Biotech Daily

Tuesday May 3, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: USCOM UP 10%, ADMEDUS DOWN 10%**

*** AVEXA'S TALI 'EFFECTIVE FOR ATTENTION TRAINING IN CHILDREN'**

*** SOMNOMED UNDERWRITTEN RIGHTS ISSUE TO RAISE $10.5m**

*** EUROPE GRANTS PSIVIDA'S MEDIDUR ORPHAN STATUS**

*** POLYNOVO PRINCIPAL INVESTIGATORS MEET FOR US BTM BURN STUDY**

*** FOUNDER HARRY ROSEN BELOW 5% OF PHOSPHAGENICS**

*** BIOTECH DAILY POLICY ON MEGA-DAY-TRADERS**

*** IDT OPENS NEW ADELAIDE CMAX TRIALS FACILITY**

*** NOVOGEN TO CLOSE YALE JOINT VENTURE CANTX**

*** RECCE PREPARES RECCE-327 ANTIBIOTIC FOR FDA TRIAL PROCESS**

*** A-BIO DEMANDS NUSEP PAY $4.6m, PRIME NEGOTIATIONS CONTINUE**

*** DANIEL MOORE REPLACES GI DYNAMICS CHAIRMAN JACK MEYER**

*** OPTISCAN BOARD: ALAN HOFFMAN, PETER FRANCIS, DR IAN GRIFFITHS**

MARKET REPORT

The Australian stock market climbed 2.11 percent on Tuesday May 3, 2016 with the ASX200 up 110.8 points to 5,353.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and one was untraded.

Uscom was best, on a fluid management report, up 10 percent to 22 cents with 72,268 shares traded. Antisense rose 8.8 percent; Atcor, IDT and Orthocell were up more than six percent; Airxpanders, Mesoblast and Pro Medicus rose four percent or more; Bionomics, Cochlear, CSL and Polynovo were up more than three percent; Neuren and Viralytics rose more than two percent; Clinuvel, Compumedics, Medical Developments, Osprey, Resmed and Sirtex were up more than one percent with Nanosonics up 0.45 percent.

Admedus led the falls, down 3.5 cents or 9.9 percent to 32 cents with 1.3 million shares traded. Prana lost 8.05 percent; Universal Biosensors fell 6.8 percent; Anteo was down 5.6 percent; Benitec fell 4.35 percent; Actinogen and Avita were down more than three percent; Impedimed and Prima shed more than two percent; Opthea was down 1.1 percent; with Ellex and Reva down by less than one percent.

AVEXA

Avexa says that its Tali attention training system can be effective for children with developmental disorders.

In February, Avexa completed the acquisition of the training attention and learning initiative (Tali) process, a collaboration between Monash University's Prof Kim Cornish, Grey Innovation and Torus Games to address the limited awareness and treatment of intellectual disabilities, including autism (BD: Oct 12, 2015; Feb 15, 2016).

Yesterday the company said that the efficacy results had been accepted for publication in would be published was presented in the Journal of Child Psychology and Psychiatry.

Avexa chairman Iain Kirkwood told Biotech Daily the results were presented in January at the Experimental Psychology Society Conference at University College London.

The presentation, entitled 'Building cognitive architecture in children with developmental disorders using a computerized attention training program', was co-authored by Avexa scientific advisory board chair Prof Cornish and chief research officer Dr Hannah Kirk.

An abstract is at: http://www.eps.ac.uk/images/epsfiles/2016/jan_prog_amend.pdf.

The presentation abstract said that children with developmental disorders had heightened attention difficulties, which were linked to poorer cognitive, academic and social outcomes.

The presentation said that attention training programs had promising results in typically developing and clinical populations, such as attention deficit hyperactivity disorder, but few studies had assessed intervention in children with developmental disorders.

The abstract said a double blind, randomized, controlled trial assigned children with developmental disorders (IQ < 70; n = 76) aged of four to 10 years to an adaptive attention training program or a non-adaptive control program with short and long-term effects of the 25 session, home-based training evaluated on multiple outcome measures.

After training, children in the attention-training group showed greater improvements in selective attention than the control group and the improvements were maintained three months after training had ceased, the abstract said.

The abstract said that greater improvements in numeracy skills were observed in the attention training group at the three-month follow-up.

The abstract said the findings provided "the first indication that attention training is feasible and effective for children with developmental disorders".

The journal article is entitled 'Computerised attention training for children with intellectual and developmental disabilities' and is expected to be published in the Journal of Child Psychology and Psychiatry later this year.

Avexa was unchanged at 2.3 cents.

SOMNOMED

Somnomed says it expects to raise $10,502,337 through a fully-underwritten two-for-25 "accelerated, pro-rata, non-renounceable entitlement offer" at $2.50 a share.

Somnomed said that an institutional offer would conclude on May 4 and eligible retail shareholders at the record date of May 5 would be able to subscribe for two new shares for every 25 shares held, with the retail offer opening on May 10 and closing on May 27, 2016.

The company said that the funds would provide working capital and any capital investment associated with the direct-to-patient business.

Somnomed said that Wilson HTM Corporate Finance had been appointed lead manager and TDM Asset Management had agreed to subscribe for any shortfall not taken up by the book-build process.

Somonmed requested a trading halt until May 5, 2016 and last traded at $2.80.

PSIVIDA

Psivida says the European Commission has granted orphan medicinal product designation to Medidur for posterior uveitis.

Psivida chief executive officer Dr Paul Ashton said that orphan drug designation was “an important milestone in the development of Medidur”.

“It underscores the need for the development of new therapy to treat this blinding eye disease,” Dr Ashton said.

The company said that orphan drug designation provided up to 10 years of market exclusivity in Europe following marketing approval, access to the centralized marketing authorization procedure and other regulatory and financial incentives.

Psivida said that following published EU regulatory guidance it planned to file for European marketing approval for Medidur for posterior uveitis based on the results from its first phase III trial which met its primary efficacy endpoint with high statistical significance ($p < 0.00000001$) and achieved positive safety results.

The company said that Medidur was a micro-insert injected into the back of the eye providing sustained release of 0.18 mg of the corticosteroid flucinolone acetonide at a controlled rate directly to the retina for three years.

Psivida was untraded at $3.90.

POLYNOVO

Polynovo says it has conducted the first principle investigators meeting for the six US sites for its burn feasibility study of its biodegradable temporising matrix (BTM).

Polynovo said that the trial would be conducted at the Memphis-based University of Tennessee Medical Centre, the Sacramento-based University of California Davis Medical Centre, the Winston-Salem, North Carolina-based Wake Forest Baptist Health, the Seattle-based University of Washington, Boston’s Massachusetts General Hospital and the Tampa General Hospital in Florida.

The company said that the first patients were expected to be enrolled from June with the conclusion of the feasibility trial expected in June 2017.

Polynovo said that the Royal Adelaide Hospital’s Dr Marcus Wagstaff had been appointed as the principle investigator and medical director overseeing the trial and the Conformité Européenne (CE) mark trial.

The company said that trial would be funded by the US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA).

Polynovo was up one cent or 3.6 percent to 28.5 cents.

PHOSPHAGENICS

Phosphagenics founder and former chief executive officer Harry Rosen says his indirect holding has been reduced below the five percent substantial mark.

Mr Rosen said that through Paroha Nominees he sold 5,200,000 shares for $98,515 or 1.9 cents a share, reducing his holding to 59,026,436 shares (4.7%).

In 2014, Mr Rosen said that his 64,226,436 share holding was diluted from 6.31 percent to 5.09 percent in the $19.3 million capital raising (BD: Jul 11, Sep 2, 2014).

Phosphagenics fell 0.1 cents or 4.8 percent to two cents with 10.1 million shares traded.

BIOTECH DAILY EDITORIAL

Yesterday, the Delaware-based Goldman Sachs Group became substantial in Sirtex with 2,952,631 shares or 5.16 percent.

A large proportion of the 11 pages of individual trades were shares borrowed and returned at “no applicable price”, along with trades ranging from one share to up to 77,982 shares.

Several institutions “place bets” on biotechnology stocks rather than adopting longer term investment strategies and Biotech Daily takes a dim view of this mega-day-trader activity.

But Biotech Daily is more concerned that the real traders involved are using “nominee” and “custodian” companies to hide their identities.

While the concept of knowing the true identity of your co-investors is mentioned in passing in the Corporations Act it is not specifically enshrined in the law.

It should be.

Last year, Goldman Sachs repeatedly increased above or reduced below the five percent substantial threshold in Nanosonics, primarily borrowing or returning shares for no applicable consideration (BD: Oct 2, 5; Dec 2, 4, 7, 2015).

Sirtex has previously been the target of similar trading by UBS AG, the Commonwealth Bank of Australia and the Sydney-based Challenger, all of which conducted the trades on behalf of nominee companies and in relation to lending agreements.

Last year’s policy of attempting to change their behavior by reporting the day-trader approach to biotechnology investment was not successful.

Biotech Daily will report when these sorts of short term investors appear for the first time in companies where they have previously been below substantial.

The Corporations Act needs to be changed to identify all shareholders equally.

IDT AUSTRALIA

IDT says that its CMax clinical trials facility has moved from the Royal Adelaide Hospital campus to new facilities, also on North Terrace in central Adelaide.

IDT said that was at its old facility for more than 20 years and the new CMax trials unit was “Australia's most contemporary, dedicated early-phase clinical trial facility, providing a foundation for leading medical science organisations to deliver world-leading research”.

IDT chief executive officer Paul MacLeman said that the facility cost “a few million dollars” and was opposite the new Royal Adelaide Hospital.

The company said that the leased facility was built to its specifications and was formally opened on April 29, 2016 South Australia Assistant Minister Katrine Hildyard and IDT chairman Graeme Kaufman.

IDT said that current projects include a second study investigating a wearable device providing an early warning system for hypoglycaemic events in diabetic patients and a gene therapy study developed by a Japanese biopharmaceutical company for the treatment of peripheral arterial disease.

South Australia’s Minister for Health Industries Jack Snelling said that each phase I trial at CMax would inject revenue into the local economy, sometimes as much as $1 million and involve more than 50 staff, including 30 nurses and 15 laboratory technicians.

“Adelaide is also an important site for phase II and phase III trials, making the city a one-stop shop for pharmaceutical companies,” Mr Snelling said. “The South Australian Government is targeting health industry investment [and] an important part of this is attracting clinical trials from the United States, Europe and China.”

CMax head of clinical service Jane Kelly said the new facility was adjacent to Adelaide’s Biomed City “one of the largest health focused city precincts in the Southern Hemisphere”.

IDT climbed two cents or 6.25 percent to 34 cents.

NOVOGEN

Novogen says it is “on-track” to start a phase I trial of Cantrixil for ovarian cancer by the end of 2016 and will wind-up its Yale University joint venture Cantx.

Novogen said the trial design had been amended “in light of emerging data” to focus more specifically on patients with ovarian cancer to better understand its effects in the target population, and it was no longer expected to be restricted to patients with malignant ascites.

The company said that clinical research organisation Quintiles had been engaged to support the study and it planned to submit an investigational new drug application to the US Food and Drug Administration in August 2016 and enrol the first patient by the end of 2016.

Novogen said it had concluded funding to the Cantx joint venture with Yale University, and Cantx would be wound-up, with all licenced Novogen intellectual property be returned to Novogen.

The company said that Cantx was formed in November 2013 as a joint venture with Yale University and some its staff, with Novogen owning 85 percent (BD: Nov 7, 2013).

Novogen chief executive officer Dr James Garner said that “Cantx has been a helpful vehicle for performing some of the supportive experiments that have informed our development of Cantrixil”.

“As we move into clinical trials, a simpler arrangement will be advantageous and we will be returning the licenced intellectual property to Novogen’s stewardship,” Dr Garner said.

Dr Graner said that Novogen might be required to recognise “an impairment to certain intercompany loans” between Novogen and Cantx, which would be reported when fully determined.

Dr Garner said the company had completed most of the investigational new drug application enabling work and was finalizing protocol design with external advisors and potential investigators, while completing manufacture of the product.

“Our goal is to offer a meaningful new treatment option for patients with ovarian cancer and we plan to give Cantrixil the best opportunity possible to demonstrate its potential in a clinical setting,” Dr Garner said.

Novogen fell half a cent or 4.2 percent to 11.5 cents.

RECCE

Recce says its Perth laboratory will produce Recce-327 antibiotic for pre-clinical of efficacy tests in mice against infections caused by superbugs.

Recce said that the safety and efficacy testing was expected to take about six months.

The company said that it would begin the product’s pilot-manufacture in a laboratory in Boston, Massachusetts where essential infrastructure, raw materials and proximity to the US Food and Drug Administration was much more available than in Australia, which would take a total of about 12 months.

Recce said that the Boston pilot-plant would produce Recce-327 for tests of safety, comprising multiple, separate, acute and chronic detailed tests in rats and other animals to assess dosing and pharmacological patterns of action.

The company said that during this process, chemistry would be presented to the FDA, regarding the manufacturing of Recce-327, including stability and formulation data.

Recce said that the FDA was “quite likely to request additional testing” and all parts of the process had been costed and funded.

Recce fell half a cent or 2.4 percent to 20 cents.

NUSEP HOLDINGS

Nusep says it has received a letter of demand from A-Bio Pharma Pte Ltd for $S4,758,695 ($A4,627,026).

Nusep said that A-Bio was a third party which previously occupied the Prime Biologics production facility in Singapore and the claim was under a previously announced debt agreement and carried on Nusep's balance sheet but with payment guaranteed by Prime.

The company said that negotiations "with a consortium of overseas purchasers" were continuing on the sale of its Prime Biologics series B class shares and its blood separation GF100 machine and included the responsibility for the A-Bio claim.

Nusep said that if it could successfully conclude the negotiations it would receive a cash payment, the purchaser consortium would take responsibility for negotiating and paying the A-Bio claim and it would no longer be carried by Nusep.

The company said that A-Bio had acknowledged its negotiations with the consortium and had extended the payment date to May 30, 2016.

Nusep said that in parallel with the negotiations on the share sale agreement, it was in the process of recovering its assets rented to Prime and used as part of the process for achieving regulatory certification for the Singapore production facility.

Nusep was up 0.4 cents or 40 percent to 1.4 cents with 1.9 million shares traded.

GI DYNAMICS

GI Dynamics say that Daniel Moore has been elected chairman, replacing Jack Meyer, effective immediately.

GI Dynamics said that Mr Moore had been an independent, non-executive director and member of the compensation committee since September 2014 and vice chairman since March 2016.

The company said that Mr Moore had experience in executive leadership, management, sales and operations in global medical devices with a track record of increasing revenues, increasing profitability and involvement in turning around companies.

GI Dynamics said that Mr Moore and chief executive officer Scott Schorer would implement strategies to turn around the company with an emphasis on non-US commercial activities for Endobarrier therapy for obesity and type 2 diabetes.

The company said that Mr Moore was previously Cyberonics chief executive officer from 2007 to 2015 when Cyberonics merged with Sorin SpA to form Livanova PLC, of which he continued as non-executive chairman.

GI Dynamics said that prior to Cyberonics, Mr Moore held senior positions with Boston Scientific for 17 years.

The company said that Mr Moore was a director of the Epilepsy Foundation of America, the Medical Device Manufacturers Association and was currently the chairman of Brainscope Co.

GI Dynamics said the Mr Moore held a Bachelor of Arts from Harvard University and a Masters of Business Administration from Boston University.

The company said that outgoing chairman Jack Meyer would remain a non-executive director and retire at the end of his elected term at the 2017 annual general meeting.

GI Dynamics fell 0.1 cents or 6.25 percent to 1.5 cents with 1.1 million shares traded.

OPTISCAN

Optiscan says that following its recent capital raising it has appointed Alan Hoffman as chairman, with Peter Francis and Dr Ian Griffiths as non-executive directors.

Last week, Optiscan said it had debt funding of $600,000, with a facility of $500,000 secured against the 2016 R&D Tax Incentive claim (BD: Apr 29, 2016).

Optiscan said that director Ian Mann would remain on the board but Peter Delaney would step-down from board, remaining an executive at the company.

The company said that Mr Hoffman had more than 20 years' experience in management roles at Shell Australia, the Wesfarmers Group and the Coventry Group.

Optiscan said that Mr Francis was a partner of the Melbourne-based FAL Lawyers and was the chairman of Benitec ,

The company said that Dr Griffiths was currently the chief executive officer of the Wound Management Innovation Co-operative Research Centre and previously was Aortech Biomaterials chief executive officer as well as the chief executive officer of Polynovo Pty Ltd and Novoskin Pty Ltd.

Optiscan said that the board had commissioned an independent report to carry out a strategic review and provide strategies to rebuild shareholder value.

The company said that the business plan would form the cornerstone of a capital raising in late May or early June 2016.

Optiscan was in a suspension and last traded at two cents.