Biotech Daily

Tuesday June 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LIVING CELL UP 30%; NEUREN DOWN 8%**

*** LIVING CELL 81-WEEK DATA: 'NTCELL EFFICACY FOR PARKINSON'S'**

*** SIRTEX RECRUITS TRIAL OF SIR-SPHERES AGAINST SORAFENIB**

*** FDA OKAYS MAYNE'S GENERIC DOFETILIDE FOR HEART RHYTHM**

*** RESAPP ENROLS 322 PERTH PATIENTS, BRISBANE SITE OPENS**

*** AVITA APPOINTS MINTCARE FOR MALAYSIA DISTRIBUTION**

*** BLUECHIIP SUPPLIES TWO SAMPLE KITS TO POTENTIAL PARTNERS**

*** ADMEDUS UNDERTAKES REVIEW AND RESTRUCTURE**

*** PRIMA REGAINS NASDAQ $US1 COMPLIANCE**

*** SUDA: 'ON-MULTI-TRACK DESPITE SHARE PRICE'**

*** SCIGEN APPOINTS DR MAREK DZIKI DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.2 percent on Tuesday June 7, 2016 with the ASX200 up 10.6 points to 5,371.0 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and five were untraded. All three Big Caps fell.

Living Cell was the best, up as much as 3.7 cents or 74 percent to 8.7 cents before closing up 1.5 cents or 30 percent at 6.5 cents with 16.7 million shares traded. Antisense climbed 8.3 percent; Biotron was up 4.6 percent; Acrux and Reva rose more than three percent; Actinogen was up 1.2 percent; with Medical Developments, Starpharma and Viralytics up by less than one percent.

Neuren led the falls, down 0.5 cents or 7.9 percent to 5.8 cents with three million shares traded. Compumedics lost 7.0 percent; Polynovo and Pro Medicus fell five percent or more; Admedus, Cellmid, Clinuvel, IDT, Oncosil, Orthocell, Pharmaxis and Universal Biosensors were down more than three percent; Factor Therapeutics shed 2.9 percent; Bionomics, Opthea and Resmed were down one percent or more; with Cochlear, CSL, Ellex, Nanosonics and Sirtex down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says that 81 weeks after treatment all four patients in its phase I/IIa trial of NTCell for Parkinson's disease have shown "reversal of the progression" of disease.
Living Cell said that Parkinson's disease was measured by the Unified Parkinson's Disease Rating Scale, which rose by four to five points a year as the disease progressed.
The company said that after 81 weeks there was a clinically and statistically significant improvement in the patients' neurological scores from their pre-implant baseline.
Living Cell said that ability of the NTCell encapsulated pig choroid brain cells to decrease the Rating Scale scores by an average of 14 points after 81 weeks was "clinically significant, representing a 2.8 to 3.5 year reversal of neurological deterioration".
The company said that the first patient had sustained improvement at 130 weeks after the NTCell implant and all four patients were well and there were no safety concerns.
Living Cell said that the data would be presented at the Congress of Parkinson's Disease and Movement Disorders in Berlin June 19 to 23, 2016, by principal investigator Dr Barry Snow in a presentation entitled 'Safety and clinical effects of NTCELL [immunoprotected (alginate-encapsulated) porcine choroid plexus cells for xenotransplantation] in patients with Parkinson's disease (PD): 81 to 130 weeks follow-up'.
Living Cell chief executive officer Dr Ken Taylor said the "continued positive outcome of the study" gave confidence as the company awaited the results of the 18-patient phase IIb study, to confirm the most effective NTCell dose, define any placebo component and identify the target Parkinson's disease patient sub group (BD: Mar 24, 2016).
"Our goal, subject to continued satisfactory data, is to obtain provisional consent and launch NTCell as the first disease modifying treatment for Parkinson's disease in 2017," Dr Taylor said.
Living Cell closed up 1.5 cents or 30 percent at 6.5 cents with 16.7 million shares traded.

SIRTEX MEDICAL

Sirtex says it has completed recruitment in its 360-patient phase III trial of SIR-Spheres compared to sorafenib for unresectable hepatocellular carcinoma, or liver cancer.
Sirtex said that the study was a multi-centre, open-label, randomized, controlled trial of selective internal radiation therapy (SIRT) using SIR-Spheres Y-90 resin microspheres compared to sorafenib, marketed as Nexavar.
The company said that the primary objective was to assess efficacy in overall survival, with secondary objectives including a comparison of the side effects and quality of life.
Principal investigator and National Cancer Centre Singapore consultant surgeon Prof Pierce Chow said that Sirvenib study was "the largest Asia-Pacific study to directly compare SIRT and sorafenib".
"The search for more effective and better tolerated treatments [for liver cancer] is important, as so few proven treatment options currently exist," Prof Chow said.
Sirtex chief executive officer Gilman Wong said that the Sirvenib clinical study was "designed to examine the efficacy and safety of SIR-Spheres Y-90 resin microspheres compared to sorafenib, the current standard of care systemic treatment in advanced [hepatocellular carcinoma], in a predominately Asian population," Mr Wong said.
"Consequently, the generation of high quality level 1 evidence arising from this study will be an important determinant in gaining accelerated adoption should the study deliver positive findings," Mr Wong said.
Sirtex said that the Sirvenib study was conducted at 27 centres in 10 Asia-Pacific countries, including New Zealand, with results expected by July 2017.
Sirtex fell 27 cents or 0.9 percent to $28.38 with 332,816 shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says that the US Food and Drug Administration has granted approval for its dofetilide capsules for irregular heart rhythm indications.

Mayne said that the capsules, in 125mcg, 250mcg and 500 mcg doses, were a generic version of Pfizer's Tikosyn, an anti-arrhythmic agent used to prevent irregular heartbeats such as atrial fibrillation and atrial flutter.

The company said that it was the first company to file a substantially complete abbreviated new drug application to the FDA "containing a paragraph IV certification for dofetilide capsules and as a result has been awarded 180-days of market exclusivity" and it had begun a commercial launch.

Mayne said that Tikosyn had US sales of about $US200 million for the year to April 2016.

Mayne chief executive officer Scott Richards said the company was "proud to be the first generic alternative to Tikosyn in the US, bringing significant cost savings to patients requiring this life-saving drug".

"As the company's first generic product to receive 180-days of market exclusivity, the approval and launch of dofetilide is a significant milestone," Mr Richards said.

"Today's approval accelerates our growth and underscores our investment and commitment to bringing complex generic products to the marketplace," Mr Richards said.

Mayne said that the approval coincided with the FDA withdrawing the Tikosyn risk evaluation and mitigation strategies program, which limited the drug's availability and dispensation to certified prescribers, pharmacies and wholesalers.

The company said that the removal of the drug's program meant that its dofetilide capsules could be more readily stocked by pharmacies nationwide, improving availability for current and new patients.

Mayne said it had an agreement with partner active pharmaceutical ingredient supplier Johnson Matthey to equally share the profits from the sale of this product.

The company said it had more than 35 generic and branded drug products in development targeting US markets with sales greater than $US6.5 billion and expected further product launches over the coming year with 12 FDA applications pending.

Mayne was up 3.5 cents or 2.2 percent to $1.595 with five million shares traded.

RESAPP HEALTH

Resapp says that it has enrolled 322 adult patients in its first adult study of its cough detection of respiratory illness algorithm at Perth's Joondalup Health Campus.

Resapp said that 236 patients had a confirmed respiratory disease and 86 were control cases.

The company said that enrolment had begun at the Brisbane-based Wesley Emergency Centre which would "significantly increase the rate of enrolment and greatly expand the range of respiratory illnesses captured".

Resapp said that the Wesley study was its first clinical site to perform electronic data collection using Apple Ipads which would increase the speed of data verification and analysis.

Resapp chief executive officer Dr Tony Keating said that the company was "very pleased with the rate of patient enrolment at Joondalup".

"At that one site we are already close to achieving our initial target total enrolment of 400 adult patients and with the Wesley also recruiting patients we expect to exceed our initial target shortly," Dr Keating said.

Dr Keating said he expected the first preliminary analysis of the adult data by July 2016.

Resapp fell one cent or 2.5 percent to 39.5 cents with 10.5 million shares traded.

AVITA MEDICAL

Avita says it has appointed wound care distributor Mintcare for its products in Malaysia.
Avita said the Singapore-based Mintcare specialized in the distribution of wound care products throughout the Asia-Pacific and would focus on Malaysia first in its marketing of the regenerative medical devices for burns, wounds and skin conditions.
The company said that Mintcare had four salespersons in Malaysia, where vitiligo affected about 450,000 people, with 180,000 patients with chronic wounds and about 1,200 people hospitalized with large burns each year.
Avita said that its Recell spray-on skin technology would be launched at a wound care conference in Sabah, Malaysia in August.
The company said that Mintcare had a presence in Hong Kong, Indonesia, Philippines, Sri Lanka, Thailand and Vietnam.
Avita said that it had distribution agreements for China, Japan and South Korea.
Avita was unchanged at 11 cents.

BLUECHIIP

Bluechiip says that it has orders from two new firms to trial its sample-tracking technology.
Last week, Bluechiip chief executive officer Andrew McLellan told Biotech Daily that the company's aim was to sign new partners to include the tags in their storage systems and he had about 30 potential partners with negotiations continuing with about half of them (BD: Jun 3, 2016).
Today, Bluechiip said that a US-based cryogenics consumables manufacturer and a local research institution had purchased developer kits to evaluate the benefits of the tags.
Mr McLellan said "momentum is building as we continue to expand our partnering pipeline and sell more product".
"Sales of developer kits is an important step in the sales process as potential partners are able to further evaluate and validate the incorporation of Bluechiip technology into their products and processes," Mr McLellan said.
Bluechiip was up 0.2 cents or 9.1 percent to 2.4 cents.

ADMEDUS

Admedus says it is going through a "restructuring initiative to address issues such as costs, commercial performance and strategic priorities".
Admedus interim executive chairman Wayne Paterson said the restructure aimed "to improve commercial effectiveness, as well as accelerate the company's path to profitability significantly".
Mr Paterson said that the review followed the departure of chief executive officer Lee Rodne and significant changes to the board (BD: Feb 9, 10; May 23, 2016).
Mr Paterson said that the initiative would address all facets of the company's research and development programs "to ensure we are prioritising our resources to projects that are the most likely to succeed and benefit the company and shareholders".
Mr Paterson said that the company was undertaking a strategy review of its portfolio prioritisation, an operational review of commercial operations, an organizational review, a financial review, a clinical program review of research and development initiatives and clinical trials and a manufacturing review targeting yield and cost improvements.
Mr Paterson said the company would focus on operating expenditure reductions, performance improvement and a clear path to profitability" with results by July 11, 2016.
Admedus fell 1.5 cents or 3.95 percent to 36.5 cents.

PRIMA BIOMED

Prima says that its American depositary shares have maintained a closing bid price of $US1.00 or more for 10 consecutive business days regaining Nasdaq compliance.
Prima said that the American depositary shares (ADSs) would remain listed on the Nasdaq Global Market under the code PMBD.
In March, Prima said it had been notified by the Nasdaq that it was non-compliant with the minimum bid price rule of $US1.00 a share (BD: Mar 7, 2016).
Prima was unchanged at 4.6 cents.

SUDA

Suda says it is in licencing and partnering negotiations, applying for funds for a phase III Artimist for paediatric malaria trial and progressing SUD-003 for erectile dysfunction.
Suda said that the update noted "the weakness in its share price" and said that negotiations continued to licence its oro-mucosal sprays across products and territories and it "could finalize several agreements in the next few weeks and months".
The company said it met with more than 20 Chinese pharmaceutical companies at the China-Bio conference in Suzhou in May, with some at due diligence and term discussions.
Suda said that its business development team was at the BIO International Convention in San Francisco from June 6 to 9, 2016, with about 40 meetings with prospective partners, including companies with which it had "advanced term-sheet negotiations".
The company said it aimed to apply to the Australian Therapeutics Goods Administration for Artimist by the end of 2016 and was applying for grants for a phase III trial.
Suda said it has completed in-vitro and ex-vivo studies of a new formulation of SUD-003 for erectile dysfunction, with the data suggesting the rate of absorption and bioavailability was significantly enhanced compared to its first-generation spray and it was finalizing a new patent application and initiating an in-vivo study designed to validate the improvements to the formulation, with data expected by the end of 2016.
Suda chief executive officer Stephen Carter said that "the weakness in our share price is disappointing and doesn't reflect the progress and strength of our business".
Suda was up 0.2 cents or 10 percent to 2.2 cents with 3.4 million shares traded.

SCIGEN

The Singapore-based, Polish-owned Scigen says it has appointed Dr Marek Dziki as a non-executive director.
Last week, Scigen said that executive chairman Dr Slawomir Ziegert had resigned and left 95.57 percent owner, the Warsaw, Poland-based Bioton SA (BD: Jun 6, 2016).
Today, Scigen said that Dr Dziki was a medical doctor and held a Doctorate of Philosophy from the University in Lublin, Poland and a Masters of Business Administration from the International Business School in Warsaw.
According to the ASX, Scigen was "co-developing and marketing genetically engineered biopharmaceutical products for human healthcare … [for] gastroenterology, endocrinology and immunology", the most recent preliminary final report said that revenue for the year to December 31, 2015 was $US23,527,000 ($A31,938,870) with net profit after tax of $US1,268,000 ($A1,721,110) and its market capitalization was $522,438.
Scigen was untraded at one cent.