would be successfully resolved.
In February, Phosphagenics said that a 45-patient trial of its improved oxycodone patch developed in collaboration with US partner 3M delivered 4.5 times more oxycodone over 72 hours than the original prototype (BD: Feb 15, 2012).
Today the company said that once the phase III clinical program began, further changes could not be made easily to the product and it needed to optimize the commercial design prior to the pivotal phase III trial by October 2013.
Phosphagenics said that Labtec was part of the German Tesa SE group of companies, which in turn was a member of the Hamburg-based Beiersdorf group.
The company said that it expected to complete the final design for its oxycodone patch within the next three months and while continuing to work with 3M, it had engaged Labtec for additional development and manufacturing capability.
Phosphagenics said that Labtec was a specialist in opioid patch development and had successfully developed a fentanyl patch that was the largest selling fentanyl patch in Germany and had also developed a sufentanil patch currently in late stage clinical trials.
Phosphagenics said that it would continue to work with 3M as a development partner and likely manufacturer in the US.
Phosphagenics said that based on current projections, the trial was fully-funded by the capital raising undertaken late last year.
Phosphagenics fell half a cent or 2.8 percent to 17.5 cents with 1.6 million shares traded.

GENETIC TECHNOLOGIES

On the Nasdaq last night, Genetic Technologies climbed $US1.58 or 65.6 percent to $US3.99 with 1.5 million shares traded.

The price movement appears related to yesterday's announcement of increased sales of the Brevagen breast cancer test, which did not provide specific numbers, as well as an update on coverage and reimbursement in the US.

On the ASX today, Genetic Technologies climbed as high as 14 cents, closing up 4.4 cents or 51.2 percent to 13 cents with 12 million shares traded.

BIOXYNE (HUNTER IMMUNOLOGY)

Bioxyne has appointed investment banking advisers Torreya Partners LLC to assist a review, including plans for the company's technologies

Bioxyne said it expected to release data next month from its phase IIb safety and efficacy trial of HI-164OV for chronic obstructive pulmonary disease (COPD) exacerbations.

Earlier this month, Bioxyne chief executive officer David Radford said that if the 320-patient trial results went well, the company hoped for a licencing deal or possibly a sale of the whole business by the end of 2012 or early 2013 (BD: May 7, 2012).

Today, Mr Radford said there was "growing interest among the respiratory medical community and pharmaceutical industry in the release of the phase IIb data from our trial and a recognition of the potential future value of an effective new therapy that could help address the medical needs of COPD patients worldwide".

"Bioxyne is engaged with a growing number of potential strategic corporate partners in multiple geographies," Mr Radford said.

"Torreya Partners will help us manage this important process in a timely and efficient manner to achieve the best long term results and create shareholder value," Mr Radford said.

Bioxyne was up one cent or 4.35 percent to 24 cents.

ACRUX

Ellerston Capital has become a substantial shareholder in Acrux with the acquisition of 8,984,253 shares or 5.40 percent.

The initial substantial shareholder notice said the shares were acquired by the Park Street Sydney-based Ellerston between February 24 and May 22, 2012 and were held by HSBC Custody Nominees, Cogent nominees, JPM Nominees and National Nominees.

The Ellerston notice gave two different numbers for shares held and person's votes and at the time of publication no one from the company was available to explain the discrepancy.

Acrux was up six cents or 1.5 percent to $4.07 with 1.1 million shares traded.

ACTINOGEN

A company associated with Actinogen executive director David Zohar has reduced its substantial holding and been diluted through a share rights issue.

David Zohar Associates said in its substantial shareholding that it had reduced and been diluted from 20,875,449 shares (25.94%) to 20,675,449 shares (23.62%).

Last month Actinogen said that the Australian Securities and Investments Commission alleged that Mr Zohar issued false or misleading information when he was a director of a different company and Mr Zohar would defend the matter (BD: Apr 24, 2012).

Actinogen was untraded at 2.4 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has appointed Peter Truelove as national sales and marketing director.

Mayne said the newly-created role would focus on increasing its Australian pharmaceutical business which currently generates annual sales of about $10 million through proprietary products including Astrix, Doryx, Eryc and Magnoplasm.

The company said it would focus on expanding the products offered to include in-licenced and acquired specialty pharmaceutical products, together with expansion of existing products market share through enhanced sales and marketing strategies.

Mayne Pharma said Mr Truelove was previously the sales and marketing director for Fresenius Kabi (Australia and New Zealand) and spent 11 years with Hospira Pty Ltd (previously Mayne Pharma and F H Faulding & Co) in national sales leadership roles, including as head of commercial operations, where he had responsibility for sales of about $150 million a year.

Mayne Pharma fell one cent or 3.2 percent to 30 cents.

IMPEDIMED

Impedimed says it has won the Biocom award for ‘life changing’ technology for its L-Dex U400 at the Medical Device and Diagnostics Expo in California.

The company said the award was “for a company that has had the biggest difference on an individual while addressing the greatest medical need”.

Impedimed said it was” excited to receive this award for the U400 limb application for lymphoedema”.

The company’s L-Dex U400 is used for the early detect of lymphoedema following surgery for breast cancer.

Impedimed fell half a cent or 1.45 percent to 34 cents.