Biotech Daily

Tuesday March 18, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: COMPUMEDICS UP 22%, PRIMA DOWN 7%**

*** ANTISENSE BEGINS ATL1102 FOR STEM CELL MOBILIZATION TRIAL**

*** COMPUMEDICS $767k STRASBOURG UNIVERSITY HOSPITAL DEAL**

*** GENETIC TECHNOLOGIES EXPECTS BREVAGEN 2.0 BY OCTOBER**

*** NOVOGEN: 'TRX-1 OVARIAN CANCER EFFICACY IN MICE'**

*** BANK OF AMERICA, MERRILL LYNCH TAKE 8% OF SUDA**

*** GENERA: 'FDA PANEL SUPPORT FOR ROCHE BACKS PAPTYPE'**

*** BIOXYNE TO RELEASE 15m ESCROW SHARES**

*** BIOPROSPECT REQUESTS FURTHER BIOTECH TRADING HALT**

*** IDT LOSES CFO ROMAN NAJDECKI, GAINS JOANNA JOHNSON**

MARKET REPORT

The Australian stock market rose 0.51 percent on Tuesday March 18, 2014 with the S&P ASX 200 up 27.0 points to 5,344.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, 11 were unchanged and five were untraded.

Compumedics was the best, up 1.6 cents or 21.6 percent to nine cents with 74,152 shares traded, followed by Oncosil up 11.5 percent to 14.5 cents with 3.0 million shares traded.

Patrys climbed 9.8 percent; Acrux and Ellex were up more than four percent; Antisense, Cellmid and Prana were up more than three percent; Starpharma rose 2.5 percent; Medical Developments and Universal Biosensors were up more than one percent; with Cochlear, CSL and Mesoblast up by less than one percent.

Prima led the falls, down 0.3 cents or 7.1 percent to 3.9 cents with 3.7 million shares traded.

Psivida lost 5.8 percent; Living Cell, Pharmaxis and Viralytics fell more than four percent; Admedus fell 3.45 percent; Alchemia, Benitec and GI Dynamics shed more than two percent; Anteo and QRX were down more than one percent; with Sirtex down 0.4 percent.

ANTISENSE THERAPEUTICS

Antisense says it has begun dosing in its 10-patient phase I stem cell mobilization proof-of-concept trial of ATL1102.

Antisense said that the trial would assess the safety, tolerability and effect of ATL1102 on the release of haematopoietic stem cells (CD34+) into the blood when dosed alone and in combination with the existing therapy granulocyte colony stimulating factor (G-CSF).

The company said that the randomized, open label study of ATL1102 dosed over five days in 10 healthy volunteers was being conducted by contract research organization Nucleus Network at Melbourne's Alfred Hospital, with results expected by mid-2014.

Antisense said that the mobilization, or release, of stem cells from the bone marrow into the blood was part of an important medical procedure used to improve outcomes for patients undergoing chemotherapy to treat certain cancers.

The company said that the stem cells released into the blood were collected and stored before high dose chemotherapy and then re-infused to replace those lost during chemotherapy in order to reestablish the immune system.

Antisense said that ATL1102 targeted VLA-4 receptor and the basis for using ATL1102 in the stem cell mobilization indication was related to the role of VLA-4 in regulating the release of CD34+ stem cells from the bone marrow, with another drug that also targets VLA-4 having been shown to increase CD34+ stem cell release in humans.

The company said that in a previous study in multiple sclerosis patients, ATL1102 demonstrated similar activity to that drug by increasing CD34+ levels in the blood.

Nucleus Network medical director and principal investigator Dr Jason Lickliter said the phase I trial was designed to evaluate whether ATL1102 can improve mobilization of CD34+ stem cells when used in combination with standard mobilization therapy to levels that would make it clinically beneficial for use in the collection of stem cells for transplantation.

Antisense managing director Mark Diamond said the "stem cell mobilization opportunity for ATL1102 while commercially attractive with, by our estimation, a market potential of several hundred million dollars per annum, also presents as an excellent return on investment proposition given costs are expected to be relatively low for developing the drug in this indication".

Antisense was up half a cent or 3.1 percent to 16.5 cents.

COMPUMEDICS

Compumedics says it will supply France's Strasbourg University Hospital ambulatory sleep diagnostic equipment to the value of EUR500,000 ($A767,000).

Compumedics said it would "participate in a EUR200,000 grant" from the regional government in France to fund specific modifications and improvements to the installation.

The company said the deal would further strengthen its brand and presence in France and underpin future business in the region.

Compumedics said it had employed a direct sales representative in France for several years and the deal would build further on the work and business already won in the country.

Compumedics executive chairman Dr David Burton said the company "always recognized the importance of having key sales representatives based in Europe and the emerging markets to capitalize on business opportunities as the world continues to re emerge positively from the [global financial crisis]".

Compumedics was up 1.6 cents or 21.6 percent to nine cents.

GENETIC TECHNOLOGIES

Genetic Technologies expects to have its expanded use Brevagen 2.0 breast cancer test completed and available by October.

At an investor briefing at Melbourne stockbrokers Lodge Partners, Genetic Technologies scientific director Dr Richard Allman said that the existing Brevagen test had seven DNA single-nucleotide polymorphisms (SNPs) or genetic variations used as markers to detect the likelihood of breast cancer.

Dr Allman said that the Brevagen 2.0 had a very large increase in the numbers of SNPs, allowing the test to be used for the first time in African-American and Hispanic women and thereby significantly increasing the addressable market for the test.

Genetic Technologies' wholly owned US subsidiary Phenogen Sciences is marketing the test in the US and Phenogen's head of sales and marketing Mark Ostrowski told the meeting that the company had hired "high caliber" staff, had increasing quarterly sales and was improving the internal reporting system and developing contacts with key opinion leaders.

Mr Ostrowski said that a number of factors would lead to flattened sales for the current three months but that was "temporary".

Mr Ostrowski acknowledged that the original test was suitable only for Caucasian women and that had been a limiting factor for sales and that would be addressed by the new Brevagen 2.0 test.

Mr Ostrowski said that the complex nature of the US health care industry mean that without a specific American Medical Association current procedural terminology (CPT) code, it was difficult to receive insurance company reimbursement.

He said that with the development of the new test and more clinical studies leading to peer-reviewed scientific evidence, the company hoped to have its own specific CPT code within two years.

Mr Ostrowski said the company received a minimum of $US250 from patients, but up to $US2,200 in reimbursements per test from insurance payers.

He said the company was also seeking to broaden the target risk group to whom physicians should advise the Brevagen test from the existing 15 to 19 percent to 12 to 19 percent and there was a case to be made for the test being able to be used to confirm low-risk women who might not need yearly mammograms, with a consequential cost saving to the health care industry.

Mr Ostrowski said that several large breast cancer centres were "on the verge of launching Brevagen".

He said that having a US-based laboratory meant that it could increase its customer base to Medicare, Medicaid and the US Armed Forces, which excluded non-US laboratories.

Dr Allman said that the company had included all available SNPs in the new test, which "greatly increases its utility as well as a very big performance increase".

Dr Allman said that the Brevagen 2.0 could lead to improved breast cancer survival, better focused treatment and that would convince insurers and those who set the clinical guidelines, such as the US National Comprehensive Cancer Network, with whom Genetic Technologies had had discussions.

Genetic Technologies and Phenogen Sciences launched the Brevagen genetic test for assessing non-familial breast cancer risk in 2011 (BD: Jun 20, 2011).

Genetic Technologies was unchanged at 5.7 cents.

NOVOGEN

Novogen says Yale University joint venture company Cantx has demonstrated potent anti-cancer effects of Trx-1 in mice xenografted with human ovarian cancer stem cells.
Novogen said that Cantx was seeking to treat abdominal cancers by developing a product to be administered intra-peritoneally with the ability to seek out tumor cells and to eliminate the full hierarchy of cells within tumors.
The company said that the final product was envisaged to be Trx-1 in a smart-drug delivery system.
Novogen said that the first key step in the process was confirmation that Trx-1 alone would be effective and the mouse study confirmed that..
The company said the study was conducted at Yale's School of Medicine by Prof Gil Mor, with ovarian cancer stem cells obtained from a patient with refractory ovarian cancer injected intra-peritoneally, where they grew in a disseminated manner, forming multiple tumors in locations that resembled those observed in patients with ovarian cancer.
"Until now, we have not been able to identify a drug from any company that is effective in this model," Prof Mor said.
"So it is very exciting to observe an anti-tumoral effect with Trx-1," Prof Mor said.
"The second step that we hope to report on very soon is the final product of Trx-1 in a smart delivery system, rather than the standard cyclodextrin carrier used in this study," Prof Mor said.
"The advantage of an intra-peritoneal product is that it delivers drug directly to where it is needed," Prof Mor said.
"And while we are focusing for the moment on ovarian cancer, there is every reason to believe that the same strategy will be applicable to other types of tumors contained within the abdominal cavity, such as pancreatic and colorectal cancers," Prof Mor said.
Novogen and Cantx chief executive officer Dr Graham Kelly said the mouse results was "a key inflection point for the company and its super-benzopyran drug technology platform".
Dr Kelly said that the mouse study set out to replicate as much as possible the clinical situation.
"These ovarian cancer stem cells produce tumors comprising daughter cells that are highly chemo-resistant as well as being highly aggressive and tumorigenic," Dr Kelly said.
"Trx-1 had shown high potency against human ovarian cancer stem cells and their daughter cells in vitro, leading us to believe that it is the first drug to be effective across the full spectrum of ovarian cancer cells at the same dosage, but this was the evidence that we needed to progress this drug into the clinic," Dr Kelly said.
Novogen was up half a cent or 2.6 percent to 19.5 cents.

SUDA

The Bank of America Corp and related bodies have increased their substantial shareholding in Suda from 48,723,480 shares (5.46%) to 62,444,080 shares (6.75%).
The Charlotte, North Carolina-based Bank of America substantial shareholder notice said that 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.
The notice said that on November 28, 2013 and March 13, 2104 Merrill Lynch (Australia) Futures bought 16,000,000 shares for $996,560 or 6.2 cents a share and Merrill Lynch International acquired borrowed and returned shares without stating any payment.
Suda was unchanged at 6.6 cents with 1.4 million shares traded.

GENERA BIOSYSTEMS

Genera says that a US Food and Drug Administration panel's support for a competitor human papillomavirus test confirms the principle behind its Paptype test.

Genera said that the FDA's Microbiology Devices Panel of the Medical Devices Advisory Committee unanimously decided that the benefits of using Roche's Cobas human papillomavirus (HPV) test as a first-line, primary screening tool in women 25 years and older to assess their risk of cervical cancer based on the presence of clinically relevant high-risk HPV DNA, outweighed the risks.

The company said that if approved, the Cobas HPV test would be the first human papillomavirus test indicated as the first-line primary screen of cervical cancer in the US and "could see the HPV testing market develop as the largest and fastest growing segment of the $US5 billion molecular diagnostics market".

Genera said the ability of the Roche test to simultaneously genotype HPV 16 and 18 was a key determinant in the FDA committee assessing that a number of women would benefit from using the test as primary screening for cervical cancer.

The company said that a Roche trial demonstrated that nearly one in seven women with normal Papanicolaou, or Pap, test cytology, who were HPV 16 positive, had high-grade cervical disease that was missed by cytology.

Genera said that like the Roche test, its Paptype test simultaneously genotyped high risk HPV types, but went further by genotyping all 14 high risk types.

The company said that HPV types 16 and 18 accounted for 70 percent of cervical cancer cases but the incorporation of simultaneously genotyping of all 14 high risk HPV types, which caused 99.7 percent of cases, had the potential to substantially increase specificity of an HPV test, particularly when used within a long-term screening program.

Genera executive chairman Lou Panaccio said that the Paptype HPV test was protected by "a robust portfolio of patents, many of which have been granted in the past few years with coverage extending to 2025 and beyond".

Mr Panaccio said that "the main criticism of HPV testing has been that in most cases a woman's immune systems can clear the HPV virus".

"So many women, particularly young women, may be sent for additional examinations or biopsies that might not be necessary," Mr Panaccio said.

"Simultaneous genotyping can help overcome this issue as it is persistent infection with the same high risk genotype that causes cervical cancer in women," Mr Panaccio said.

Genera said clinical study samples run at London's Wolfson Institute of Preventive Medicine showed that the Paptype test had comparable sensitivity to all other commercially available tests including the Roche Cobas HPV test but Paptype was the only test able to simultaneously genotype all 14 high risk types delivering higher specificity, with further studies planned in a screening population to confirm the potential superior specificity of Paptype compared to other tests, including Roche's Cobas.

The company said Wolfson Institute's approach was to establish sensitivity primarily in a referral population and specificity primarily in a screening population.

"The recent FDA Advisory Committee recommendation for the Cobas HPV test bodes well for Genera," Mr Panaccio said.

Genera said it expected Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark registration of the solid phase version of Paptype during 2014 with plans to sell in Australia, Europe and South American in 2014 and 2015 and to find a partnering arrangement for the US market in 2014.

Genera was untraded at nine cents.

BIOXYNE

Bioxyne says it will release 14,999,046 shares from ASX escrow on April 4, 2014.
Bioxyne said the escrow period began on March 28, 2012 and related to the company's application for ASX listing following the completion of the takeover of Hunter Immunology (BD: Oct 11, 2011, April 3, 2012).
The company said that following the release of the escrow shares there would be no further restricted or escrowed securities on issue and it would have 200,343,101 shares on issue and available for trading.
Bioxyne fell 0.1 cents or 11.1 percent to 0.8 cents.

BIOPROSPECT

Bioprospect has requested a trading halt pending an announcement on whether it is proceeding with the next stage in the proposed Invatec and Heartlink transaction.
Last year, Bioprospect requested a trading halt "pending an announcement pertaining to its investment in a medical/biotechnology" and came out of the halt to say it was conducting due diligence on the two technologies (BD: Dec 3, 2013).
In February the company said it had raised $1 million to acquire and develop the cardiac monitoring test for depression and other mental illnesses and an extraordinary general meeting approved the acquisition (BD: Jan 28, Feb 19, 2014).
Bioprospect was originally commercializing Termilone for termites but became entangled with Solagran's pine needle extract for cancer and Alzheimer's disease as a supplement for horses (BD: Sep 24, 2009).
In 2011, the company hoped to become an oil and gas drilling operation working with Frontier Gasfields (BD: Jun 2, 2011).
Bioprospect was up 0.1 cents or 25 percent to 0.5 cents with 1.0 million shares traded, prior to the trading halt at 10.09am.

IDT AUSTRALIA

IDT says Joanna Johnson has been appointed chief financial officer and company secretary, replacing Roman Najdecki effective from today.
IDT said that Mr Najdecki was retiring "after a long and successful career leading the finance function at many Australian biotechnology and pharmaceutical companies".
The company said that Ms Johnson was a chartered accountant with more than 18 years' experience in financial roles within the pharmaceutical industry and was previously Generic Health's chief financial officer.
IDT said Ms Johnson had 14 years experience in pharmaceutical manufacture and distribution, starting with Faulding and later as Hospira's Asia-Pacific director of finance.
The company said that the head of legal and corporate development Dr David Sparling would act as joint company secretary.
IDT said it "wishes to thank Mr Najdecki for the key role he has played in starting the transition of the company from a service to a product based business and wishes him well in his retirement".
Biotech Daily has liaised with Mr Najdecki at several companies and also wishes him well in his retirement.
IDT was untraded at 30 cents.