Biotech Daily

Tuesday April 28, 2015

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: ONCOSIL UP 9%, NEUREN DOWN 10%**

*** GBS INVESTEE CELLADON FALLS 81% ON MYDICAR HEART FAILURE**

*** NANOSONICS $9.3m Q3 RECEIPTS TAKE 4C POSITIVE, AGAIN**

*** EMA BACKS ORPHAN STATUS FOR PRANA'S PBT2 FOR HUNTINGTON'S**

*** KANSAS UNIVERSITY CANCER CENTER JOINS IMPEDIMED L-DEX TRIAL**

*** PROTEOMICS WINS MIDDLE EAST GENERICS TESTING CONTRACT**

*** MINDEROO (METAL) GROUP REDUCES TO 8% OF ADMEDUS**

*** JK, HOGAN, TISIA, HENDERSON INCREASE, DILUTED IN ACTINOGEN**

*** PRESCIENT APPOINTS DR TERRENCE CHEW CMO**

*** NOVOGEN RE-COMPLIES WITH NASDAQ EQUITY VALUE RULES**

MARKET REPORT

The Australian stock market fell 0.57 percent on Tuesday April 28, 2015 with the S&P ASX 200 down 34.2 points to 5,948.5 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and two were untraded. All three Big Caps fell.

Oncosil was the best, up 0.8 cents or 9.2 percent to 9.5 cents with 6.85 million shares traded, followed by Patrys up 9.1 percent to 1.2 cents with 100,000 shares traded.

IDT climbed 7.4 percent; Ellex was up 5.9 percent; Cellmid was up 4.2 percent; Bionomics rose 2.4 percent; with Admedus, Medical Developments, Optiscan and Osprey up more than one percent.

Neuren led the falls on the day of its annual general meeting in which all resolutions were passed easily, down 1.1 cents or 10.0 percent to 9.9 cents with 4.5 million shares traded.

Genetic Technologies lost 7.5 percent; Cochlear, Impedimed and Prima fell more than four percent; Actinogen, Antisense, Atcor, Circadian, GI Dynamics, Resmed and Viralytics were down three percent or more; Avita, Clinuvel, Compumedics, Mesoblast and Sirtex shed more than two percent; with Acrux, Anteo, CSL and Starpharma down one percent or more.

CELLADON CORP, GBS VENTURE PARTNERS

Celladon fell 80.7 percent on the Nasdaq on news that that its phase IIb trial of gene therapy Mydicar for heart failure did not meet its primary and secondary endpoints.

Melbourne's GBS Venture Partners owned about six percent of the San Diego, California-based Celladon, which said that the trial, entitled 'Calcium Up-Regulation by Percutaneous Administration of Gene Therapy In Cardiac Disease' (Cupid2) was a randomized, double-blind, placebo-controlled, trial evaluating a single, intracoronary infusion of Mydicar, or adeno-associated viral-1 (AAV1) sarco/endoplasmic reticulum Ca^{a2}+ ATPase (SERCA2a), compared to placebo, added to a maximal, optimized heart failure drug and device regimen.

Celladon's statement is at: http://ir.celladon.net/releasedetail.cfm?ReleaseID=908592.

Last year, GBS announced that Celladon had listed on the Nasdaq at $US8.00 a share to develop the congestive heart failure gene therapy, partly developed at Melbourne's Baker IDI Heart and Diabetes Institute, with the then GBS partner Dr Joshua Funder as a director of Celladon (BD: Jan 31, 2014).

Dr Funder told Biotech Daily at that time that GBS had followed the company for nine years, invested in it in 2012 and held about six percent of the company.

Today, GBS managing partner Dr Brigitte Smith told Biotech Daily that Celladon's Mydicar "failed comprehensively" on all endpoints.

"We sold ahead of the announcement, enough to recoup our original investment," Dr Smith said.

The most recent US Securities and Exchange Commission filing from April 20, 2015 showed that GBS Bioventures IV held 1,367,687 shares or 5.79 percent, an increase from the 1,341,004 shares or 5.75 percent filed to the SEC on March 6, 2015.

Dr Smith said that no one expected the failure with other significant investors including Johnson & Johnson, Novartis, Pfizer and Novo Nordisk.

An SEC filing from Dr Funder filed on May 21, 2014 said that he had exercised options at $US9.58 for 10,000 shares.

More recent filings were not available at the time of publication.

Last night on the Nasdaq, Celladon closed down $US11.04 or 80.7 percent to $US2.64 with 32,340,485 shares traded, having previously hit a 52 week high of $US28.25.

NANOSONICS

Nanosonics has posted its third positive Appendix 4C Quarterly Report in 12 months, with a net positive cash flow of $1,143,000 for the three months to March 31, 2015.

Nanosonics reported total receipts from customers received in the three months of $9,294,000, an increase over receipts for the three months to December 31, 2014 of $6,891,000, which resulted in a net cash burn of $9,000.

The company previously posted a positive cash flow for the three months to September 30, 2014 of $2,109,000 on receipts of $8,899,000, as well as for the three months to March 31, 2014 of $2,220,000 on receipts of $7,535,000.

Nanosonics chief financial officer McGregor Grant told Biotech Daily that the company had previously announced a change of business strategy and that coming quarters could vary from today's results during the transition.

ASX general manager of media and communications Matthew Gibbs told Biotech Daily the ASX required Appendix 4C reports until a company had filed positive cash flows in four successive reports, with a minimum of eight positive cash flow reports, although there were allowances for companies reporting consistent cyclical variations.

Nanosonics was unchanged at $1.67.

PRANA BIOTECHNOLOGY

Prana says the European Medicines Agency's Committee for Orphan Medicinal Products has recommended orphan designation of PBT2 for Huntington's disease.
Prana said that following the finalization of documents the European Medicines Agency would forward the opinion to the European Commission for a decision on the designation.
The company said that the EC granted orphan designation to encourage the development of medicines to treat rare diseases, that were life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in Europe.
Prana said that Huntington's disease was a neurodegenerative genetic disorder that affected muscle coordination and led to cognitive decline and behavioral symptoms with estimates that there were between 40 to 100 cases per million people in Europe.
The company said that the EC offered orphan medicinal product developers incentives including scientific advice, market exclusivity for 10 years for approved drugs and reduced fees.
Last year, Prana said that PBT2 had met its primary end point of safety and tolerability, and a secondary endpoint of improved measures of cognitive performance in its 109-patient phase II trial in Huntington's disease and the US Food and Drug Administration had granted PBT2 orphan drug status for the indication (BD: Feb 18, Sep 5, 2014).
Prana was unchanged at 14 cents.

IMPEDIMED

Impedimed says that the University of Kansas Cancer Center in Kansas City has joined its L-Dex post-approval clinical trial.
Impedimed said that Dr Jamie Wagner was a member of the National Lymphedema Network's Medical Advisory Committee and had been appointed as the principal investigator for the University of Kansas Cancer Center trial site.
Last year, Impedimed began the 1100-patient, five year, international, post-approval clinical study to objectively establish the clinical utility of its L-Dex device for the early detection of lymphoedema, post breast cancer (BD: Jun 26, 2014).
Impedimed fell four cents or 4.3 percent to 88.5 cents with 2.1 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has an undisclosed generic drugs analytical services contract with an unnamed Middle East-based biopharmaceutical company.
Proteomiocs said that the biopharmaceutical company was a major producer of bio-similars, or generic drugs, across a wide spectrum of treatment targets, including blood disorders and multiple types of cancers.
The company said it would use its proteomics technology platform to provide analysis of bio-similar drugs to prove comparability of its drug against the patented version and to provide quality control of its different batches.
Proteomics said that it would provide extensive structural and physico-chemical analysis of the client's bio-similar drug.
The company said that US Food and Drug Administration guidelines recommended generic drug manufacturers undertake such testing to prove fingerprint-like similarity prior to moving into clinical trials.
Proteomics said that the contract was its largest single generics contract and the client had other bio-similar drugs in its pipeline, offering the potential for additional contracts.
Proteomics was up two cents or 9.8 percent to 22.5 cents.

ADMEDUS

The Perth Western Australia-base Minderoo Group says it has reduced its substantial holding in Admedus from 173,027,958 shares (10.73%) to 155,000,000 shares (8.40%).
Minderoo, formerly the Metal Group, and associated with Western Australian miner Andrew Forrest, said that between April 13 and April 28, 2015, it sold 18,027,958 shares for $1,498,687 or an average price of 8.3 cents a share.
Admedus was up 0.1 cents or 1.3 percent to eight cents with 8.9 million shares traded.

ACTINOGEN

The Perth, Western Australia-based JK Nominees and Tisia Nominees say they have increased their holdings in Actinogen but have been diluted in last week's placement.
Last week, Actinogen said it had raised $10.0 million at 9.5 cents a share and hoped to raise a further $1.0 million through a share plan (BD: Apr 24, 2015)
Today, Kim Hogan for JK Nominees said the company increased its holding from 20,000,000 shares to 34,717,184 shares but had been diluted from 7.91 percent to 5.8 percent.
Tisia Nominees director Tom Henderson said that Tisia also increased its holding from 20,000,000 shares to 34,717,184 shares but had been diluted from 7.91 percent to 5.8 percent.
Actinogen fell 0.3 cents or three percent to 9.7 cents with 2.3 million shares traded.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says it has appointed pharmaceutical executive Dr Terrence Chew as its chief medical officer, effective immediately.
Prescient said that Dr Chew would oversee clinical development and regulatory strategy for its two novel oncology candidates.
The company said that Dr Chew was a haematologist and oncologist with more than 20 years' experience in the biotechnology and pharmaceutical industries.
Prescient said that Dr Chew had worked as a consultant to numerous companies providing advice on clinical trials, drug development and regulatory processes including most recently as Immuneworks head of clinical and regulatory affairs and as a consultant to Argos Therapeutics where he advised on the company's oncology and HIV programs.
The company said that Dr Chew had held senior positions at Peregrine Pharmaceuticals where he managed strategy for a portfolio of drugs targeting cancer and viral diseases and had steered five new drug applications through the US Food and Drug Administration, including marketed oncology drugs Daunoxome, Taxotere and Depocyt.
Prescient managing director Dr Rob Crombie said that Dr Chew's appointment was "vital to aggressively steer the company's clinical programs".
Dr Crombie said that Dr Chew's experience would be "critical to advance novel drug candidate PTX-200 through phase Ib/II trials" in breast and ovarian cancer with a third trial of the drug in leukaemia to begin in coming months, along with planned trials of PTX-100 in multiple myeloma and breast cancer later in 2015.
Prescient said that Dr Chew held an undergraduate degree in biochemistry from the University of California at Berkeley and a medical degree from the University of California in Los Angeles, as well as a Regulatory Affairs Certification.
Prescient was up 0.2 cents or 2.4 percent to 8.4 cents.

NOVOGEN

Novogen says that the Nasdaq has accepted that the company has regained full compliance with a minimum equity listing rule.

Novogen said that last year the Nasdaq issued a deficiency notice requesting a plan to regain compliance, requiring either a minimum of $US2,500,000 in stockholders' equity as of June 30, 2014, at least $US35,000,000 market value of listed securities, or $US500,000 inf net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years (BD: Nov 12, 2014; Jan 29, 2015).

Today, Novogen said that its recent increase in market value, as well as the substantial increase of its assets with the capital-raising program, allowed it to regain compliance.

Novogen executive chairman Dr Graham Kelly said the company “regards itself as a joint US-Australian company”.

“Roughly half of our shareholders are US residents,” Dr Kelly said.

“We have a joint venture company with one of the leading universities in the US,” Dr Kelly said.

“We are conducting increasing collaborations with leading US research institutions and hospitals as our drug technologies get better appreciated,” Dr Kelly said.

“The US eventually will be the leading market for our drug candidates,” Dr Kelly said.

“Maintaining our Nasdaq listing is vital to us,” Dr Kelly said.

Novogen fell half a cent or 1.5 percent to 32 cents with 7.6 million shares traded.