

Biotech Daily

Wednesday June 5, 2013

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: TISSUE THERAPIES UP 15%, VIRALYTICS DOWN 9%

* FDA FAST-TRACKS NEUREN'S NNZ-2566 FOR RETT SYNDROME

- * JAPANESE COMPOSITION PATENT FOR MESOBLAST STEM CELLS
- * BENITEC TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION
- * CONSEGNA CLAIMS QUALITATIVE BREATHEASSIST SUCCESS
- * SIRTEX CALLS FOR SHAREHOLDER INPUT ON PAY INCREASES
- * AUSBIOTECH, BEACON ASIA BIOTECH INVEST CONFERENCE

MARKET REPORT

The Australian stock market fell 1.34 percent on Wednesday June 5, 2013 with the S&P ASX 200 down 65.6 points to 4,835.2 points.

Eight of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and eight were untraded.

Tissue Therapies was the best, up two cents or 15.4 percent to 15 cents, with 875,725 shares traded, followed by Antisense up 10 percent to 1.1 cents with 3.8 million shares traded.

Neuren climbed 3.8 percent; Anteo, Cochlear and Ellex rose more than two percent; with Heartware, Nanosonics, Resmed and Sirtex up by less than one percent.

Viralytics led the falls, down 2.5 cents or 9.1 percent to 25 cents with 189,961 shares traded.

Avita lost 8.6 percent; both Circadian and Patrys were down 6.7 percent; GI Dynamics and QRX fell more than four percent; both Cellmid and Phosphagenics were down 3.45 percent; Impedimed, Medical Developments, Osprey and Prima shed more than two percent; Acrux, Reva and Starpharma were down more than one percent; with CSL and Mesoblast down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has granted Fast Track designation for its program to develop NNZ-2566 for Rett syndrome.

Neuren said that Fast Track designation was designed to expedite the development and review of important new medicines intended to treat serious diseases and fill unmet medical needs.

Neuren said it began a phase II clinical trial of NNZ-2566 for Rett syndrome at Texas Children's Hospital Baylor College of Medicine in April 2013.

The company said that the trial would enrol up to 60 adolescent and adult subjects, allowing for some early discontinuations, to meet a target of 48 who complete all scheduled doses and assessments.

Neuren said that enrolment and follow-up were expected to be completed by July 2014 with top line results announced by the end of 2014.

Neuren chief executive officer Larry Glass said the designation would "assist Neuren in accelerating the development of a treatment for the core features of Rett syndrome and is recognition of the critical unmet needs of these girls and women".

"Neuren and the Rett Syndrome community are hopeful that NNZ-2566 will offer meaningful clinical benefits for patients and families affected by this devastating disorder," Mr Glass said.

Neuren said that NNZ-2566 was a synthetic analogue of a naturally occurring neuropeptide derived from Insulin-like growth factor 1 (IGF-1), produced by brain cells. The company said that in animal models, NNZ-2566 inhibited neuro-inflammation and normalized the function of microglia with consequent improvements in molecular, cellular, anatomic and behavioral outcomes.

The company said that Rett syndrome was a post-natal neurological disorder which occurred almost exclusively in females following apparently normal development for the first six months of life.

Neuren said that, typically, between six to 18 months of age, patients experienced a period of rapid decline with loss of purposeful hand use and spoken communication. The company said that many patients had recurrent seizures and experienced a variety of motor problems including increased muscle tone, or spasticity, and abnormal movements. Neuren said that people with Rett syndrome were never able to provide for their own needs and the rare disorder was believed to be second only to Down syndrome as a genetically-determined cause of chronic neurological problems.

Neuren was up 0.2 cents or 3.8 percent to 5.5 cents with 10.9 million shares traded.

MESOBLAST

Mesoblast says Japan's Patent Office has granted a patent covering all compositions-ofmatter and uses of its mesenchymal precursor cell regardless of tissue source. Mesoblast said the patent covered the technology platform, irrespective of the mesenchymal precursor cell tissue source, including bone marrow, adipose (fat), placenta, umbilical cord and dental pulp.

The company said that the Japanese patent provided exclusive commercial rights in Japan to September 2025 to all compositions-of-matter and uses of the mesenchymal precursor cells technology platform and followed the recent extension of compositions-of-matter patents by the US Patent and Trade Mark Office to March 2029 and two patents from China's State Intellectual Property Office that provided commercial rights and protection through to 2025.

Mesoblast fell three cents or 0.5 percent to \$6.13 with 560,128 shares traded.

BENITEC BIOPHARMA

Benitec has requested a voluntary suspension to follow the previous trading halt, requested on June 3, "regarding a proposed capital raising" (BD: Jun 3, 2013). Benitec last traded at 1.6 cents.

CONSEGNA GROUP

Consegna says that a majority of 36 athletes and trainers trialing its Breatheassist nasal plugs believed they aided oxygen delivery in exercise sessions.

Consegna chief executive officer Michael Johnson told Biotech Daily that a 2005 clinical trial demonstrated that the Breatheassist devices increased airflow by 38 percent.

"Plenty of athletes are using Glaxosmithkline's Breath Right nasal strips," Mr Johnson said.

"Our challenge is to get people to switch to a product that outperforms the GSK product," Mr Johnson said.

"The survey shows that people are prepared to switch", Mr Johnson said.

Consegna said the qualitative study recorded the attitudes and experiences of athletes and trainers before and after use of the Breatheassist prototype BA1.0 to provide input to improve the design of the market ready BA2.0 product and provide an independent assessment of user preferences and potential product uptake.

The company said that the trial was both qualitative and quantitative, evaluating user perception of the product and their experiences when using the product while exercising or training.

Consegna said that the 36 athletes and used the Breatheassist prototype BA1.0 during three separate exercise sessions involving either running, cycling, rowing, participating in aerobic gym classes or weight training.

The company said that 31 respondents (86%) reported that they believed Breatheassist technology would deliver more air into their lungs and 30 respondents (83%) believed that Breatheassist will allow them to be able to breathe more easily during exercise.

Consegna said that 33 (91%) believed that elite athletes and 34 (94%) of people training at an elite level would benefit from the technology, with 28 (77%) believing the technology would enable them to train at a higher intensity.

The company said that after trying the BA1.0 during three exercise and training sessions "two-thirds of respondents reported that they felt they got more air into their lungs when using the Breatheassist Sport [and] 60 percent felt less fatigued during training.

"Close to half felt their breathing returned to normal more quickly than usual when using the Breatheassist Sport and 80 percent of all respondents would expect to buy the Breatheassist technology online," Consegna said.

The company said that the study provided the company with specific issues and opportunities for improvement sizing and comfort that were being addressed in the design refinement process.

Mr Johnson said the trial "validated core benefits of the Breatheassist technology, especially the 38 percent increase in airflow".

"The results confirm a compelling commercial proposition, addressing an unmet need in a massive, growing market," Mr Johnson said.

Consegna fell 0.2 cents or 8.7 percent to 2.1 cents.

SIRTEX MEDICAL

Sirtex has proposed significant increases to executive and director pay and has called for shareholder input.

Sirtex said that executive pay increased significantly for companies with a market capitalization of more than \$450 million and Sirtex was above \$550 million.

The company said that "P75 positioning" was mid-way between the middle and top of market remuneration practice for a role and "achieved an appropriate balance between remuneration necessary to retain key staff and our responsibility to shareholders to manage costs".

Sirtex said its policy was to set the fixed remuneration component of a package at the mid-point of market practice and use incentives to achieve the P75 level, placing an emphasis on performance.

The company said that fixed remuneration increases would range up to 35 percent for the coming year, while at-risk incentive ratios for the chief executive officer and his direct reports would increase by a factor averaging approximately 1.5 times.

Sirtex said that the chief executive officer Gilman Wong's short term incentive target percentage should increase from 30 percent to 50 percent and his long term incentive target percentage should increase from 45 percent to 75 percent, with increases for his direct reports to be lower.

The company said it would review remuneration this month and where significant increases in fixed remuneration were warranted, it was intended to phase them in so as to manage the absorption of additional costs.

Sirtex said a rights plan had been designed reflecting a preference for directors to sacrifice part of their fees to buy company shares on-market and the difference between the non-executive director's P50 base fee which is paid in cash and the P75 fee target would be reflected in a salary-sacrifice style compulsory grant of rights vesting after one year and then replaced by shares acquired on-market, with strict and lengthy dealing restrictions, in accordance with Australian Taxation Office requirements. Sirtex was up one cent or 0.1 percent to \$11.21 with 230,282 shares traded.

AUSBIOTECH

Ausbiotech is hosting the Asia Biotech Invest Conference, its second Hong Kong meeting, this time co-hosted by Hong Kong's Beacon Events.

Ausbiotech said the two day conference on June 4 and 5, 2013 heard presentations from 12 Australian biotechnology companies, as well as investment sessions with more than 280 professional investors and analysts.

The industry organization said that the appetite for the conference, echoed the sentiment that a lot of speculative investment money, once focused solely on the resources sector was finding its way into biotechnology, which many investors regard as the next sector for high returns.

Ausbiotech said that with an ageing Asian population, there was an intensified focus on faster results, better patient self care, and improved treatment options.

Ausbiotech said that the Hong Kong meeting attracted 18 presenting companies as well delegates from Australia, Bangladesh, Canada, China, India, Indonesia, Japan, Korea, Macau, Malaysia, Singapore, Switzerland, Taiwan, Thailand, UK and US.