



Biotech Daily

Thursday August 6, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: ACTINOGEN UP 16%, CELLMID DOWN 10%**
- * **US GRANTS GENETIC TECHNOLOGIES BREVAGENPLUS PATENTS**
- * **NOVOGEN LODGES 2 ANTI-TROPOMYOSIN AUSTRALIAN PATENTS**
- * **ANALYTICA RIGHTS ISSUE RAISES \$2.8m OF HOPED-FOR \$3.8m**
- * **SUDA 'DELIGHTED' BY FDA RESPONSE TO SUD-001 MIGRAINE PROGRAM**
- * **ISONEA AIRSONEA 'MAJOR ADVANCE' TO WORK WITH BREATHING**
- * **FEDERAL GOVERNMENT APPOINTS DAVID THODEY CSIRO CHAIR**
- * **POLYNOVO CEO PAUL BRENNAN 12.6m LONG-TERM OPTIONS**
- * **IMMURON TO ISSUE 6m DIRECTOR OPTIONS 'IN LIEU OF CASH'**
- * **ANATARA CHAIR MEL BRIDGES, PARMA INCREASE, DILUTED TO 12.5%**
- * **STIRLING PRODUCTS (DOCA) RESTRUCTURE EGM**

MARKET REPORT

The Australian stock market fell 1.13 percent on Thursday August 6, 2015 with the ASX200 down 63.9 points to 5,610.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and two were untraded.

Actinogen was the best, up 0.9 cents or 16.1 percent to 6.5 cents with 213,000 shares traded, followed by Neuren up 10 percent to 11 cents with 9.8 million shares traded.

Osprey climbed 8.3 percent; Genetic Technologies was up 7.1 percent; Ellex and Universal Biosensors were up more than six percent; Biotron was up five percent; Atcor, Optiscan and Prima rose more than four percent; Antisense and Resmed were up more than one percent; with Cochlear, Mesoblast and Psivida up by less than one percent.

Cellmid led the falls, down 0.4 cents or 10 percent to 3.6 cents with 5.5 million shares traded. Polynovo lost 8.7 percent; Avita fell 5.9 percent; Anteo and Circadian fell more than four percent; Clinuvel and Orthocell were down more than three percent; Benitec shed 2.6 percent; with CSL, IDT, Medical Developments and Nanosonics down more than one percent.

GENETIC TECHNOLOGIES

Genetic Technologies says it has been granted two US patents covering three single-nucleotide polymorphism genetic markers in its Brevagenplus breast cancer test.

Genetic Technologies has previously said that the Brevagenplus test had 77 separate but chief executive officer Eutillio Buccilli told Biotech Daily that these three single-nucleotide polymorphisms (SNPs) were “the core markers of the original seven marker test as well as the new Brevagenplus breast cancer risk assessment test.

According to the US Patent and Trademark Office website, both patents are entitled ‘Markers for breast cancer’ and the description includes correlations between polymorphisms and breast cancer, as well as methods of diagnosing, prognosing and treating breast cancer, along with systems and kits for diagnosis, prognosis and treatment of breast cancer and methods of identifying breast cancer modulators.

Mr Buccilli said the patents provided protection to December 2026.

In a media release to the ASX Genetic Technologies said that the patent family was assigned to Cambridge University, England and licenced exclusively to the company.

Genetic Technologies said that the patents were “an important part of the commercialisation strategy for our first-in-class breast cancer risk assessment test”.

The company said that the markers “were amongst the first of the breast cancer susceptibility loci to be consistently and robustly confirmed across multiple genome-wide association studies, such that their inclusion in Brevagenplus provides the test with an additional significant proprietary competitive advantage over other SNP-based tests that might be developed”.

Genetic Technologies said that the proprietary technology in the Brevagenplus test provided “significant benefits over existing breast cancer risk assessment algorithms ... [and the] recently granted US patents greatly enhance the value proposition of the test”.

Genetic Technologies was up 0.2 cents or 7.1 percent to three cents with 4.1 million shares traded.

NOVOGEN

Novogen says it has lodged two patents covering its anti-tropomyosin technology platform with IP Australia, formerly the Australian Patent and trademark office.

Novogen told Biotech Daily that the patents were entitled ‘Functionalised and substituted carbazoles as anti-cancer agents’ and ‘Functionalised and substituted indoles as anti-cancer agents’ and were filed on July 16, 2015 with expected durations of 20 years.

Novogen said that the purpose of the patents was “for the company to claim ownership of two families of anti-tropomyosin compounds and pharmaceutical compositions thereof, or composition of matter, and their use as treatments for a disease or disorder”.

In its media release to the ASX, Novogen drug discovery and development vice-president Dr Andrew Heaton said the patent specifications covered a wide range of novel anti-tropomyosin compounds, including the lead anti-tropomyosin drug candidate Anisina and added to two previous patents lodged in May 2015.

Novogen said that the active ingredient of Anisina was a small molecule targeting a protein component of the actin microfilament, called tropomyosin, or Tpm3.1, which researchers had shown to be essential for tumor cell survival in vitro.

The company said that in-vitro studies had shown that inhibiting Tpm3.1 with anti-tropomyosin compounds caused tumor cell death across a range of cancer cell types.

Novogen said that pending the outcome of its manufacturing and toxicology programs, Anisina was expected to start phase I clinical trials in 2016.

Novogen fell half a cent or 2.9 percent to 16.5 cents.

ANALYTICA

Analytica says its rights issue raised \$1,817,317 with the shortfall expected to raise \$982,683, taking the total to \$2,800,000, of the hoped-for \$3.76 million.

Analytica said that the partly-underwritten, one-for-two, renounceable rights issue at 0.8 cents a share had 227,164,628 shares taken up and was undersubscribed by 242,445,222 shares (BD: Jul 8, 2015).

The company said that 122,835,372 shortfall shares would be taken up by underwriter Patersons Securities investors.

Analytica said the rights issue included three-for-one short and long term options and it would issue 116,166,666 options exercisable at 1.1 cents by February 29, 2016 and 116,166,666 options exercisable at 1.4 cents on or before February 28, 2018.

Analytica was unchanged at 0.9 cents with 2.3 million shares traded.

SUDA

Suda says the US Food and Drug Administration has responded to its SUD-001 sumatriptan oral spray for migraine development plan.

Suda said that the FDA "acknowledged its proposed development strategy and requested only minor justifications to the study design".

The company said that it had submitted "a type C meeting briefing package" to the FDA on June 13, 2015 containing details of the proposed pivotal study and other activities intended to support a new drug application.

Suda said the FDA had no comments regarding plans for chemistry, manufacturing, controls and non-clinical studies of SUD-001.

The company said that the FDA requested a paediatric study plan for children aged 6 to 17 years who could benefit from an oral-spray migraine therapy.

Suda said that the development strategy was intended to accelerate registration of SUD-001 by using a pharmaco-kinetic approach not requiring clinical efficacy studies in migraine patients.

The company said that its two-part pivotal study would assess the pharmaco-kinetic parameters of SUD-001, such as the plasma concentration of sumatriptan, compared to the currently approved formulations of sumatriptan in about 70 healthy subjects.

Suda chief executive officer Stephen Carter said Suda was "delighted that the FDA has broadly accepted our development plan" designed to support a new drug application. Mr Carter said that company was on-track to begin the pivotal pharmaco-kinetic study early in 2016.

Suda was up 0.3 cents or 8.8 percent to 3.7 cents with 7.8 million shares traded.

ISONEA

Isona says that incorrect positioning of its first generation Airsona asthma sensor "could result in recordings without breath sounds".

Isona said that not recording breath sounds would lead to "no capacity to detect continuous adventitious breath sounds" and the new Airsona wheeze monitor was "a major advance" with new software for breath sound screening to ensure the device would only record and pass sounds to wheeze analysis when breath was detected.

Isona said that the mobile telephone application "warns when breath is not detected and allows the user to reposition the sensor correctly without the need to stop the recording and start again".

Isona was up 0.7 cents or 13.7 percent to 5.8 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Federal Government says Telstra chief executive officer David Thodey has been appointed Commonwealth Scientific and Industrial Research Organisation chair.

A media release from the Minister for Industry and Science Ian Macfarlane said Mr Thodey became chief executive officer and executive director of Telstra in May 2009, formally retired as chief executive officer on April 20, 2015 and would leave Telstra on August 21, 2015 and join the CSIRO board in November.

The media release said that “the appointment is more evidence of the Australian Government’s clear strategy to put science at the centre of industry policy”.

“Mr Thodey is one of Australia’s most well-known and respected businessmen,” Mr Macfarlane said. “He will bring a wealth of industry acumen to Australia’s peak science agency as it plays an increasingly central role in maximising our economic opportunities and industry growth.”

The Federal Government media release said that before Telstra, Mr Thodey had a 22-year career at IBM, in senior marketing and sales positions.

The media release said that Mr Thodey had information and communications technology, digital business and data services experience.

The Federal Government said that Mr Thodey holds a Bachelor of Arts in Anthropology and English from Victoria University, Wellington, New Zealand.

POLYNOVO

Polynovo says that chief executive officer Paul Brennan will be entitled to up to 12,555,285 long term incentive options pending share price hurdles.

Polynovo said that the options would vest in three tranches of 4,185,095 options each, three months after the weighted average share price exceeded 18 cents, 25 cents and 35 cents respectively, for more than three months.

The company said that all the options would be exercisable at nine cents each by August 6, 2018.

Polynovo fell one cent or 8.7 percent to 10.5 cents.

IMMURON

Immuron says it will issue 6,000,000 options to chairman Dr Roger Aston and directors Daniel Pollock Stephen Anastasiou and Peter Anastasiou.

Immuron said that Dr Aston would receive 3,000,000 options with 1,000,000 options to each of the three other directors.

The company said that the options would be exercisable at not less 35 cents each within four years from the date of issue, subject to shareholder approval.

Immuron said that the unlisted options would be issued “in lieu of additional cash remuneration in recognition of the additional services which each director has performed which have been deemed far in excess of those services usual for a non-executive director of a company with Immuron’s positioning, together with additional services that will be required to be exerted over the coming 12 [to] 24 months”.

The company said that 2,000,000 of Dr Aston’s options would vest following a continuous period of 12 months of service to August 2016, with the further 1,000,000 options vesting after a further 12 months of service to August 2017.

Immuron said the directors options would vest following 12 months of continuous service to August 2016.

Immuron fell half a cent or 1.7 percent to 28.5 cents.

[ANATARA LIFESCIENCES](#)

Chairman Mel Bridges says he has increased his holding in Anatarra from 5,669,230 shares to 5,746,844 shares but has been diluted from 15.02 percent to 12.51 percent. Mr Bridges says that through the Capalaba, Queensland-based Parma Corp he bought 77,614 shares on-market on December 10, 22 and 23, 2014 and in the Anatarra share plan at 78 cents a share on July 29, 2015, for a total of \$35,650 or an average price of 45.9 cents a share.

Anatarra closed unchanged at 88 cents.

[STIRLING PRODUCTS \(SUBJECT TO A DEED OF COMPANY ARRANGEMENT\)](#)

Stirling Products administrators say an extraordinary general meeting will vote on a series of resolutions relating to the company's restructure.

In 2011, Stirling was placed in administration having failed to commercialize Immunoxel for AIDS, tuberculosis, kidney disease, H1N1 influenza, or swine 'flu (BD: Jul 26, 2011).

In 2009, Stirling claimed 100 percent efficacy for drug-resistant tuberculosis with the Immunoxel natural product citing a 12-patient Kiev, Ukraine trial (BD: Apr 16, 2009).

Stirling managing director and former Victoria Police officer Peter Boonen told Biotech Daily his company was involved in the commercialization of Immunoxel and the intellectual property was owned by the Kiev-based Ekomed.

The company also claimed the supplement worked for swine flu (BD: Apr 29, 2009) and AIDS (BD: May 11, 2009).

In 2010, Stirling said it had bought a \$20 million factory for \$4 million (BD: Mar 3, 2010), acquired an inhaler device (BD: Apr 29, 2010) and added kidney health to its Immunoxel claims, along with claiming support from Kidney Health Australia and Governor General Quentin Bryce, but the Governor General's office told Biotech Daily that Ms Bryce opened Kidney Week, but did not mention Stirling Products or the partnership (BD: May 25, 2010). Despite Appendix 4C announcements that it was low on funds, Stirling said it had acquired the \$7 million Telemedcare for \$511,000 (BD: Aug 3, 2010) and a profitable pathology business for \$3 million in shares (BD: Sep 16, 2010).

In November 2010, Stirling proposed to issue 1,616,657,716 new shares to cover its placements, acquisitions, convertible notes and provide working capital (BD: Nov 2, 2010). The company hoped to raise \$6 million in December 2010, but by February 2011 had lowered expectations to \$3 million (BD: Feb 8, 2011).

In June 2011, Stirling said it had lost its newly-appointed chief executive officer Jeremy Cocks, was attempting to sell its Sydney properties, list on London's Alternative Investment Market and wanted to issue 2.6 billion new shares (BD: Jun 7, 2011).

Stirling entered into trading halts on several issues and last traded at 0.2 cents.

Today, Stirling said that the deed administrator was Robert Whitton of the Sydney accountancy firm William Buck.

The resolutions include the ratification of the prior issue of 333,766,926 shares at 0.021 cents, a 2,000-to-one consolidation and place up to 14,000,000 post consolidation shares at no less than five cents each to raise \$700,000 to pay deed of company arrangement contributions, expenses and debts and working capital.

The meeting will be held at William Buck, Level 29, 66 Goulburn Street, Sydney, on September 3, 2015 at 10am (AEST).

Stirling was suspended and last traded at 0.2 cents.

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