Biotech Daily

Wednesday June 27, 2018

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: STARPHARMA UP 6%; OPTISCAN DOWN 7%**

*** PRANA BACK IN THE CLINIC WITH PBT434 FOR PARKINSON'S**

*** STARPHARMA, MUNDIPHARMA TAKE VIVAGEL BV TO EUROPE**

*** INVITROCUE RAISES $3.6m**

*** NANOSONICS TROPHON2 WINS CE MARK**

*** ADMEDUS, STAR BRIGHT CLOSER TO VACCINES DEAL**

*** BOTANIX RECRUITS 1st PATIENTS FOR BTX1503 ACNE TRIAL**

*** NUHEARA: LIVEIQ COMPLETES ENGINEERING VALIDATION TEST**

*** CANN TO BUILD MELBOURNE AIRPORT MARIJUANA FACILITY**

*** SG HISCOCK TAKES 9% OF NEUROTECH**

*** EYEPOINT APPOINTS DR GÖRAN ANDO DIRECTOR**

*** CFO SOLUTION REPLACES BRAIN RESOURCE CO SEC ROBERT WARING**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Wednesday June 27, 2018 with the ASX200 down 1.7 points to 6,195.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell and 10 traded unchanged.

Starpharma was the best, up seven cents or 6.4 percent to $1.17 with 984,999 shares traded. Prescient climbed 4.35 percent; Imugene improved 3.85 percent; Admedus and Oncosil rose more than two percent; Bionomics, Genetic Signatures, LBT and Medical Developments were up one percent or more; with Cochlear, Polynovo and Telix up by less than one percent.

Optiscan led the falls, down half a cent or 7.1 percent to 6.5 cents with 51,000 shares traded. Uscom lost 6.45 percent; Cyclopharm fell 4.4 percent; Immutep was down 3.3 percent; Actinogen, Airxpanders, Cynata, Factor Therapeutics, Impedimed, Mesoblast, Reva and Volpara shed more than two percent; Compumedics, Ellex, Opthea, Orthocell and Pharmaxis were down more than one percent; with CSL, Nanosonics, Resmed and Sirtex down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says it has commenced screening and recruitment for its up-to 88-patient, phase I trial of PBT434 for Parkinson's disease, with first dosing expected "soon".

Prana executive chairman Geoffrey Kempler and recently appointed chief medical officer Dr David Stamler said they were giving a series of briefings to investors and media on the progress of the trial and the company.

Mr Kempler said that the company had funds for about 12 months which would take it beyond the end of the two-part trial.

In 2014, Prana fell 70 percent on news that its imaging trial of PBT2 for Alzheimer's disease did not meet its primary endpoint of reducing amyloid beta plaques having earlier climbed when a phase II trial of PBT2 for Huntington's disease met the primary endpoint of safety and tolerability but met only one secondary endpoint for cognitive efficacy of several secondary endpoints (BD: Feb 18, 19, Apr 1, 2014).

In 2015, Prana said the US Food and Drug Administration had issued a partial clinical hold limiting the dose of PBT2 for patients with Huntington disease and last year, Prana said that European regulators wanted more pre-clinical work before allowing a phase III trial of PBT2 for Huntington's disease (BD: Feb 13, 2015; Dec 23, 2017).

Today, Mr Kempler and Dr Stamler said that PBT434 was a completely separate molecule to PBT2 and targeted iron inside cells rather than PBTs mode of action which targeted copper and zinc outside cells.

Dr Stamler said that PBT434 was shown to bind to iron and remove it from the cells for excretion and that iron in cells had been implicated in Parkinson's disease.

In March, Prana published mouse data showing evidence for PBT434 to prevent the loss of neurons and improved function for multiple system atrophy (BD: Mar 7, 2018).

The company described the compound as "the first of a new generation of small molecules from the quinazolinone class of drugs that was specifically designed to block the accumulation and aggregation of alpha-synuclein, an abundant brain protein widely believed to be involved in the pathogenesis of Parkinson's disease and related disorders".

Prana said at that time that alpha-synuclein was of "great interest" because aggregated forms of the protein were considered a pathological hallmark of Parkinsonian conditions and were a recognised therapeutic.

Today, Dr Stamler said that the company had undertaken further pre-clinical work in dogs to determine a therapeutic dose window prior to the first human clinical trial.

Dr Stamler said that the first part of the trial would be a single ascending dose study of up to 48 healthy volunteers, in cohorts of eight subjects per dose, to investigate the pharmaco-kinetics, safety and blood levels of the drug, as well as finding the maximum tolerated dose.

Dr Stamler said that second part of the trial would use a multiple ascending dose model with daily dosing of three different levels of PBT434 for one week.

Mr Kempler said that when Dr Stamler was appointed chief medical officer and head of clinical development, he brought with him his San Francisco-based team from Auspex Pharmaceuticals which was responsible for the approval of Austedo, or deutetrabenazine, for the treatment of chorea associated with Huntington's disease in 2017 and was acquired by Teva Pharmaceuticals for $US3.5 billion (BD: Jun 5, 2017).

Mr Kempler said that PBT2 effectively had been shelved but the company was considering possible partner or licencing alternatives.

"We have thousands of molecules," Mr Kempler said.

"And an active drug discovery program, Dr Stamler said.

Prana was unchanged at 4.2 cents.

STARPHARMA

Starpharma says it has extended its licence with Mundipharma to market Vivagel for bacterial vaginosis, to 43 more than countries with an up-front payment of $2.0 million.
Starpharma said the Singapore-based Mundipharma licence would be extended to include European countries, Russia, the Commonwealth of Independent States and Latin America, in addition to the previously announced China, Japan, Korea, the Middle East and Africa (BD: May 3, 2018).
The company said the extended licence included milestone payments of up to $20.9 million, including the $2.0 million up-front payment, taking the total of the licence to Mundipharma up to $33.3 million.
Starpharma said that Mundipharma would launch Vivagel BV in Europe under its Betadine brand in early 2019.
In May, Starpharma said it would receive a $1.3 million up-front payment for the up to $12.2 million 15-year licence (BD: May 3, 2018).
The company said it was in negotiations for marketing rights for Vivagel BV in North America, having lodged its new drug application with the US Food and Drug Administration in April, 2018, and expected to announce further licencing deals in the near future (BD: Apr 30, 2018).
Starpharma chief executive officer Dr Jackie Fairley said that “Europe represents a very important market for Vivagel BV and, with this licence in place, Vivagel BV will soon be available to millions of European women who suffer from BV”.
Starpharma was up seven cents or 6.4 percent to $1.17 with 984,999 shares traded.

INVITROCUE

Invitrocue says it will raise $3,600,000 through the issue 30,000,000 shares at 12 cents a share, to sophisticated investors to provide funds for working capital.
Invitrocue said that the placement included one option attached to every five shares purchased, exercisable at 12 cents within five years of issue.
The company said the issue would not require shareholder approval as it was within the 15 percent capacity according to listing rule 7.1 of the Australian securities exchange.
Invitrocue was up half a cent or 4.8 percent to 11 cents.

NANOSONICS

Nanosonics says it has received Conformité Européenne (CE) mark approval for the Trophon2 ultrasound probe infection control system.
Nanosonics said this followed US and Canadian regulatory approval for the second generation Trophon system; with plans to launch in Europe, the US, and Canada by October 2018 (BD: Apr 27, May 4, 2018).
Nanosonics chief executive officer Michael Kavanagh said the approval enabled Nanosonics to “launch Trophon2 for customers in both North America as well as Europe in the same time frame”.
“The Trophon2 delivers a range of exciting new customer focused features including new capabilities that were specifically developed based on feedback from [Europe],” Mr Kavanagh said.
Nanosonics fell three cents or 0.9 percent to $3.27 with 2.6 million shares traded.

ADMEDUS

Admedus says it will retain 29.1 percent of the Star Bright majority-owned vaccines business, with chief executive officer Wayne Paterson chairman for five years,.

In April, Admedus said that the Hong Kong investment company Star Bright Holding intended to take 60 percent of Admedus Vaccines, formerly known as Coridon, for $18 million, with a non-refundable break-fee of $500,000 for a six-month exclusivity period to finalize the terms of the agreement (BD: Apr 27, 2018).

At that time, Admedus said Admedus Vaccines was developing DNA vaccines for the prevention and treatment of infectious diseases and cancers, including Epstein-Barr virus, or glandular fever, with research led by Gardasil inventor and head of the Brisbane-based Translational Research Institute Prof Ian Frazer.

Today, the company said a new company would be established, with Admedus holding 29.1 percent and Mr Paterson to be the chairman for a minimum of five years.

Admedus said that Prof Ian Frazer would be the principal researcher and chief scientific officer, with an “initial investment to focus on [herpes simplex virus-2 and human papillomavirus] head and neck cancer vaccines in the first two years”.

The company said that an application for listing the new company on the Hong Kong stock exchange would be planned, subject to regulatory requirements.

Mr Paterson said the signing was “an important step in this process and we look forward to continuing negotiations with Star Bright who share our enthusiasm for the work of Prof Frazer and the Admedus Vaccines team”.

Admedus was up half a cent or 2.2 percent to 23.5 cents with 1.1 million shares traded.

BOTANIX

Botanix says it has recruited the first patients for the 360-patient, phase II trial of its synthetic cannabidiol BTX1503 for acne.

Botanix said the 12-week, randomized, blinded and controlled study would evaluate the safety and efficacy of BTX1503 in patients with moderate to severe acne, across five dose groups in the US and Australia.

The company said that the study would assess treatment effects on acne lesions, as well as safety, tolerability and patient satisfaction and take about 12 months to complete.

In January, the company said its phase Ib trial showed BTX1503 was safe and effective at reducing acne after four weeks, reducing lesions by 47 percent (BD: Jan 29, 2018).

Botanix was up half a cent or five percent to 10.5 cents with 6.2 million shares traded.

NUHEARA

Nuheara says it has completed engineering validation testing for its Liveiq earbuds, which are on track for shipping by the end of 2018.

Nuheara said the test allowed it to complete automated production line assembly of circuit boards, verify production test systems, develop assembly line procedures with the contract manufacture and assemble Liveiq units for firmware development, electronic and mechanical testing.

Nuheara chief executive officer Justin Miller said the company was “incredibly excited that our Liveiq development remains on track for shipping”.

“Liveiq is the world’s first hybrid active noise cancellation hearing bud and promises to deliver a new level of sophistication, intelligence, affordability and street appeal, to a much broader lifestyle-oriented audience,” Mr Miller said.

Nuheara was up 0.1 cents or one percent to 9.8 cents with 2.6 million shares traded.

CANN GROUP

Cann says it has a leasing agreement with Australia Pacific Airports for a stage three medical marijuana cultivation and manufacturing facility in Tullamarine, Melbourne.
Cann said that Australia Pacific Airports would fund and conduct “the primary build” of the 37,000 square metre (9.14 acres, 3.7ha) facility, which lay within the Melbourne Airport precinct, and was being designed by Aurora Larssen Projects, a subsidiary of Aurora Cannabis which held 22.9 percent owner of Cann.
In April, Cann said it had signed a design and consulting services agreement with Aurora Larssen for its third Melbourne facility, to follow its location-undisclosed Southern and Northern facilities (BD: Apr 19, 2018).
Today, the company said it would be responsible for the fit-out and technology deployment for the facility once it was completed, which would employ 170 staff and cost about $100 million, paid by a combination of debt and equity, having last year raised $75 million through a placement and share plan (BD: Dec 13, 2017; Jan 21, 2018).
Cann said that under the lease agreement it was permitted to operate cultivation, manufacturing, warehousing and distribution of medicinal cannabis and would be responsible for all necessary government approvals.
Cann was up 21 cents or 7.5 percent to $3.00 with 609,964 shares traded.

NEUROTECH

Melbourne’s SG Hiscock says it has increased its substantial holding in Neurotech from 6,760,403 shares (6.21%) to 9,660,403 shares (8.86%).
SG Hiscock said it bought 500,000 shares for $100,220 or 20 cents a share on January 1, 2018 and 2,000,000 shares for $424,797.22 or 21.2 cents a share on June 25, 2018.
Neurotech was up half a cent or 2.8 percent to 18.5 cents.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA)

Eyepoint says it has appointed former Novo Nordisk A/S chairman Dr Göran Ando as a director.
Eyepoint said that Dr Ando had more than 35 years of drug development and general management experience.
The company said that Dr Ando began his career at Pfizer, was president of the Astra Research Centre and held appointments at Glaxosmithkline PLC, including as head of research and development.
Eyepoint said that Dr Ando joined Pharmacia AB in 1995 as deputy chief executive officer leading research and development, manufacturing, information technology, business development and mergers and acquisitions, during which time the company which became Pharmacia & Upjohn had 17 new drugs approved in the US.
The company said that Dr Ando was Cell Tech Group PLC chief executive officer and a director of Novo Nordisk until March 2018 and was currently serves a director of companies in Europe, the US and Singapore.
Dr Ando was formerly a director of Brisbane’s CBio, now Invion, following a board spill requisition to remove founder and chairman Stephen Jones along with directors Prof John Funder and James Greig (BD: Aug 25, 2010, Sep 5, 7, Nov 21, 2011).
Eyepoint said that Dr Ando held a Bachelor of Arts degree from Sweden’s Uppsala University and a Doctor of Medicine from Sweden’s Linköping University.
On the Nasdaq, Eyepoint fell six US cents or 3.1 percent to $US1.87 ($A2.53) with 209,061 shares traded.

BRAIN RESOURCE

Brain Resource says it has appointed the CFO Solutions' Phillip Hains and Harvey Bui to as joint company secretaries, replace Robert Waring effective from July 1, 2018.

Brain Resource said Mr Hains held a Master of Business Administration from Melbourne's Royal Melbourne Institute of Technology (RMIT) university and had almost 30 years' experience in corporate secretarial, accounting and general management through his agency the CFO Solution.

The company said Mr Bui was an accountant with the CFO Solution, with 10 years' experience in accounting, finance and corporate compliance advisory and formerly worked for Ernst & Young.

Brain Resource was up 0.1 cents or 2.8 percent to 3.7 cents.