Biotech Daily

Wednesday March 16, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENETIC TECHNO UP 5%, ANTEO DOWN 11%**

*** GI DYNAMICS TO APPLY TO FDA FOR NEW ENDOBARRIER TRIAL**

*** CVC: 'REMOVE BIONOMICS GRAEME KAUFMAN, TREVOR TAPPENDEN'**

*** NUSEP RAISES $1.1m, $1.8m SHORTFALL TO BE PLACED**

*** PRIMA IMP321, ADJUVANT FOR MELANOMA 'INDUCES T-CELL RESPONSE'**

*** PSIVIDA MEDIDUR DATA SHOWS SMALL INCREASE IN IOP**

*** ITL MYHEALTHTEST JOINS HCF CATALYST INCUBATOR**

*** 3D, MACH 7 DISTRIBUTION DEAL WITH SOUTH AFRICA'S INTRIHEALTH**

*** TISSUE THERAPIES 'CAPITAL RAISING' TRADING HALT**

*** M-D PAUL RENNIE, KZEE, EAR TAKES 25% OF PARADIGM**

*** DR JEF VANGENECHTEN TO REPLACE ANTEO CEO DR GEOFF CUMMING**

*** ARTHUR CHARLAFTIS, KOS SCLAVOS, MIKE DA GAMA JOIN MEDADVISOR**

MARKET REPORT

The Australian stock market edged up 0.15 percent on Wednesday March 16, 2016 with the ASX200 up 7.6 points to 5,119.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and five were untraded.

Genetic Technologies was the best, up 0.1 cents or 5.3 percent to two cents with 2.8 million shares traded. Oncosil and Uscom were up more than three percent; Living Cell and Mesoblast rose more than two percent; Acrux, Impedimed, Medical Developments and Polynovo were up more than one percent; with Clinuvel, Cochlear, Psivida and Reva up by less than one percent.

Anteo led the falls, down 0.6 cents or 11.3 percent to 4.7 cents with 10.3 million shares traded. Cellmid lost 10 percent; Avita, Benitec, Universal Biosensors and Viralytics fell four percent or more; Starpharma was down 3.05 percent; Admedus, Biotron, Ellex, IDT, Pro Medicus and Resmed were down more than one percent; with CSL, Nanosonics and Sirtex down by less than one percent.

GI DYNAMICS

GI Dynamics says that data from its Endo trial supports the pursuit of a new US Food and Drug Administration investigational device exemption trial.

Last year, GI Dynamics terminated the planned 500-patient trial with 325 patients enrolled, following seven cases of hepatic abscess, and yesterday said the pivotal trial for obesity and type 2 diabetes failed to meet its primary safety and efficacy endpoints (BD: Jul 30, 31, 2015; Mar 15, 2016).

Today, GI Dynamics chairman Jack Meyer told an investor teleconference that despite missing the Endobarrier trial's primary safety and efficacy endpoints there was sufficient data to show "statistically significant" benefits in reduction of blood glucose HbA1C levels and weight loss.

Mr Meyer refused to release the "p" significance values, saying that publishing the data to investors and the public would compromise clinicians' abilities to publish the final data in peer-reviewed journals.

Mr Meyer did not specify the number of patients receiving the Endobarrier and followed up for 12 months, not the number of "sham" controls, who had an endoscopic procedure but without the implantation of any device in their duodena.

Asked for the numbers of trial patients providing 12 month data, Mr Meyer said that the patients had been randomized two-to-one.

Mr Meyer said that there was an average 0.71 percentage points reduction in HbA1C blood glucose levels for the active Endobarrier group compared to the sham controls.

Mr Meyer said that 60.7 percent of the Endobarrier cohort achieved an average weight loss of equal to or more than five percent, compared to the sham cohort's 20.3 percent.

Mr Meyer said that the data was not complete because apart from closing the trial early with a reduced number of patients, many of the enrolled and randomized patients had the Endobarrier removed without 12-months of review.

GI Dynamics director Dan Moore told the teleconference that the company had learned from the Endo trial and expected to design a new trial that would win an FDA investigational device exemption approval.

"We believe if we enrolled 500 [patients] or had data on all the enrolled patients, we would have hit the primary and secondary endpoints," Mr Moore said.

Mr Meyer said that most of the weight loss and reduction in blood glucose was in the early months post-implantation, with a plateau between six and nine months.

Mr Meyer said that the hepatic abscesses bacterial liver infections occurred after the nine month point so modifying the trial protocol to remove the Endobarrier at nine months could help resolve that issue.

He said that a reduction in proton pump inhibitor drugs and the use of prophylactic antibiotics could be considered for a new trial protocol.

Mr Meyer said that GI Dynamics was working with the regulators to find sites that would accept a new trial protocol, which he described as an "algorithm".

"The priority is FDA approval for a new trial IDE," Mr Meyer said.

Mr Meyer said GI Dynamics had $20 million at December 31, 2015 which was "enough to get through 2016 but conducting another trial would require another fund raise".

GI Dynamics raised $80 million in its initial public offer in 2011, a further $57.5 million in 2013 and $34 million in 2014 (BD: Aug 30, 2011; Jul 3, 2013; May 2, 2014).

The company "separated" chief financial officer Bob Crane in 2014, sacked its chief medical officer Dr David Maggs in 2015 and today said that chief executive officer Mike Dale who replaced chief executive officer Stuart Randle in August 2014 would finish with the company today (BD: Aug 29, Dec 9, 2014; Jun 19, 2015).

GI Dynamics climbed 0.6 cents or 30 percent to 2.6 cents with 3.7 million shares traded.

BIONOMICS

The Sydney-based CVC has called for the removal of Bionomics chairman Graeme Kaufman and director Trevor Tappenden.

In an announcement entitled ‘Notice Under Section 203D’ Bionomics said that it was “considering its response to the notice and its contents”.

Earlier this month, a Bionomics general meeting voted 188.4 million votes (64.1%) against resolutions to approve 16,082,988 warrants to four investment groups, with 105.3 million votes (35.9%) in favour (BD: Mar 3, 2016).

Bionomics proposed issuing warrants over 4,020,747 shares to each of the four groups, CVI Investments, Empery Asset Master, Sabby Healthcare and Biotechnology Value Fund, exercisable at 59.38 cents a share within five years of issue.

Last year, Bionomics raised $16,404,649 at 40.8 cents a share for a phase II trial of BNC210 for post-traumatic stress disorder, when it had been trading around 48 cents, which led to complaints from investors about the 15 percent discount (BD: Dec 8, 2015).

Today, Bionomics said it had begun “a consultation process to consider the views of shareholders as to the governance arrangements and future direction of the company … [and was] working to bring additional skills to the board through an on-going recruitment process”.

CVC said that under section 203D(2) of the Corporations Act 2001 it was its intention to call an extraordinary general meeting to be held no earlier than two months from the notice to vote on the immediate removal of Mr Kaufman and Mr Tappenden.

CVC said it would propose a resolution to remove any other directors appointed by the board between the dates of this notice and the general meeting inclusive.

CVC said it held more than five percent of the votes that may be cast at a general meeting and would requisition the meeting at its own and not Bionomics cost, as permitted under section 249F of the Corporations Act.

“CVC does not take this action lightly, but considers that under the stewardship of the incumbent board there has been a series of fundamentally flawed decisions which have led to a significant erosion in shareholder value, have been materially prejudicial to the company's current and in many instances longstanding and supportive shareholders and have displayed a lack of financial and strategic competence to the material detriment of all the company's stakeholders,” the company said.

“This must change and the directors must be held accountable,” CVC said.

“Further, it would be unnecessary and misdirected for the same incumbent board to oversee an expensive international search process for more new directors not aligned with the interests of current shareholders,” CVC said.

CVC said it intended to propose the appointment of new, financially and strategically competent and more shareholder-aligned replacement directors.

“CVC reminds the board, board-appointed advisers and shareholders that the resources of the company must not be used to advance and promote the tenure of existing directors,” the company said.

“In the event of action by the board which is directed towards buttressing incumbent-director control of the company, rather than being for the real benefit of shareholders, CVC intends to seek appropriate relief to protect the interests of shareholders,” CVC said.

The CVC request was signed by director Alexander Beard.

Last month CVC became substantial in Bionomics with 24,901,120 shares or 5.18 percent of the company, buying 10,000,000 shares on-market at 33.1 cents a share.

CVC is a substantial shareholder in Cyclopharm and Mr Beard was previously a director of Cyclopharm.

Bionomics was unchanged at 29 cents.

NUSEP HOLDINGS

Nusep says it has raised $1,059,146 in a fully-underwritten non-renounceable rights issue at one cent a share, leaving a shortfall of $1,787,024 to be placed by the underwriter.
Nusep said that each new share came with an attaching option exercisable at 1.6 cents by November 30, 2016 and that when the shortfall was placed by the underwriter Transocean Securities it would raise a total of $2,846,170.
Nusep was unchanged at one cent.

PRIMA BIOMED

Prima says an investigator-led trial of IMP321 with an adjuvant to a therapeutic vaccine for melanoma induced a T-cell response in all 16 patients.
Prima said that the vaccine trial investigated the combination of five different melanoma peptide antigens together with the adjuvants IMP321 and Montanide which aimed to boost longer term immune responses.
The company said that mild side effects were observed consistent with Montanide alone and of the 16 patients receiving the IMP321 combination, 81 percent experienced antigen specific CD8 responses and 100 percent experienced antigen specific CD4 responses to at least one peptide.
Prima said that the trial was “a long-standing academic collaboration” between its chief scientific officer and Immutep founder Dr Frédéric Triebel and scientists at the Ludwig Centre for Cancer Research at the University of Lausanne, Switzerland.
Prima acquired IMP321 with Immutep in 2014, but does not appear to have mentioned the melanoma trial (BD: Oct 2, 2014).
Today, Prima said that the research paper was entitled, ‘Vaccination with sLAG-3-Ig (IMP321) and peptides induces specific CD4 and CD8 T-cell responses in metastatic melanoma patients: report of a phase I/IIa clinical trial’ was published in the journal Clinical Cancer Research and an abstract of the article is available at: http://clincancerres.aacrjournals.org/content/early/2015/10/23/1078-0432.CCR-15-1212.
The company quoted lead investigator Prof Daniel Speiser saying that it was “remarkable that serial vaccinations induced antigen specific T-cell responses in all 16 vaccinated melanoma patients”.
“We are very encouraged by the results from this second collaborative study using IMP321 as an adjuvant to boost our peptide vaccine effectiveness, which support the further development of peptide vaccines as part of a combination approach to treating cancer,” Prof Speiser said.
Dr Triebel said the trial “demonstrated additional safety and immune monitoring data on IMP321 in this vaccine adjuvant setting”.
“This is another clear demonstration of the potency of IMP321 as an antigen presenting cell activator able to boost tumor-specific T cells,” Dr Triebel said.
Prima said that the phase I/II trial was designed with a primary endpoint to measure cancer antigen specific immune responses in metastatic melanoma and to assess the safety of the combination of a low IMP321 dose to cause a local antigen presenting cell booster effect at the vaccine site, with the vaccine adjuvant Montanide together with the melanoma antigens.
The company said that the Australian phase I two active immunotherapies in melanoma (Tactimel) study would investigate the safety of much higher doses of IMP321 to cause a systemic antigen presenting cell booster effect, in combination with a PD-1 immune check point inhibitor.
Prima was unchanged at 4.2 cents.

PSIVIDA CORP

Psivida says that further analysis of six-month safety data from its first phase III trial of Medidur for posterior uveitis shows “a small average increase in intraocular pressure”.
Psivida chief executive officer Dr Paul Ashton said that the average increase in intraocular pressure for Medidur-treated eyes was “lower than that observed in the same period in the clinical trials for Ozurdex and Retisert, the two FDA-approved sustained release treatments for posterior uveitis”.
Psivida said that intraocular pressure in Medidur-treated eyes increased on average 1.1mmHg more than control eyes, with an intraocular pressure (IOP) of 1.8mmHg compared to 0.7mmHg.
The company said that the percentage of eyes requiring treatment with eye drops for intraocular pressure was comparable between Medidur and control eyes.
Psivida said that “only one percent” more Medidur-treated eyes than control eyes received treatment with eye drops for elevated intraocular pressure, with 19 percent compared to 18 percent over six months.
Dr Ashton said the new safety data showed “a small average increase in IOP for Medidur treatment relative to control and comparable incidence of treatment with eye drops for IOP in both groups”.
“Our first trial also showed Medidur to be highly effective,” Dr Ashton said.
“We earlier reported that this trial achieved its primary end point, prevention of recurrence of disease at six months, with high statistical significance [of] p less than 0.0000001, Dr Ashton said (BD: Jan 25, 2016).
Psivida said it planned to meet with the US Food and Drug Administration by July 2016 to discuss the first phase III trial results and to confirm that data from two trials would continue to be required for a US new drug application currently planned by July 2017.
The company said that as a result of the high statistical significance achieved in the first phase III trial, it planned to file for European Union marketing approval based on data from the single trial in late 2016.
Psivida was up two cents or 0.5 percent to $3.87.

ITL

ITL says its Myhealthtest direct-to-consumer pathology test provider has been accepted into HCF’s inaugural health technology accelerator program, Catalyst.
ITL said that the New South Wales-founded HCF (previously the Metropolitan Hospitals Contribution Fund) was Australia’s largest not-for-profit health fund with more than 1.5 million members.
The company said that the Catalyst program was designed to identify and support Australian start-up and scale-up businesses creating technologies that improved the health care system.
ITL said that, under the guidance of the accelerator program, its Myhealthtest wholly-owned subsidiary was developing products and services that would provide better health outcomes for the community.
The company said that the Myhealthtest HbA1c test for the management and diagnosis of diabetes, as well as the tests in the pipeline, could be a useful service to HCF members.
HCF chief strategy officer Sheena Jack said her company had “a longstanding reputation as an innovator, so it is only fitting that we create new ways to nurture the people and ideas that will drive the next wave of health-tech innovation”.
ITL was up half a cent or 2.4 percent to 21 cents.

3D MEDICAL

3D Medical says that merger partner Mach7 has a five-year distribution agreement with the Johannesburg, South Africa-based Intrihealth.
3D said that Intrihealth would distribute the Mach7 Enterprise Imaging Platform across 40 diagnostic sites in South Africa and generate monthly revenue based on the number of diagnostic images.
Intrihealth's website said the company was "the leading diagnostics … provider in Africa, specialising in the long-term storage of clinical exam data across all imaging platforms".
3D said that Intrihealth selected the Mach7 imaging platform as the underlying software technology to provide standardization, scalability and vendor neutral archive functionality to its hosted medical image management platform.
3D was up 0.1 cents or 1.7 percent to six cents.

TISSUE THERAPIES

Tissue Therapies has requested a trading halt "pending an announcement regarding a proposed capital raising, including a placement".
Trading will resume on March 18, 2016 or on an earlier announcement.
Tissue Therapies last traded at 4.7 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm managing-director Paul Rennie says he has increased his holding in Paradigm from 21,214,543 shares (24.22%) to 21,547,876 shares (24.60%).
Mr Rennie said that the investment was with Kzee Pty Ltd and Ear Investments and on March 10, 2016 the group bought 333,333 shares on-market for $99,999.90 or 30 cents a share.
Paradigm was up half a cent or 1.6 percent to 31 cents.

ANTEO DIAGNOSTICS

Anteo says that chief executive officer Dr Geoff Cumming intends to retire and Dr Jef Vangenechten has been appointed as chief executive officer.
Anteo said that Dr Cumming joined the company in 2009 and will continue as a director until September 16, 2016, through the transition of chief executive officer and the recruitment of a chief operating officer and chief financial officer.
The company said that Dr Vangenechten was currently the chief executive officer of Diasource Immunoassays SA and had agreed to take the combined role of global chief executive officer, effective from June 1, 2016.
Anteo said that Dr Vangenechten was "a veteran of the bio-technology industry in Europe and held a Doctorate of Philosophy in biology and physiology.
The company said that Dr Vangenechten would be based in Brussels and travel to Brisbane where the research and development would remain based.
Anteo chairman Mark Bouris said that Dr Cumming had led the company since 2009 and "was instrumental in bringing about the recent acquisition of Belgian-based diagnostics company, Diasource Immunoassays SA and raising the necessary funds".
"These achievements will be pivotal in seeing Anteo move toward a cash flow positive position," Mr Bouris said.
Anteo fell 0.6 cents or 11.3 percent to 4.7 cents with 10.3 million shares traded.

MEDADVISOR

Medadvisor says it has appointed Arthur Charlaftis, Kos Sclavos and Mike da Gama to its advisory board.

Medadvisor said that REA Group chief operating officer Mr Charlaftis, Pharmacy Guild of Australia (Queensland) vice-president Mr Sclavos and Nostradata executive director Mr da Gama brought “years of experience and thought leadership in the pharmacy and pharmaceutical fields” and would offer strategic counsel as the company commercialized its connected health platform.

Medadvisor chief executive officer Robert Read said that “having access to the right talent and experience is a valuable asset to the management and board”.

“Mr Charlaftis will be instrumental in helping drive further development of the Medadvisor platform and generating even greater engagement with consumers, and Mr Sclavos brings to the position a wealth of experience in the pharmacy industry and will enable the company to leverage new opportunities with pharmacies Australia-wide, as well as providing guidance on future programs focused on improving health outcomes for patients,” Mr Read said.

“We are also very pleased to welcome Mr da Gama to the advisory board, where his highly valuable pharmaceutical industry and data analysis experience will help lead Medadvisor’s penetration into multiple revenue generating channels,” Mr Read said.

The company said that Mr Charlaftis was a former Glaxosmithkline Australia vice president and held senior roles at Eli Lilly.

Medadvisor said that Mr Sclavos was a former president of the Pharmacy Guild of Australia.

The company said that Mr da Gama was previously a director of Medadvisor International, assisting with governance and pharmacy integration and had sales and marketing experience at Glaxosmithkline Australia and Arrow Pharmaceuticals.

Medadvisor was unchanged at 3.6 cents with 1.6 million shares traded.