



Biotech Daily

Friday June 20, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: UNIVERSAL BIO UP 10%, BENITEC DOWN 9%**
- * **VICTORIA \$17.5m CANCER RESEARCH GRANTS**
- * **NSW \$50k SUPPORTS 7 DELEGATES TO BIO 2014**
- * **CYCLOPHARM CYCLOTRON COLLATERAL WATER DAMAGE**
- * **QUEST CLOSE TO FILING LUNG CANCER TEST WITH CELLMID MIDKINE**
- * **INNATE PHASE IIB MIS416 TRIAL FOR MS DELAYED 8 WEEKS**
- * **BONE BACK TO PRE-CLINICAL STUDIES FOR BN006 FOR ARTHRITIS**
- * **KFT FOR GJK TAKES 10% OF UNIVERSAL BIOSENSORS**
- * **CBA TAKES 7% OF CSL**
- * **BENITEC LOSES DIRECTOR DR MEL BRIDGES**

MARKET REPORT

The Australian stock market fell 0.89 percent on Friday June 20, 2014 with the S&P ASX 200 down 48.7 points to 5,419.5 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged, six were untraded. All three Big Caps fell.

Universal Biosensors was the best for the second day in a row, up two cents or 10.3 percent to 21.5 cents with 702,724 shares traded.

Cellmid climbed eight percent; Prana rose seven percent; Atcor was up five percent; Avita, GI Dynamics and Phosphagenics were up more than four percent; Alchemia, Patrys and Pharmaxis climbed more than three percent; Impedimed, Prima and Starpharma rose more than two percent; Bionomics was up more than one percent; with Acrux and Sirtex up by less than one percent.

Benitec retreated 11.5 cents or 8.9 percent to \$1.175 with 526,890 shares traded.

Admedus lost 6.9 percent; both Biotron and Oncosil fell 4.55 percent; Antisense, Ellex, Medical Developments and Mesoblast were down more than three percent; with Cochlear, CSL, Neuren, Osprey, Resmed and Viralytics down more than one percent.

VICTORIA GOVERNMENT

The Victoria Government says that 25 cancer researchers will receive a total of \$17.5 million in Victorian Cancer Agency grants.

The Victoria Minister for Health David Davis said that the Victorian Cancer Agency grants “help improve the quality of cancer treatment in Victoria and continue to support research”. “Victoria has long been at the forefront of medical research, with our excellent research institutes and committed researchers,” Mr Davis said. “These research grants will ensure that we continue to lead the way in developing and trialling new treatments and in working towards improved cancer survival rates and cures.”

“The Napthine Government’s \$17.5 million investment in cancer research reflects our ongoing commitment to improving patient outcomes and the survival rate of cancer patients,” Mr Davis said.

A Victorian Government media release said that the Cancer Agency was established in 2006 played “a major co-ordinating role in cancer research in Victoria” and would administer the grants.

“The Victorian Cancer Agency’s aim is to make cancer patient care, outcomes and survival in Victoria among the best in the world, through the rapid translation of cancer research into clinical care which will have a direct impact on patients,” Mr Davis said.

“Our competitive grants help to turn laboratory breakthroughs into actions at the patient bedside and on to the community,” Mr Davis said.”

The media release said that the grants would help improve cancer patient outcomes and experience by funding the translation of new research findings into clinical practice; build and develop a highly-skilled cancer research workforce, and attract and retain renowned clinicians and researchers; develop an integrated cancer research platform that builds on and links existing research infrastructure; improve research collaboration and integration across the Victorian cancer system; support the development of a strong research culture in health services, and focus scientific and clinical research on improvements in clinical practice; and build closer partnerships with industry and the private and charitable sectors to maximize benefits from investment.

“This latest round of grants will help take Victoria another step forward in the fight against cancer, with a focus on specific tumor streams, rare cancers and clinician-led research which addresses the health needs of patients,” Mr Davis said.

“Improving cancer services is one of the Victorian Coalition Government’s top priorities,” Mr Davis said. “Cancer is the leading cause of death for Victorians, with one in three affected by the disease.”

“While cancer survival has increased in Victoria from 48 percent in 1990 to 66 percent in 2012, the health system must continue to work on finding new treatments,” Mr Davis said.

“Our research grants will give us the best chance of achieving this,” Mr Davis said.

A detailed list of the recipients is at: <http://bit.ly/1w0wgC9>.

NEW SOUTH WALES GOVERNMENT

New South Wales has provided \$50,000 to sponsor seven biotechnology organizations in that State at BIO 2014 meeting in San Diego, California, from June 23 to 26, 2014.

A media release from New South Wales Minister for Health and Medical Research Jillian Skinner said the seven recipients were Viralytics, Datapharm Australia, Advanced Surgical Design & Manufacture, Southern Star Research, Cellbank Australia, George Clinical and the S11 consortium of New South Wales universities.

The New South Wales Government said it had a booth at the convention to showcase the State’s research and medical device capability, economic and trade strengths.

CYCLOPHARM

Cyclopharm says that its cyclotron at Macquarie University Hospital has “suffered substantial water damage” following a fire in the floor above the facility.

Cyclopharm said that on the evening of Wednesday June 18, 2104 a vehicle caught fire in the Basement Level 1 car park of the Hospital and its cyclotron was directly below on Basement Level 2 and the facility suffered water damage in extinguishing the fire.

Cyclopharm said that the extent of the damage was yet to be ascertained, but the facility was fully insured and the claim was expected to be significant.

Cyclopharm was unchanged at 21 cents.

CELLMID

Cellmid says that Quest Diagnostics has “achieved major advances ... in particular with the clinical studies performed” on a lung cancer test using Cellmid’s midkine.

Cellmid said the 2009 licence to the Madison, New Jersey-based Quest enabled Quest to include midkine as one of the biomarkers and provided for a milestone payment on regulatory approval as well as royalties.

In 2009, Cellmid (then Medical Therapies) licenced midkine for the development of novel lung cancer diagnostics to the California-based Celera Corp (BD: Oct 29, 2009).

In 2012 following Quest’s acquisition of Celera in 2011, Cellmid said that Quest confirmed that midkine was one of six biomarkers and Quest stressed that it continued to work to the launch of a lung cancer diagnostic test including midkine (BD: Mar 5, 2012).

Today, Cellmid said that Quest had advised that samples obtained from the US National Cancer Institute-sponsored prostate, lung, colorectal and ovarian trial were being tested on the Luminex platform and the data was expected to be submitted to the Institute’s data review committee later this year.

The company said that Quest had reported on four other clinical studies conducted as part of its clinical validation program for the lung cancer test.

Cellmid said that since 2009 Quest had been developing a blood test to replace biopsy for determining whether pulmonary nodules identified through computer tomography or chest x-rays were cancerous and Quest confirmed last year that validation of the six-marker blood test was completed on the commercial Luminex diagnostic platform.

Cellmid said that Quest also reported in 2013 that they had signed an agreement with the National Cancer Institute to participate in the chest x-ray screening prostate, lung, colorectal and ovarian trial as part of their clinical validation program.

Cellmid said that Quest noted there was “growing support for a lung cancer screening program in the US with recommendation from the US Preventative Screening Task Force” with an estimated target market of seven million people a year at high risk for lung cancer. Quest has until October 31, 2014 to commercialize their lung cancer blood test with MK included, after which they maintain their ability to use midkine, but would lose exclusivity. Cellmid was up 0.2 cents or eight percent to 2.7 cents with 5.1 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate its 90-patient phase IIb trial of MIS416 for secondary progressive multiple sclerosis has been delayed by about eight weeks (BD: Apr 15, 2014)

In April, Innate said it expected to begin enrolment in June 2104 but today said that “due to finalization of arrangements with clinical investigators and trial sites taking longer than initially anticipated” it expected to enroll the first patient in August 2014.

Innate fell 1.5 cents or 8.1 percent to 17 cents.

BONE MEDICAL

Bone says it has begun further studies on BN006 for rheumatoid arthritis, which it hopes to conclude "by the end of July 2014 with results anticipated in the month following".

Bone said that in 2013 studies showed that in a commonly-used rheumatoid arthritis animal model, oral BN006 was as effective as the injected adalimumab (Humira) the best selling treatment for rheumatoid arthritis, with 2013 sales of \$US10.6 billion.

In January 2013, Bone said that initial findings from its BN006 proof-of-concept experiment for rheumatoid arthritis showed that BN006 reduced inflammation and the reduction appeared to be dose-related with only a modest reduction of tumor necrosis factor (BD: Jan 21, 2013).

Bone said at that time that the trial used a collagen-antibody induced arthritis model, but did not specify whether it was a human, animal or in-vitro laboratory study.

In April 2013, Bone's then chief executive officer Peter Young told Biotech Daily that interim phase I results from an eight-patient, randomized, cross-over design, proof of concept phase I trial showed that BN006 had an anti-inflammatory effect on rheumatoid arthritis equivalent to that of adalimumab, at about half the dose (BD: Apr 9, 2013).

Bone said in April 2013 that the objective of the concept study was to evaluate BN006's ability to reduce inflammation in the widely accepted collagen-antibody induced arthritis disease model and to compare its effect to adalimumab for rheumatoid arthritis.

Yesterday, recently Bone chairman Rob Towner said that "the 2013 results provided preclinical proof of concept for BN006 and so we are very excited to continue studies to progress this breakthrough future therapy for rheumatoid arthritis".

"BN006 has the potential to be a far superior treatment as it has shown to achieve a therapeutic effect without as much immune-system suppression as other treatments, thereby reducing the risk of infection to patients as well as being a more patient-friendly orally-deliverable treatment," Mr Towner said.

Bone said that the 2013 studies showed that BN006 was efficacious even at the lowest dose tested and the current experiments would test a lower range of dosages with the aim of confirming the full breadth of BN006's dose response and more fully characterize BN006's profile after oral delivery.

The company said that positive results would advance BN006 nearer to the commencement of human clinical trials, a major milestone for this product program.

Bone said that London's William Harvey Research Institute was investigating BN006's mechanism of action to "throw further light on the nature of the receptor on the macrophage to which BN006 binds".

The company said the Brisbane-based Q-Pharm study of its oral parathyroid hormone product for osteoporosis was expected to begin by the end of June 2014.

Bone was up 0.1 cents or 5.3 percent to two cents with 1.5 million shares traded.

UNIVERSAL BIOSENSORS

KFT Investments says it has increased its substantial holding in Universal Biosensors from 9,427,185 Chess depositary interests (5.38%) to 17,975,043 CDIs (10.236%).

KFT said it bought 8,547,858 CDIs on-market for \$1,555,539 or 18.2 cents a share.

KFT as trustee for GJK Principal Trust became substantial in Universal Biosensors last week (BD: Jun 11, 2014).

The becoming a substantial shareholder notice said that the Chirnside Park, Victoria-based KFT held CDIs for GJK and Kaasim Pty Ltd held CDIs as trustee of the George Kepper Superannuation Fund.

Universal Biosensors was up two cents or 10.3 percent to 21.5 cents.

CSL

The Commonwealth Bank of Australia and related entities have increased their substantial holding in CSL from 29,251,328 shares (6.01%) to 33,886,396 shares (7.08%). The Commonwealth Bank said the shares were held by companies and nominee firms including Citicorp, ASB Group, First State Investments (Hong Kong), HSBC UK, Avanteos Investments, Share Direct Nominees, Colonial First State, Citibank Hong Kong, Acadian, Northern Trust Co, UBS Nominees, JP Morgan, Realindex Investments, NAB Nominees, Nomura Bank (Luxembourg), State Street Global, BNP Paribas, First State Investments (Singapore), Bank of New York Mellon, RBC Dexia and UBS Nominees. CSL fell 77 cents or 1.1 percent to \$67.45 with 1.8 million shares traded.

BENITEC BIOPHARMA

Benitec says that non-executive director Dr Melvyn Bridges has resigned after nearly seven years with the company.

Benitec chairman Peter Francis said that Dr Bridges had been “a key contributor in the transformation of Benitec over recent years”.

“During Mel’s time on the board, the company has transitioned from pre-clinical to clinical stage, increased its capitalization to around \$150 million from \$15 million, established a broad program pipeline and entered the clinic with a first in man human trial in ddRNAi gene silencing in the US,” Mr Francis said.

“Mel’s contribution to these outcomes has been significant,” Mr Francis said.

Dr Bridges said he would focus on his “Brisbane-based boards and personal business opportunities”.

Benitec said it wanted to publicly express its sincere appreciation to Dr Bridges “for his wisdom, support and guidance over the past seven years”.

Benitec fell 11.5 cents or 8.9 percent to \$1.175.