

Biotech Daily

Tuesday July 11, 2017

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH EDGE UP: PRANA UP 11.5%, BENITEC DOWN 7%
- * PSIVIDA LICENCES DURASERT FOR POSTERIOR UVEITIS TO ALIMERA
- * COGSTATE EXPECTS REVENUE UP 27% TO \$35m, \$1m LOSS
- * EUROSTARS GRANTS USCOM FURTHER \$330k FOR SPACER PROJECT
- * SYDNEY UNI DIABETES PROGRAM ADOPTS ITL MYHEALTHTEST
- * BROOKESTONE TO SELL NUHEARA IQBUDS IN ALL US SHOPS
- * MARIJUANA LICENCE FOR AUSCANN PARTNER TASMANIAN ALKALOIDS
- * HYDROPONICS CANNABIS LICENCE
- * MESOBLAST: 6m OSIRIS CROHN'S SHARES; 7m EXECUTIVE OPTIONS
- * DIMERIX REQUESTS 'DMX-200 KIDNEY TRIAL RESULTS' TRADING HALT
- * INNATE PLEADS SCHULTZ TO ASX 42% QUERY
- * MACQUARIE GROUP BELOW 5% OF IMPEDIMED

MARKET REPORT

The Australian stock market edged up 0.08 percent on Tuesday July 11, 2017 with the ASX200 up 4.5 points to 5,728.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Prana was the best, up 0.6 cents or 11.5 percent to 5.8 cents with 52,816 shares traded. Factor Therapeutics climbed 9.4 percent; ITL rose 7.2 percent; Atcor was up 6.4 percent; both Living Cell and Orthocell improved 4.55 percent; Acrux, Admedus and Prima were up more than three percent; Compumedics, Osprey and Viralytics rose one percent or more; with Medical Developments, Pro Medicus and Starpharma up by less than one percent.

Benitec led the falls, down one cent or 6.7 percent to 14 cents with 112,026 shares traded, followed by Neuren down 6.25 percent to six cents with 1.25 million shares traded. Bionomics and Ellex lost more than five percent; Airxpanders and Oncosil fell more than four percent; Mesoblast and Nanosonics shed more than two percent; Impedimed, LBT and Universal Biosensors were down more than one percent; with Cochlear, CSL, Opthea, Resmed and Sirtex down by less than one percent.

PSIVIDA CORP

Psivida says it has amended its licence and collaboration agreement with Iluvien-distributor Alimera to cover uveitis in Europe, the Middle East and Africa (EMEA). Psivida said it had granted the rights to the Durasert three-year treatment for posterior segment uveitis to the Alpharetta, Georgia-based Alimera Sciences allowing it to pursue a secondary indication for Iluvien for posterior segment uveitis, which could accelerate the uveitis indication approval as well as commercialization.

The company said that Alimera already had the rights to Iluvien for diabetic macular oedema and Psivida retained commercialization rights for posterior segment uveitis in all other countries, including the US.

Psivida said the new agreement granted Alimera the rights to Durasert in Europe, the Middle East and Africa under the Iluvien trademark in exchange for tiered sales-based royalty payments, ending the existing profit share arrangement for Iluvien for diabetic macular oedema, effective from July 1, 2017, and improving its revenue generation from diabetic macular oedema indication sales.

The company said that sales-based royalty payments started at two percent and increased to six percent on the earliest of: Alimera's receipt of the first EU country marketing approval for Iluvien for the treatment of posterior segment uveitis; January 1, 2019; and one year from Alimera's filing of a marketing authorization application in the EU for posterior segment uveitis.

Psivida said royalties would rise to eight percent based on total Iluvien revenues in excess of \$US75 million in any calendar year.

The company said that under the previous agreement, its net profits were to be partially offset by accumulated net Iluvien commercialization losses and the new agreement capped accumulated losses at \$US25 million, of which \$US10 million was cancelled in exchange for the posterior uveitis rights, with \$US5 million to be cancelled pending Alimera milestones, and the balance subject to a partial offset against royalties. Psivida said it would withdraw its EU marketing approval application and orphan drug designation for posterior segment uveitis and Alimera would be responsible for filing a type II variation for Iluvien for the treatment of posterior segment uveitis in the 17 countries in the EU where it is approved for the treatment of diabetic macular oedema. Psivida chief executive officer Nancy Lurker said that the agreement "fulfils a core Psivida" objective to out-licence Durasert EMEA rights as a means to optimize product value ... [and] could accelerate commercialization uptake and revenue realization for Psivida". "The EMEA revenue opportunity for Durasert is estimated to be \$US30 to \$US50 million and in the US it is estimated to be \$US80 to \$US120 million," Ms Lurker said. Ms Lurker said that company was "on-track" to file a new drug application to the US Food and Drug Administration by the end of this year. Psivida was unchanged at \$2.50.

COGSTATE

Cogstate says that it expects unaudited revenue for the year to June 30, 2017 to be up 27 percent to \$34.6 million, with a net loss before tax of about \$1.0 million.

Cogstate said that revenue growth in the first half the year was not sustained throughout the second half.

The company said that it had cash of \$9.3 million at June 30, 2017, an increase of \$1.8 million over the previous year.

Cogstate fell 6.5 cents or 5.8 percent to \$1.06.

USCOM

Uscom says Eurostars has granted it a further \$330,000 under a European "smart spacer pulmonary recovery training and drug compliance program".

Uscom said the project, entitled 'Incentive based smart spacer to promote pulmonary recovery training and drug uptake' focused on the development of a new medical device that increased the efficiency of drug delivery from inhalation dispensers, supported by software to re-inforce the appropriate on going use of medication.

The company said the second stage grant took total Eurostars funding to develop better spacers for asthma and chronic obstructive pulmonary disease to \$820,000 over two years, with the total grant value to the consortium \$3.09 million (BD: Apr 3, 2017). Uscom was untraded at 19 cents.

ITL HEALTH GROUP

ITL says a Sydney University diabetes prevention program is using its Myhealthtest to identify people at risk of pre-diabetes and type 2 diabetes.

ITL said that diabetes researcher Dr Nick Fuller from Sydney University's Charles Perkins Centre was conducting lifestyle modification programs to raise awareness of prediabetes and diabetes prevention.

The company said the program was "a world first diabetes prevention program of this scale investigating standard care and the addition of natural medicines to see if they have added benefit for diabetes prevention".

ITL said that for one year, program participants would be provided with ongoing professional support including weight loss advice from dietitians and exercise physiologists and would receive regular medical monitoring including blood tests and full body composition scans measuring the amount of muscle and fat in the body, along with cognitive function testing and dental health examinations.

The company said that the Myhealthtest finger-prick blood sample was spotted onto a specialized card, returned by mail with results delivered to the consumer online, which could be shared with healthcare providers and others as desired.

"The Myhealthtest finger prick blood test allows us to effectively screen people in the lifestyle programs to help identify those one in six Australian adults who have prediabetes." Dr Fuller said.

Myhealthtest general-manager Dr Nick Cerneaz said the adoption by the Sydney University program was "validation of Myhealthtest's hard work and achievements to date".

"Our next generation pathology testing sets the industry standard for preventative and convenient at home healthcare," Dr Cerneaz said.

ITL was up 3.5 cents or 7.2 percent to 52 cents.

NUHEARA

Nuheara says that the Merrimack, New Hampshire-based Brookstone will sell its Iqbuds sound filtering and hearing devices in all of its 201 US shops.

Nuheara said the expansion followed an initial 60 days of sales through Brookstone's online shop, Brookstone's Amazon Store and at 51 of their physical shops, which comprised 41 airport outlets and 10 shopping mall shops (BD: Mar 8, 2017).

Nuheara was up half a cent or 5.4 percent to 9.7 cents with 30.2 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says the Australian Office of Drug Control has granted partner Tasmanian Alkaloids a medicinal cannabis licence and a research and development licence. Auscann said it had partnered with opiate-producer Tasmanian Alkaloids to cultivate, manufacture and distribute medicinal cannabis (BD: May 17, 2017).

The company said that the SK Capital Partners-owned Tasmanian Alkaloids produced about 40 percent of the world's opiate crop in Tasmania.

Auscann said that the Tasmanian licences were in addition to its medical cannabis cultivation licence granted by the Office of Drug Control (BD: May 5, 2017).

Auscann managing-director Elaine Darby said the licence was "a major milestone for the strategic partnership and represents significant progress in our joint strategy to become a leading producer and supplier of high quality medicinal cannabis to Australian patients". Auscann said it would import medicines from its partner Canopy Growth Corp, North America's largest producer of medicinal cannabis, ahead of the parties being able to supply Australian medicines, to address immediate need.

Auscann was up two cents or 4.7 percent to 44.5 cents with 1.9 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics has ended a trading halt for an announcement of a medicinal cannabis research licence for subsidiary Canndeo to say the licence was granted before the halt. Last week, Hydroponics said that Canndeo was a wholly owned subsidiary and the licence was related to the Australian Office of Drug Control (BD: Jul 7, 2017).

Today, the company said that the licence, granted on July 6, was one of the first granted and would allow Canndeo to conduct research on the use of cannabis for medicinal purposes.

Hydroponics fell three cents or 9.5 percent to 28.5 cents with 1.96 million shares traded.

MESOBLAST

Mesoblast says it has issued 6,029,545 shares to Osiris Therapeutics "as contingent consideration ... [for its] Crohn's disease program".

Mesoblast said the payment was included in the 2013 acquisition of the Osiris mesenchymal stem cell business (BD: Oct 11, 2013)

The company said it was continuing negotiations with Mallinckrodt Pharmaceuticals for a potential commercial and development partnership for two of its lead product candidates (BD: Dec 23, 2016; Jan 22, 2017).

In an Appendix 3B new issue announcement, Mesoblast also said it had issued 272,579 shares on the exercise of options in relation to the employee share option plan and 6,945,000 unquoted options to buy shares under the employee share option plan for executives and other senior management.

Mesoblast fell six cents or 2.9 percent to \$1.99 with 940,167 shares traded.

DIMERIX

Dimerix has requested a trading halt pending an announcement of its phase II trial of DMX-200 for chronic kidney disease".

Trading will resume on July 13, 2017 or on an earlier announcement.

Dimerix last traded at one cent.

INNATE IMMUNOTHERAPEUTICS

Innate has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 41.9 percent from 4.3 cents on June 28 to 6.1 cents today, July 11, 2017 and noted a significant increase in the trading volume. In June, Innate fell 93 percent on news its trial of MIS416 multiple sclerosis trial showed no "clinically meaningful or statistically significant" efficacy (BD: Jun 27, 2017) Innate closed up 1.7 cents or 38.6 percent to 6.1 cents with 46.75 million shares traded.

IMPEDIMED

The Sydney-based Macquarie Group says it has ceased its substantial shareholding in Impedimed.

Two weeks ago, Macquarie Group said it had become a substantial shareholder in Impedimed with 20,647,529 shares or 5.50 percent (BD: Jun 30, 2017).

Today the Group said that between June 27 and July 5, 2017 it bought sold and returned borrowed shares at prices ranging from 72 to 83 cents a share.

The Macquarie substantial shareholder notice filed more than 15 pages of information on "controlled bodies corporate".

Impedimed fell one cent or 1.3 percent 74 cents.