



# Biotech Daily

Wednesday November 25, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: COMPUMEDICS, PRIMA UP 14%; POLYNOVO DOWN 11%**
- \* **ADELAIDE UNI TRIALS AMPLIPHI BACTERIOPHAGE FOR GOLDEN STAPH**
- \* **SEMENTIS TO RAISE \$2m FOR CHIKUNGUNYA, ALLERGY VACCINES**
- \* **POLYNOVO RAISES \$8.5m, PLAN, TO TAKE NOVOSKIN, NOVOWOUND**
- \* **PRESCIENT PLACES \$1m, TOTAL RAISED \$2m**
- \* **GORDAGEN UP TO \$3m LOAN, CHAIRMAN FRED NADJARIAN RETIRES**
- \* **USCOM REBADGES THOR DEVICES 'SPIROSONIC'**
- \* **ISONEA STARTS AIRSONEA CHICAGO TRIAL**
- \* **HONG KONG, AUSTRALIA PATENTS FOR ORTHOCELL ATI, CELGRO**
- \* **CBA, RELATED PARTIES BELOW 5% OF SIRTIX, YET AGAIN**
- \* **TALU BELOW 5% OF UNIVERSAL BIOSENSORS**
- \* **CHAIRMAN ANDREW KROGER TAKES 28% OF CRYOSITE**
- \* **PAUL HOPPER, ASSOCIATES INCREASE, DILUTED TO 12% OF PRESCIENT**
- \* **BIO-MELBOURNE INNOVATION WEEK BREAKFAST WITH THE MINISTER**

## MARKET REPORT

The Australian stock market fell 0.63 percent on Wednesday November 25, 2015 with the ASX200 down 32.7 points to 5,193.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and one was untraded.

Compumedics and Prima were equal best, up 14.3 percent to 40 cents and 5.6 cents, respectively, with 894,823 shares and 19.2 million shares traded, respectively. Optiscan climbed 8.8 percent; Universal Biosensors was up 6.7 percent; Uscom and Viralytics improved more than five percent; Benitec, IDT, Living Cell and Tissue Therapies were up more than four percent; Circadian was up 3.1 percent; Anteo rose 2.3 percent; with Pro Medicus, Resmed and Sirtex up one percent or more.

Polynovo led the falls, down two cents or 11.1 percent to 16 cents with 1.5 million shares traded. Genetic Technologies retreated 10.3 percent; Admedus, Atcor, Mesoblast and Oncosil fell five percent or more; Biotron and Osprey lost four percent or more; Acrux and Cellmid were down more than three percent; Impedimed and Psivida shed more than two percent; Cochlear, Medical Developments, Neuren, Orthocell and Starpharma were down one percent or more; with CSL down 0.4 percent.

## AMPLIPHI BIOSCIENCES

Ampliphi says the University of Adelaide will run the phase I study of its bacteriophage AB-SA01 for rhinosinusitis associated with staphylococcus aureus infection.

Ampliphi said that the nine-patient trial would be conducted at Adelaide's Queen Elizabeth Hospital and was sponsored by the University of Adelaide, with the company supplying the drug manufactured at its Ljubljana, Slovenia facility.

The company said it would provide financial support and assist with study coordination and monitoring laboratory testing as well as scientific input, protocol recommendations and assist with data management support.

Ampliphi chief executive officer Michael Scott Salka said the study was "a significant step ... on our mission to attack the rising menace of drug-resistant bacterial infections".

Mr Salka said that advancing the bacteriophage-based therapy into the clinic would "demonstrate the potential of phage therapy to provide relief to the millions of patients ravaged every year by antibiotic-resistant bacteria".

Ampliphi said that dosing was expected to begin in the next few weeks.

Ampliphi is based in San Diego, California with offices in Sydney and Slovenia and on the Nasdaq last night fell 10 US cents or 1.68 percent to \$US5.86 with 25,356 shares traded.

## SEMENTIS

Melbourne's Sementis hopes to raise \$2 million a five cents a share for pre-clinical work on its attenuated virus vaccine for chikungunya, peanut allergy and cat allergy.

Sementis chief executive officer and former Biota executive Dr Jane Ryan told an investor briefing in Melbourne that the mosquito-borne chikungunya was an emerging disease being spread from the Caribbean with infections detected in the Americas, South East Asia and Australia.

Dr Ryan said that the company's 'Sementis Copenhagen Vector' was based on the poxvirus, vaccinia virus, and a fully attenuated version was being developed in Chinese hamster ovary (CHO) cell lines initially to be trialled for chikungunya and if successful to be then trialled for the two allergies.

Dr Ryan said that the technology had been developed by Sementis chief scientific officer Dr Paul Howley and the laboratory works was being undertaken at the University of South Australia, with research conducted at the Queensland Berghofer Institute for Medical Research.

Dr Ryan said that an unnamed contract manufacturing organization would produce the vaccine and a US Department of Health and Human Services grant would defray up to 70 percent of the \$US3.3 million in costs.

Dr Ryan said that the vaccine for chikungunya had been tested in mice, as it had for peanut allergy and the company was expecting to conduct toxicology studies.

Dr Ryan said the company would need to raise a further \$18 million to take it to the beginning of phase I trials in all three indications, with the first trial for chikungunya about 18 months away.

Sementis said that chairman Maurice O'Shannassy was a major shareholder with 21,722,408 shares, \$1,000,000 in 5,882,353 convertible notes and 500,000 options.

The company said that Dr Howley held 19,750,000 shares and director Dr Tom Quirk, formerly a director of Biota, Virax and Peptech, held 233,300 shares.

Sementis said that it had 126,286,298 shares on issue which would become 157,054,298 shares if all convertible notes were converted.

For more information contact Mike Richardson: [mikerichardson@corporatewriters.com.au](mailto:mikerichardson@corporatewriters.com.au).

Sementis is a public unlisted company.

## POLYNOVO

Polynovo says it has raised \$8.5 million in a placement at 13.5 cents a share, will offer a share plan and will acquire 100 percent of subsidiaries Novoskin and Novowound.

Polynovo said the placement to sophisticated investors was oversubscribed.

The company said it would offer a share purchase plan at 13.5 cents a share to investors on the register on the record date of November 24, 2015, the plan would open on December 2 and close on December 16, 2015.

Polynovo said it would acquire the 20 percent minority interests in Novoskin Pty Ltd and Novowound Pty Ltd from entities associated with Prof John Greenwood and Julian Burton, who would receive Polynovo shares and cash in consideration.

The company said that Novoskin was established in 2010 to conduct the non-clinical development of Polynovo's biodegradable temporising matrix (BTM) and Novopore and was assigned the marketing rights for all wound applications, except for negative pressure wounds.

Polynovo said that the joint venture was to conclude once human trials were started and with the current clinical trials program well-established it was "the right time to acquire full ownership".

The company said Novowound was established as a joint venture for the non-clinical development of the biodegradable temporising matrix for negative pressure wounds and was assigned the marketing rights for all negative pressure wound applications.

Polynovo said that Prof Greenwood conducted animal and human trials over the past five years, which generated "significant data and confirmation of the safety profile of the products for use in our regulatory dossiers".

The company said that the transaction was conditional on due diligence.

Polynovo said that the consideration would be 32,000,000 shares, subject to shareholder approval, \$500,000 cash at settlement; \$1,000,000 cash on March 1, 2016, \$500,000 cash on May 31, 2016 and \$500,000 cash on June 29 2016.

The company said that the advantages of acquisition were significant and included control over marketing of the products, entitlement to 100 percent of all revenue including up-front payments, royalties and sales for the use of the BTM in full thickness burns and surgical wounds and from Novopore foam in wound applications, satisfying parties who wanted to deal with the head company and not a subsidiary, simplifying the corporate and reporting structure, improved ability for tax losses from trials and product development and Prof Greenwood and Mr Burton would become shareholders.

Polynovo said it recognized the significant contribution that Prof Greenwood made in the development of the BTM and it was negotiating a consulting role for his involvement in the clinical and product development programs.

Polynovo two cents or 11.1 percent to 16 cents with 1.5 million shares traded.

## PRESCIENT THERAPEUTICS

Prescient says it has followed yesterday's \$927,421 share plan at 5.4 cents a share with a placement of about \$1,042,200 at the same price.

Prescient said that the total funds of about \$2 million was expected "to provide for efforts to achieve multiple milestones across its clinical programs over the next 12 to 18 months".

The company said the funds would allow it to begin and complete a phase Ib acute myeloid Leukaemia trial at the Florida-based Moffitt Cancer Center, begin recruitment for a phase II breast cancer trial at New York's Montefiore Medical Center and continue recruitment in a phase Ib ovarian cancer trial underway at the Moffitt Cancer Center.

Prescient was untraded at six cents.

## GORDAGEN PHARMACEUTICALS

Gordagen says it has an up to \$3 million loan facility and chairman Fred Nadjarian will retire from the board and be appointed special advisor to the scientific advisory board. Gordagen said it intended to appoint "at least two independent non-executive directors by [April] 2016 to help drive the company's success in the rapidly growing nutraceuticals market".

Gordagen said it had an up to \$3 million "research and development" loan facility from Metamor Capital Partners with a minimum drawdown of \$1,169,706.

In August, Gordagen received \$1,103,708 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program for expenditure in the year to June 30, 2015.

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily the loan was tied to the tax credit value and it expected a similar level credit in 2016 (BD: Aug 18, 2015).

Dr Tong said the loan would allow the company to pursue its market entry in the US and Japan and the company planned "to launch our first product, our heart health nutraceutical, NE1-Heart, and phase II clinical studies in the US for our exercise and muscle recovery product NE1-Elite within the first half of 2016".

"We are pleased to be able to take advantage of the Australian Federal Government's R&D Tax Incentive program, which does an excellent job encouraging investment in innovative research," Dr Tong said.

Gordagen is a private company.

## USCOM

Uscom says it has rebadged its Thor range of medical devices which has begun sales as the Uscom Spirosonic range of spirometers.

Uscom said that the devices for improving diagnosis and treatment of asthma and chronic obstructive lung disease had been renamed, rebranded, relabelled and repriced and were being prepared for sale in global markets over the next 12 months.

The company said that the devices were US Food and Drug Administration cleared and covered by reimbursement codes for between \$50 and \$87 per test and would retail for \$2,000 to \$3,000 (BD: Nov 20, 2015).

Uscom executive chairman Prof Rob Phillips said the release of the Spirosonic range would "spearhead our entry into the UK and US spirometer market and we are currently negotiating with specialist distributors in these jurisdictions".

"The objective is to be generating substantial revenue from these devices within the next 12 months," Mr Phillips said.

Uscom was up one cent or 5.3 percent to 20 cents.

## ISONEA

Isonnea says it has institutional review board approval for a 90-patient trial of its Airsonea asthma diagnostic at the University of Chicago.

Isonnea said that the principal investigator would be the pulmonary function laboratory and adult cystic fibrosis program director Prof Edward Naureckas.

The company said that the study would collect and record breath sounds data using the Airsonea platform from patients in all age groups under realistic ambient conditions, with a study hypothesis that Airsonea was "as accurate, sensitive and specific, in detection and quantifying wheeze as the consensus of physicians and a panel of technical experts".

Isonnea was unchanged at 5.3 cents.

## ORTHOCELL

Orthocell says it has been granted a Hong Kong patent for its tenocyte product and an Australian patent covering its collagen-based Celgro.

Orthocell said that the Hong Kong patent was entitled 'Culture medium, culturing method and use of tenocytes' covering its autologous tenocyte implantation (Ortho-ATI) technology until March 23, 2027, and the Australian patent was entitled 'Method for Producing a Collagen Membrane and Uses Thereof' covering Celgro to June 12, 2033. Orthocell managing-director Paul Anderson said the patents "further strengthens our international [intellectual property] position and complements already granted patents in the US, Singapore, China and New Zealand.

The company said that the patents related to the manufacture of novel bio-scaffolds to aid in the surgical repair of soft tissue injuries such as tendon, cartilage, bone and the delivery of cells to surgical sites and to the manufacture of tenocyte cells the building blocks of human tendon.

Orthocell fell half a cent or 1.1 percent to 45.5 cents.

## SIRTEX MEDICAL

The Commonwealth Bank of Australia and a large number of related parties say that, yet again, they have reduced below five percent substantial in Sirtex.

In October, the Commonwealth Bank said it had returned to substantial in Sirtex with 2,897,052 shares (5.06%) taking 101 pages to cite purchase and borrowing of shares, with some trades as small as single shares, scores of trades involving fewer than 10 shares and hundreds of trades of fewer than 50 shares (BD: Oct 9, 2015).

Today the CBA took 114 pages to cite the purchase, sale, borrowing and return of shares between October 9 and November 23, 2015 with some trades, again, as small as single shares.

Sirtex climbed 50 cents or 1.3 percent to \$39.52 with 456,612 shares traded.

## UNIVERSAL BIOSENSORS

The Brisbane-based Talu Ventures says it has ceased its substantial holding in Universal Biosensors selling 10,000,000 Chess depositary interests for \$4,300,000.

In 2013, the Brisbane-based Talu Ventures has acquired CM Capital's 17,794,384 Universal Biosensors Chess depositary interests (10.2%) and said it had taken over as the manager and trustee from CM Capital of CM Capital Venture Trust No 3 and CM Capital 3A (BD: Nov 14, 2013).

With a holding of 7,794,382 shares Talu retains 4.4 percent of Universal Biosensors. Universal Biosensors was up three cents or 6.7 percent to 48 cents.

## CRYOSITE

Cryosite chairman Andrew Kroger says he has increased his substantial shareholding in his company from 11,975,816 shares (25.56%) to 13,275,816 shares (28.33%).

The substantial shareholder notice said that Mr Kroger bought 1,300,000 shares on-market on November 24, 2015 at 27.5 cents a share.

Cryosite was up half a cent or 1.8 percent to 28 cents.

### PRESCIENT THERAPEUTICS

Director Paul Hopper and associates have increased their holdings but have been diluted in Prescient from 8,905,002 shares (15.56%) to 8,976,472 shares (12.06%).

Mr Hopper said the group acquired 71,470 shares for \$3,859 or 5.4 cents in the company's share plan but was diluted in the plan (BD: Nov 24, 2015).

### BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says Victoria Minister for Small Business, Innovation and Trade Philip Dalidakis will open Innovation Week at its November 30 Bio-Breakfast.

The Network said that the Bio-Breakfast would be "the opening event for a week long series of events for Innovation Week 2015 which is led by the Australian Science & Innovation Forum in partnership with the Academy of Technological Sciences & Engineering with support from the office of the lead scientist of Victoria".

The Network said that the convergence of technology and health was creating a positive change for our society and support for innovation in Australia was critical to ensure economic and social outcomes, job creation and improving the quality of life.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "Innovation Week brings together leaders from science, technology and business to see ideas and discoveries return their full potential value to society."

The Network said that the speakers included Mr Dalidakis; Blamey Saunders Hears managing-director Dr Elaine Saunders; Curve Tomorrow's operations director George Charalambous and the Academy of Technological Sciences & Engineering chief executive officer Dr Margaret Hartley.

The November 30, 2015 Bio-Breakfast will be held at the Monash Conference Centre Seminar Rooms 1, 2, and 3, Level 7, 30 Collins Street, Melbourne, with registration from 7.15am, buffet breakfast to 8am followed by presentations and the address from the Minister.

To register go to: <http://www.biomelbourne.org/events/view/399>.