# Biotech Daily

Tuesday June 4, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: COMPUMEDICS UP 19%, BIONOMICS DOWN 3%**

*** CIRCADIAN PHASE I VGX-100 TRIAL TREATS 34 SOLID TUMOR PATIENTS**

*** ANTISENSE BEGINS ATL1102 MS TOX STUDY; PUBLICATION**

*** VIRALYTICS ENROLS 35th PHASE II CAVATAK MELANOMA PATIENT**

*** ATP INNOVATIONS' IGNITION LABS HAS $125k FOR 5 START-UPS**

*** SIGNOSTICS APPOINTS THERMO FISHER DISTRIBUTOR**

*** IMUGENE PLAN RAISES $183k; RECEIVES $181k R&D TAX PAYMENT**

*** IMMURON, TAKEDA TERMINATE TRAVELAN LICENCE**

*** HEALTHLINX ADMINISTRATORS, CREDITORS MEETING**

*** BIO-MELBOURNE 'INNOVATION PRECINCTS' BIO-BREAKFAST**

## MARKET REPORT

The Australian stock market was up 0.26 percent on Tuesday June 4, 2013 with the S&P ASX 200 up 12.5 points to 4,900.8 points. Eleven of the Biotech Daily Top 40 stocks were up, eight fell, 13 traded unchanged and eight were untraded.

Compumedics was the best, up 0.8 cents or 18.6 percent to 5.1 cents, with 20,000 shares traded, followed by Neuren up 12.8 percent to 5.3 cents with 4.7 million shares traded and Anteo up 11.7 percent to 6.7 cents with 1.7 million shares traded.

Nanosonics and Patrys climbed more than seven percent; Cochlear and Genetic Technologies were up five percent or more; GI Dynamics and QRX were up more than four percent; Cellmid was up 3.6 percent; with Mesoblast and Universal Biosensors up more than one percent.

Bionomics led the falls, down one cent or 2.6 percent to 38 cents with 87,906 shares traded, followed by Allied Health down 2.4 percent to 4.1 cents with 9.1 million shares traded and Acrux down 2.1 percent to $3.71 with 357,400 shares traded.

Alchemia, Prima and Reva fell more than one percent; with CSL, Heartware and Sirtex down by less than one percent.

## ANTISENSE THERAPEUTICS

Antisense says it has begun dosing primates in its China toxicology study of ATL1102 for multiple sclerosis and is preparing earlier phase IIa results for publication.

In 2008, Antisense and its then partner Israel's Teva Pharmaceutical said a randomized, double-blind, placebo-controlled phase IIa study met its primary endpoint showing a significant reduction by 54.4 percent (p = 0.01) in the cumulative number of new active brain lesions in patients taking ATL/TV1102 for eight weeks, compared to placebo, as measured by magnetic resonance images (BD: Jun 30, 2008).

In 2010, Teva handed ATL1102 back to Antisense (BD: Mar 24, 2010).

Today, Antisense said the six month chronic primate toxicology study was being conducted at Pharmaron in China and was intended to underpin and validate plans to secure a partner to take ATL1102 to a phase IIb multiple sclerosis trial.

Antisense said that dosing was expected to be completed by the end of the 2013, with results in early 2014.

Antisense said that the efficacy outcomes from the 2008 study were viewed to be as good as, if not superior to, those achieved with Tysabri which had sales of more than $US1.5 billion in 2012.

The company said that both its antisense ATL1102 and the monoclonal antibody Tysabri targeted the VLA-4 receptor.

Antisense said ATL1102 "could be as potent as Tysabri but potentially safer, cheaper to manufacturer and more conveniently administered".

The company said it was working with the phase IIa trial's principal investigator, the University of Cologne's Prof Volker Limmroth to finalize a scientific paper on the phase IIa trial results for submission to a scientific journal for publication later this year.

Antisense was unchanged at one cent with 10.4 million shares traded.

## CIRCADIAN TECHNOLOGIES

Circadian says 34 patients have been treated with either VGX-100 or a combination of VGX-100 and bevacizumab with one drop-out and one dose limiting toxicity.

Circadian said that interim data from its phase I dose escalation trial of its anti-vascular endothelial growth factor C (VEGF-C) monoclonal antibody VGX-100 for advanced solid tumors was presented at the American Society of Clinical Oncology meeting in Chicago.

The poster presentation said that 16 patients were recruited to the weekly VGX-100 dose-escalation arm of the trial with one drop-out not related to the treatment and 18 patients were recruited to the combination of bi-weekly bevacizumab and weekly VGX-100 dose-escalation arm with one dose limiting toxicity at the lowest dose cohort.

The poster summary said that the five cohorts of VGX-100 at weekly doses up to 20 mg/kg alone completed accrual without any dose limiting toxicities.

The summary said that the four cohorts of VGX-100 at weekly doses of 2.5mg/kg, 5mg/kg or 10mg/kg in combination with bevacizumab given every two weeks at doses of 5mg/kg or 10mg/kg were completed with one dose limiting toxicity.

The summary said "the combination of inhibiting the VEGF-A and VEGF-C signaling pathways with VGX-100 and bevacizumab appears promising".

The summary said that patient accrual for the remaining two cohorts was "near completion" and further evaluation of VGX-100 alone or in combination with bevacizumab was on-going.

Circadian was untraded at 30 cents.

## VIRALYTICS

Viralytics says that 35 patients of the target of 54 evaluable patients have been enrolled in its phase II study of Coxsackievirus A21 for late stage malignant melanoma.
Viralytics said that the phase II study of intra-tumoral Cavatak (Coxsackievirus A21) in patients with stage IIIc and stage IV malignant melanoma who had not experienced any treatment-related serious adverse events had an interim efficacy milestone of at least three objective responses, which had been achieved.
The company said that the enrolment of 35 patients completed the first stage of patient recruitment in the clinical trial.
Viralytics said the independent data monitoring committee would convene by October 2013 to review the interim efficacy and patient tolerability to multiple Cavatak injections.
Viralytics chief executive officer Dr Malcolm McColl said that completing the first stage of enrolment was “a significant milestone and we are very pleased with the accelerated recruitment rate through 2013”.
“With nine current clinical trial sites and additional sites planned to enter the study we look forward to strong progress in the second half of 2013,” Dr McColl said.
Viralytics was unchanged at 27.5 cents.

## ATP INNOVATIONS

The Sydney based ATP Innovations ‘seed accelerator’ Ignition Labs will provide an initial $25,000 to each of five health and medical technology startups.
ATP Innovations said that it was “taking applications for its highly competitive, intensive business development program”.
ATP Innovations said that it was looking for five health and medical technology startups “that will make a positive impact on personal health, social health and the delivery of modern healthcare … [and was] the first health and medical technology focused accelerator to be launched in Australia”.
ATP Innovations said that since 2006 it had worked with more than 80 businesses which had raised more than $80 million from private investors, secured more than $18 million of competitive government grants, filed 240 patents and trademarks applications with 94 granted and has had six portfolio companies acquired.
The company said the aim was to convert early stage ideas into fundable businesses over three to six months through mentors, cash investment, structured customer and business validation activities, entrepreneurial education and industry networks.
ATP Innovations commercial development director and Ignition Labs founder Ben Wright told Biotech Daily that the funds for the program came from his company and the mentors involved.
Mr Wright said that the competitive entry program was looking for “companies with a technical proof-of-principle that in six months could be an investable business”.
ATP said that under the Ignition Labs Health and Medtech program five teams would each receive $25,000 in seed capital with the possibility of further funding, intensive coaching from qualified mentors and workspace within ATP Innovations at the Australian Technology Park at the National Innovation Centre in Eveleigh in Sydney.
ATP said that the three month plus three month program would begin in September 2013 and culminate in investor roadshows in Australia and abroad.
ATP said the program would consider health and medical technologies including class 1 and 2 devices, instrumentation, diagnostics, connected devices, mobile health or software.
ATP said that applications close in July 14, 2013 and more information about the program was available at: www.ignitionlabs.com.au.

## SIGNOSTICS

The Adelaide based Signostics has appointed Thermo Fisher Scientific as its distributor for its handheld ultrasound Signos RT in Australia and New Zealand.

Signostics chief executive officer Warren Ortmann said the distribution agreement with the New York Stock Exchange-listed company was “great news for Signostics and will help the new Signos RT penetrate the local Australian and New Zealand healthcare markets”.

“This is yet another big step for Signostics and builds on our growing global distribution channels throughout Europe and our recently announced FDA 510(k) clearance for the Signos RT in the lucrative American market,” Mr Ortmann said.

Thermo Fisher Scientific healthcare general manager Jarrod Percy said the Signos RT was a “truly portable and flexible point-of-care imaging tool and incorporating it into our existing product portfolio”.

“Signostics has developed a revolutionary product which we believe will have a significant impact across our domestic Australian and New Zealand markets.” Mr Percy said.

Signostics said the Signos RT was a lightweight handheld ultrasound for high quality imaging in real time at the point-of-care for medical practitioners, healthcare professionals and veterinarians globally across a broad range of clinical settings.

Signostics is a private company.

## IMUGENE

Imugene says its share purchase plan has raised $183,000 through applications for 33,888,932 shares at 0.54 cents a share.

Imugene said it had received $181,354 cash refund from the Federal Government’s R&D Tax Incentive program.

Imugene was untraded at 0.6 cents.

## IMMURON

Immuron says it has agreed with Takeda Pharmaceuticals Australia Pty Ltd, previously known as Nycomed, to terminate the licence for the sale of Travelan in Australia.

Immuron said it would generate greater revenues and command a higher gross margin from the sale of Travelan for travelers diarrhoea, through direct sales to wholesalers.

The company said that the Takeda licence was agreed in April 2010 and Takeda promoted and marketed Travelan through a number of campaigns and had seen a growth in sales.

Immuron said it paid Takeda an undisclosed transition payment.

Immuron interim chief executive officer Amos Meltzer said that the company increased its gross margin over the last two years by reducing its production and manufacturing costs, but selling directly to wholesalers should increase the company’s gross margins.

“This is the first of a set of measures that are intended to improve the company’s financial position,” Mr Meltzer said.

Immuron said it regained the exclusive right to sell Travelan in Australia and New Zealand, with Takeda having the right until June 30, 2013 to sell its inventory, while also retaining from Takeda all of the existing marketing and promotional materials currently being used, allowing for a seamless transition.

Immuron was untraded at 0.4 cents.

## HEALTHLINX

Healthlinx administrators David Ross and Shanon Thomas of accountants Hall Chadwick says a report to creditors has been circulated and a meeting planned for June 11, 2013.
The administrators said that the meeting would be held at Hall Chadwick, Level 10, 575 Bourke Street, Melbourne at 10am (AEST) and would only be open to creditors and the administrators would recommend creditors adjourn the meeting for up to 45 days.
Healthlinx attempted to commercialize its Ovplex ovarian cancer diagnostic, which was composed of five biomarkers including CA-125, claiming it was superior to CA-125 alone, but never published comprehensive comparative sensitivity and specificity data, and last week, requested a suspension pending a funding announcement (BD: Apr 30, 2013).
In March, former chief executive officer Nick Gatsios resigned as a director and the company said an unnamed lender would provide $1,000,000 through a loan and convertible bond via Gleneagle Securities Nominees (BD: Mar 21, 2013).
Late last year Healthlinx said the agreement to licence Ovplex to Mane Cancer Diagnostics had expired as sale conditions had not been met (BD: Jan 20, 2013).
Healthlinx last traded at 0.1 cents.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its June 11, 2013 Bio-Breakfast will focus on the Federal Government's Industry Innovation Precincts $504 million Fund.
Bio-Melbourne Network chief executive officer Michelle Gallaher said that as part of the Federal Government package there would be up to 10 Industry Innovation Precincts "that will bring together industry, research and service providers to accelerate specific sectors including biotechnology".
"Led by industry, the precincts will support the development of existing [small and medium sized enterprises] by linking them to research and industry leaders and creating environments where new businesses may emerge" Ms Gallaher said.
Ms Gallaher said the first two precincts had been announced for manufacturing and food and both head-quartered in Melbourne.
Ms Gallaher said that up to eight more precincts would be selected through a competitive process, with all bids being industry led.
The Bio-Melbourne Network said the June 11 Bio-Breakfast would be an industry update on the bids coming from Victoria as well as other states, particularly those relevant to health and biotechnology and where companies and organizations could "fit into this innovation ecosystem".
Speakers at the Bio-Breakfast include the Commonwealth Scientific and Industrial Research Organisation's director of Melbourne Precincts Manufacturing Materials and Minerals Ros Hore.
The Bio-Breakfast will be held in the Shell Building's Conference Centre, 1 Spring Street, Melbourne.
Registration is from 7:15am with presentation and discussion from 8am.
For more information go to: http://www.biomelbourne.org/events/view/284.