



Biotech Daily

Monday July 27, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ANTEO UP 12%, TISSUE THERAPIES DOWN 11%**
- * **VICTORIA AWARDS 8 VESKI \$450k THREE-YEAR GRANTS**
- * **FEDERAL GOVERNMENT OPENS ANSTO ELECTRON MICROSCOPE**
- * **INVION, HOVIONE PARTNER ON INHALED INV104 FOR ASTHMA**
- * **NUSEP ADVANCES SPERM SEPARATION, RESOLVING 'LEGACY' ISSUES**
- * **PRIMA PLAN RAISES \$10m**
- * **OKS AGX ALLOWS AGENIX TO KEEP THROMBOVIEW**
- * **US PATENT FOR SUDA'S SUD-002 FOR NAUSEA AND VOMITING**
- * **ORTHOCELL PLEADS SCHULTZ, CLIMBS 17% ON LENGTHY ASX QUERY**
- * **RESONANCE CSO PROF TIM ST PIERRE WINS WESTERN E&Y GONG**

MARKET REPORT

The Australian stock market rose 0.43 percent on Monday July 27, 2015 with the ASX200 up 23.8 points to 5,589.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and one was untraded.

Anteo was the best, up 1.1 cents 11.7 percent to 10.5 cents, with 5.6 million shares traded.

Benitec climbed 7.3 percent; Admedus and Cellmid were up more than five percent; Genetic Technologies, Prana and Uscom were up more than three percent; Biotron and Cochlear rose more than two percent; Bionomics, CSL, Impedimed and Medical Developments were up more than one percent; with Mesoblast and Nanosonics up by less than one percent.

Tissue Therapies led the falls, down 0.7 cents or 10.9 percent to 5.7 cents with 587,848 shares traded, followed by Polynovo down 10 percent to 9.9 cents with 120,050 shares traded. Antisense lost 9.1 percent; Acrux shed 8.7 percent; Actinogen was down 6.25 percent; Avita and Universal Biosensors fell more than five percent; Circadian fell 4.65 percent; Clinuvel and Compumedics lost more than three percent; IDT, Starpharma and Viralytics shed more than one percent; with Resmed and Sirtex down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government has awarded eight Victorian Endowment for Science, Knowledge and Innovation grants to bring researchers back to the State.

Victoria Minister for Education James Merlino says eight researchers had won the Victorian Endowment for Science, Knowledge and Innovation (Veski) science and innovation awards, worth \$450,000 over three years.

In a media release Mr Merlino said the awards were designed to “encourage collaboration between universities and industry, driving the development of new products and services”.

Mr Merlino said that three Veski innovation fellowship recipients had returned to Victoria from posts in the UK, Canada and Denmark.

The Victoria Government said that Prof Colby Zaph has shifted his research from Canada to Monash University, with a focus on biological methylation, for the regulation of immunity and inflammation; Prof Roger Pocock had from Denmark to Monash University to continue research using worms to discover how the brain forms and how it functions, with a specific focus on schizophrenia; and Prof Richard Sandberg had returned from the UK to the University of Melbourne for his work on super computers to reduce noise and predict turbulence.

The media release said that the five recipients of the Victorian post-doctoral research fellowships were Dr Adam Chrimes, Dr Luke Kelly, Dr Kaye Morgan, Dr Jing Ren and Phuc Ung.

The Victoria Government said that since the inception of the Veski fellowships in 2004, 24 researchers had received the grants.

“We’re supporting Victorian researchers in science and technology,” Mr Merlino said.

“Our strength lies in knowledge and these worthy recipients are amongst those who will drive our innovation and ideas to new heights,” Mr Merlino said.

“These fellowships play an important role in attracting Australians back to Victoria and encouraging overseas colleagues to join them,” Mr Merlino said.

FEDERAL GOVERNMENT

The Federal Government says that an electron microscopy facility has been opened at the Australian Nuclear Science and Technology Organisation.

In a media release, the Parliamentary Secretary to the Minister for Industry and Science Karen Andrews said the \$6 million facility was purpose-built to allow ANSTO’s electron microscopes “to operate at their full performance capabilities and [used] advanced architectural design to mitigate external influences”.

The Federal Government said that electron microscopes used beams of electrons to create high magnification images, but external influences such as electromagnetic fields, vibrations and temperature variation could compromise performance.

The Government said that among its many applications, electron microscopy assisted the maintenance of the safety and reliability of the open pool Australian light water (Opal) research reactor, which was vital to ANSTO’s production of nuclear medicines.

“Nuclear medicines are used to diagnose and treat a wide range of illnesses including cardiac conditions, cancers and skeletal injuries,” Ms Andrews said.

“It is estimated one in two Australians will benefit from the nuclear medicines that originate from ANSTO, that’s roughly 10,000 patient doses administered each year”, The media release said that the shielded laboratory maximized microscope performance and the new building would enable ANSTO “to conduct world-class research into nuclear materials and radiation, particularly the behaviour of materials for use in extreme environments”.

INVION

Invion says the Portugal-based Hovione Scientia has committed to progressing development of inhaled INV104 (zafirlukast) as a potential treatment for asthma. Invion said that Hovione was “expert in inhalation development and manufacturing” and the two companies would collaborate to develop the technology, a dry powder formulation of INV104 delivered by Hovione’s inhaler.

The company said that INV104 was a novel non-steroidal anti-inflammatory for use in moderate to severe asthmatics.

In 2013, Invion licenced zafirlukast for asthma and other respiratory conditions from the Wilmington Delaware-based Accolade Pharma for \$500,000 to develop and commercialize all inhaled formulations and applications of zafirlukast and said it would develop the drug for asthma (BD: Oct 28, 2013).

The company said at that time that research and development executive vice-president and chief medical officer Dr Mitchell Glass led development and submission of oral zafirlukast, marketed as Accolate, for asthma, for Zeneca (now AstraZeneca) to US Food and Drug Administration approval in 1998.

Dr Glass is the chairman of Accolade and a substantial shareholder.

The 2013 agreement said that Accolade would receive 20 percent of the net sales received by the licensee [Invion] in connection with the development and commercialisation of zafirlukast.

Today, Invion said that all oral prescriptions of the drug came with a side effect warning and early data indicated that INV104 has an attractive safety and efficacy profile when delivered by inhalation at less than 1.0 percent of the oral dose.

Invion said that Hovione would provide expertise on chemistry, particle engineering, formulation, device and manufacturing to develop and manufacture a zafirlukast dry powder inhaler.

The company said that the collaboration extended from fully integrated scale-up and manufacture of zafirlukast dry powder inhaler for non-clinical and clinical studies to further secure for Hovione the exclusive rights to manufacture commercial supplies of the zafirlukast inhaler.

Invion said it would oversee all non-clinical and clinical development and was responsible for regulatory submissions.

Invion said it would pay an annual royalty to Hovione on total net sales of the zafirlukast inhaler.

The company said that zafirlukast had an “extensive clinical database illustrating both its safety and efficacy” and the collaboration had overcome the major impediment to reformulation and development of INV104 by producing a formulation devoid of banned propellants.

Invion said it had agreement from the FDA to proceed in an accelerated development of the novel formulation and device and the collaboration had made “excellent progress towards a stable formulation”.

Invion chief executive officer Dr Greg Collier said this agreement was a win-win for both companies and pivotal to Invion’s plan to rapidly progress development of INV104.

“We are reformulating this compound for inhalation and remain confident that delivering this compound directly into the lung in this manner will provide superior benefit and bypass any problems associated with systemic delivery,” Dr Collier said.

Hovione senior director of product development and licencing Carla Vozzone said that “aligning Hovione’s knowledge in inhalation with Invion’s clinical expertise builds synergies for a winning proposition”.

Invion was up 0.2 cents or 8.3 percent to 2.6 cents with 6.5 million shares traded.

[NUSEP](#)

Nusep executive chair Alison Coutts has told investors the company has “fantastic” technology but is “still battling issues with the previous management”.

Ms Coutts told the Melbourne investor lunch that Nusep owned 68 percent of the class B non-voting shares in the Singapore-based Prime Biologics, which came with a debt of \$4.3 million and accruing interest at five percent per annum.

Prime Biologics was spun-out from Nusep using its technology for the separation of proteins such as albumen and immunoglobulin from blood (BD: Oct 15, 2012).

In 2013, Ms Coutts replaced the then chairman John Manus.

According to its website, Mr Manus is Prime’s managing-director and former Nusep managing-director Dr Hari Nair is the executive chair.

Nusep has representation on the Prime board, which was previously held by Ms Coutts but has been transferred to Nusep director and major shareholder Andrew Goodall, who with related parties holds 38.9 percent of Nusep.

Ms Coutts said that for Nusep to maintain its investment in Prime, the first payment of about \$1 million would be due by March 2016.

Ms Coutts said that Nusep had been negotiating to sell its share of Prime but the deal fell through and last week the company announced that it had put the 68 percent holding on the open market (BD: Jul 23, 2015).

She said that there appeared to be a selling down in the thinly-traded Nusep and the board was working to resolve the legacy issues.

“The company needs a mattress under its share price,” Ms Coutts said.

Ms Coutts said that the Spermsep technology used hydrogel polymer membranes with pores and electrophoresis to attract the negatively charged sperm cells.

She said the technology had been shown not to damage sperm DNA, unlike competitor methods including centrifuging, density gradient and other separation methods.

“You can separate all sorts of good stuff or the bad stuff from the good stuff,” Ms Coutts said.

“The technology is fantastic,” Ms Coutts said.

Ms Coutts said that the Nusep system was cheaper, quicker and more convenient and the in-vitro fertilization market for both humans and animals was increasing, with the US in-vitro fertilization market expected to increase from \$US9.3 billion in 2012 to \$US21.6 billion by 2020.

Ms Coutts said that male infertility was a factor in about 40 percent of human in-vitro fertilization cases and the Spermsep technology, which had previously resulted in four live births, would be tested to demonstration that it was superior for separating problematic sperm samples.

She said that an in-vitro trial to “show that we can extract sperm from difficult samples and define the benefits and difficulties” was expected to begin by the end of 2015 at Newcastle University under the direction of Prof John Aitken and take about six months.

Ms Coutts said that the trial would be conducted in conjunction with in-vitro fertilization centres with no cost to Nusep apart from supplying the machines and consumables.

Ms Coutts said that discussions were underway with another university for a potential collaboration.

“We are doing work on a new membrane for a range of uses, but there is a lot more work to be done,” Ms Coutts said.

Ms Coutts said the company was also working on a reconfiguration of the machines that perform the separations, which she described as “an engineering issue” to ensure that there could be no cross-contamination between samples.

Nusep was up 0.3 cents or 10.7 percent to 3.1 cents with 63,532 shares traded.

PRIMA BIOMED

Prima says its share purchase plan has raised \$10 million to fund its IMP321 clinical trial program (BD: Jul 8, 2015).

Prima said that “due to overwhelming shareholder demand, the board exercised its right to increase the amount raised under the [plan] from \$5 million to \$10 million”.

The company said that applications received over and above the \$10 million would be scaled back on a “first in, first served” basis.

Prima chief executive officer Marc Voigt said it was “very gratifying that our shareholders have been so supportive”.

“Together with the Ridgeback funding, which will be voted on at our [extraordinary general meeting] on July 31, and which is essential for initiating our two clinical trials for IMP321 this year, the proceeds from the [plan] gives us funding certainty to the end of 2016,” Mr Voigt said.

Prima was unchanged at 5.9 cents.

AGENIX

Agenix says that OKS AGX Inc has exercised its discretion not to proceed with the assignment of Thromboview and Agenix retains the intellectual property.

Agenix said that it would reassess the commercialisation prospects of the technology in light of the OKS decision and previous extensive efforts to partner the project.

The company said that the settlement deed terms and conditions remained in force “which removed a significant legacy barrier to allowing the company to move to pursue strategic alternatives with a view to achieving an increase in shareholder value and near term revenues”.

In March, Agenix said it had agreed with OKS AGX to settle Supreme Court proceedings arising for a \$5 million share agreement from 2008 (BD: Mar 13, 2015).

Agenix was untraded at 1.2 cents.

SUDA

Suda says the US Patent and Trademark Office has granted a patent entitled ‘Buccal, Polar and Non-Polar Spray Containing Ondansetron’.

Suda said that the patent provided broad protection in the US for its first-in-class oral spray formulation of ondansetron to treat nausea and vomiting induced by chemotherapy, radiotherapy and in post-operative settings.

The company said that the patent had been granted or was pending in other major jurisdictions.

Suda said that clinical studies had demonstrated that SUD-002 8mg spray was statistically bioequivalent to the commercially available 8mg ondansetron tablet.

The company said that SUD-002 was well tolerated and could be administered in multiple doses.

Suda said that SUD-002 delivered statistically faster absorption compared to the tablet as defined by median time to detectable drug levels of ondansetron.

The company said it was working with its US partner for SUD-002 to prepare for a meeting with the US Food and Drug Administration to discuss the program.

Suda was up 0.1 cents or three percent to 3.4 cents with 3.35 million shares traded.

ORTHOCELL

Orthocell has told the ASX that despite publishing research on its technology, it did not expect that research to have a material impact on its share price.

The ASX said that Orthocell's share price increased from 33 cents on Jul 3, 2015 to 38 cents on July 7 and again rose from 42 cents on July 13 to 48 cents on July 14 closing at 46.5 cents on July 15, 2015.

On July 16, Orthocell said its 'cell factory' derived proteins pipeline product had been further validated with data from a collaborative research project in rabbits, co-authored by Orthocell chief scientific officer Prof Ming Hao Zheng (BD: Jul 16, 2015).

Orthocell said that it became aware that the research had been published at 12.31am (AWST) on July 15, 2015 and the announcement was released on the ASX "promptly and without delay on opening of trading on ASX on July 16, 2015".

Orthocell climbed 13 cents or 16.9 percent to 90 cents with two million shares traded.

RESONANCE HEALTH

Resonance says that chief scientific officer Prof Tim St Pierre has won the Western Region Ernst and Young Entrepreneur of the Year award for technology.

Resonance said that Prof St Pierre would compete for the national award in Sydney in October and the overall winner would go to Monaco in June 2016 for global final.

The company said that Prof St Pierre led the development of its Ferriscan magnetic resonance imaging-based technology to measure liver iron.

Resonance was up 0.2 cents or 4.8 percent to 4.4 cents.