

Biotech Daily

Monday July 15, 2013

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: ANTISENSE UP 13%, CIRCADIAN DOWN 12.5%
- * GBS DECLINES 'INSUFFICIENT' \$30m FEDERAL INVESTMENT FUND
- * EURO METHODS PATENT FOR ATCOR'S SPHYGMOCOR
- * WEHI UNCOVERS IMMUNE RESPONSE CELL MECHANISM
- * COGSTATE SAYS TEST HELPS DIAGNOSE ALZHEIMER'S
- * INVION PLACEMENT, DIRECTORS' SHARES EGM
- * IMUGENE RELEASES 100m ESCROW SHARES
- * ALCHEMIA LOSES CHAIRMAN MEL BRIDGES, GAINS TIMOTHY HUGHES
- * PROGEN APPOINTS HENG HSIN TANG M-D, DIRECTOR CHANGE

MARKET REPORT

The Australian stock market was up 0.14 percent on Monday July 15, 2013 with the S&P ASX 200 up 7.2 points to 4,981.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and five were untraded.

Antisense was the best, up 0.2 cents or 13.3 percent to 1.7 cents with 21.1 million shares traded, followed by Pharmaxis up 11.1 percent to 20 cents with 3.95 million shares traded.

Impedimed climbed 9.5 percent; Cellmid was up 6.7 percent; Atcor and Living Cell were up more than four percent; GI Dynamics, Prana and Universal Biosensors were up more than three percent; Acrux, Bionomics, Heartware, Nanosonics and Resmed rose more than one percent; with CSL up 0.1 percent.

Circadian led the falls, down 3.5 cents or 12.5 percent to 24.5 cents with 1,200 shares traded, followed by Phylogica down 10 percent to 1.8 cents with 24,020 shares traded.

Ellex lost six percent; Psivida fell 5.3 percent; QRX and Sirtex shed more than two percent; Alchemia, Allied Health and Anteo were down more than one percent; with Cochlear, Medical Developments, Mesoblast and Starpharma down by less than one percent.

GBS VENTURE PARTNERS

GBS Venture Partners says it has declined the offer of a licence to \$30 million in the Innovation Investment Fund Round 3 Tranche 4.

GBS managing director Dr Brigitte Smith told Biotech Daily that with her company raising matching funds, the \$60 million would not be sufficient for a large enough portfolio spread of about 10 companies.

"If we were offered \$50 million we might have applied for it and we might apply in the future," Dr Smith said. "We still have the capacity to fund two to three more deals with our existing fund of \$10 million to \$12 million and are actively looking for projects."

In a media release, Dr Smith said that GBS was "pleased to have been selected as a potential IIF venture manager, [but] the proposed allocation does not provide adequate funds for the clinical trials stage of commercialization of Australian medical technologies". GBS said that in March 2013 it was offered \$30 million in matching Innovation Investment Fund (IIF) funds as one of three successful applicants and had been in discussions with Ausindustry to explore an expanded allocation, but based on a final decision that there were no additional funds available, the company declined to proceed.

"Australia already has a number of successful seed funds investing in early stage medical technologies," Dr Smith said. "Our IIF application proposed a fund large enough to support the next stage of these companies with sufficient capital to test the clinical efficacy and safety of new medicines and devices and launch global healthcare products."

"Although not sufficient for the clinical development of new Australian medicines and medical devices, the proposed quantum of IIF funds might be better suited to other technologies which require less capital to reach international markets," Dr Smith said. "GBS' IIF application had the support of superannuation funds that invest in Australian venture capital," Dr Smith said.

"The proposed fund was also supported by global pharmaceutical companies and other individual and institutional investors investing for the first time in Australian innovation," Dr Smith said. "We regret that the IIF allocation was below the amount our strategy required." "GBS remains committed to our ongoing investment program from GBS BioVentures IV, a \$123 million life sciences specialist venture fund," Dr Smith said.

"We are looking for several more investments for this fund and continue to actively manage over 25 portfolio companies across multiple funds," Dr Smith said.

"Of the 39 new medicines approved by the [US Food and Drug Administration] last year, 21 were deemed novel and two were developed by GBS portfolio companies" Dr Smith said.

Dr Smith said that GBS supported Peplin's PEP005, now Leo Pharma's Picato, for actinic keratosis and Chemgenex's Omapro, now Teva's Synribo for chronic myeloid leukaemia.

ATCOR MEDICAL

Atcor says it has been granted a European patent for its Sphygmocor non-invasive measure of central aortic blood pressure and arterial stiffness.

Atcor said that the patent, entitled 'Method and apparatus for determination of central aortic pressure' had been granted in the US and Japan and covered an alternative method by which central aortic blood pressure could be derived until December 2024.

Atcor said the patent provided expanded commercial opportunity, added to its portfolio of commercially-relevant intellectual property and confirmed the company's status as "the leader in this field" and was the eighth granted patent covering multiple geographic jurisdictions.

Atcor was up 0.3 cents or 4.3 percent to 7.3 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its scientists have uncovered the mechanism that controls whether cells that are able to suppress immune responses live or die. The Institute said the discovery of the cell death processes that determined the number of

regulatory T cells an individual has could lead to better treatments for immune disorders. The Institute said that regulatory T cells were members of a group of immune cells called

T cells and most T cells actively responded to clear the body of infections, whereas regulatory T cells were considered to be immune suppressing cells because they couldn switch-off an immune response to a particular molecule.

WEHI said that this immune suppression was important for preventing an inappropriate immune attack of the body's own tissues, which was the underlying cause of autoimmune diseases such as lupus and type 1 diabetes.

The Institute said that a shortage of regulatory T cells was linked with the development of autoimmune and inflammatory conditions, while some people with higher than normal numbers of regulatory T cells could not fight infections properly.

WEHI said that Dr Daniel Gray and Antonia Policheni made the discovery about how regulatory T cell numbers were controlled as part of an international team of researchers jointly led by Dr Gray and Dr Adrian Liston, the head of Belgium's Flanders Institute for Biotechnology Laboratory for Autoimmune Genetics at the University of Leuven.

The Institute said the researchers found that regulatory T cells were constantly being produced in the body, but their numbers were held steady by a process of cell death. WEHI said that cell death, or apoptosis, was important in many immune cell types for the removal of excess, defective or damaged cells and the decision of these cells on whether to live or die was controlled by the Bcl-2 protein family, which included proteins that could either promote cell survival or trigger cell death, in response to many different stimuli. Dr Gray said the team had discovered that Bcl-2 family proteins were important determinants of regulatory T cell numbers.

"Regulatory T cell death is highly dependent on the activity of two opposing Bcl-2 family proteins, called Mcl-1 and Bim," Dr Gray said.

"Mcl-1 is required for regulatory T cell survival, allowing them to suppress unhealthy immune responses, while Bim triggers the death of regulatory T cells," Dr Gray said. "Without Mcl-1 activity, regulatory T cell numbers fall, provoking lethal autoimmune disease," Dr Gray said. "Conversely, if Bim activity is lost, regulatory T cells accumulate in abnormally high numbers."

Dr Liston said the finding opened new ways to control regulatory T cell numbers. "Already, there is considerable interest in a new class of agents, called 'BH-3 mimetics' that target Bcl-2-like molecules including Mcl-1," Dr Liston said.

"If agents that can influence regulatory T cell survival can be developed, we could see new ways to suppress autoimmune disease, by boosting regulatory T cell numbers, or to enhance beneficial immune responses, by silencing regulatory T cells," Dr Liston said. The study, entitled 'Antiapoptotic Mcl-1 is critical for the survival and niche-filling capacity of Foxp3+regulatory T cells' was published in the journal Nature Immunology and an abstract is at: <u>http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.2649.html</u>.

IMUGENE

Imugene says that 100,000,000 shares will be released from escrow on July 31, 2013. Imugene executive director Dr Nicholas Ede told Biotech Daily that following the release, there would be 376,162,516 shares available for trading on the ASX. Imugene was untraded at 0.5 cents.

COGSTATE

Cogstate says its cognition tests have assisted the Australian Imaging Biomarkers and Lifestyle study of Alzheimer's disease.

Cogstate said that the study data was presented at the Alzheimer's Association International Conference in Boston, Massachusetts, showed the interplay between two known Alzheimer's disease risk factors, the build-up of amyloid plaques in the brain and the gene variation BDNF Val66Met.

Cogstate chief scientific officer Prof Paul Maruff said the research painted a clearer picture of who was most at risk of developing Alzheimer's disease.

"Our studies ... confirmed both elevated brain amyloid and this common gene variation are risk factors for Alzheimer's disease, with the presence of both signaling those at highest risk and patients in whom cognitive deterioration was more rapid," Prof Maruff said.

"This is important because it can help to identify those with the most to gain from early drug treatment and perhaps even behavioral intervention designed to prevent [Alzheimer's disease]," Prof Maruff said.

"Both approaches to prevention are currently a major international focus of companies and research groups," Prof Maruff said.

"This research will also help to identify those older people who have mild cognitive impairment but who have a low risk of [Alzheimer's disease], meaning their impairment may have other causes such as depression or stress which are more readily treatable," Prof Maruff said.

Cogstate said that Prof Maruff was a co-author on four studies presented in Boston, based on data collected for the study using its testing as a measure of cognitive health.

The company said that the Australian Imaging Biomarkers and Lifestyle study began in 2006 and involved more than 1000 people aged more than 60 years, was looking for biomarkers, cognitive characteristics, and other factors contributing to Alzheimer's disease.

Cogstate said that key findings of the four studies included that among healthy older people and people who met clinical criteria for mild cognitive impairment, high brain amyloid levels indicated that Alzheimer's disease-related neuro-degeneration had begun and that memory will now decline at a constant rate.

The company said that the studies showed that in healthy older people with abnormally high brain amyloid levels who also carry the BDNF Val66Met gene, memory and other aspects of cognition would decline faster than in those who did not carry the variant. Cogstate said that older people diagnosed with mild cognitive impairment and who had normal brain amyloid levels, did not show decline in memory over time and their cognitive impairment could be due to other more readily-treatable causes such as depression or stress.

The company said that the sensitivity of its cognition testing was also confirmed as a "useful tool" for the identification of Alzheimer's disease-related memory impairment in clinical settings.

Prof Maruff said a clearer picture of Alzheimer's disease risk was emerging with about 30 percent of Australians aged more than 60 years known to have high brain amyloid levels and within this group, about one in three would also carry the BDNF Val66Met gene variation, further increasing risk.

"A better understanding of these [Alzheimer's disease]-related population and biological factors places us closer to developing effective ... treatments and intervention strategies," Prof Maruff said.

Cogstate was unchanged at 34 cents.

INVION (FORMERLY CBIO)

Invion will vote to issue 50,278,783 placement shares to investors, including five directors, and issue 10,000,000 options to chief executive officer Dr Greg Collier.

In June, Invion raised \$1,910,594 in a placement at 3.8 cents a share (BD: Jun 11, 2013). The company said that six resolutions related to approval to participate in the placement for directors including Dr Collier through Beacon Super Fund, Dr Mitchell Glass, Dr James Campbell, Dr Ralph and Ms Lesley Craven, Dr William Garner through EGB Advisors and Fusion Biosciences, a company related to Dr Collier and Dr Campbell.

Invion proposes to issue 10,000,000 options to Dr Collier in five annual tranches of 2,000,000 options from October 9, 2013 to October 9, 2017.

The company said that the free options would be exercisable at 150 percent of the price at the date of issue, October 9, 2013, and would expire on November 9, 2017. Invion was unchanged at three cents.

<u>ALCHEMIA</u>

Alchemia says chairman Mel Bridges has retired after 10 years in the role, with newlyappointed director Nathan Drona acting as interim chairman (BD: Mar 22, 2013). Alchemia said that Timothy Hughes had been appointed as a non-executive director and The company said that Mr Hughes had experience in investment management and finance and previously held senior positions with Rothschilds in Australia for 1983 to 1996 including chief investment officer, chief economist, head of fixed interest and currency, as well as board director and member of the executive committee.

Alchemia said that Mr Hughes was investment counsel with NGS Super and chief investment officer of the Catholic Superannuation Fund and was currently a director of Value Capital Management in Sydney.

The company said that Mr Hughes held a Bachelor of Science from the University of Melbourne and a Bachelor of Arts in economics and a Master of Natural Resources from the University of New England.

Alchemia fell half a cent or 1.5 percent to 32 cents.

PROGEN PHARMACEUTICALS

Progen says that non-executive director Heng Hsin Tang has been appointed 0.6 parttime acting managing director on a base salary of \$118,285 a year effective from today. The company said that Mr Tang held a Bachelor of Civil Engineering and a Masters of Business Administration from the University of Queensland.

The company said Indrajit Solomon Arulampalam had been appointed a non-executive director replacing Dr Woei-Jia Jiang who had resigned today "for family reasons". Progen fell three cents or 15.4 percent to 16.5 cents.