



Biotech Daily

Thursday May 9, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: ALCHEMIA UP 7%, ELLEX DOWN 8%**
- * **HIGH COURT RESERVES CDPP v JM GTG DECISION**
- * **CIRCADIAN: VGX-300 WORKS FOR AMD IN MICE**
- * **FOUR AUSTRALIAN FELLOWS OF ROYAL SOCIETY**
- * **BIO-MELBOURNE'S 5th CONNECTING WOMEN LUNCH**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Thursday May 9, 2013, with the S&P ASX 200 down 1.4 points to 5,198.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and eight were untraded. All three Big Caps were up.

Alchemia was the best, up 2.5 cents or 7.1 percent to 37.5 cents with 737,491 shares traded.

Medical Developments and Reva climbed more than five percent; Circadian was up 4.35 percent; Anteo and Pharmaxis were up more than three percent; Genetic Technologies and Neuren rose more than two percent, the latter for the third day in a row; Cochlear, CSL, QRX and Viralytics were up more than one percent; with Resmed up 0.6 percent.

Ellex led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 18,340 shares traded.

Cellmid lost 6.1 percent; Impedimed fell 5.45 percent; Mesoblast, Osprey and Prima were down more than three percent; Clinuvel and Sirtex shed more than two percent; Acrux was down 1.5 percent; with Psivida down 0.7 percent.

COMMONWEALTH DIRECTOR OF PUBLIC PROSECUTIONS v JM

The full bench of the High Court of Australian has reserved its decision in a matter related to the trading of shares in GTG.

The case described as the Commonwealth Director of Public Prosecutions versus JM (M73/2012) was heard in Canberra on May 7 and 8, 2013 and related to “the meaning of an artificial price” in relation to Section 1041A of the Corporations Act (BD: Dec 14, 2012). In the transcripts published by the High Court, part of the case turned on the decision in the Federal Court by Justice Alan Goldberg in the case of the Australian Securities and Investments Commission (ASIC) versus the former Select Vaccines chief executive officer Dr Martin Soust (BD: Apr 23, 2010).

At that time Dr Soust was disqualified from managing corporations for 10 years, fined \$80,000 and ordered to pay legal costs.

Justice Goldberg said at that time that Dr Soust contravened Section 1041A of the Act by taking part in, and carrying out, a transaction that had the effect of creating an artificial price for trading in shares in Select Vaccines (now Select Exploration).

On the first day of the High Court hearing on May 7, barrister Paul Holdenson QC for the CDPD was quoted in the transcripts saying “there was always an issue between the parties concerning the construction of section 1041A of the Corporations Act and, hence, the correctness of the decision of his Honour Justice Goldberg in the Federal Court in the case of ASIC v Soust”.

“The Crown says that ‘artificial price’ in section 1041A connotes a price created not for the purpose of implementing or completing a transaction between genuine parties wishing to buy and sell securities, but rather for a purpose unrelated to achieving the outcome of the interplay of genuine market forces of supply and demand; that purpose being to ensure that the price for GTG was kept at levels designed to minimise the calls made on the accused under the margin lending arrangements,” the transcript reported Mr Holdenson saying.

The court transcripts, amounting to about 100 pages of text, contain detailed legal argument referring to a number of precedent court cases relating to the meaning of an artificial price, including matters heard in the Victorian Supreme Court by Justice Mark Weinberg (BD: Sep 2, 2011; Nov 27, 2012).

In the transcripts, Mark Moshinsky SC for JM is quoted saying that there was a difference between the question posed in the case heard by Justice Weinberg and the restated question from the majority of the Court of Appeal.

The transcripts quote Mr Moshinsky saying: “The submission that we make is one needs to have a comparator to look at is the price artificial in the sense that it is different from the other prices that are being traded at the same time or a normal market price.” “Otherwise, merely showing the subjective purpose is not enough to show that the price is ipso facto artificial,” Mr Moshinsky is quoted as saying.

“That is our submission, your Honour,” Mr Moshinsky is quoted as saying.

The High Court reserved its decision to a date to be fixed.

An officer of the Court told Biotech Daily that the decision could be expected to be published in three to six months.

The High Court documents are at: http://www.hcourt.gov.au/cases/case_m73-2012.

CIRCADIAN TECHNOLOGIES

Circadian says its VGX-300 compares to Eylea in a laser-induced mouse model of wet age-related macular degeneration (AMD).

Circadian said that data presented at the Association for Research in Vision and Ophthalmology conference in Seattle Washington showed that circulating blood plasma levels of vascular endothelial growth factor C (VEGF-C) were markedly increased in age-related macular degeneration patients and that VGX-300, an inhibitor of VEGF-C, was comparably to the marketed agent Eylea in a laser-induced mouse model of the disease. The company said that the data "strongly implicates VEGF-C in the pathogenesis of wet [age-related macular degeneration] and confirms the potential of VGX-300 as a novel therapeutic for the disease either as a single agent or as an adjunct to existing agents targeting VEGF-A".

Circadian said that the work was undertaken through its 100 percent owned subsidiary Opthea Pty Ltd with collaborator Dr Kameran Lashkari of the Schepens Eye Research Institute at Harvard Medical School.

The company said that Dr Kameran Lashkari presented a poster, entitled 'Expression of VEGF-C, VEGF-D and their cognate receptors in experimental and clinical choroidal neovascularisation', which showed a major link between vascular endothelial growth factor-C levels and age-related macular degeneration and that assessment of Opthea's drug development candidate, VGX-300, a soluble form of VEGF receptor-3 that blocked VEGF-C and VEGF-D in a mouse model of wet age-related macular degeneration confirming its potential as a therapy for the disease.

Circadian said that the poster showed for the first time, that circulating levels of VEGF-C were markedly elevated in age-related macular degeneration patients and that VGX-300 could inhibit the growth and leakage of new blood vessels in the retina, both hallmarks of wet age-related macular degeneration, in a laser-induced model of the disease in mice. The company said that the efficacy of VGX-300 was comparable to that of Eylea, which was similar in structure to VGX-300 but had a different mechanism of action and blocked VEGF-A, rather than VEGF-C and VEGF-D.

Circadian said that Eylea was first marketed in 2011 for wet age-related macular degeneration and had sales of \$838 million in 2012 and was forecast to reach \$1.3 billion in 2013.

The company said that Opthea was created in 2012 to develop Circadian's portfolio of VEGF-C and VEGF-D inhibitors for ophthalmic disease and was developing VGX-300 for wet age-related macular degeneration, the leading cause of blindness for people over the age of 50 years in the US and Europe.

Dr Lashkari said that there was an unmet medical need for improved treatment for wet age-related macular degeneration patients.

"Despite the recent advances made with the approval of agents targeting VEGF-A for this disease such as Eylea and Lucentis, at least 40 to 50 percent of these treated patients will exhibit a sub-response, indicating that this persistent angiogenesis and vascular leakage in the retinal tissue of these patients is driven by more than just one growth factor, VEGF-A," Dr Lashkari said.

Opthea chief executive officer Dr Megan Baldwin said the findings of the increased levels of VEGF-C in age-related macular degeneration patients as well as the results from the mouse model indicated that VEGF-C blockade could be a new therapeutic approach for wet age-related macular degeneration.

Dr Baldwin said she expected to begin clinical trials in by the end of 2014.

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

THE ROYAL SOCIETY

The London-based Royal Society says that four Australians are among the 54 Fellows appointed in this year's round.

The Royal Society says it is 'a self-governing Fellowship of many of the world's most distinguished scientists ... [with a] fundamental purpose, reflected in its founding Charters of the 1660s, ... to recognize, promote, and support excellence in science and to encourage the development and use of science for the benefit of humanity'.

The Royal Society said that Walter and Eliza Hall Institute senior principal research scientist Prof Terry Speed was "regarded internationally as the expert on the analysis of microarray data".

"This results partly from the sheer ingenuity of his work, and in part it is due to his commitment to working closely with biomedical scientists, enabling him to appreciate first-hand the biological challenges and the consequent requirements of new methodology [and he had made] seminal contributions to bioinformatics, statistical genetics, the analysis of designed experiments, graphical models and Bayes networks".

The Society said that University of Sydney professor of biology Prof Steve Simpson was "one of the world's foremost entomologists and nutritional biologists [whose] seminal work on locust swarming has provided a unifying framework, ranging from chemical events in nervous systems of individual insects to mass migration, using techniques from molecular biology, population genetics, neurophysiology, biochemistry, behavior, biomathematics, statistical physics, computer science, engineering, robotics, evolutionary theory and landscape ecology."

The Royal said that the University of New South Wales' Prof Martin Green was cited "for his extensive and distinguished contributions to photovoltaic science and technology ... identifying the fundamental limits upon silicon solar cell performance" and the Kingston Ontario-based Queens University Prof Ronald Kerry Rowe was "one of the most distinguished civil engineers of his generation [whose] research in the fields of geo-technical and geo-environmental engineering has had major impact on the profession."

The Society appointed 44 Fellows, eight Foreign (non-Commonwealth) Fellows, author Bill Bryson as an Honorary Fellow and Prince Andrew the Duke of York as a Royal Fellow.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will hosting its fifth 'Connecting Women in Biotechnology Luncheon on May 31, 2103 at the Myer department store.

Bio-Melbourne Network chief executive officer Michelle Gallaher said that "the annual luncheon provides an opportunity for women in the life sciences industry to hear from and have direct contact with industry role models and met mentors in a non-confronting environment".

"The luncheon provides a vehicle so that women can establish and grow their professional networks and reignite old contacts," Ms Gallaher said.

The Network said that as with previous years the Connecting Women in Biotechnology Luncheon would draw on surprise guest speakers to reveal their opinions, insights and often entertaining stories of life in this innovative industry.

This year's Luncheon will be held at Mural Hall, Level 6, Myer, Bourke Street, Melbourne. For more information and to book go to <http://www.biomelbourne.org/events/view/271>.