Biotech Daily

Tuesday July 14, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TISSUE THERAPIES UP 84%; LIVING CELL DOWN 11%**

*** PSIVIDA:' MEDIDUR SIGNIFICANT BENEFIT FOR UVEITIS'**

*** NOVOGEN: ANISINA BOOSTS CHEMO FOR NEUROBLASTOMA IN MICE**

*** ITL: MYHEALTHTEST, HbA1c TEST LAUNCHED FOR DIABETES WEEK**

*** ELLEX, MELBOURNE UNI $355k 2RT IMMUNE SYSTEM ARC GRANT**

*** TISSUE THERAPIES ACQUIRES VITROGRO IP FROM QUT**

*** COGSTATE: 'TRIALS CONTRACTS PUSH REVENUE UP 62%'**

*** UNNAMED US UNIVERSITY STUDIES ANTISENSE ATL1102 FOR CANCER**

*** PROCTOR & GAMBLE FUND 6th OBJ WORK PLAN**

*** REPRODUCTIVE HEALTH DISTRIBUTES IN CHINA, HONG KONG, MACAU**

*** GENETIC TECHNOLOGIES PLANS US BREVAGENPLUS TRIALS**

MARKET REPORT

The Australian stock market climbed 1.9 percent on Tuesday July 14, 2015 with the ASX200 up 104.2 points to 5,577.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and three were untraded.

Tissue Therapies was the best, up 3.1 cents or 83.8 percent to 6.8 cents with 9.3 million shares traded, followed by Psivida up 11.3 percent to $5.70 with 23,821 shares traded.

Benitec climbed 9.0 percent; Oncosil was up five percent; Biotron and Impedimed were up more than four percent; CSL, Nanosonics and Neuren were up more than three percent; Actinogen, Bionomics, Circadian, Cochlear, IDT, Sirtex and Starpharma rose more than two percent; with Admedus, Clinuvel, Mesoblast and Viralytics up more than one percent.

Living Cell led the falls, down half a cent or 10.6 percent to 4.2 cents, with 100,000 shares traded.

Prana lost 6.1 percent; Cellmid fell 5.6 percent; both Compumedics and Genetic Technologies were down 3.57 percent; Anteo and Universal Biosensors shed more than two percent; Prima lost 1.8 percent; with Acrux down 0.6 percent.

PSIVIDA

Psivida says that an 11-patient phase II trial of Medidur for posterior uveitis has shown a significant benefit over standard-of-care.

Psivida said that 11 patients with recurrent non-infectious intermediate, posterior or pan uveitis were randomized to receive a masked low or a high dose of Medidur in the three-year on-going phase II investigator-sponsored study, with “fellow eyes” with uveitis treated with standard of care, which included steroid eye drops.

The company said that at the most recent follow-up visit, with patients followed for between 12 and 24 months, none of the eyes treated with Medidur had any recurrence of uveitis, while fellow eyes treated with standard of care averaged 2.33 recurrences and the difference was statistically significant (p = 0.014).

Psivida said that eyes treated with Medidur experienced a significant improvement in visual acuity, gaining an average of 17 letters from baseline letters at 12 months on the Snellen eye chart (p = 0.014 at 12 months).

The company said that at the last follow up visit reported, the average gain from baseline in Medidur-treated eyes was more than 20 letters, while eyes treated with standard of care declined an average of 10 letters.

Psivida said that the most common adverse event in study eyes was elevated intraocular pressure with three study eyes developing elevated intraocular pressure and were treated with eye drops, with filtering procedures subsequently performed in two of these eyes, but those two eyes still gained an average of more than 25 letters from baseline at the last observation.

The company said that the study remained dose-masked so results could not be separated for the low and high doses of Medidur.

Psivida said that its 120-patient phase III trial was studying low dose Medidur.

The company said that Durham, North Carolina-based Duke University School of Medicine professor of ophthalmology Prof Glenn Jaffe presented the results at the American Society of Retina Specialists in Vienna, Austria, July 10-14, 2015, reporting the statistically significant reduction in recurrence of uveitis and a statistically significant improvement in visual acuity in eyes treated with Medidur.

Psivida said that at three months in its first phase III trial, four percent more study eyes, two-thirds of which received Medidur, experienced elevated intraocular pressure than the fellow non-study eyes, none of which received Medidur (BD: Mar 27, May 20, 2015).

The company said that initial intraocular pressure elevation was an indication of the likelihood of subsequent clinically significant intraocular pressure increases and “the minimal difference observed in elevated [intraocular pressure] in the assessment suggests highly favorable results for a key safety measure of the trial, the number of eyes that develop clinically significant increases in [intraocular pressure] within 12 months of receiving Medidur relative to control eyes”.

Psivida chief executive officer Dr Paul Ashton said the results in Prof Jaffe’s study were “very dramatic”.

“The efficacy of Medidur in controlling uveitis and restoring visual acuity was spectacular,” Dr Ashton said. “At the extreme, in addition to completely arresting any recurrence of uveitis, Medidur restored vision to two eyes that were legally blind at baseline.”

Psivida said that Medidur was an injectable micro-insert to treat posterior uveitis that provides sustained release of the corticosteroid flucinolone acetonide for three years and is the same micro-insert as Iluvien which has been approved in the US and Europe for diabetic macular oedema.

Psivida climbed 58 cents or 11.3 percent to $5.70.

NOVOGEN

Novogen says a proof-of-concept mouse study shows that Anisina can improve the effectiveness of chemotherapy in children and reduce life-long side-effects.

Novogen said that the results showed that anti-tropomyosin drug candidate Anisina, formerly known as ATM-3507, significantly improved the efficacy of the standard-of-care microtubule targeting compound vincristine in the neuroblastoma model.

The company said the study results were presented by Columbus, Ohio-based Nationwide Children's Hospital Research Institute principal investigator Dr Timothy Cripe at the Cancer Molecular Therapeutics Research Association meeting in Boston, Massachusetts, July 12 to 16, 2015.

Novogen said that the study showed that animals could be dosed with a formulation of Anisina in combination with the standard of care "and recapitulate in an animal model of neuroblastoma the same effect as observed in the test tube".

The company said study the evaluated Anisina alone or in combination with vincristine, in a mouse model of human neuroblastoma, with animals treated with: no drug; Anisina 150mg/kg; vincristine 0.5mg/kg; or Anisina 150mg/kg with vincristine 0.5mg/kg.

The company said that Anisina on its own was effective in reducing tumor growth by about 35 percent and Dr Cripe said that of the five animals receiving both Anisina and vincristine three had a complete response, with tumors deemed too small to be measured and with one animal showing a maintained complete response.

"Anisina has the potential to improve the effectiveness of the current standard of care chemotherapeutic, vincristine," Dr Cripe said. "In some cases doses of vincristine used in the clinic could be lowered thereby minimizing the risk of leaving children with side-effects that have life-long consequences."

Novogen anti-tropomyosin program director Dr Justine Stehn said that studies were underway "to validate the combinatorial effect of Anisina with a microtubule targeting compound in an animal model of adult cancer with the objective still being to have first-in-man studies commencing by mid-2016 once we have completed the standard battery of toxicology studies that are requisite for any experimental drug prior to entering the clinic".

Novogen said that neuroblastoma was a cancer that was most frequently observed in the young with more than 90 percent of diagnoses in children under five years of age.

Novogen was up 1.5 cents or 6.4 percent to 25 cents with 4.7 million shares traded.

ITL

ITL says takeover target Canberra pathology test provider Myhealthtest Pty Ltd was formerly launched yesterday to coincide with National Diabetes Week.

ITL said Myhealthtest's first diagnostic would be its HbA1c diabetes test and it would provide a free test to all 3,500 members of the Australian Capital Territory Diabetes when the test became available at the end of July.

The company said that a research article published in the BMC Clinical Pathology Journal on July 8, 2015 by Australian National University researchers showed that the Myhealthtest dried blood spots "gave comparable results to venous collected whole blood samples and were in agreement with the gold standard for HbA1c testing".

The article is at: http://www.biomedcentral.com/1472-6890/15/13.

In April, ITL said it expected to acquire Myhealthtest for up to $3,350,000 through a series of milestone-based call options (BD: Apr 29, 2015).

At that time, ITL executive chairman Bill Mobbs owned 67 percent of Myhealthtest and 38.63 percent of ITL.

ITL was up 2.5 cents or 11.4 percent to 24.5 cents.

ELLEX MEDICAL LASERS

Ellex says that University of Melbourne research collaborator Prof Erica Fletcher has been awarded a $355,000 Australian Research Council Linkage grant.

Ellex chief executive officer Tom Spurling said that the project, entitled 'Using lasers to prime the immune system' would "give our researchers a better understanding of the mechanism of action and potential uses of the 2RT laser currently in use in clinical trials for the treatment of early-stage age-related macular degeneration".

The company said that Prof Fletcher and Dr Bang Bui would lead the University of Melbourne research team to detail the precise effects that retinal rejuvenation therapy, or 2RT had on cells, cell populations and the body as a whole.

Ellex said the research would provide "fundamental knowledge on the impact of 2RT on cell biology of immune cells and cell signalling pathways in the retina".

"This could have significant applications beyond ophthalmology," Mr Spurling said.

Ellex was unchanged at 31 cents.

TISSUE THERAPIES

Tissue Therapies says it has acquired all the intellectual property around its Vitrogro extracellular matrix (ECM) wound treatment the Queensland University of Technology.

Tissue Therapies interim chief executive officer Nigel Johnson told Biotech Daily that the agreement was confidential but the company maintained a "strong positive relationship" with the University.

In a media release, Mr Johnson said the company was "aware of the importance of this agreement to shareholders and potential partners and sought to agree this changed arrangement … to strengthen our current position."

"Securing ownership of the [intellectual property] around our lead application Vitrogro ECM will provide the market with more certainty around the company's assets and commercial potential," Mr Johnson said.

Tissue Therapies said that the European Medicines Agency's scientific advice working party (SAWP) had accepted a revised plan for the development of Vitrogro ECM, confirming a viable pathway for taking Vitrogro ECM to market in Europe as a medical device (BD: Jun 1, 2015) .

The company said that Vitrogro ECM had been developed for managing chronic wounds, in particular chronic venous leg ulcers, that did not follow normal wound repair and had been present for more than four weeks despite standard care.

Tissue Therapies rose 3.1 cents or 83.8 percent to 6.8 cents with 9.3 million shares traded

COGSTATE

Cogstate says that revenue for the 12 months to June 30, 2015 was up 62 percent to $19.9 million compared to $12.3 million for the previous corresponding period.

Cogstate said that underlying revenue excluding "pass-through cost recoveries" was up 42 percent to $16.1 million compared to the previous year's $11.3 million.

The company said that it had "record sales contracts" for the 12 months to June 30, 2015 with $27.5 million of clinical trials sales contracts up 163 percent compared to the previous year.

Cogstate said that contracts were denominated in US dollars and the exchange rate used at June 30, 2015 was 76.5 Australian cents to $US1.00, compared to 90 Australian cents at June 30, 2014.

Cogstate was up three cents or 13.6 percent to 25 cents.

ANTISENSE THERAPEUTICS

Antisense says that a researcher at an unnamed US university has undertaken a pilot mouse model study of ATL1102 for cancer.

Antisense managing-director Mark Diamond told Biotech Daily that he could not provide greater detail until the company had completed filing a new patent application around the data from the pilot study.

The company said that the researcher approached Antisense with a request to conduct animal studies with ATL1102 in the university's established cancer animal model.

Antisense said it had provided a small quantity of ATL1102 drug product for the conduct of the pilot study and follow-on animal studies which were being run at the university's cost.

The company said that results from the follow on studies were expected "this year which could add further value to ATL1102".

Antisense has completed a phase II trial of ATL1102 for multiple sclerosis and is pursuing European early access programs as well as potential partnerships for the drug for multiple sclerosis (BD: Dec 9, 2014; May 27, 2015).

Antisense was unchanged at 10 cents with 1.4 million shares traded.

OBJ

OBJ says it has a new work plan with Procter and Gamble under the product development agreement to generate product claims support data.

OBJ said the work plan was the sixth to be fully funded by Proctor and Gamble and would use OBJ's skin science laboratory capabilities to provide the scientific proof required by various regulatory authorities in support of the claims they wanted to make for a new product incorporating its transdermal technology.

OBJ director Jeff Edwards said the engagement "to generate claims support data is another example of the close and collaborative relationship developing between the companies that now goes beyond technology provision alone".

"The high level of confidence with which [Procter and Gamble] now views OBJ's scientific as well as technical expertise across its products, demonstrates the growing productive relationship between the parties," Mr Edwards said.

OBJ said the product development agreement began in April 2014, allowing various Proctor and Gamble brands and franchises to work with OBJ under agreed terms.

The company said that Procter and Gamble brand managers could negotiate specific work plans for their particular developments undertaken and protected under the agreement.

OBJ said that the agreement initially contained two work plans and following the success of the SK-II Eye Wand launch there was growing interest by the brands.

OBJ was up 0.7 cents or 12.96 percent to 6.1 cents with 5.6 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it has signed distribution agreement with Medicare International Trading for the sale of Embryocellect in China, Hong Kong and Macau.

Reproductive Health said that Medicare was based in Hong Kong and distributed in mainland China through its Chinese company Miaoquan Enterprise which was based in Shenzhen.

Reproductive Health was up 3.5 cents or 21.2 percent to 20 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will run a series of US Brevagenplus breast cancer diagnostic clinical trials to provide evidence of its impact on treatment decision-making.

Genetic Technologies said that to secure and/or improve the level of commercial payer coverage in the US it needed further studies to demonstrate the product's value proposition and clinical benefits.

Genetic Technology chief executive officer Eutillio Buccilli said that the data generated from the additional studies and clinical trials was "indicative of our conviction in Brevagenplus and long-term strategic approach to investing in a scientific publication program designed to strengthen the commercial position for this flagship test".

The company said that the first trial was scheduled to begin by January 2016 with completion expected by July 2016.

Genetic Technologies said that two longer-term clinical trials we expected to begin by July 2016 and were designed to run for up to two years.

The company said that one of the longer term studies would prospective, looking at patient outcomes, with the other being retrospective, assessing the impact of the test on magnetic resonance imaging screening rates.

"The company's pre-raising cash position was a huge impediment and severely restricted our ability to undertake cost-out initiatives and implement the new strategy," Mr Buccilli said.

"With a strong balance sheet and costs firmly under control, management is now able to focus on managing the business and driving commercial growth," Mr Buccilli said.

Genetic Technologies fell 0.1 cents or 3.6 percent to 2.7 cents with 1.8 million shares traded.