



Biotech Daily

Friday February 19, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 16%, BIONOMICS DOWN 9%**
- * **PRO MEDICUS H1 REVENUE UP 65% TO \$14m, PROFIT UP 83% TO \$3m**
- * **IDT H1 REVENUE UP 5% TO \$6.45m, LOSS UP 15% TO \$3.5m**
- * **CLINUVEL H1 REVENUE UP 35% TO \$1.7m, LOSS DOWN 56% TO \$3.3m**
- * **DIMERIX COMBINATION THERAPY ALLOWED US PATENT**
- * **AUSTRALIA PATENTS FOR NOVOGEN'S CANTRIXIL, TRILEXIUM, ANISINA**
- * **SIMAVITA SHARE PLAN RAISES \$175k**
- * **OBJ REQUESTS 'TRIAL RESULTS' TRADING HALT**
- * **AUCKLAND'S MILFORD TAKES 5% OF LIVING CELL**
- * **BIO-MELBOURNE: EU, US ALIGNMENT WITH DR THOMAS LÖNNGREN**
- * **UNIVERSAL BIO LOSES CEO PAUL WRIGHT, ANDREW DENVER ACTING**

MARKET REPORT

The Australian stock market fell 0.79 percent on Friday February 19, 2016 with the ASX200 down 39.2 points to 4,952.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and four were untraded.

Antisense was the best, up 0.7 cents or 15.9 percent to 5.1 cents with 12,073 shares traded. Mesoblast climbed 9.1 percent; Impedimed and Pharmaxis rose more than seven percent; Medical Developments and Prana were up five percent or more; Ellex and Opthea improved more than four percent; Osprey was up 3.6 percent; Acrux and Clinuvel rose more than two percent; Actinogen and CSL were up more than one percent; with Viralytics up 0.7 percent.

Bionomics led the falls, down three cents or 9.1 percent to 30 cents with 961,475 shares traded. IDT lost 6.6 percent; Biotron, Cellmid and Oncosil were down more than five percent; Avita, Neuren, Polynovo and Tissue Therapies fell four percent or more; Pro Medicus and Universal Biosensors were down more than three percent; Anteo and Atcor shed more than two percent; Nanosonics and Orthocell were down more than one percent; with Admedus, Cochlear, Sirtex and Starpharma down by less than one percent.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2015, was up 65.3 percent to \$14,285,000 with net profit after tax up 82.9 percent to \$2,941,000.

Pro Medicus said it would pay an unfranked 1.5 cents a share dividend for investors at the record date of March 11, to be paid on March 25, 2016.

The company said that in the six months to December 31, 2015, it had signed an \$11 million imaging technology contract with the Pittsburgh's Allegheny Health Network and a \$3 million deal with a German hospital network.

Pro Medicus chief executive officer Dr Sam Hupert said the increase in revenue was "largely a result of transactional fees from the implemented contracts" and the company continued to build in North America, pursuing both the enterprise imaging and large teaching hospitals and private imaging centre markets.

Dr Hupert said Pro Medicus had one-off costs as well as expenses relating to increased business activity, adding US staff and higher legal fees to pursue more contracts.

The company said that diluted earnings per share was up 80.4 percent to 2.85 cents at December 31, 2015 with cash and cash equivalents at December 31, 2015 of \$16,190,000 compared to \$12,935,000 at December 31, 2014.

Pro Medicus fell 11 cents or 3.5 percent to \$3.01.

IDT AUSTRALIA

IDT says that revenue for the six months to December 31, 2015 was up 4.9 percent to \$6,450,000 with loss up 14.8 percent to \$3,538,000.

IDT said that cost increases were incurred ahead of rising revenues as the company built capacity and it expected a profitable second half of the financial year.

The company said that it also received revenue was from its CMax clinical trial business at the Royal Adelaide Hospital.

IDT said that diluted loss per share fell 45.45 percent from 3.3 cents in the previous year to 1.8 cents for the six months to December 31, 2015.

The company said it had cash and cash equivalents of \$4,982,000 at December 31, 2015, compared to \$129,000 at June 30, 2015.

IDT fell two cents or 6.6 percent to 28.5 cents.

CLINUVEL

Clinuvel says that revenue for the six months to December 31, 2015, was up 35.1 percent to \$1,723,508 with net loss after tax down 55.6 percent to \$3,261,046.

Clinuvel said most of the revenue came from the supply of its Scenesse (afamelanotide 16mg) implants under the reimbursement schemes of Italy and Switzerland, which was up 52.3 percent to \$1,317,195 for the six months to December 31, 2015.

The company said that while the number of implants supplied under the reimbursement schemes increased period-on-period, reflecting the increasing awareness and demand for the drug within the patient communities, the revenue result benefited from a stronger Euro and Swiss Franc relative to the Australian dollar.

The company said that diluted loss per share fell 57.8 percent to 7.3 cents for the six months to December 31, 2015, while net tangible assets per share fell 33.3 percent to 20 cents at December 31, 2015 compared to 30 cents at December 31, 2014.

The company said it had cash and cash equivalents of \$7,498,767 at December 31, 2015, compared to \$13,574,506 at June 30, 2015.

Clinuvel climbed nine cents or 2.9 percent to \$3.19.

DIMERIX

Dimerix says that the US Patent and Trade Mark Office has allowed a patent covering the use of DMX-200 in the treatment of kidney disease.

Dimerix said that the patent, entitled 'Combination Therapy' would provide protection until January 2032.

The company said that DMX-200 combined two existing drugs, the chemokine receptor CCR2 blocker propagermanium used for its anti-inflammatory properties and the angiotensin II type I receptor blocker irbesartan used for treatment of hypertension.

Dimerix said that DMX-200 had been shown to improve the outcome of chronic kidney disease by significantly reducing proteinuria in animal models of the disease.

The company said the patent claims encompassed the use of a multitude of CCR2 and angiotensin receptor blockers in combination to treat a broad range of diseases.

Dimerix said that an extension of the patent term might be available in the US and other regions, to compensate for the time taken to develop a pharmaceutical, once a pharmaceutical product protected by the patent was registered in the US.

The company said that the allowance of the use claims in the US followed the grant of use and pharmaceutical composition claims in Australia last year and the same patent family was under examination in Europe, Japan and other markets.

Dimerix said that a phase II study in patients with chronic kidney disease was underway with the aim of confirming safety and reduction of proteinuria at 24 weeks of treatment.

Dimerix executive chairman Dr James Williams said that securing "such broad patent use claims in an important pharmaceutical market provides enormous opportunities, both for the DMX-200 program in chronic kidney disease, which affects more than 26 million people in the US, as well as for broader licensing opportunities".

Dimerix said that the allowance of the US patent triggered a milestone A of the class A performance shares issued to Dimerix Bioscience vendors on July 3, 2015, with the 75,000,040 performance shares converting to 75,000,040 Dimerix shares.

Dimerix was up 0.1 cents or 20 percent to 0.6 cents.

NOVOGEN

Novogen says that IP Australia has granted patent for the super-benzopyran family, covering Cantrixil and Trilexium and a patent covering Anisina has been accepted.

Novogen said that a patent entitled 'Functionalised benzopyran compounds and use thereof' provides protection for the super-benzopyran family until February 2035.

The company said that a patent entitled 'Functionalised and substituted indoles as anti-cancer agents' covering the first lead anti-tropomyosin compound Anisina had been examined and accepted and had entered the standard three-month opposition window prior to being granted and would provide coverage until July 2035.

Novogen North America chief executive officer Dr Andrew Heaton said the patents helped "validate the company's discovery platforms and [were] critical milestones".

"The [super-benzopyran] patent covers a wide range of new chemical entities, including Cantrixil and Trilexium," Dr Heaton said.

"Critically, the patent covers composition of matter, a new abridged method of manufacture, and treatment for a wide variety of cancer types," Dr Heaton said.

"Passing scrutiny in Australia will aid the on-going global roll-out of this patent," Dr Heaton said. "The availability of the global patent prosecution highway will permit accelerated examination in overseas jurisdictions, based on acceptance of an Australian application."

Novogen was up half a cent or five percent to 10.5 cents.

SIMAVITA

Simavita says its share purchase plan has raised \$175,000 through the issue of 1,225,000 CHESS depositary interests (CDIs) at 15 cents each.

Simavita said that one free CDI would be allotted for every 20 CDIs acquired.

The company said that the funds raised would be used to support the continued roll-out of its technologies in the US and Europe, appoint distributors and licencees and for continued product innovation.

Simavita was up one cent or 9.1 percent to 12 cents.

OBJ

OBJ has requested a trading halt "pending an announcement in relation to the receipt of results from the University of Queensland on the Bodyguard clinical trial".

Trading will resume on February 23, 2016 or on an earlier announcement.

OBJ last traded up 0.3 cents or 4.8 percent to 6.6 cents with 1.1 million shares traded.

LIVING CELL TECHNOLOGIES

The Auckland New Zealand-based Milford Asset Management says it has become a substantial shareholder Living Cell with 24,313,934 shares or 5.08 percent.

The substantial shareholder notice said that the registered holder was NNL custodians and it had bought 12,577,578 shares on February 17, 2016 at 5.47 cents a share.

Living Cell was untraded at 5.3 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its February 25, 2016 Bio-Workshop will discuss EU marketing authorisation, market access and the need for US alignment.

The Network said that the workshop would be led by former European Medicines Agency executive director Dr Thomas Lönngrén, who was previously the Swedish Medical Products Agency's deputy director general.

Dr Lönngrén was formerly a director of CBio (now Invion) and last year was appointed a director of Analytica (BD: Aug 10, 2015).

The industry organization said that the workshop was entitled 'In Conversation with Thomas Lönngrén: EU Market Authorisation, Market Access - and the Need for US Alignment'.

The Network said that attendees would hear Dr Lönngrén's personal view on the emerging trends in drug development in EU and US, including the regulators and payers response, drawing on his decades of experience in the pharmaceutical development sector and a current interpretation of the important considerations for strategies in developing effective global regulatory and health technology assessment development programs.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said "there will be a dynamic and interactive [question and answer] workshop tailored to meet the interests of participants with in-depth discussion".

The February 25, 2016 Bio-Workshop will be held in the Bio-Melbourne Network Boardroom, Milton House, 25 Flinders Lane, Melbourne.

Registration is from 11.15am for the workshop running from 11.30am until 2pm, inclusive of lunch and networking.

To register go to: <http://www.biomelbourne.org/events/view/411>.

UNIVERSAL BIOSENSORS

Universal Biosensors says chief executive officer Paul Wright will retire effective from March 10, 2016, with chairman Andrew Denver appointed acting chief executive officer. Mr Wright said that with two commercial products on the market and the release of solid full year results for 2015, Universal Biosensors was “well placed to consolidate its position as an innovative and dynamic point-of-care diagnostics company”.

Universal Biosensors said that Mr Wright had been “instrumental in fostering strong relationships” with Siemens and Johnson & Johnson’s Lifescan and in identifying new opportunities for the company’s technology.

In 2010, Mr Denver assumed the role of executive chairman and interim chief executive officer following the departure of Mark Morrison, stepping down when Mr Wright was appointed in 2011 (BD: Sep 9, 2010; Mar 1, 2011).

Universal Biosensors said that an executive search had begun and Mr Denver would resume the role of executive chairman and interim chief executive officer on a base salary of \$300,000 a year plus superannuation and would not receive his chairman’s allowance. Universal Biosensors fell 1.5 cents or 3.7 percent to 39.5 cents.