



Biotech Daily

Thursday October 8, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: BIONOMICS UP 20%; GENETIC TECHNOL DOWN 5%**
- * **MERCK INVESTS \$13m IN BIONOMICS, EXTENDS PAIN COLLABORATION**
- * **LONZA TO MANUFACTURE BENITEC DRUGS**
- * **ELLEX INCREASES SALES, REDUCES COSTS, FOREX BENEFIT**
- * **US PATENT FOR SUDA ORAL SPRAY SILDENAFIL (VIAGRA)**
- * **NANOSONICS AGM FOR 278k, \$364k EXECUTIVE 'PERFORMANCE RIGHTS'**
- * **ONCOSIL APPOINTS EXECUTIVES DAVID JAMES, DR GREG ROGERS**
- * **IDT APPOINTS EX-HOSPIRA HUGH BURRILL DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.24 percent on Thursday October 8, 2015, with the ASX200 up 12.5 points to 5,210.4 points.

Twenty of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Bionomics was the best, up nine cents or 19.6 percent to 55 cents with 2.3 million shares traded.

Biotron, Compumedics and IDT climbed more than seven percent; Oncosil was up 6.45 percent; Actinogen and Benitec were up more than five percent; Acrux and Atcor improved four percent or more; Admedus, Clinuvel, Polynovo and Pro Medicus were up more than three percent; Antisense and Living Cell rose more than two percent; Mesoblast, Prima, Resmed and Universal Biosensors were up more than one percent; with Cochlear CSL, Impedimed and Orthocell up by less than one percent.

Genetic Technologies led the falls, down 0.1 cents or 5.3 percent to 1.8 cents with 256,960 shares traded.

Optiscan fell 4.55 percent; Cellmid and Sirtex lost more than three percent; Nanosonics shed 2.2 percent; Anteo, Ellex and Medical Developments were down one percent or more; with Starpharma down 0.7 percent.

BIONOMICS

Bionomics says it has extended its strategic collaboration with Merck & Co for the discovery and development of drug candidates to treat chronic and neuropathic pain. Bionomics said that the agreement with the Kenilworth, New Jersey-based Merck, known as Merck Sharpe and Dohme outside the US and Canada built on a July 2013 collaboration on the discovery and development of novel, small molecule drug candidates for the treatment of chronic and neuropathic pain using its Ionx and Multicore drug discovery platforms.

In 2013, Bionomics said the two-year agreement with Merck provided option exercise fees and development and regulatory milestone payments of up to \$US172 million (then \$A190.4 million) and the company could also be eligible for undisclosed royalties on net sales of products from the collaboration (BD: Jul 31, 2015).

Today, Bionomics said that Merck & Co would buy 21,659,230 shares at 59.38 cents, a 29 percent premium to its closing price on October 7, 2015, a total cost of \$12,861,251.

Merck Research Laboratories business development and licencing senior vice-president Dr Iain Dukes said that “establishing strong long-term external collaborations is central to our business development strategy”.

“We have been impressed with the progress made by Bionomics to date on both our cognition and pain programs and look forward to advancing these programs further,” Dr Dukes said.

Bionomics chief executive officer Dr Deborah Rathjen said she was “delighted to welcome Merck & Co as a shareholder of Bionomics”.

“This investment provides further validation of our science,” Dr Rathjen said.

“The extension of our agreement with Merck & Co on the discovery and development of novel small molecule candidates for the treatment of chronic and neuropathic pain reflects the solid progress made by the Bionomics team as we strive to deliver therapies with the potential to make a significant difference in the lives of patients,” Dr Rathjen said.

Bionomics was up nine cents or 19.6 percent to 55 cents with 2.3 million shares traded.

BENITEC BIOPHARMA

Benitec says it has a manufacturing services agreement with Lonza Houston to develop a scalable manufacturing process for its drugs in development.

Benitec said that the Basel, Switzerland based Lonza was a biological, cell and viral gene therapy manufacturing company and would develop the process for its DNA-directed RNA interference (ddRNAi)-based, adeno-associated virus (AAV)-delivered products intended for therapeutic use in humans.

The company said that the relationship would “leverage Lonza’s expertise to facilitate the development of a cost effective, scalable and robust suspension culture-based manufacturing platform ... anticipated to enable the production of sufficient material to meet the potential demand for treating diseases that affect millions of people such as hepatitis C”.

Benitec head of manufacturing Dr Claudia Kloth said that Lonza was “an ideal partner for us to optimize our large-scale production process based on its solid expertise and track record in process development and production of AAV-based gene therapeutics”.

Lonza’s head of emerging technologies Dr Andreas Weiler said the agreement “continues the development of our robust and large-scale AAV platform for the production of AAV-based viral gene therapies”.

Benitec was up 2.5 cents or 5.4 percent to 49 cents.

ELLEX MEDICAL LASERS

Ellex says that sales revenue for the three months to September 30, 2015 was up 11.45 percent to \$14.6 million compared to the prior corresponding period.

Ellex said the improved sales performance was due to a 17 percent increase in sales of branded products, a \$1.4 million benefit due to the devaluation of the Australian dollar against the Yen, US dollar and Euro and a decrease of \$2.1 million due to a planned reduction in contract manufacturing and as a result of reduced third-party product sales, primarily in Japan.

Ellex chief executive officer Tom Spurling said the company started the financial year with positive momentum.

“The across-the-board organic increase in Ellex-branded product sales of 17 percent was very pleasing,” Mr Spurling said.

“It also bolstered the performance of our Japanese business, which in 2015, had a heavy emphasis on the sale of certain lower-margin third-party products,” Mr Spurling said.

“The growing volume of Ellex-branded sales also reflects the strength of our brand, our comprehensive product range and our innovative product development program,” Mr Spurling said.

Ellex said that the effort to increase sales of products, combined with the planned reduction in lower margin contract manufacturing was expected to improve sales margins and performance.

Ellex fell half a cent or 1.1 percent to 46.5 cents.

SUDA

Suda says the US Patent and Trademark Office has allowed its first patent application for its sildenafil based products SUD-003 and SUD-004.

Suda said that the patent application was entitled ‘Oral Spray Formulations and Methods for Administration of Sildenafil’ and provided coverage to December 2032.

The company said that a patent directed to similar subject matter had been granted in New Zealand and patent applications were pending in other jurisdictions.

Suda said the allowed claims covered the oral spray administration of sildenafil, the active pharmaceutical ingredient in SUD-003 and SUD-004, at a pH of between 1.5 and 2.4 for the treatment of sexual dysfunction induced by selective serotonin reuptake inhibitor (SSRI) anti-depressants and for pulmonary arterial hypertension.

The company said that SSRI-induced sexual dysfunction was a common condition, affecting up to 75 percent of patients taking SSRIs such as Prozac, Zoloft and Paxil.

Suda said that pulmonary arterial hypertension “affects the blood pressure between the heart and the lungs”, increased with age and was more common among women, people aged 75 years or older and heart failure was often linked to the disease and the market was forecast to reach \$US3.6 billion in 2015.

The company said the patent complemented its intellectual property portfolio for oral spray formulations of sildenafil in the treatment of erectile dysfunction and it had a second sildenafil patent family granted in Australian and Singapore with applications pending in the US and other jurisdictions.

Suda chief executive officer Stephen Carter said the US patent “reinforces our proprietary position covering the oral spray delivery of sildenafil for erectile dysfunction and pulmonary arterial hypertension”.

“Pfizer’s sildenafil tablet Viagra achieved sales of \$US1.7 billion in 2014 with the majority generated from sales the US market,” Mr Carter said.

Suda fell 0.1 cents or 3.3 percent to 2.9 cents with 4.5 million shares traded.

NANOSONICS

Nanosonics will vote to grant chief executive officer Michael Kavanagh 206,882 “performance rights”, along with 70,992 performance rights for Dr Ron Weinberger. Nanosonics said that the vesting of the free performance rights in two tranches, both on August 31, 2018, was subject to total shareholder return performance conditions measured against the long-term incentive scheme comparator groups 1 and 2. The company said that the comparator groups included companies “considered alternate investment vehicles by local and overseas investors, have similar operations and/or are impacted by similar cyclical factors.

Nanosonics said that along with the revenue-earning Ansell, Cochlear, Ellex, Compumedics, Cyclopharm, Clover Corp, Fisher and Paykel Healthcare, ITL and Universal Biosensors, the first comparator group included no or low revenue companies Analytica, Allegra, Airxanders, GI Dynamics, IM Medical (in suspension), Isona and Reva.

The second comparator group includes companies that are in the S&P ASX 300, but are not in the S&P ASX100, known as the S&P ASX Small Ordinaries.

The company’s notice of meeting said shareholders would vote on the remuneration report and the election of director Richard England.

The meeting will be held in the Brisbane Room, Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney on November 6, 2015 at 11am (AEDT).

Nanosonics fell three cents or 2.2 percent to \$1.32.

ONCOSIL MEDICAL

Oncosil says it has appointed David James as head of manufacturing operations and Dr Greg Rogers as manufacturing engineering manager.

Oncosil; said that Mr James was appointed effective from October 5, 2015, having worked in the role as part-time consultant since February and Dr Rogers would be appointed effective from November 2, 2015.

The company said Mr James had more than 20 years’ experience, including six years with Sirtex as operations manager, responsible for managing production, logistics, customer service and engineering, including responsibility for the design, construction and commissioning of Sirtex’s first in-house manufacturing plant in Wilmington DC.

Oncosil said that Mr James held a Masters in Business and Technology from the University of New South Wales and was” a chartered chemist” with the Royal Australian Chemical Institute.

The company said that Dr Rogers had more than 27 years in leadership, operations, quality control and change management roles in the medical device and diagnostics sectors, as well as the fast-moving consumer goods and heavy engineering industries.

Oncosil said that previously Dr Rogers was Ingeneus general manager of manufacturing, responsible for developing the manufacturing capability for its hand held and ophthalmic lasers for Australian, US and European markets.

The company said that Dr Rogers was Somnomed's the regulatory and quality manager, had held management roles with Resmed, where he was manufacturing director managing 220 staff and worked for the Australian Therapeutic Goods Administration and before that was the executive manager for Downer Rail.

The company said that Dr Rogers held a Bachelor of Engineering and a Bachelor of Science from the University of Sydney and a Doctorate of Philosophy from the University of New South Wales.

Oncosil was up one cent or 6.45 percent to 16.5 cents with 3.9 million shares traded.

IDT AUSTRALIA

IDT says that it has appointed Hugh Burrill as a director, effective from today.

IDT said that Mr Burrill had held senior pharmaceutical industry executive roles, including Hospira's head of research and development, where he was responsible for overall pipeline portfolio management and research and development of generic and specialty pharmaceuticals.

The company said that Mr Burrill previously held other senior roles within Hospira and the original Mayne Pharma, was CCH Pharma managing-director and since 2007 had been a director and deputy chair of Nova Aerospace Pty Ltd.

IDT was up 2.5 cents or 7.1 percent to 37.5 cents.