Biotech Daily

Tuesday August 7, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LBT UP 8%; NEUREN DOWN 43%**

*** ACADIA $630m FOR NEUREN TROFINETIDE NORTH AMERICA RIGHTS**

*** IMMUTEP DOSES IMP321 TACTIMEL TRIAL 4th COHORT**

*** ALCIDION: MKM SOFTWARE FOR ALFRED HEALTH**

*** SIENNA APPOINTS SHAANXI GAOYUAN CHINA DISTRIBUTOR**

*** CANADA PATENT FOR IMMUTEP LAG3, IMP731**

*** IDT, CANN MARIJUANA MANUFACTURING DEAL**

*** JCP REDUCES TO 7.2% OF NANOSONICS**

*** RHYTHM RELEASES 9.75m ESCROW SHARES**

*** SCIGEN TO DELIST FROM ASX AUGUST 28**

*** G MEDICAL REQUESTS HONG KONG LISTING TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.3 percent on Tuesday August 7, 2018 with the ASX200 down 19.1 points to 6,253.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and eight were untraded.

LBT was the best, up one cent or eight percent to 13.5 cents with 434,253 shares traded.

Genetic Signatures climbed 7.3 percent; Osprey was up 6.5 percent; Airxpanders improved 4.55 percent; Avita, Dimerix and Factor Therapeutics rose two percent or more; Compumedics, CSL and Orthocell were up more than one percent; with Cyclopharm, Pro Medicus and Resmed up by less than one percent.

Despite a $630 million deal, Neuren led the falls, down $1.15 or 43.1 percent to $1.52 with 3.2 million shares traded.

Prescient lost 8.7 percent; Imugene fell 4.35 percent; Benitec, and Polynovo shed two percent or more; Bionomics, Mesoblast, Nanosonics, Pharmaxis and Telix were down more than one percent; with Clinuvel, Cochlear, Ellex, Sirtex and Starpharma down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says Acadia will pay $630 million in upfront fees, milestones and royalties for a North American licence to trofinetide for Rett syndrome and other indications.

Neuren said the San Diego, California-based Acadia Pharmaceuticals would pay $US10 million ($A13.54 million) upfront and up to $US455 million ($A616.2 million) in milestones as well as royalties to licence trofinetide for Rett syndrome, Fragile X and other indications for North America, alone.

Neuren executive chairman Dr Richard Treagus told Biotech Daily the licence covered all indications in North America as well as a first negotiation option for other territories.

Dr Treagus said Neuren was entitled to one third of the market value of any rare paediatric disease priority review voucher, if awarded by the US Food and Drug Administration on approval of a new drug application for trofinetide, as well as full access to all data generated by Acadia for Neuren's applications in other jurisdictions.

Dr Treagus said that FDA priority review vouchers had "recently traded from $US110 million to $US245 million".

In a media release, Neuren said it was eligible for tiered, escalating, double-digit percentage royalties on net sales of trofinetide in North America with milestone payments of $US105 million for Rett syndrome and Fragile X syndrome and up to $US350 million subject to annual net sales of trofinetide in North America.

The company said Acadia would fund and execute the remaining development for trofinetide in Rett syndrome in North America, except for the completion by Neuren of certain preparatory activities, and Neuren had an obligation not to develop a competing product in indications for which Acadia developed and commercialized trofinetide.

Neuren said that Acadia planned to start a 180-girl, phase III study of trofinetide for Rett syndrome by the end of 2019 following completion of additional manufacturing activities.

The company said the Acadia phase III trial would measure the Rett syndrome behavior questionnaire (RSBQ), a caregiver assessment, and the clinical global impression of improvement (CGI-I) and a physician assessment, as co-primary efficacy endpoints.

Acadia head of research and development Dr Serge Stankovic said that a potential treatment for Rett syndrome was "a perfect fit with Acadia's mission to develop novel therapies to improve the lives of patients with central nervous system disorders".

"Today there are no approved treatments for the girls and women suffering from Rett syndrome," Dr Stankovic said.

Dr Treagus said that Acadia had "a proven record in developing and commercializing medicines in central nervous system disorders".

"Acadia's additional capabilities and resources will immediately make a very significant difference, enabling us to advance our shared goal of developing this novel treatment option for Rett syndrome patients," Dr Treagus said.

Rettsyndrome.org chief science officer Dr Steve Kaminsky said his organization "grateful to Neuren for their dedication to the development of trofinetide".

"Acadia's commitment to advance trofinetide to phase III brings us closer to the first potential treatment for Rett syndrome with a drug designed to address the underlying biology and improve the lives of those suffering from the condition," Dr Kaminsky said.

Neuren said that trofinetide had been granted FDA fast track status and orphan drug designation in the US and Europe.

The company said its phase II, double-blind, placebo-controlled, dose-ranging study in 82 girls aged five to 15 years with Rett syndrome showed "statistically significant and clinically meaningful improvement" on the Rett syndrome behavior questionnaire and the clinical global impression of improvement measures (BD: March 22, 2017).

Neuren fell $1.15 or 43.1 percent to $1.52 with 3.2 million shares traded.

IMMUTEP

Immutep says all six patients in part B of its two active immune-therapeutics in melanoma (Tacti-mel) phase I trial have begun dosing.

Immutep said the fourth cohort of the trial would be dosed with 30 milligrams of IMP321, or eftilagimod alpha, in combination with Keytruda, or pembrolizumab, for up to 12 months.

Earlier this year, the company said it had dosed the first of six patients in the fourth cohort of the 24-patient trial (BD: Mar 22, 2018).

Immutep said that safety assessment was the main objective of the study, with interim data from the first three cohorts indicating that the treatment was producing “long lasting and durable responses in a subset of patients”.

Immutep was unchanged at 3.6 cents with 1.4million shares traded.

ALCIDION GROUP

Alcidion says its subsidiary MKM Health will develop software for the Melbourne’s Alfred Health, which is based at the Alfred Hospital.

Alcidion said MKM would design and develop a reporting and data visualization platform for Alfred Health and a data warehousing platform that would be deployed at its three hospitals; the Alfred Hospital, Caulfield Hospital and Sandringham Hospital, as well as multiple satellite services.

Alcidion was up 0.2 cents or 4.3 percent to 4.9 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says the Xi’an, China-based Shaanxi Gaoyuan In-vitro Diagnostic Reagents Co will distribute its in-vitro adjunct diagnostic for bladder cancer in mainland China.

Sienna said that regulatory approval from the China Food and Drug Administration was required before it could begin sales and while approval was sought it would begin training Gaoyuan’s sales, marketing and technical support staff.

Gaoyuan general manager Wenguang Yan said the company had “significant experience selling in-vitro diagnostic cancer tests to pathology laboratories across China, including our own biomarker-based test for cervical cancer”.

Sienna was up 0.7 cents or 8.75 percent to 8.7 cents.

IDT AUSTRALIA, CANN GROUP

IDT says it will provide Cann Group with manufacturing support for its marijuana formulations.

IDT chief executive officer Dr David Sparling said that Cann was “an industry leading science-based player in the quickly evolving Australian medicinal cannabis space”.

Dr Sparling said IDT’s manufacturing facilities were “ideally suited to undertake this work and our track record in completing highly complex projects to global [good manufacturing practice] quality standards ensures we can add significant value to Cann’s development efforts”.

Cann chief executive officer Peter Crock said that with IDT his company would develop “a range of delivery systems and dosage forms that can meet the varying needs of patients”.

Cann was up four cents or 1.4 percent to $2.93.

IDT was up 1.7 cents or 21.8 percent to 9.5 cents with 1.4 million shares traded.

IMMUTEP

Immutep says the Canadian Intellectual Property Office has granted a patent relating to IMP731 for organ transplant rejection and autoimmune disease.

Immutep said that the patent, titled 'Cytotoxic anti-LAG-3 monoclonal antibody and its use in the treatment or prevention of organ transplant rejection and autoimmune disease', would provide intellectual property rights until April 30, 2028.

The company said that the patent covered the use of an antibody which treated T-cell mediated autoimmune disease by depleting "potentially pathogenic, recently activated, LAG-3 expressing T-cells that are enriched at the disease site in T-cell driven immuno-inflammatory disorders".

Immutep said that depletion of the LAG-3 expressing T-cells "should spare other T-cells which may be necessary for disease control".

Immutep said that rights for the development of the IMP731 antibody, originally developed by French subsidiary Immutep SAS, were granted to Glaxosmithkline in December 2010, which developed a registered humanized antibody from it known as GSK2831781, which has the same function of depleting potentially pathogenic LAG-3 expressing T-cells.

Immutep said the patent has corresponding patents in the US, Europe and Japan.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 25,078,032 shares (8.38%) to 21,622,248 shares (7.22%).

The Melbourne-based JCP said that between June 13 and August 2, 2018 it sold shares, with the single largest sale of 535,873 shares for $1,736,995, or $3.24 a share.

JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.

Nanosonics fell five cents or 1.5 percent to $3.24 with 914,289 shares traded.

RHYTHM BIOSCIENCES

Rhythm says that 7,250,000 shares will be released from ASX escrow on August 29, 2018, with an additional 2,500,000 to be released on September 3, 2018.

Rhythm executives told Biotech Daily that following the release of the shares, the company would have 62,250,000 shares available for trading, with a further 38,500,000 shares held in ASX escrow, for a total of 100,750,000 shares on issue.

Rhythm fell two cents or 11.1 percent to 16 cents.

SCIGEN

Scigen says it will be removed from the ASX on August 28, 2018, following its purchase by SAC Capital Private on behalf of Hangzhou, China's Yifan International.

Earlier this year, the Singapore-based Scigen said Yifan had bid 5.07 US cents (then 6.8 Australian cents) to acquire the company, including the 90.54 percent of the company owned by the Warsaw, Poland-based Bioton SA (BD: May 16, 2018).

Today, the company said the ASX would suspend its chess depositary interests (CDIs) from trading on August 22, 2018, with all remaining CDIs to be transferred to Yifan by August 27, 2018.

Scigen was unchanged at 6.6 cents.

G MEDICAL INNOVATIONS

G Medical says it has requested a trading halt “pending an announcement in relation to a potential listing of its Hong Kong subsidiary”.
Trading will resume on August 9, 2018 or on an earlier announcement.
G Medical last traded at 18.5 cents.