Biotech Daily

Wednesday May 27, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 18%, ANALYTICA DOWN 8%**

*** FEDERAL $20bn MRFF LEGISLATION INTRODUCED**

*** REVA CONFIDENT OF FANTOM, CE MARK TRIAL, US IPO**

*** FDA APPROVES SUNSHINE HEART PIVOTAL C-PULSE TRIAL RESTART**

*** ANTISENSE ATL1102 EU EARLY ACCESS FOR MULTIPLE SCLEROSIS**

*** RESONANCE HEPAFAT-SCAN TRIAL, SANDER BANGMA APPOINTED G-M**

*** BANK OF AMERICA SELLS, BORROWS, DILUTED, INCREASES IN SUDA**

*** APPLICATIONS OPEN FOR NSW MEDICAL DEVICE PROGRAM**

*** IQ3 TO RAISE UP TO $3m FOR IQX**

*** NARHEX VOTES TO BECOME RESAPP HEALTH**

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday May 27, 2015 with the S&P ASX 200 down 48.1 points to 5,725.3 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell and nine traded unchanged. All three Big Caps fell.

Optiscan was the best, up one cent or 18.2 percent to 6.5 cents with 2.65 million shares traded.

Uscom climbed 7.7 percent; Oncosil was up five percent; Tissue Therapies rose 4.4 percent; GI Dynamics was up 3.45 percent; Viralytics rose 2.75 percent; with Admedus, Avita, Bionomics and Medical Developments up more than one percent.

Analytica led the falls for the second day in a row, down 0.1 cents or 8.3 percent to 1.1 cents with 5.3 million shares traded, followed by Antisense down eight percent to 11.5 cents with 704,881 shares traded.

Atcor, Biotron and Cellmid fell four percent or more; Circadian, IDT, Prima and Universal Biosensors lost more than three percent; Acrux, Actinogen, Ellex, Genetic Technologies, Nanosonics and Neuren shed more than two percent; Anteo, Cochlear, CSL, Impedimed, Living Cell and Sirtex were down more than one percent; with Mesoblast, Resmed and Reva down by less than one percent.

FEDERAL GOVERNMENT

The Federal Treasurer Joe Hockey has told Parliament that legislation has been introduced today to establish the Medical Research Future Fund.
In Question Time today, Mr Hockey said the $20 billion fund would produce a reliable predictable source of funds for medical research above and beyond existing funds.
A Federal Government media release said the legislation, entitled 'The Medical Research Future Fund Bill 2015, would create "the biggest endowment fund of its kind in the world".
"Subject to the passage of the legislation, the Medical Research Future Fund will be established from August 1, 2015," the Federal Government said.
The media release said the Fund would receive an initial contribution of $1 billion from the Health and Hospitals Fund, along with savings from the Health budget to be contributed until the Fund reaches $20 billion, projected to be in 2019-'20, with the first $10 million in additional medical research funding to be distributed in 2015-'16 and more than $400 million to be distributed over the next four years.
The media release said that the Fund would be invested and managed by the Future Fund Board of Guardians, and the Government would establish an expert advisory board to provide advice on the medical research strategy and priorities.

REVA MEDICAL

Reva executive chairman Robert Stockman and chief financial officer Katrina Thompson say a US initial public offer is expected to raise "significantly more" than $US50 million.
In Melbourne to meet investors ahead of tomorrow's annual general meeting in Sydney, Mr Stockman told Biotech Daily that the Fantom II trial had opened centres in Brazil, Europe and Australia with a target of 110 patients in the first Conformité Européenne (CE) mark-directed cohort, with a second cohort of 110 patients planned to support the commercial launch of the drug-eluting, bioresorbable, Fantom coronary stent.
Mr Stockman said that the first cohort's primary endpoint was safety and efficacy at six months, while the second cohort's primary endpoint was at nine months.
Mr Stockman said that the company was very encouraged by the "100 percent" positive results from the first four of seven patients who had reached the four month observation point in the Fantom I pilot trial (BD: May 22, 2015).
He said that the company had received a large number of inquiries from leading cardiologists and doctors attending last week's European Association of Percutaneous Cardiovascular Interventions (Euro PCR) meeting in Paris, France because of the positive early results.
"In five years of coming to Australia, I have never felt as comfortable and confident about the trial and its prospects," Mr Stockman said.
"The sense of calmness among investors is reassuring," Mr Stockman said.
Mr Stockman said that although he was retiring as chief executive officer and hoped to have a replacement later this year, he would continue as Reva's executive chairman.
Ms Thompson said that the company had about $US20 million at March 31, 2015, which gave Reva "about a year" of cash.
Mr Stockman said Reva would need to fund a 2,000 patient US Food and Drug Administration trial, that would cost more than $US50 million, so the initial public offer for the Nasdaq, scheduled for June or July, would raise significantly more than that amount.
Mr Stockman said that Reva was well-aware of its competition, but had the only fully-visible, bioresorbable, coronary scaffold available, which was as small, as strong, pliable and durable as any of its competitors.
Reva fell half a cent or one percent to 50.5 cents.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration has approved the resumption of patient enrolment in its C-Pulse aorta cuff pump pivotal trial.

In March, Sunshine Heart said it was “taking a temporary pause from enrolment” in the ‘Counter HF’ trial, following four patient deaths which it said appeared non-device related (BD: Mar 9, 2015).

Sunshine Heart said that the pivotal US trial was a prospective, randomized, multi-center, controlled study evaluating the safety and efficacy of the C-Pulse system for the treatment of New York Heart Association class III and ambulatory class IV heart failure, expected to randomize 388 patients in up to 40 clinical sites.

Today, the company said that it had begun the process to provide all pivotal study centers with the information required for their investigational review boards to approve the continuation of study enrollment.

Sunshine Heart chief executive officer Dave Rosa said that resuming enrolment “has been our top priority and was accomplished within the timelines originally announced”.

Sunshine Heart said that in February 2015 the FDA unconditionally approved an interim analysis for the Counter HF study, potentially to reduce the approval timeline.

On the Nasdaq last night, Sunshine Heart fell 16 US cents or 3.74 percent to $US4.12 ($A5.32 equivalent to 2.7 cents prior to departing the ASX) with 190,808 shares traded.

ANTISENSE THERAPEUTICS

Antisense says that the Amsterdam, Netherlands-based Mytomorrows will implement an early access program for ATL1102 for multiple sclerosis.

Antisense said that the program would be established in the European Union, allowing companies to provide eligible patients with ethical access to investigational medicines for unmet medical needs.

The company said that access was provided in response to physician requests where other treatments had been unsuccessful and no alternative or appropriate treatment options are available to these patients.

Antisense said that multiple sclerosis was a chronic disease progressively destroying the central nervous system and affecting about 400,000 people in Europe and more than one million worldwide.

The company said that ATL1102 was directed at the target very-late antigen-4 (VLA-4) and had been shown to reduce brain lesions in a phase II clinical trial (BD: Jun 30, 2008).

Antisense said that subject to Mytomorrows receiving regulatory approvals and support for the ATL1102 program, it expected to provide ATL1102 to European Union treatment centers at prices comparable to current medicines used for multiple sclerosis.

The company said it planned to access an existing source of ATL1102 material for use in the early access program, which could be available by the end of 2015, pending quality retesting.

Antisense said Mytomorrows would pay for early access activities including data collection and approvals and would receive a share of related revenue less drug and associated costs including those to Isis Pharmaceuticals from whom ATL1102 was licenced.

The company said that separate to the early access program, it was seeking a partner for the on-going clinical development and potential commercialization of ATL1102 and in the event of future licencing revenue and sales of ATL1102, Mytomorrows would be entitled to a percentage of revenue as compensation for the services provided, but only in those countries where an early access program had been established.

Antisense fell one cent or eight percent or 11.5 cents.

RESONANCE HEALTH

Resonance says the Atlanta, Georgia-based Emory University will conduct a 50-paediatric patient validation study of its Hepafat-Scan for non-alcoholic fatty liver disease.
Resonance said the study comparing the Hepafat-Scan directly with liver biopsies would be conducted at Atlanta's Children's Healthcare, with results expected within 12 to 18 months.
The company said that non-alcoholic fatty liver disease was an obesity-related liver disease that increased the risk of liver cancer and cirrhosis, type II diabetes, cardiovascular disease and metabolic syndrome and was the leading cause of liver disease for both adults and children in the US and was increasing worldwide, with no approved pharmaceutical treatments.
Resonance said its Hepafat-Scan was non-invasive medical imaging using magnetic resonance imaging to measure liver fat.
The company said that the Hepafat-Scan had regulatory clearances in the US, EU and Australia.
Resonance said that the gold standard for assessment of liver fat was biopsy which was painful, invasive and lacking in sensitivity due to its subjective and semi-quantitative nature.
The company said that the independent validation study of Hepafat-Scan was important in consolidating the value of the test in providing an accurate liver fat measurement in non-alcoholic fatty liver disease patients of all ages.
Resonance has appointed its development and service manager Sander Bangma as general manager, replacing Liza Dunne who resigned earlier this year (BD: Jan 29, 2015).
"We have worked with Children's Healthcare of Atlanta for a number of years in the provision of our Ferriscan service to measure liver iron overload," Mr Bangma said.
"We are delighted that we can now further our collaboration with such a highly-respected institution to provide the Hepafat-Scan service in this study under the direction of a leading clinician in the field of paediatric [non-alcoholic fatty liver disease]," Mr Bangma said.
"Hepafat-Scan can assist clinicians in their diagnosis and treatment of patients, providing them with accurate information at an earlier disease stage," Mr Bangma said.
"This study intends to show that this information will lead to improved patient outcomes," Mr Bangma said.
"Collecting data like this may ultimately support inclusion of Hepafat-Scan in clinical guidelines for routine care of [non-alcoholic fatty liver disease] patients," Mr Bangma said.
Resonance fell 0.3 cents or 7.1 percent to 3.9 cents.

SUDA

The Bank of America and related bodies say they have increased their holding in Suda from 77,146,856 shares to 77,387,842 shares but have been diluted from 7.84 percent to 6.81 percent.
Last year, the Charlotte, North Carolina-based Bank of America said it had "borrowed" and "returned" shares under a prime brokerage agreement and the Sydney-based Merrill Lynch (Australia) Futures and London-based Merrill Lynch International were the holders of the shares as beneficial owner and as the borrower of securities in a prime brokerage agreement, respectively (BD: Jul 22, Dec 5, 2014).
In March, Suda raised $5.3 million in a placement of 146.5 million shares at 3.6 cents a share (BD: Mar 27, 2015).
Suda fell 0.1 cents or 3.2 percent to three cents with 44,000 shares traded.

NEW SOUTH WALES GOVERNMENT, ATP INNOVATIONS

The New South Wales Minister for Health Jillian Skinner says applications have opened for the Medical Device Commercialisation Training Program.

A media release from Ms Skinner said that post-doctoral researchers, doctoral, Doctorate of Philosophy and Masters candidates completing degrees in New South Wales this year were eligible to apply.

“It is vital we bring to market medical devices which can enhance the quality of life for people living with a range of medical conditions,” Ms Skinner said.

“Graduates of the 2014 Medical Device Commercialisation Training Program launched companies, raised capital from investors, engaged industry partners and to date have raised $1.2 million in grants to create job opportunities here and abroad,” Ms Skinner said.

The media release said that the Training Program would see 20 applicants chosen to undertake a three-month program with technology incubator ATP Innovations, to develop key skills such as entrepreneurial literacy, persistence and understanding of the process of commercialization.

The State Govermnent said that at the end of the program, some participants could be awarded educational scholarships, sponsored opportunities to explore global markets or seed capital to start their own business.

The Sydney-based ATP Innovations is a private company owned by University of Sydney, University of New South Wales, University of Technology Sydney and the Australian National University.

ATP said that applicants must have a demonstrated interest in medical device innovation and commercialization, and ideally, would have access to intellectual property of their own, or belonging to their institution or company and a track record of accomplishment and publication in their field.

ATP said that applications opened today May 27 and close on June 25, 2015.

To apply, go to: to http://www.health.nsw.gov.au/ohmr/Pages/nsw-medical-device-tp.aspx.

For more information contact: programs@atp-innovations.com.au.

IQ3 CORP

IQ3 says it is the lead manager for a private placement to raise $3 million for IQX from sophisticated and professional investors.

The IQX website says it is a life sciences investment company.

IQ3 was untraded at 49 cents.

NARHEX LIFE SCIENCES

Narhex says that all resolutions at its extraordinary general meeting to acquire Resapp Diagnostics and change its name to Resapp Health have been passed overwhelmingly.

Narhex has requested a voluntary suspension pending compliance with Chapters 1 and 2 of the Listing Rules (BD: Apr 24, 2015).

Narhex last traded at 0.8 cents