

Biotech Daily

Thursday December 11, 2014

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: OPTISCAN, PRANA UP 10%, GI DYNAMICS DOWN 12%

* ACRUX, ELI LILLY SUE AMNEAL OVER AXIRON PATENTS

- * PRESCIENT (VIRAX) TAKES AKTIVATE; PAUL HOPPER ON \$180k
- * WEHI'S PROF GUILLAUME LESSENE WINS \$50k NFMRI MEDAL
- * CELLMID REQUESTS CAPITAL RAISING TRADING HALT

MARKET REPORT

The Australian stock market fell 0.53 percent on Thursday December 11, 2014 with the S&P ASX 200 down 28.0 points to 5,231.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded.

Optiscan and Prana were equal best, both up 10 percent, to 5.5 cents and 22 cents, respectively, with 6.7 million and 1.5 million shares traded, respectively.

Biotron climbed 7.1 percent; both Bionomics and Living Cell were up five percent; Neuren and Pharmaxis rose two percent or more; Alchemia, Benitec and CSL were up more than one percent; with Mesoblast up 0.2 percent.

GI Dynamics led the falls, down 3.5 cents or 11.7 percent to 26.5 cents with 1.95 million shares traded.

Genetic Technologies and Patrys lost more than six percent; Uscom fell five percent; Admedus, Atcor, Avita, Clinuvel and Starpharma lost more than four percent; Impedimed, Nanosonics, Oncosil and Osprey were down more than three percent; Acrux and Prima shed more than two percent; Phosphagenics, Sirtex and Tissue Therapies were down one percent or more; with Cochlear, Medical Developments and Resmed down by less than one percent.

<u>ACRUX</u>

Acrux says that with Eli Lilly and Co, it had filed a lawsuit against Amneal Pharmaceuticals for infringement of four issued US patents that cover Axiron.

Acrux said that the legal action against the Bridgewater, New Jersey-based Amneal relating to the Axiron testosterone replacement therapy patents was joined by Eli Lilly Export SA and Acrux DDS Pty Ltd.

The company said that the patents were owned by wholly-owned subsidiary Acrux DDS and were licenced exclusively to Eli Lilly.

Acrux said that the lawsuit was filed in the US District Court for the Southern District of Indiana in response to a notice letter sent by Amneal regarding its filing with the US Food and Drug Administration of an abbreviated new drug application for a testosterone metered dose transdermal product.

The company said that the Amneal stated that the application contained "Paragraph IV certifications with respect to US Patents 8,419,307, 8,435,944, 8,784,878 and 8,807,861, which were expected to expire between 2026 and 2030".

Acrux said that the patents included claims relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron.

The company said that a Paragraph IV certification alleged invalidity, unenforceability and/or non-infringement of a patent.

Acrux said that it and Lilly were committed to asserting their intellectual property rights. Acrux said that like the litigation against Perrigo Israel Pharmaceuticals and the Dublin, Ireland-based Actavis Inc, owner of Watson Laboratories, the conduct of the lawsuit will not have a material impact on its operating expenditure (BD: May 27, Nov 13, 2013). Acrux fell three cents or 2.6 percent to \$1.14 with 1.7 million shares traded.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says it has finalized the acquisition of Aktivate Therapeutics and its novel cancer drug candidate triciribine phosphate monohydrate.

Prescient, formerly known as Virax, said it paid \$US300,000 in cash and issued 6,700,005 shares to the vendors for the acquisition and would issue a further 5,000,000 shares to the vendors on meeting major clinical and regulatory milestones.

Prescient chairman Steven Engle said completion of the Aktivate acquisition was "another important milestone for the company".

"The completion of the Aktivate transaction is Prescient's second major oncology acquisition this year and significantly strengthens the company's product pipeline," Mr Engle said.

"We now have two novel cancer compounds with the prospect of five mid-stage clinical trials," Mr Engle said.

Prescient said that TCN-P is a small molecule that blocks the AKT growth-promoting pathway that led to cancer and AKT was the most frequently altered signaling pathway in cancer and played a key role in the development of many cancers including those being currently pursued by the company including breast and ovarian cancer and leukaemia. The company said that as a consequence of the increased workload in the US and the additional oversight resulting from the Aktivate acquisition, it had requested executive director Paul Hopper increase his day-to-day involvement and his remuneration would increase to \$180,000 a year from December 1, 2014.

Last week Prescient completed its one-for-20 capital consolidation and is trading under the temporary ASX code of VHLDA pending the change to PTX on December 15, 2014. Prescient or Virax was up one cent or 8.3 percent to 13 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Prof Guillaume Lessene has won the inaugural \$50,000 Dr John Dixon Hughes Medical Research Innovation Medal. The Institute said that Prof Lessene won the National Foundation for Medical Research and Innovation awarded prize for his discovery and development of potential anti-cancer drugs.

WEHI said that Prof Lessene had "dedicated the past decade ... to discovering and developing small molecules that target the programmed cell death pathway, apoptosis, that is important in cancer development and resistance to chemotherapy".

The Institute said that Prof Lessene's work contributed to the discovery of a new class of drugs, called BH3-mimetics, that trick cancer cells into apoptosis.

WEHI said that Prof Lessene said his group set out to develop novel inhibitors of the prosurvival Bcl-2 protein family, components of the apoptotic machinery that were major factors in the development of cancer and resistance to therapy.

"Cancer cells avoid programmed death by producing high levels of one or more prosurvival molecules, called the BCL-2 family of proteins," Prof Lessene said.

"Harnessing the power of small molecules to interrogate biological pathways controlling cell death will not only lead to a better understanding of cell death and its role in cancer, but also deliver new chemical leads in areas of unmet need in oncology," Prof Lessene said.

WEHI said that BH3-mimetics had transformed the field of cancer therapy and were showing promise for treating some blood cancers, such as chronic lymphocytic leukaemia. The Institute said that Prof Lessene was its lead scientist in a collaboration with the France-based Servier Laboratories to develop new agents that could be effective in treating several types of cancer, particularly blood cancers.

Institute director Prof Doug Hilton said that Prof Lessene was one of the institute's shining stars.

"The type of molecules that regulate apoptosis are not conventional drug targets, and many in the pharmacological industry considered them undruggable," Prof Hilton said. "Undeterred, Guillaume and his team have discovered pharmaceutical agents with

exquisite specificity for the apoptotic machinery," Prof Hilton said.

"His outstanding contribution to biomedicine has garnered a strong international reputation and signals his emergence as a leader in medical research and innovation," Prof Hilton said.

WEHI said that the Dr John Dixon Hughes Medal for Medical Research Innovation was a biannual award offered by the NFMRI to a researcher under the age of 45 for outstanding contribution towards the development and advancement of a biomedical innovation related to the nature, prevention, diagnosis, treatment and incidence of disease and other health problems that have a significant impact on human health.

CELLMID

Cellmid has requested a trading halt pending an announcement "in relation to a proposed capital raising that is material to the company's business".

Trading will resume on December 15, 2014 or on an earlier announcement. Cellmid last traded at 2.8 cents.