Biotech Daily

Wednesday June 19, 2013

Daily news on ASX-listed biotechnology companies

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*** IMPEDIMED PLEADS SCHULTZ TO ASX 28% QUERY**

MARKET REPORT

The Australian stock market climbed 0.98 percent on Wednesday June 19, 2013 with the S&P ASX 200 up 47.0 points to 4,861.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, two traded unchanged and six were untraded.

Uscom was the best, up 3.5 cents or 21.2 percent to 20 cents with 7,500 shares traded, followed by Avita up 20.8 percent to 14.5 cents with 3.1 million shares traded and Impedimed up 15 percent to 11.5 cents with 440,000 shares traded. Benitec climbed 6.7 percent; Medical Developments and Psivida were up more than five percent; Cellmid and Universal Biosensors rose four percent or more; Cochlear, Neuren, Patrys, Pharmaxis and Phosphagenics were up more than three percent; Heartware, Nanosonics and Sirtex rose more than two percent; with Acrux, Alchemia and Resmed up more than one percent.

Ellex led the falls, down 1.5 cents or 6.7 percent to 21 cents with 155,500 shares traded. Viralytics lost 5.4 percent; Anteo, Bionomics and Prana fell more than four percent; Allied Health, Circadian, Clinuvel and Tissue Therapies were down more than three percent; CSL, Genetic Technologies, Optiscan, Prima, Reva and Starpharma were down more than one percent; with QRX down 0.8 percent.

FEDERAL OPPOSITION

The Federal Opposition has restated its promise to protect medical research funding.
In March the Federal Liberal Representative for Higgins, Kelly O'Dwyer, told a Bio-Melbourne Network Bio-Breakfast that if the Coalition won the coming election, research and development funding would be protected at current levels (BD: Mar 5, 2103).
In a media release entitled 'Fostering Australian scientific research' the Leader of the Opposition Tony Abbott and the Shadow Minister For Innovation, Industry And Science Sophie Mirabella said that "cutting red tape, protecting medical research funding and providing policy certainty are essential parts of the Coalition's commitment to foster science and research in Australia".
Mr Abbott and Ms Mirabella said that the Liberal Party and National Party Coalition would provide "the long-term, stable policies and vision that our nation's scientists and researchers need to excel in their work".
"We will cut the red tape that accompanies government research programs, as well as providing our scientists and researchers with the certainty to plan," the media release said.
The media release said that if elected, the Coalition would cut "$1 billion in red tape annually so that businesses and research centres have more resources to spend on research and spend less time filling in paperwork".
An officer in Mr Abbott's office told Biotech Daily that the $1 billion in red tape cuts applied "across all areas and portfolios of Government" not just innovation and research.
A document entitled 'The Coalition's Deregulation Reform Discussion Paper' dated November 2012 said that the $1 billion figure was a reduction target.
The 2012-'13 Federal Budget the allocation to the National Health and Medical Research Council was $771.2 million, with $500 million for Innovation Precincts, $135.3 million over five years for the Australian Research Council, $350 million for the Innovation Investment Funds and about $80 million for Commercialisation Australia (BD: May 15, 2013).
Mr Abbott and Ms Mirabella said in the media release that a Coalition government would protect medical research funding, "an area where Australia's talented scientists give us such a comparative advantage"; provide $2 million to complete the Primary Connections science education program aimed at stimulating science in primary schools; promote more collaboration with regional neighbors through a two-way Colombo Plan that will send Australians to the Asia-Pacific region and bring the region's best and brightest to Australia; provide $35 million to the Juvenile Diabetes Research Foundation's Clinical Trial Network for type 1 diabetes research; create greater capacity for international collaboration by aiming for 40 percent of students to complete high school studying a foreign language; and provide policy certainty for scientists and researchers.
Mr Abbott and Ms Mirabella said the Coalition "understands that science and research are the foundation for Australia's future advancement in manufacturing, innovation and in a range of industries from pharmaceuticals to telecommunications".

MEDICINES AUSTRALIA

Medicines Australia said it welcomed the Coalition's announcements.
Medicines Australia chief executive Dr Brendan Shaw said that regulatory reform was an important part of encouraging medical research and development "and the Coalition's recent announcements on this are welcome".
"Reforming the regulation of things like medical research, [research and development] and clinical trials is a key part of developing Australia's future competitiveness in high skill, high wage, innovative industries," Dr Shaw said.
"One area of reform where we need to keep the momentum going is the reform of regulation around clinical trials of new medicines," Dr Shaw said.

ALLIED HEALTHCARE GROUP

Allied Health says 44.4 percent subsidiary Coridon it has ethical approval for 20-patient phase I dose-ranging trial of its herpes simplex virus 2 (HSV-2) vaccine.

Allied said that Coridon founder Prof Ian Frazer was developing the first-in-class vaccine for HSV-2 using an optimization technology that had the potential of being both a preventative and therapeutic vaccine.

The company said that the phase I study would vaccinate 20 healthy volunteers with an intra-dermal injection into the forearms with a goal to examine the safety of the vaccine, as well as detect if an antibody and T-cell response could be generated.

Allied said that, along with safety data, the results would indicate if the vaccine could stimulate a protective antibody response as well as a therapeutic T-cell response.

“We have seen very encouraging results from animal studies and we expect pivotal data showing that our vaccine, which incorporates our patented optimization technology, to produce similar immune responses in the clinic,” Prof Frazer said.

Allied said that the phase I trial would demonstrate the vaccine’s safety and how well tolerated it was, as well as determining the effective dose and showing that the vaccine generated a robust immune response.

Allied chief executive officer Lee Rodne said that the trial approval was “a further significant milestone in Allied’s commercialization of next generation vaccines that are designed to have the power to both prevent and treat infectious diseases and cancers”.

“The clinical trial will also prove the value of this technology in humans for use in a wide range of vaccines,” Mr Rodne said.

Allied said that HSV-2, herpes affected more than one in six Americans between the ages of 14 and 49 years and up to 500 million people worldwide, with no current cure available.

Allied closed down 0.2 cents or 3.7 percent to 5.2 cents with 13.1 million shares traded.

GI DYNAMICS

GI Dynamics says that France has approved a 174-patient study of Endobarrier for obesity and type 2 diabetes and will provide EUR1.16 million ($A1.64 million).

GI Dynamics said that the French Ministry of Social Affairs and Health approved the randomized, multi-center clinical utility study of the Endobarrier duodenum lining tube, which would be coordinated by the University Hospital of Lille.

The company said the study was part of the ‘soutien aux techniques innovantes couteuses’ (STIC or support for innovative and expensive techniques) program, which provided government funding for innovative medical technologies that have been validated by prior clinical studies with a view to establishing reimbursement for new devices.

GI Dynamics chief executive officer Stuart Randle said the company was “thrilled that the French Government has recognized the benefits of Endobarrier therapy and agreed to fund this important new study [which would] … help to clearly understand the economic impact of Endobarrier therapy and its role in the management of type 2 diabetes and obesity and is a significant step toward achieving broader reimbursement in France.”

The company said that the trial protocol was submitted by the University Hospital Lille’s head of the department of general and endocrine surgery Prof François Pattou, who led the pilot study in Lille, last year and would enroll patients at centers in Lille, Toulouse, Lyon, Marseille, Montpellier, Paris and Strasbourg to evaluate the impact and cost of 12 months of treatment with the Endobarrier compared to 12 months of conventional treatment including dietary counseling, physical activity and lifestyle changes, on metabolic syndrome in patients suffering from obesity, both with and without diabetes.

GI Dynamics was untraded at 60 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has an agreement with the Rockville, Maryland-based Fedmed Inc to act as national provider network for its Brevagen breast cancer tests.
Genetic Technologies said the agreement, through its wholly-owned US subsidiary Phenogen Sciences, linked it to a national provider network with more than 550,000 physicians, 60,000 ancillary care providers and 4,000 hospitals nationwide and more than 40 million covered lives.
The company said that the agreement with Fedmed was the seventh credentialing agreement with US Preferred Provider Organisations and brought the cumulative total number of covered lives for which its Brevagen risk assessment test could be adjudicated as 'in-network' to more than 102 million people.
Genetic Technologies said that in-network reimbursement payments were more than 25 percent higher than those considered out-of-network, with the time taken to collect the funds also being materially shorter.
Genetic Technologies fell 0.1 cents or one percent to 9.8 cents.

PRANA BIOTECHNOLOGY

Prana says it has funded an independently created "world first, patient-reported outcomes study for Huntington's disease".
Prana said that a poster presentation, entitled 'The Huntington's Disease patient-reported outcome of problems (HD-PROP): feasibility and applicability in clinical research' at the Congress of Parkinson's Disease and Movement Disorders in Sydney this week, detailed a new benchmarking system to assess the problems experienced by people with Huntington's disease.
The company said that the HD-PROP test was developed by researchers at the Georgetown University Medical Centre and the Medstar Health Research Institute, both based in Washington DC-based, who were involved in its 109-patient, phase II trial of PBT2 for Huntington's disease, which was fully recruited and nearing completion.
Prana said the test aimed to overcome some of the challenges associated with assessing clinically relevant outcomes in Huntington's disease, where progressive motor, cognitive and psychiatric symptoms could interfere with comprehension of lengthy patient self-report questionnaires and communication of responses.
The company said the HD-PROP test might be a useful tool to evaluate its clinical trial results.
Prana said the test asked trial participants three questions about their Huntington's disease (HD) at the start of the trial: What problem is most bothersome? In what way is this problem bothersome? How severe is this problem?
Poster co-author Prof Ira Shoulson said it was "the first time this type of patient response testing has been applied to HD and we expect it will form an important part of future trials".
"Patient-reported outcomes are an important area of focus for the US Food and Drug Administration and along with clinical measures provide a more complete understanding of the relevance as well as safety and effectiveness of potential treatments," Prof Shoulson said.
Prana said that at the start of its phase II trial, 97 percent of participants reported at least one bothersome problem, 87 percent reported at least two problems and 67 percent reported at least three problems.
The company said that motor symptoms, cognitive symptoms, functional decline and behavioral symptoms were the most commonly reported first, second and third problems.
Prana fell one cent or 4.2 percent to 23 cents with 1.5 million shares traded.

SUNSHINE HEART

Sunshine Heart says that its C-Pulse aorta cuff has been implanted in 25 patients with a total of 25-patient years of implantation, reaching “a major milestone”.
Sunshine Heart said the cumulative 25 years of active C-Pulse treatment for Class III and ambulatory Class IV heart failure was more than one billion inflation and deflation cycles and the 25th patient was implanted on June 14, 2013 at Berlin’s German Heart Institute.
The company said that C-Pulse had never recorded a neurologic event associated with the device (a stroke or transient ischemic attack), which was a potential advantage of the C-Pulse device which did not contact the blood stream nor require blood thinning agents.
Sunshine Heart said that to date, no known cardiovascular blood-contacting mechanical support devices had shown these results in a published pilot or pivotal clinical trial.
The company said that an additional two patients had been targeted for weaning from the technology in addition to two previously weaned patients that were permanently disconnected from the device based on improvement in their heart failure symptoms.
Sunshine Heart said that the C-Pulse was being evaluated in 388-patient US pivotal trial, and two sites had been activated with 10 more in the activation process.
Sunshine Heart said that a 50-patient European post-market study was underway, with one site activated and two patients implanted, and three additional sites ready to enrol.
On the Nasdaq last night, Sunshine Heart was up 31 US cents or 5.4 percent to $US6.05.

ANTEO DIAGNOSTICS

Anteo says it has an agreement for a feasibility study with a healthcare company to investigate and evaluate the potential of Mix&Go surface chemistry adhesion products.
Anteo said the objective of the 12-month study was to assess whether Mix&Go provided an advantage in the development of a new device for the healthcare company.
Anteo fell 0.3 cents or 4.5 percent to 6.4 cents with 1.1 million shares traded.

ISONEA

Isonea says it has appointed Hong Kong’s Refined Manufacturing to scale-up production of the Airsonea mobile wheeze-monitoring device for asthma sufferers.
Isonea said that Refined Manufacturing specialized in high volume, precision production of electronic, optical, and computer related products for health and consumer markets and would produce the Airsonea device for an expected Australian launch in September 2013.
Isonea chief executive officer Michael Thomas said that selecting a high quality manufacturing partner was an important milestone for the Company.
Isonea was up 4.5 cents or 12.2 percent to 41.5 cents with 2.4 million shares traded.

IMPEDIMED

Impedimed has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 28.2 percent from 7.8 cents to 10 cents, yesterday June 18, 2013, and noted an increase in trading volume.
Impedimed was up 1.5 cents or 15 percent to 11.5 cents.