Biotech Daily

Monday July 11, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: SIRTEX UP 6.5%, ACTINOGEN DOWN 8%**

*** SIRTEX DOSE SALES UP 16% TO MORE THAN $200m**

*** AVITA RAISES $9m**

*** RACE RAISES $4m FOR BISANTRENE CANCER DRUG**

*** HONG KONG APPROVES IMUGENE HER-VAXX GASTRIC CANCER TRIAL**

*** US PATENT FOR USCOM BP+**

*** ADMEDUS: '32% STAFF CUT, $12m COST CUT, BREAK EVEN JULY 2018'**

*** JUNIPER PRODUCES PHARMAUST MONEPANTEL (PPL-1) FOR TRIALS**

MARKET REPORT

The Australian stock market climbed 2.04 percent on Monday July 11, 2016 with the ASX200 up 106.6 points to 5,337.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Sirtex was the best, up $1.70 or 6.5 percent to $27.88 with 857,884 shares traded.

Anteo and Prana climbed five percent or more; Benitec, Ellex, Impedimed and Neuren were up more than four percent; Antisense and Osprey were up more than three percent; IDT, Uscom and Viralytics rose more than two percent; Biotron, Cochlear, Compumedics, CSL, Nanosonics, Orthocell, Pro Medicus and Resmed were up more than one percent; with Clinuvel up 0.6 percent.

Actinogen led the falls, down 0.6 cents or 7.7 percent to 7.2 cents, with 463,790 shares traded, followed by Avita down 7.1 percent to 9.2 cents with 2.5 million shares traded.

Atcor and Cellmid lost more than three percent; Acrux and Prima shed two percent or more; Admedus, Mesoblast, Pharmaxis, Reva and Universal Biosensors fell more than one percent; with Airxpanders and Medical Developments down by less than one percent.

SIRTEX MEDICAL

Sirtex says that unaudited dose sales of SIR-Spheres microspheres for the 12 months to June 30, 2016 increased 16.4 percent over the prior corresponding period.
Last year, Sirtex reported record dose sales of 10,252 doses, with sales revenue of $176,088,000. (BD: Aug 13, 2015).
With an increase of 16.4 percent, Biotech Daily calculates sales revenue for the year to June 30, 2016 at $204.9 million.
Today, Sirtex said that the increase was “at the upper end of the 15 to 17 percent dose sales guidance provided” in June (BD: Jun 1, 2016).
The company said that the Americas recorded second half and full year dose sales growth of 19.2 percent and 19.0 percent, respectively, with Europe, the Middle East and Africa up 11.2 percent and the Asia-Pacific region up 8.9 percent.
Sirtex chief executive officer Gilman Wong said the “strong double-digit growth in global dose sales reflects the continued momentum we have achieved in this large, underpenetrated market opportunity for SIR-Spheres microspheres”.
The company said it would report its 2016 financial year results on August 24, 2016.
Sirtex climbed $1.70 or 6.5 percent to $27.88 with 857,884 shares traded.

AVITA MEDICAL

Avita says its rights issue at nine cents a share has raised $9,014,835 to support its US launch and accelerate commercialization.
In June, Avita said it hoped to raise up to $11,455,040 in the two-for-nine rights issue which was underwritten to $5 million by Morgans Corporate (BD: Jun 16, 2016).
Avita chief executive officer Adam Kelliher said the company had “some crucial upcoming milestones, both clinically and commercially and we will keep building value around our unique regenerative medicine approach”.
Avita fell 0.7 cents or 7.1 percent to 9.2 cents with 2.5 million shares traded.

RACE ONCOLOGY

Race Oncology says it has raised $4.3 million in an oversubscribed initial public offer at 20 cents a share to reinstate and commercialize Bisantrene for cancer.
Last year, Race Oncology said it hoped to raise up to $10 million to develop Bisantrene for cancer (BD: Aug 27, 2015).
Race chief executive officer and former Biota chief executive officer Peter Molloy told Biotech Daily that Bisantrene was a phase II/III drug previously trialled in 44 clinical studies and on more than 2,000 patients, which showed it did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer.
Mr Molloy said that Bisantrene had been approved in France for acute myeloid leukaemia (AML) but never launched, because it was effectively “lost” in a string of pharmaceutical company mergers including the Lederle-Immunex merger, then sold to Wyeth and then to Pfizer, with $US100 million spent on it by Lederle and the US National Cancer Institute.
Mr Molloy said that the Dr Bill Garner created Update Pharma to rediscover Bisantrene and reopen the investigational new drug application (IND) with the US Food and Drug Administration through a 505(b)(2) process.
Mr Molloy said the offer was led by the Perth, Western Australia-based CPS Capital and the company expected to list on the ASX on July 13, 2016 under the code RAC.

IMUGENE

Imugene says the University of Hong Kong institutional review board has approved its phase Ib/II study of its HER-Vaxx immuno-oncology therapy for gastric cancer.
Imugene said it expected to enrol patients “within the coming months”.
The company said that the phase Ib/II trial would be conducted in two parts with up to 18 patients in the initial phase Ib trial to be treated with HER-Vaxx in combination with chemotherapy at three dose levels.
Imugene said the first stage of the study would provide safety data, immunogenicity data, which measured how many of the HER2 antibodies were produced, evaluate the booster schedule and determine the optimal dose to take into the phase II study or recommended phase II dose.
The company said that the open label phase II study would recruit about 68 patients randomized into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone.
Imugene chief operating officer Leslie Chong said the approval was a “significant milestone and achievement [which] puts us on track to provide much needed therapy to our patients and to obtain valuable data for Imugene”.
The company said that principal investigators included Hong Kong’s Dr Thomas Yau of Hong Kong along with Thailand’s Dr Wirote Lausoontornsiri, Dr Arunee Dechaphunkul, Dr Jedzada Maneechavakajorn, Dr Suebpong Tansanvimon and Dr Chaiyut Charoentum, and Taiwan’s Dr Yee Chao and Dr Chia-Jui Yen.
Dr Yau said that HER2-positive gastric cancer in Asia was “a considerable area of unmet medical need not just because of disease incidence but also due to cost and availability issues surrounding the antiHER2 monoclonal antibody drugs”
“For Hong Kong there were around 1,100 new gastric cancer cases last year, representing a high relative frequency,” Dr Yau said.
Imugene was unchanged at 0.95 cents with 1.5 million shares traded.

USCOM

Uscom says the US Patent and Trademarks Office has allowed a patent covering the central algorithms of its BP+ central blood pressure monitor.
Uscom said that the patent, entitled ‘Method for estimating a central pressure waveform with a blood pressure cuff’ provided coverage until May 2029.
The company said that the patent covered “the key central pressure calculations made by the supra-systolic Uscom BP+ to measure the blood pressure wave forms generated at the heart … [providing] more direct measures than simple blood pressure measures made at the arm, as is common in most current technologies”.
Uscom said that central blood pressure measurements and wave form analysis were an emerging standard-of-care for the evaluation of cardio-vascular physiology and disease and the patent combined with the prior supra-systolic patents ensured that the Uscom BP+ was commercially protected.
The company said that central blood pressure measurement was reimbursed in the US, the BP+ device was being prepared for released in the US and was expected to retail at $US3,000, significantly lower than most of its competitors which range as high as $US20,000.
Uscom company said that monitoring the effectiveness of drug treatments in hypertension and heart failure was one application of the BP+ and a number of pharmaceutical companies were investigating the technology.
Uscom was up half a cent or 2.1 percent to 24.5 cents.

ADMEDUS

Admedus executive chairman Wayne Paterson says the company will reduce staff by 32 percent, cut costs by $12 million a year and will break even by July 2018.
Admedus requested a trading halt ahead of the investor teleconference and internet presentation.
Mr Paterson said that staff numbers would be reduced from 99 to 68 full-time equivalent staff positions.
Mr Paterson said that following a company review it would increase its focus on its three divisions of Cardiocel tissue repair, surgical and medical supplies and the immune therapy division, formerly Coridon, headed by Prof Ian Frazer.
Mr Paterson said he expected a “read-out” from the phase II trial for herpes simplex virus 2 (HSV-2) by the end of 2016.
Mr Paterson said that the Adapt-treated bovine cardiac tissue Cardiocel had potential in a pipeline of indications from its current use in cardiac repair to vascular repair, dura mater, vessels and abdominal repair.
He said the company would be able reduce the cost of manufacturing Cardiocel and was seeking improvements in both production and supply.
Mr Paterson said the company was working to have Cardiocel registered and available in Australia by the end of 2016.
He said that the search for a permanent chief executive officer could take a further six months.
In response to questions, Mr Paterson said that “the elephant in the room” was a potential capital raising “to protect the balance sheet” but did not provide any further details.
In response to a question on remuneration and options, Mr Paterson cited global executive salaries and said the company needed to be “competitive”.
Last week, Biotech Daily received an email from an anonymous investor questioning the pay-out to former chief executive officer Lee Rodne and Mr Paterson’s salary package.
At the time of publication, Mr Paterson had not responded to a question on the subject.
Last year, Admedus said revenue for the year to June 30, 2015 was $10,224,000 with net loss after tax of $25,254,000, and cash of $24,025,859 (BD: Aug 28, 2015).
Admedus fell half a cent or 1.4 percent to 34.5 cents.

PHARMAUST

Pharmaust says that Juniper Pharma Services has completed the manufacture of 1,000 capsules of monepantel, formerly PPL-1, for its cancer programs.
Pharmaust said that the Nottingham, England-based Juniper capsules would be provided to the University of Cambridge for its dog cancer trial (BD: Jun 27, 2016).
The company said that 20,000 capsules would be produced to support the clinical work and would enable dog owners to administer the drug without the palatability challenges in the previous Sydney trial in 2014 and 2015.
Pharmaust said that Juniper would retain capsules for on-going stability trials to determine whether there was any deterioration of the product over time.
Pharmaust said that both the human and dog trials would determine the effects of monepantel on tumor growth as determined by measurement of the size of tumors and whether progression was slowed.
Pharmaust was up 0.3 cents or 3.5 percent to 8.8 cents.