Biotech Daily

Friday April 17, 2015

Daily news on ASX-listed biotechnology companies

* **ASX DOWN, BIOTECH UP: GI DYNAMICS UP 28%, BIOTRON DOWN 13%**

*** HEARTWARE PUMP 'NOT INFERIOR' FOR DESTINATION THERAPY**

*** SUNSHINE HEART: 'MINOR CHANGES' TO RESTART PIVOTAL TRIAL**

*** ADMEDUS RIGHTS ISSUE $16.1m TAKES TOTAL TO $28.1m**

*** PHOSPHAGENICS BEGINS PHASE II TPM-OXYCODONE PATCH TRIAL**

*** PROTEOMICS RAISES $3m, OPENS UP 17.5%**

*** BENITEC LICENCES ASKLEPIOS ADENO-ASSOCIATED VIRUS**

*** THORNEY TAKES 5.8% OF MESOBLAST**

*** NOVOGEN, FEINSTEIN COLLABORATE ON BRAIN CANCER**

MARKET REPORT

The Australian stock market fell 1.17 percent on Friday April 17, 2015 with the S&P ASX 200 down 69.6 points to 5,877.9 points. Eighteen of the Biotech Daily Top 40 stocks were up, 16 fell, three traded unchanged and three were untraded. All three Big Caps fell.

GI Dynamics was best, up 3.5 cents or 28 percent to 16 cents with 13,375 shares traded, followed by Universal Biosensors up 10 percent to 27.5 cents with 375,502 shares traded.

Atcor and Pharmaxis climbed more than nine percent; Cellmid, Impedimed and Optiscan were up eight percent or more; Acrux and Starpharma rose more than six percent; Tissue Therapies was up five percent; Prima was up 4.2 percent; Circadian was up 3.3 percent; Genetic Technologies and Viralytics rose more than two percent; Avita, IDT and Osprey were up more than one percent; with Reva up 0.9 percent.

Biotron led the falls, down two cents or 13.3 percent to 13 cents with 4.7 million shares traded.

Both Analytica and Compumedics lost 9.1 percent; Clinuvel was down 6.4 percent; Nanosonics shed 5.2 percent; Actinogen, Antisense, Benitec, Neuren and Oncosil fell more than four percent; Admedus, Bionomics, Prana and Sirtex were down more than three percent; Resmed shed 2.3 percent; Cochlear and Mesoblast were down one percent or more; with CSL and Medical Developments down by less than one percent.

HEARTWARE INTERNATIONAL

Heartware says that data from its first 'Endurance' destination therapy clinical trial cohort, demonstrated that the 446-patient trial achieved the primary endpoint of non-inferiority.

Heartware said the patients were randomized to receive either the Heartware ventricular assist system or, as part of a control group, any approved alternative left ventricular assist device approved for destination therapy, in a two-to-one ratio.

The company said that 55.0 percent of the investigational device patients attained the primary endpoint of stroke-free survival at two years, defined as alive on the originally-implanted device, transplanted or explanted due to patient recovery, with 57.4 percent of patients in the control arm achieving the primary endpoint of the study.

Heartware said that non-inferiority of the investigational device was established at a significance of p = 0.0060.

The company said that the results were presented at the International Society for Heart and Lung Transplantation Meeting in Nice, France from April 15 to 18, 2015.

University of Michigan Health System Center for Circulatory Support director and co-principal investigator Dr Francis D Pagani said that "as the largest, randomized, destination therapy trial to date involving ventricular assist devices, the observations from Endurance demonstrate the potential of the Heartware system as a longer term treatment option for advanced heart failure patients who have exhausted medical therapy and are ineligible for a heart transplant".

"Survival with the [Heartware] pump at two years was comparable to the control device ... and device and design improvements, including sintering of the inflow cannula, resulted in improvements in outcomes, including a marked reduction in pump thrombosis," Dr Pagani said.

Heartware said that of the 200 patients receiving the investigational device with a sintered inflow cannula, approved by the FDA in 2011, 57.5 percent attained the primary endpoint.

The company said that sintering titanium was a process by which minute beads were metallurgically affixed to a titanium surface facilitating tissue adhesion and sintering of the pump on the outer surface of the implanted inflow tube was designed to promote tissue ingrowth on the lower section of the inflow tube.

The company said that secondary endpoints included adverse events such as bleeding and infection, as well as functional status, assessment of neuro-cognitive function and patient quality of life.

Duke University clinical affairs executive and co-principal investigator Dr Joseph Rogers said that treatment with the investigational device "was associated with improvements in quality of life, [New York Heart Association] functional classification and sustained improvement in the six-minute walk distance of more than 90 meters".

"The observed stroke rate was higher in the investigational device arm, whereas device malfunctions leading to exchange or urgent transplant were more frequent in the control group," Dr Rogers said.

Heartware chief executive officer Doug Godshall said that "attaining the primary endpoint in this first cohort is encouraging, yet we view it as our core mission to continually improve patient outcomes with the Heartware system".

Heartware said it would enroll up to 310 device patients and up to 155 controls in the second destination therapy cohort to confirm the observations from the Endurance trial, with a primary endpoint of change in stroke incidence at 12 months on the originally-implanted device with enrollment expected to be completed in mid-2015.

Last night on the Nasdaq, Heartware fell $US2.85 or 3.27 percent to $US84.39 ($A108.51, equivalent to $3.10 per CDI prior to the company's departure from the ASX) with 938,834 shares traded.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration has requested minor protocol changes to its 'Counter HF' C-Pulse aorta cuff pump trial to resume patient enrollment.

In March, Sunshine Heart said it was "taking a temporary pause from enrolment" in the pivotal 388-patient trial, following four patient deaths which it said appeared non-device related (BD: Mar 9, 2015).

The company said at that time that the enrolment "pause" was in accordance with the study protocol where in the event more than three of the first 20 subjects died for any reason, including non-device related deaths, it would work with the US Food and Drug Administration to discuss a plan to resume enrolment.

Overnight in the US, Sunshine Heart said that the FDA did not indicate concerns regarding safety of the device and requested the updated protocol include information on several minor items, the most significant of which were the details regarding a proposal to incorporate a physician subject selection committee.

The company said that the data safety monitoring board, reviewed the trial data and recommended continuing the study.

Sunshine Heart chief executive officer Dave Rosa said the company was "prepared for these types of minor protocol modifications and as such, we'll be submitting these amendments by early next week".

On the Nasdaq last night, Sunshine Heart rose two US cents or 0.4 percent to $US4.80 ($A6.17 equivalent to 3.1 cents prior to departing the ASX) with 357,773 shares traded.

ADMEDUS

Admedus says its one-for-seven rights issue at seven cents a share was fully-subscribed and has raised $16.1 million.

Admedus said the funds were in addition to the March placement which raised $12.0 million (BD: Mar 18, 2015).

The company said that given the excess demand for shortfall shares, a scale-back of requests for additional shares would be implemented so that shareholders received a maximum of 10 times their rights entitlement.

Admedus said that Morgans Corporate was the lead manager to the rights issue.

Admedus fell 0.3 cents or 3.6 percent to eight cents with 6.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says it has begun dosing in its 28-patient phase II trial of its tocopheryl phosphate mixture or TPM-oxycodone patch for post herpetic neuralgia.

Phosphagenics said that the study was a double-blind, randomized, cross-over trial investigating the safety and efficacy of the patch.

The company said that recruitment began in February and the trial was expected to be completed by the end of 2015.

Phosphagenics chief scientific officer Dr Paul Gavin said the objective was "to develop a product that provides local pain relief for [suffering post herpetic neuralgia] sufferers and avoid the typical opioid-related systemic side effects associated with conventional opioid administration".

The company said that the trial was being conducted at five sites across Australia.

Phosphagenics climbed 19.9 percent to 3.3 cents closing unchanged at 2.8 cents with 9.1 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Yesterday, Proteomics opened under the ASX code PIQ, at 23.4 cents, 17.5 percent above its initial public offer at 20 cents, raising $3.05 million of its hoped-for $6 million
In November, Proteomics managing director Dr Richard Lipscombe and chairman Terry Sweet told Biotech Daily that the Perth, Western Australia-based company had revenues of about $1 million a year from its existing analytical services and consultancy business and the company had an internally-developed, single platform technology, which enabled "industrial scale analyses of proteins" (BD: Nov 14, 2014).
Dr Lipscombe said at that time that the technology supported the provision of services and consultancy work as well as the development of new diagnostics and new therapies and the capital raising was intended to support all three arms of the business.
He said that Proteomics had a partnership with the University of Western Australia for the company's first diagnostic, a test for diabetic kidney disease, and was in discussions with diagnostic companies and laboratories to roll-out the test.
In December, Proteomics extended its initial public offer as it was "in material negotiations with a major Chinese drug and diagnostic development company in relation to a significant agreement to commercialize and market [its] next generation diagnostic test for the early diagnosis of diabetic kidney disease" (BD: Dec 18, 2014).
Proteomics fell half a cent or 2.2 percent to 22 cents.

BENITEC BIOPHARMA

Benitec says it has a licence with Asklepios Biopharmaceutical to use Askleios adeno-associated virus capsids to incorporate a specific DNA element into DNA constructs.
Benitec said it used the Chapel Hill, North Carolina-based Asklepios adeno-associated virus technology in TT-034, its current phase I/IIa trial for the treatment of hepatitis C.
The company said it would maintain access to the use of Asklepios patents and Asklepios would receive and undisclosed upfront payment, along with development and commercial milestones, as well as a related product royalty.
Benitec chief executive officer Dr Peter French said that developing DNA-directed RNA-interference (ddRNAi) as a new therapy involved "a number of cutting edge technologies and executing the [Asklepios] licence builds further protection around TT-034 as a disruptive [hepatitis C] therapy".
Asklepios vice-president Jade Samulski said the combination of the AAV technology and Benitec's ddRNAi expertise were "an excellent complement to each other, and provides an important opportunity for a transformative treatment of chronic [hepatitis C]".
Benitec fell 3.5 cents or 4.2 percent to 79 cents.

MESOBLAST

Thorney Opportunities says it has become a substantial shareholder in Mesoblast with 18,851,000 shares or 5.81 percent.
In 2013, Thorney Holdings increased its holding in Mesoblast from 17,342,093 shares to 17,600,000 shares but was diluted from 6.83 percent to 5.59 percent (BD: Mar 18, 2013).
In its notice Thorney said that between February 10 and April 14, 2013, a total of 2,162,779 shares were acquired by Thorney Opportunities, Thorney Investment Group Australia Pty Ltd, Tiga Pty Ltd, Thorney Holdings Pty Ltd and Jamahjo Pty Ltd, Jasforce Pty Ltd and Urban Land Nominees Pty Ltd, but did not disclose the payment for the shares acquired.
Mesoblast fell four cents or one percent to $3.79 with 455,780 shares traded.

NOVOGEN

Novogen says it has an agreement with New York's Feinstein Institute for Medical Research to collaborate on treatments for brain cancers.

Novogen said the research focus would be development of its lead super-benzopyran drug candidate TRXE-009 as a treatment for primary and secondary brain cancer in adults and children, including glioblastoma and medulloblastoma, along with the potential of super-benzopyran drugs to deliver a novel approach to chemotherapy by converting cancer stem cells into stem cells displaying normal stem cell behavior and develop drug candidates as radio-sensitizers designed to augment the effectiveness of radiotherapy in treating brain cancers.

The company said that TRXE-009 had proven to be effective in-vitro against adult brain cancer cells, or glioblastoma, and paediatric brain cancer cells, or diffuse intrinsic pontine glioma and medulloblastoma, marking it as a "highly promising drug candidate for the treatment of these cancers".

Novogen said the collaboration was focused on these tumors.

Novogen chief executive officer Dr Graham Kelly said that "the ability of TRXE-009 to kill brain cancer stem-like cells gives us particular confidence that we can finally kill off the root cause of any cancer within the brain".

"The proviso is that we can deliver it across the blood-brain barrier, and that is something that we will not know with any certainty until we bring TRXE-009 into the clinic," Dr Kelly said.

Dr Kelly has previously said that TRXE-009 was "highly active in vitro against a range of pediatric brain cancer cells that are notoriously resistant o chemotherapy [and] ... has been designed to cross the blood-brain barrier" (BD: Mar 4, 2015).

"The collaboration with the Feinstein Institute is designed to maximize that likelihood," Dr Kelly said today.

"If we can do that, then we have a good chance of delivering breakthrough treatment options to adults and children with primary brain cancers and for patients with cancers such as melanoma that involve the brain and elsewhere," Dr Kelly said.

Novogen said that TRXE-009 would be studied using a variety of new approaches, such as direct microinjection into the brain and intravenous administration with a range of constructs known to facilitate the transport of drugs across the blood-brain barrier, some of which had been developed by its chemists.

Feinstein Institute brain tumor biotechnology center co-director Dr John Boockvar said the Feinstein Novogen collaboration was "critical to supporting the discovery of new treatments for patients who suffer from life-threatening brain cancer".

"Patients who suffer from brain cancer don't have optimal therapies to turn to," Dr Boockvar said.

Novogen climbed 3.5 cents or 9.3 percent to 41 cents with 20.1 million shares traded.