Biotech Daily

Tuesday October 6, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BIOTRON UP 22%; ONCOSIL DOWN 9%**

*** 'CALL US' VICTORIA MINISTER TELLS AUSBIOTECH; US FUNDING**

*** VICTORIA TO LEGALIZE MEDICAL MARIJUANA IN 2017, TRIALS**

*** BURNET, INNOVIRON CREATE PRECLINICAL CRO 360-BIOLABS**

*** ADMEDUS RELEASES SHEEP TRI-LEAFLET VALVE RESULTS**

*** HEARTWARE REPLIES TO INVESTOR VALTECH COMPLAINT**

*** HONG KONG'S SENRIGAN TAKES 15% OF REVA**

*** KEVIN FISCHER REPLACES GENETIC TECHNOLOGIES CFO BRIAN MANUEL**

*** BIO-MELBOURNE QUALITY-BRIEFING TOURS TRAJAN SCIENTIFIC**

MARKET REPORT

The Australian stock market was up 0.33 percent on Tuesday October 6, 2015, with the ASX200 up 16.9 points to 5,167.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and four were untraded.

Biotron was the best, recovering from post-phase II trial falls, on a letter and presentation to investors, up one cent or 22.2 percent to 5.5 cents with 4.7 million shares traded, followed by Tissue Therapies up 12.5 percent to 4.5 cents with 320,503 shares traded.

Universal Biosensors climbed 9.7 percent; Polynovo was up 7.4 percent; Actinogen and Pro Medicus were up more than five percent; Avita was up 4.4 percent; Impedimed climbed 3.4 percent; Pharmaxis rose 2.2 percent; Admedus and Benitec were up more than one percent; with Mesoblast, Resmed and Viralytics up by less than one percent.

Oncosil led the falls, down 1.5 cents or 9.1 percent to 15 cents with 5.4 million shares traded.

Ellex lost 6.6 percent; Atcor fell four percent; Bionomics, Cellmid, Clinuvel and Prana were down more than three percent; Nanosonics and Starpharma shed more than two percent; Acrux, Anteo, Medical Developments and Sirtex were down one percent or more; with Cochlear, CSL and Orthocell down by less than one percent.

AUSBIOTECH, VICTORIA GOVERNMENT

In launching Ausbiotech's Biotech Invest meeting today Victoria Minister for Small Business, Innovation and Trade Philip Dalidakis told delegates to use his Department.

The two-day investment meeting, held at Crown Casino, overlaps with the three-day Ausbiotech Conference beginning tomorrow at the Melbourne Convention Centre, across the road from the casino.

Mr Dalidakis told the meeting that in 2015, the State of Victoria was fourth in the world in life sciences for the second successive year and said that during the past 15 years the State Government had invested $2 billion in the sector.

Mr Dalidakis paid tribute to former Victoria Premier, Treasurer and Innovation Minister John Brumby for the investment in the biotechnology sector.

"Without john Brumby we couldn't talk about the success of the industry," Mr Dalidakis said.

"We have more than 100 biotech companies, 10 research institutes, 10 major public teaching hospitals and the nine existing universities," Mr Dalidakis said.

Mr Dalidakis invited delegates to call his Department and tell it what they wanted.

"We want you to knock on the door and tell us what we can do for you," Mr Dalidakis said.

"Call us. Without you we don't have a sector, without your investment we don't have an industry," Mr Dalidakis said.

"We support the industry because we believe in the industry and we can see what the industry provides … in terms of both commercialization and life sciences," Mr Dalidakis said.

Mr Dalidakis said that Victoria had 18 trade offices around the world with new ones opening in Istanbul and Singapore and one planned for South America.

"We do it better than [the Federal Government department] Austrade and better than the other states and our offices are open to you," Mr Dalidakis said.

The principal of the McLean, Virginia-based Tiber Creek Partners and Dentons law firm partner John Clerici told the meeting that more than $20 billion in non-dilutive funding was available from US Government agencies and companies needed to present a well-constructed business development case to access those funds.

"In good times, people ignore government funding, but in other times they live off it," Mr Clerici said.

Mr Clerici said that anyone pursing the funding for its own sake would fail, because the funding agencies were experienced.

"There's a lot of money out there and it can't be ignored … but avoid the gold rush mentality," Mr Clerici said.

He said the agencies were never surprised when a new disease like ebola was in the headlines and suddenly a raft of companies were knocking on their door asking for funds.

Mr Clerici said that the Department of Health and Human Services, The Biomedical Advanced Research and Development Authority, the Office of the Assistant Secretary for Preparedness and Response, National Institutes of Health, and the Department of Defence all had funding for significant projects including in some cases late stage development.

Mr Clerici said that the US Government wanted to see partnerships, particularly with non-government organizations like the Wellcome Trust, the Gates and Rockefeller Foundations, as well as foreign governments.

Mr Clerici said there was "no bias against ex-US companies" and that Canadian and Danish companies were among the most successful, but broad spectrum and commercially sustainable technologies would be favored over hard sells and blockbusters, with particular interest in microbial resistance and emerging infectious diseases.

THE VICTORIA GOVERNMENT

The Victoria Government says it has accepted most of the Victorian Law Reform Commission recommendations and will legalize medical marijuana in 2017.

A Victoria Government said that it fully accepted 40 of the 42 Victorian Law Reform Commission's Report on Medicinal Cannabis and accepted two others in principle.

The State Government said the recommendations addressed cultivation; manufacture and supply of high quality medicinal cannabis products within Victoria; patient eligibility; appropriate clinical oversight involving specialists, general practitioners, nurses and pharmacists; and the need for on-going research and clinical trials.

The Government said that "a key step to enabling access to medicinal cannabis will be to establish cultivation and manufacturing industries … to support an on-going and reliable supply of medicinal cannabis for patients" and a cultivation trial would begin at a Victorian research facility overseen by the Department of Economic Development, Jobs, Transport and Resources, which would be given new regulatory functions to licence growers to cultivate cannabis for the purpose of medicinal cannabis.

The Victoria Government said that the Commission recommended that eligibility be based on conditions and symptoms including: severe muscle spasms or severe pain resulting from multiple sclerosis; severe pain, nausea, vomiting or wasting arising from cancer, HIV/AIDS, of the treatment thereof; severe seizures resulting from epileptic conditions where other treatment options have failed or have intolerable side effects; and severe chronic pain with the approval of two specialists.

The State Government said that "as a priority [it would] provide access to medicinal cannabis for children with severe epilepsy in early 2017".

The Government said it would establish an independent medical advisory committee to provide advice about expanding eligibility and it would establish an Office of Medicinal Cannabis to oversee the manufacturing, dispensing and clinical aspects of the framework.

The media release said that the Office of Medicinal Cannabis would help encourage new research and develop clinical guidance, in consultation with the medical profession.

The Victorian Government said that it had partnered with the New South Wales Government to enable the participation of Victorians in trials to begin in 2016 and to help build the evidence base, it was working to establish a Victorian-based clinical trial.

The State Government said it would work with its Federal counterparts to ensure Victorians can access medicinal cannabis safely and legally.

Victoria Premier Daniel Andrews said that he had seen "first-hand how medicinal cannabis can change people's lives".

"This landmark reform means Victorian families will no longer have to decide between breaking the law and watching their child suffer," Mr Andrews said.

The State Minister for Health Jill Hennessy said that Victoria was "leading the way on legalizing medicinal cannabis because we know the difference it can make to a patient's quality of life and because we know the evidence is growing in support of it as a treatment option in exceptional circumstances".

"Children with severe epilepsy will be the first to access medicinal cannabis in early 2017 because their condition can be life threatening and medicinal cannabis may be their last treatment option," Ms Hennessy said.

Victoria's Minister for Agriculture Jaala Pulford said that the cultivation trial would ensure supply for patients and provide important and scientific information that would support and facilitate the development of cultivation of medicinal cannabis in Victoria.

"The trial will allow for safe and secure medicinal cannabis products to be introduced and made available for those people in exceptional circumstances in Victoria. Planning for the trial is already underway," Ms Pulford said.

THE BURNET INSTITUTE, INNOVIRON, 360-BIOLABS

The Burnet Institute says that with research services company Innoviron it has launched the Melbourne-based contract research organisation 360-Biolabs.

The Burnet said that 360-Biolabs combined "the strengths and experience of the Burnet [immune-monitoring facility] with Innoviron's … commercially-focused, anti-infective expertize".

The Institute said that 360-Biolabs would offer laboratory services for immunology and virology to support clinical trials and develop therapeutics, vaccines and diagnostics.

Former Biota head of research and 360-Biolabs chief executive officer Dr Simon Tucker said the company would attract overseas clients and investment by providing services to the rapidly growing medical technologies and pharmaceuticals sectors.

"We hope to support and help grow the local biotech sector and the clinical trials industry while providing employment opportunities and high tech jobs," Dr Tucker said.

Burnet Institute chief operating officer Geoff Drenkhahn said that since 2008 the immune-monitoring facility had provided an essential service to biotechnology and pharmaceutical companies conducting clinical and pre-clinical research in Victoria.

"Merging the capabilities of the [immune-monitoring facility] with the experienced and complementary team previously at Biota adds much greater depth of virology and commercial focus to the new 360-Biolabs … and at the same time greatly strengthens Victoria's overall competitiveness for clinical trials and biotechnology," Mr Drenkhahn said.

The Burnet Institute said that 360-Biolabs would have containment laboratories, quality management systems and accreditation.

ADMEDUS

Admedus has provided specific data from the sheep trial of its Cardiocel bovine scaffold for aortic tri-leaflet heart valve reconstructions.

Last month, Admedus began an 80-patient, European and US clinical study of Cardiocel for aortic tri-leaflet heart valve reconstructions, following the sheep study using Cardiocel for aortic stenosis, or narrowing, in conjunction with Leuven, Belgium-based Katholieke Universiteit Leuven University (BD: Sep 23, 2015).

Today, Admedus said the data was presented by the University's lead researcher Prof Bart Meuris at the European Association for Cardiothoracic Surgery meeting in Amsterdam on October 5, 2015.

The company said that the study examined nine leaflets replaced in three sheep, with no calcification or minimal calcification detected, and minimal calcification seen around the sutures and at a join; the valves were competent, demonstrating positive haemodynamics, with no leakage and excellent joining of the leaflets post reconstruction.

"The results from the study are very positive and some of the best results we have seen in this model," Prof Meuris said.

Admedus said that after six months, new collagen had formed on both sides of the leaflet as a clear sign of post-surgery remodelling around Cardiocel, with host fibroblasts detected within the Cardiocel bio-scaffold.

The company said that six months in sheep was representative of more than 10 years of data in adult patients and the results showed that Cardiocel had clear advantages over replacement of the aortic valve or reconstruction with other tissues.

Admedus said that the study showed successful valve reconstructions and supported the use of Cardiocel in the complete reconstruction of aortic heart valves to address the disadvantages found with existing bio-prosthetic valves.

Admedus was up 0.1 cents or 1.6 percent to 6.5 cents with 4.6 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says it has replied to a major investor that has criticized the proposed merger with the Tel Aviv, Israel-based Valtech Cardio.

In September, Heartware announced the agreement to acquire the Tel Aviv, Israel-based Valtech which develops devices for mitral valve and tricuspid valve regurgitation for about $1.2 billion (BD: Sep 2, 2015).

Overnight, Heartware said “we respectfully disagree with Engaged Capital, which has been a Heartware investor for just a few weeks and we believe their analysis is incomplete”.

The Newport Beach, California-based Engaged Capital did not post its comments on its website, but had a link to a copy of the Wall Street Journal dated October 5, 2015.

The Wall Street Journal article carried the headline ‘Engaged Capital Opposes Heartware Deal for Valtech Cardio’ and the sub-headline ‘Activist investor wants company to instead consider selling itself’.

The article said that “an activist investor wants to stop Heartware International Inc’s attempt to broaden its business through a deal that’s worth roughly its current value” and said that Engaged wanted Heartware to abandon the merger.

Heartware said it remained “fully committed to this strategic transaction”.

“Our position is informed by our deep experience in the advanced heart failure market, the years of diligence we conducted on the mitral and tricuspid valve regurgitation markets and the company's unique perspective on Valtech gained through our investment since 2013,” Heartware said.

“Valtech's differentiated mitral and tricuspid repair and replacement platform deepens our leadership in the advanced heart failure market and establishes us as a dynamic player in two of the highest-growth categories in this market today,” Heartware said.

“The acquisition positions Heartware for significantly accelerated revenue growth and provides a platform to expand our margin profile substantially over time,” the company said.

“Since announcing the transaction, we have received overwhelmingly positive feedback from physicians who are excited about Valtech's Cardioband, which recently received [Conformité Européenne] mark approval and the combination of Heartware and Valtech,” Heartware said.

“We are confident this acquisition will deliver significantly greater value to shareholders and patients alike than could be achieved through Engaged capital's recommended alternatives,” the company said.

“We are in active discussions with our shareholders to educate them on the strategic and financial merits of the transaction,” Heartware said.

Last night on the Nasdaq, Heartware climbed $US1.81 or 3.34 percent to $55.94 ($A78.59, equivalent to $2.245 before it left the ASX) with 913,910 shares traded.

REVA MEDICAL

Reva says the Senrigan Master Fund has become a substantial shareholder in the company, with the equivalent to 57,652,301 Chess depository instruments (15.1%).

Reva said that the Central, Hong Kong-based Senrigan held 13,902,301 Chess depository instruments (CDIs) and 4,375,000 US shares equivalent to 43,750,000 CDIs.

The substantial shareholder notice did not provide a contact name or address for Senrigan and failed to disclose the cost of the shares.

Reva was unchanged at 80 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that Kevin Fischer has been appointed to replace chief financial officer Brian Manuel, with the position effective from November 2, 2015.
Genetic Technologies said that following a transition period, Mr Fischer would replace Mr Manuel, who was “leaving to pursue a personal business opportunity but will remain with the company until the end of October 2015 to facilitate an effective handover” and Mr Fischer would be appointed as joint company secretary.
The company said that Mr Fischer had more than 10 years in senior finance roles with diagnostic companies, including Qiagen and Cellestis.
Genetic Technologies thanked Mr Manuel “for his significant contribution to the company”.
Genetic Technologies was unchanged at two cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its October 20, 2015 Bio-Briefing will tour the Trajan Scientific and Medical facility in Ringwood.
The Network said that the tour and briefing, entitled ‘Quality Initiatives; Transformation and Training for Building Business Value’, would explore quality initiatives for manufacturing transformation and reducing errors through best practice training.
The Network said the briefing would provide an opportunity to hear from two speakers on quality initiatives for manufacturing transformation and reducing errors through best practice training.
The Bio-Melbourne Network said that commitment to quality management was “essential for achieving business objectives” in biotechnology and medical technology.
Bio-Melbourne Network chief executive officer Dr Krystal Evans said that “managing quality assurance and quality control are key”.
The Network said the speakers would include Seerpharma senior consultant and training manager David Spaulding and Trajan Scientific and Medical’s general manager of glass technologies Steven van Winckel.
The October 20, 2015 Bio-Briefing will be held at the Trajan Scientific and Medical, 7 Argent Place, Ringwood with registration from 3.45pm for the Bio-Briefing from 4pm to 5pm followed by a networking session.
To register go to: http://www.biomelbourne.org/events/view/389.