Biotech Daily

Thursday October 2, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC TECH UP 18%, GI DYNAMICS DOWN 8%**

*** BERGEN HELPS PRIMA ACQUIRE IMMUTEP FOR $32m CASH, SCRIP**

*** T-CELL RESPONSE TAKES ADMEDUS HSV-2 VACCINE TO PHASE II**

*** ANSELL READY TO MARKET STARPHARMA VIVAGEL CONDOM**

*** REVA SAYS FANTOM STENT WILL BE SUPERIOR TO COMPETITORS**

*** GENERA, BECKMAN COULTER AGREEMENT, RICHARD HANNEBERY CEO**

*** BIO-MELBOURNE DEVICES, DIAGNOSTICS PARTNERING FORUM**

*** NARHEX FROM HIV, COAL, GOLD, DIAMONDS TO RESPIRATORY 'APPS'**

*** BIOTA'S DR JOSEPH PATTI STARTS ON $571k, RUSSELL PLUMB ON $286k**

*** PHARMAUST PPL-1 DOG CANCER TRIAL BEGINS**

*** HEALTHLINX ACQUIRES MANALTO SOCIAL MEDIA BUSINESS**

*** CIRCADIAN REQUESTS 'FUNDING EVENT' TRADING HALT**

*** BIOPROSPECT REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.68 percent on Thursday October 2, 2014 with the S&P ASX 200 down 36.4 points to 5,297.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and six were untraded.

Genetic Technologies was the best, up 0.4 cents or 18.2 percent to 2.6 cents with 396,142 shares traded. Compumedics climbed 8.3 percent; Cellmid and Prima were up more than seven percent; Viralytics was up 6.7 percent; Antisense and Pharmaxis were up four percent or more; Neuren and Starpharma were up more than three percent; Biotron rose two percent; with Medical Developments up 0.9 percent.

GI Dynamics led the falls, down four cents or 8.3 percent to 44 cents with 49,200 shares traded. Optiscan lost 7.9 percent; both Acrux and Patrys were down 5.3 percent; Alchemia, Clinuvel, Oncosil, Psivida and Tissue Therapies fell more than four percent; Admedus, Impedimed and Nanosonics lost more than three percent; Atcor and Mesoblast shed more than two percent; Benitec, Bionomics, Living Cell, Phosphagenics, Resmed and Sirtex lost one percent or more; with Cochlear and CSL down less than one percent.

PRIMA BIOMED

Prima says that Bergen will fund the acquisition of French immuno-oncology company Immutep SA for about $US28 million ($A32 million) in cash, shares and warrants.

Prima said that, pending shareholder approval, it would acquire the late stage, privately owned, Immutep through an investment agreement with the New York-based Bergen Global Opportunity Fund, for Immutep's complementary types of cancer immuno-therapies based on its lymphocyte activation gene 3 (LAG-3) technology.

The company said that lead product IMP321 had been tested alone and in combination with other therapies in clinical trials and Immutep held the world-wide rights excluding China and Taiwan, to commercialize IMP321.

Prima said that the trials included chemo-immunotherapy, combining immunotherapy and chemotherapy which significantly enhanced patients' immune response to cancers.

The company said that the completed phase II trial of IMP321 in metastatic breast cancer demonstrated a doubling of the tumor response rate in 30 patients treated with chemo-immunotherapy versus chemotherapy alone.

Prima said that planning for a new phase II clinical trial program with IMP321 in chemo-immunotherapy or in other combinations would begin on completion of the transaction.

The company said that the Prima-Immutep agreement provided up to $US18 million in cash, partly based on milestones; the issue of Prima shares totalling about $US3 million and based on a volume weighted average price calculation; and the issue of 200 million warrants equating to about $US7 million.

Prima said that to fund the acquisition and provide working capital, it had secured an investment agreement with Bergen for up to $US37.4 million over a 24-month period,

Prima chair Lucy Turnbull said it was the announcement was Prima's most significant.

"It is the result of a long and diligent search process led by new chief executive Marc Voigt as part of our business development program," Ms Turnbull said.

"It considerably strengthens our position in immuno-oncology, which is forecast to grow to a $US35 billion industry by 2023," Ms Turnbull said.

"It significantly expands our clinical development product portfolio to other categories of immunotherapies beyond cancer vaccines, which includes our current lead product CVac," Ms Turnbull said.

"It also provides us with partnerships with several of the world's largest pharmaceutical companies," Ms Turnbull said.

Prima said that Immutep's development partnerships included a phase II chemo-immunotherapy trial combining IMP321 with first line chemotherapy for metastatic breast cancer in partnership with China's Eddingpharm; a phase I clinical trial program of IMP731in auto-immune diseases in partnership with Glaxosmithkline with potential milestone payments of up to$US100 million and royalties; and an immune checkpoint blocker pre-clinical program of IMP701 in cancer immunotherapy partnered with the Novartis owned Costim.

The company said that Immutep generated "modest revenues" from commercial sales of LAG-3 research reagents.

Mr Voigt said the acquisition provided diverse pipeline of early and mid-stage development candidates and the opportunity to develop other pre-clinical candidates.

Prima said that Immutep had a research and development laboratory outside Paris where additional research projects for its LAG-3 technology were being explored and the company had 11 patent families covering its technology.

Prima said that Immutep founder Prof Frédéric Triebel would be appointed chief scientific officer to oversee the LAG-3 development program and advise on CVac.

Prima was up 0.3 cents or 7.9 percent to 4.1 cents with 37.9 million shares traded.

ADMEDUS

Admedus says its phase I herpes simplex virus 2 vaccine study met its primary endpoint of safety, with 19 of the 20 subjects meeting the T-cell positive response endpoint.

Admedus said that the T-cell responses supported taking the vaccine into a phase II study

Admedus chief executive officer Lee Rodne said that the “clean safety profile and cellular immune responses demonstrated in this HSV-2 study are particularly encouraging and validate the potential of our range of therapeutic vaccines”.

Admedus chief scientific officer Prof Ian Frazer said that the “strong dose-dependent cellular immune responses observed, following intradermal injection of the HSV-2 vaccine in this study, were as expected with this vaccine technology”.

The company said that the 20-patient phase I study was undertaken in healthy volunteers who were confirmed sero-negative for the herpes simplex virus 2 (HSV-2), with subjects screened prior to vaccination, in 10mcg, 30mcg, 100mcg, 300mcg and 1,000mcg doses.

Admedus said that the purpose of the study was to explore safety, as well as to examine any immune response and 19 of the 20 study subjects generated a positive T-cell response (HSV-2 cell-mediated immunity) as defined in the clinical trial protocol.

The company said that one subject receiving the 100mcg dose did not show an immune response.

Admedus said that the cell-mediated immunity response shown in the study, where the study subjects had no previous HSV-2 infection, demonstrated utility of the vaccine.

The company said that through the study, the three intradermal injections of the vaccine were found to be safe and well tolerated with some local redness being observed post injection which dissipated over time.

Admedus said that minor adverse events were reported but considered unrelated to the vaccine, with one serious adverse event reported, also unrelated to the vaccine.

The company said that there was a local immune response at the site of injection, a delayed-type hypersensitivity response, 24 and 48 hours after each vaccination.

Admedus said that the results showed “a clear dose response over the three injections and illustrated that patients confirmed to be sero-negative for HSV-2 had generated an immune response to the vaccine”.

The company said that delayed-type hypersensitivity response was a cell-mediated response and the cascade of events initiated by the T-cells leads to hardening and redness at the injection site, which was clearly evident in these study subjects.

Admedus said that third party assays testing for antibody activation found no significant antibody responses, but additional antibody assays undertaken by Prof Frazer and his team showed that antibodies against HSV-2 were present, suggesting the results for antibodies were inconclusive and would be explored further in the phase II study.

The company said that the results demonstrated that anti-DNA antibodies, post-vaccination, were not present, indicating no unwanted immune response by the study subjects to the vaccine.

Admedus said that the safety profile and the detected immune response provided the basis for the company to select appropriate vaccine doses to progress the therapeutic vaccine into a phase II study in individuals suffering recurrent genital lesions.

The company said that the phase II study was expected to begin by the end of this year.

Admedus said that there was no cure for herpes and incidence was high, with one in six people in the US between the age of 14 and 49 with the infection.

“We are looking forward to advancing our HSV-2 vaccine into a phase II clinical study later this year,” Mr Rodne said. “We will continue advancing our vaccines to treat human papillomavirus and cervical cancer.”

Admedus fell half a cent or 3.45 percent to 14 cents with 6.7 million shares traded.

STARPHARMA

Starpharma says that the Ansell condom with its Vivagel coating has been added to the Australian Register of Therapeutic Goods, the final step to a market launch in Australia.
Starpharma said that Ansell would launch the condom under the 'Lifestyles Dual Protect' name in Australian retail outlets this month.
The company said that the Vivagel condom was "a world-first product based on innovative Australian technology ... [and] the only condom of its type, providing barrier protection and also incorporating an antiviral compound, Vivagel, in the lubricant".
Starpharma said that the Lifestyles Dual Protect condoms would carry the Vivagel brand and Starpharma would receive royalties based on sales.
Starpharma chief executive officer Dr Jackie Fairley said the company was "pleased to achieve this final milestone ahead of launch".
"Following certification of the Vivagel condom by the [Australian Therapeutic Goods Administration], there was extensive global media coverage and strong commercial and consumer interest in the product," Dr Fairley said.
"The reaction on social media was quite extraordinary with the product reaching an audience of more than 10 million in the days following the announcement through extensive positive social media commentary," Dr Fairley said.
Dr Fairley said the launch would be the first marketed product for Vivagel and the first of three women's health Vivagel products.
Starpharma was up two cents or three percent to 68 cents.

REVA MEDICAL

Reva says its Fantom coronary scaffold is superior to current competitors and hopes to have Conformité Européenne (CE) mark approval in 2016.
In a teleconference detailing the $US25 million convertible notes arrangement with Goldman Sachs International and the Hong Kong-based Senrigan Master Fund, Reva chief executive officer Robert Stockman said that he expected the first Fantom implant "before year end" in its trial of up to 125 patients.
Mr Stockman said that if successful, Reva would apply for CE mark approval in 2016 and hoped to receive approval and launch in that year.
Mr Stockman said that the lead competitor Abbott Laboratories was expected to begin its clinical trial in 2016, giving Reva an opportunity to enter the multi-billion dollar stent and scaffold market.
Mr Stockman said that the Fantom scaffold had "very distinctive features and benefits the competition do not have today and will be very difficult to match".
He said that Reva's polymers were designed to have the strength and visibility during procedures equal to metal stents, but with the benefit of bio-resorbability.
"Our competitors are not able to incorporate full visibility," Mr Stockman said.
Mr Stockman said that along with its greater strength and one-step inflation, "the new device is considerably thinner".
Last week, Reva said it would raise up to $US48.2 million ($A54.9 million) through the issue of convertible notes and options to Goldman Sachs and Senrigan, with each taking half of the $US25 million in convertible notes with the 8,750,000 in attaching options raising up to $US23.2 million. (BD: Sep 26, 2014).
Today, Reva chief financial officer Katrina Thompson told the teleconference that at current exchange rates and pending certain conversion conditions, Goldman Sachs and Senrigan would each own about 19 percent of the company.
Reva fell five cents or 20 percent to 20 cents.

GENERA BIOSYSTEMS

Genera says it has a strategic commercial collaboration with Beckman Coulter Life Sciences and has appointed Richard Hannebery as chief executive officer.

Genera said that Beckman Coulter developed flow cytometry-based instrumentation systems that simplify and automate complex biomedical testing.

The company said the collaboration would work together with the initial objective of integrating the Paptype human papillomavirus (HPV) assay on a Beckman Coulter flow cytometry platform and then Genera would complete its 6,000 patient HPV screening study with the Wolfson Institute in London with the Beckman Coulter instrumentation.

Genera said that following successful integration of Paptype, it would integrate its RTI-Plex and STI-Plex assays on the Beckman Coulter platform and both companies had agreed to explore further expansion of the Genera Ampasand platform with Beckman Coulter's instrumentation platform.

Genera chairman Lou Panaccio said the company had been in discussions with Beckman Coulter "for a substantial period with a view to integrating our Ampasand based tests with their world leading instrumentation systems".

"While Genera's Ampasand based [molecular diagnostics] platform is, to a large degree, instrument agnostic, successful global commercialization is reliant on access to an instrumentation platform with operating characteristics and in-market technical support that meet the requirements of commercial pathology laboratories," Mr Panaccio said.

"Beckman Coulter is an ideal partner for Genera with instrumentation capabilities that are second to none and we believe that the strategic and cultural fit between our respective groups is outstanding," Mr Panaccio said

Genera said that Mr Hannebery was a director from 2005 to 2008, prior to the company's listing on ASX and was the corporate development director responsible for the initial agreements struck with both Healthscope and Sonic Healthcare.

The company said the Mr Hannebery rejoined the company in 2013 to resume the role and help drive the commercialization strategy (BD: May 14, 2013).

Genera was up half a cent or 1.85 percent to 27.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold a devices and diagnostics partnering forum on October 21, 2014.

The Network said that the forum, hosted by Piper Alderman and entitled 'Positioning for Partnership: Engaging with Medtech Multinationals', followed last year's Device and Diagnostics Partnering Forum and would provide "access to some of the largest players in medical technology".

The Bio-Melbourne Network said that knowing how to attract the attention of larger device companies can make the difference between success and failure for smaller companies.

The Network said that the forum would cover who to contact and at what stage of development, what the larger companies want and what they can provide and what are the key areas of interest and what would be attractive to larger companies.

Speakers include GE Healthcare Australia research manager, Dr Tim O'Meara, Cook Medical research and development director Dr Samih Nabulsi, Sorin Group partnerships managing director Elise Hogan and Device Technologies general manager Mick Shaddock.

The forum will be held at Piper Alderman, Level 23, 385 Bourke Street, Melbourne on October 21, 2014, with registration from 8.30am and the forum from 9am to 12.30pm.

To register go to: http://www.biomelbourne.org/events/view/336.

NARHEX LIFE SCIENCES

Narhex says it has a binding heads of agreement to acquire Resapp Diagnostics for 250,000,000 ordinary shares and 250,000,000 milestone shares.

Narhex said that Resapp had an exclusive licence from the University of Queensland to develop mobile telephone medical applications for the diagnosis and management of respiratory disease, based on a machine learning algorithm that used sound alone to diagnose and measure the severity of respiratory conditions.

The company said that the algorithm had been tested for pneumonia and asthma diagnosis in a clinical proof of concept study of 91 patients by the University of Queensland through funding from the Bill and Melinda Gates Foundation.

Narhex said that the trial demonstrated 96 percent and 90 percent accuracy for the diagnosis of pneumonia and asthma, respectively.

The company said that Resapp would target pneumonia, bronchitis, chronic obstructive pulmonary disease and asthma.

Narhex said that the technology sought to capitalize on the rise of tele-health consultations in the US, with 10 million tele-health consultations in the US in 2012, expected to grow to 75 million in 2014.

The company said it hoped to complete a US Food and Drug Administration clinical trial and launch an approved product in 2016.

Narhex said that “Resapp’s vision is to empower consumers to self-diagnose and manage respiratory disease by providing effective, affordable and practical [mobile telephone] health [applications]”.

The company said that the 250,000,000 milestone shares would be issued pro rata to the Resapp shareholders within seven days of Resapp or the company achieving $20 million in gross revenues or an acquisition event by Narhex.

Narhex said that the agreement was subject to due diligence, regulatory approvals, final documentation and shareholder approvals.

The company said it hoped to raise $750,000 in a placement of 150,000,000 shares at 0.5 cents a share, with one free attaching option for every two shares subscribed for in the placement, exercisable at one cent by December 31, 2016, to be used for working capital, continued assessment of the company’s West Africa opportunities and re-compliance with chapters 1 & 2 of the ASX Listing Rules.

Narhex was originally developing DG17 and DG35 for HIV, but was suspended from trading in March, 2008 for failing to lodge its half-yearly accounts (BD: Jul 17, 2009).

In 2010, administrators were appointed and in 2011 Narhex said it would go coal mining in Central Queensland, announcing later that year that it had a joint venture for DG17 with China’s Academy of Medical Science (BD: Feb 10, 2010, May 19, Nov 17, 2011).

In 2012 and 2013, Narhex acquired gold and diamond mining interests in Liberia and Guinea.

Today, Narhex said that Trident Capital had presented a mandate relating to the placement which was subject to a capital raising fee of up to six percent and the company would publish a prospectus to raise sufficient funds to enable the recompliance with ASX Listing Rules if required.

The company said that following a one-for-10 consolidation, it hoped to raise a minimum of $2,500,000 at 20 cents a share to build a management team, perform a pilot clinical trial at an Australian hospital, develop a regulatory strategy and scope FDA trials, work with physicians to determine the most important indications and begin to engage tele-health and device manufacturers around licensing.

Narhex was up 0.1 cents or 14.3 percent to 0.8 cents with 4.1 million shares traded.

BIOTA PHARMACEUTICALS

Biota says chief executive officer Dr Joseph Patti's base salary will be $US500,000 ($A571,197) with executive chairman Russell Plumb on $US250,000 (BD: Sep 29, 2014).

Biota said that Dr Patti's annual cash incentive compensation would be targeted at not less than 50 percent of his annual salary and Dr Patti was awarded options to purchase 475,000 shares of common stock, vesting over three years and exercisable at the closing price on October 1, 2014, that is $US2.45.

The company said that if Dr Patti's employment was terminated by the company for any reason other than cause, death or disability or in connection with a change in control, or if he terminated his employment for good reason other than in connection with a change in control, it would pay him a lump sum equal to the sum of his unpaid salary through such termination; plus any cash incentive compensation earned and unpaid through such termination; plus his salary for 18 months; plus the product of one and a half times the cash incentive compensation paid to Dr Patti in respect of the most recent fiscal year prior to the year in which such termination occurs; plus an amount equal to the present value of the premium payments that would be made if he were to continue to be covered under the group health, life and disability insurance for 18 months.

Biota said that if Dr Patti's employment was terminated by him for good reason or by the company for any reason other than cause, death or disability, in either case within 60 days prior to or one year after a change in control, Dr Patti would receive a lump-sum cash amount equal to the sum of his unpaid salary and vacation through such termination; plus any cash incentive compensation earned and unpaid through such termination; plus two times the sum of Dr Patti's annual base salary as then in effect and the cash incentive compensation paid to Dr Patti in respect of the most recent fiscal year prior to the year in which the change in control occurs; plus a payment equal to the present value of the premium payments that would be made if Dr Patti were to continue to be covered under the company's group health, life and disability insurance for twenty four months.

The company said that Mr Plumb's annual cash incentive compensation would be targeted at 40 percent of his annual base salary and that Mr Plumb was awarded 40,000 performance-based restricted stock units vesting on the achievement of milestones and goals established by the board.

Biota said that if Mr Plumb's employment was terminated by the company for any reason other than cause, death or disability or in connection with a change in control, or if Mr Plumb terminated his employment for good reason other than in connection with a change in control, the company would pay him a lump sum equal to the sum of his unpaid salary through such termination; plus any bonus earned and unpaid through such termination; plus his base salary for three months; plus an amount equal to the present value of the premium payments that would be made if he were to continue to be covered under the company's group health, life and disability insurance for three months.

The company said that if Mr Plumb's employment was terminated by him for good reason or by the company for any reason other than cause, death or disability, in either case, within one year after a change in control but before the end of the term, he would receive a lump-sum cash payment equal to the sum of his unpaid salary through such termination; plus any bonus earned and unpaid through such termination; plus his base salary for six months; plus an amount equal to the present value of the premium payments that would be made if he were to continue to be covered under the company's group health, life and disability insurance for six months.

Last night on the Nasdaq, Biota fell two US cents or 0.81 percent to $US2.45 ($A2.80 - equivalent to 35 cents prior to the Nabi merger, when it was trading around $1.00), with 31,253 shares traded.

PHARMAUST

Pharmaust says it has begun its dose-escalation trial of PPL-1 soft-gel capsules for dog cancer at the Animal Referral Hospital in Homebush, Sydney.
Pharmaust said that the trial would evaluate PPL-1, which had shown promising anti-cancer results in vitro and in mice and was in development for human use.
The company said that the trial would test the safety and efficacy of PPL-1 in a phase I/II design, with dogs receiving baseline staging tests and then being treated with the drug by mouth daily by their owners at home, returning to the hospital for rechecks to evaluate safety and efficacy.
Pharmaust executive chairman Dr Roger Aston said the company was “delighted that the trial is underway following the issues with the palatability of PPL-1 [and] now that this issue is resolved we are hoping to see good progress in patient recruitment”.
Pharmaust was up 0.1 cents or 11.1 percent to one cent with 1.8 million shares traded.

HEALTHLINX

Healthlinx says it has a binding term sheet to acquire 100 percent of the issued share capital of the Delaware-based Manalto, a software as a service business for social media.
Last year administrators were appointed, following the failure of the company to commercialize its Ovplex ovarian cancer test (BD: May 7, 2013).
In June, Healthlinx said it had raised $200,000 to become a mobile video-gaming business (BD: Jun 13, 2014).
Healthlinx was untraded at 50 cents.

CIRCADIAN

Circadian has requested a trading halt pending an announcement “regarding a significant event relating to funding”.
Trading will resume on October 6, 2014 or on an earlier announcement.
Circadian last traded at 19.5 cents.

BIOPROSPECT

Bioprospect has requested a trading halt “pending completion of a capital raising”.
Trading will resume on October 6, 2014 or on an earlier announcement.
Bioprospect last traded at 0.4 cents.