

Biotech Daily

Wednesday August 12, 2015

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: IDT UP 13%, OSPREY DOWN 5.45%
- * VICTORIA RELEASES RESEARCH, BIOTECH DISCUSSION PAPERS
- * CSL RECORD PROFIT UP 34% TO \$1.9bn, REVENUE UP 29% TO \$7.7bn
- * PHYLOGICA RIGHTS ISSUE RAISES \$10m
- * \$20bn MRFF PASSES SENATE, COMMERCIALIZATION IGNORED
- * IDT EARNS \$1.4m UPFRONT FROM US DISTRIBUTOR ANI
- * CELLMID APPOINTS NEW YORK'S EAS ADVISORS FOR US EXPANSION
- * PERTH'S PRINCESS MARGARET HOSPITAL JOINS RESAPP TRIAL
- * ISONEA AIRSONEA WHEEZE MONITOR US TRIAL
- * UBS AG BUYS, SELLS, BORROWS, RETURNS ACRUX SHARES TO 6.4%
- * ACTINOGEN XANAMEM PHASE I TRIGGERS 3m DR LOVERIDGE SHARES
- * MARK STUDD REPLACES NUSEP CO SEC ELISSA HANSEN

MARKET REPORT

The Australian stock market fell 1.66 percent on Wednesday August 12, 2015 with the ASX200 down 91.1 points to 5,382.1 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and three were untraded.

IDT was the best, up 3.5 cents or 12.7 percent to 31 cents with 3.3 million shares traded. Avita and Reva climbed more than six percent; Universal Biosensors was up five percent; Acrux was up 4.7 percent; Biotron and Prima rose more than two percent; with Cochlear, Ellex and Psivida up more than one percent.

Osprey led the falls, down 4.5 cents or 5.45 percent to 78 cents with 94,683 shares traded. Admedus, Atcor, Circadian, Mesoblast, Oncosil and Orthocell fell more than four percent; Actinogen was down 3.1 percent; Anteo, Antisense, CSL, Nanosonics, Neuren, Pharmaxis and Starpharma shed two percent or more; Benitec and Compumedics were down more than one percent; with Impedimed, Resmed and Sirtex down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government has released discussion papers on health and medical research strategy, as well as medical technologies and pharmaceuticals.

The Minister for Health Jill Hennessy released the Victorian Health and Medical Research Strategy Discussion Paper, which is available at <u>http://bit.ly/1MjeXpb</u>.

A Victoria Government media release said the Strategy would "identify Victoria's priorities in health and medical research, promote innovation, and prepare [the] State for the economic and healthcare opportunities on offer both nationally and internationally". The media release said that the work complemented the Medical Technologies and Pharmaceuticals Discussion Paper, which would inform the State Government's \$200 million Future Industries Fund.

The Medical Technologies and Pharmaceuticals Discussion Paper is available at: <u>http://bit.ly/1PjYAsp</u>

The Government said the objective of the Victorian Health and Medical Research Strategy was to embed health and medical research as an integral part of the Victorian health system, with the view to turning research outcomes into practical health treatments. The media release said that submissions close on August 31, 2015.

The Government said that the Health and Medical Research Discussion Paper "highlights the importance of integrating research, education and healthcare; bringing together expertise across varying specialties; implementing a world-leading clinical trials system, advancing international collaborations, industry-research engagement and innovation; and supporting the next generation health and medical research workforce".

The Government said it was "investing significantly in health and medical research to grow Victoria's pre-eminence as a hub for world-class research" and Victoria had about 150 biotechnology companies, 10 medical research institutes, 10 teaching hospitals conducting significant research and nine universities.

"We have some of the best health and medical researchers in the world ... and we want to do everything we can to support them so that they can continue to develop new and faster diagnostic tools and discover new treatments and cures," Ms Hennessy said.

"We want to hear from the sector about how we can continue to build health and medical research in Victoria, and better support our world-leading clinicians and researchers to do the fantastic work they do," Ms Hennessy said.

The Victoria Government said the Minister for Industry Lily D'Ambrosio and Ms Hennessy wanted experts in the medical technologies and pharmaceuticals sector "to have their say about opportunities and challenges facing the industry and to propose strategic opportunities for continued success and growth in the sector".

The Government said Victoria's medical technologies and pharmaceuticals sector was "a key driver of economic activity for the state" employing more than 20,000 people and generatings \$10 billion in revenue, largely through exports.

"The \$200 million Future Industries Fund is to support industry sectors that are primed for growth to become vital contributors to the Victorian economy," Ms D'Ambrosio said. "Medical technologies and pharmaceuticals play a vital role in health and medical research, turning research findings into real health outcomes," Ms Hennessy said.

"We want to build and support Victoria's medtech and pharmaceutical industry, because not only is it a key economic driver for our State, but it has the power to change lives," Ms Hennessy said.

Victoria's Parliamentary Secretary for Medical Research Frank McGuire said that Victoria was "home to about 150 biotechnology companies, as well as 10 major medical research institutes, 10 teaching hospitals conducting significant research and nine universities". "Our expertise is unquestionable," Mr McGuire said.

<u>CSL</u>

CSL says its record net profit after tax was up 33.8 percent to \$US1,379.0 million (\$A1,886.6 million) for the 12 months to June 30, 2015 on record revenue up 29.2 percent to \$US5,628.0 million (\$A7,699.4 million).

In its Appendix 4E report, CSL that in US dollar terms revenue was up 1.9 percent to \$US5,628.0 million, with net profit after tax up 5.5 percent to \$US1,379.0 million. Biotech Daily reports in Australian dollars and the difference reflects the exchange rate. CSL chief executive officer Paul Perreault told a teleconference that revenue came from its immunoglobulin, albumin and speciality products, with "mid to high double digit growth"

for albumin.

Mr Perreault said that the acquisition of the Novartis influenza vaccine business was a high point for the year and while it made CSL second to Sanofi in that area, his company had "aspirations for leadership".

In a presentation, CSL said that sales of influenza vaccines for the year to June 30, 2015 were up 18 percent to \$145 million.

Mr Perreault said that the measure of leadership would be through sales revenue and doses, but declined to specify the difference between sales volumes of Sanofi and the new CSL-Novartis business.

Mr Perreault said that CSL had 100 years in the influenza business, understood the sector and would "roll up our sleeves" and run an efficient business.

Mr Perreault said there had been significant growth in Kcentra sales to reverse bleeding along with strong growth in sales of Berinert and Zemaira and he expected recombinant factor XVII and IX products to be approved in 2016 and launched in 2017.

"I cannot be more pleased with the quality of our pipeline," Mr Perreault said. Mr Perreault said he expected net profit after tax to increase by "around five percent" in the coming financial year.

CSL said that a final unfranked dividend of 66 US cents per share would be paid to shareholders at the record date of September 9, 2015 following the unfranked interim dividend of 58 US cents a share paid on April 10, 2015.

CSL said that its net tangible asset backing per share fell 16.8 percent from \$US4.71 to \$US3.92 with diluted earnings per share up 8.3 percent to \$US2.914.

The company said that research and development spending fell 0.8 percent to \$US462.7 million compared to the previous year, and was 8.2 percent of total revenue compared to the previous year's 8.4 percent of revenue.

CSL said cash and cash equivalents fell 8.4 percent to \$US555.5 million at June 30, 2015. Mr Perreault said the company had completed its seventh share buy-back and was considering the eighth consecutive share buy-back and since 2005 share buy backs had contributed a 23 percent increase in earnings per share.

CSL fell \$2.11 or 2.2 percent to \$93.00 with 2.3 million shares traded.

PHYLOGICA

Phylogica says its one-for-one rights issue at one cent a share has raised a total of \$10,020,694 (BD: Jul 2, 2015).

Phylogica said that it received acceptances for 77.3 percent of the shares available, with further applications for additional shares of 9.9 percent or a total of 873,706,971 shares or 87.2 percent of shares available, raising \$8,737,070.

The company said that the underwriter shortfall commitment was for 128,362,396 shares or 12.8 percent of the issue, raising \$1,283,624.

Phylogica was untraded at 1.1 cents.

FEDERAL PARLIAMENT, MEDICAL RESEARCH FUTURE FUND

Bills to create the proposed \$20 billion Medical Research Future Fund have passed the Senate, ignoring calls to set aside funds for commercialization.

The Senate Standing Committee on Community Affairs reviewed submissions of the proposed legislation, including a call from the Biotech and Related Industries Leadership Group to set aside 25 percent of the funds to commercialize any technologies invented or developed by the fund.

The legislation does not include any provision for commercialization.

A Senate officer told Biotech Daily that the Medical Research Future Fund Bill 2015 and the Medical Research Future Fund (Consequential Amendments) Bill 2015 passed the Senate and would be returned to the House of Representatives to approve Senate amendments.

The officer said that should the House of Representatives approve the amendments the Bills would proceed to the Governor General for Royal Assent and become law.

One amendment that was approved was a change to the definition of "medical innovation" to include: "the application and commercialisation of medical research for the purpose of improving the health and wellbeing of Australians; and the translation of medical research into new or better ways of improving the health and wellbeing of Australians.

Research Australia and the Perth-based Harry Perkins Institute of Medical Research have welcomed the Bills passing the Senate.

IDT AUSTRALIA

IDT says that appointing the Baudette, Minnesota-based ANI Pharmaceuticals as its US distributor is "a major commercial milestone".

IDT said that ANI would pay a \$US1 million (\$A1,377,530) upfront payment to exclusively market and distribute up to 18 of its recently acquired generic pharmaceutical products. Last year, IDT acquired 23 generic drugs from Global Generics Company last year (BD: Nov 3, Dec 18, 2014).

Today, the company said that milestones of up to \$US1.25 million would be payable as the products came back on the market and the two companies would share net profits. IDT said that the total US market for the products was \$US538 million a year.

The company said that its products were fully generic pharmaceuticals, most with stable or growing markets and prices and would be sold to large pharmacy chains.

IDT said that ANI intended to launch the first of its generic products in 2016.

IDT managing-director Dr Paul MacLeman said that ANI was "an ideal US partner for IDT as it has a proven track record, having already successfully commercialized its own generic drugs, is nimble and shares IDT's zest for growth".

IDT was up 3.5 cents or 12.7 percent to 31 cents with 3.3 million shares traded.

<u>CELLMID</u>

Cellmid says it has appointed the New York-based EAS Advisors as "corporate and strategic partners in the company's US expansion".

Cellmid said the EAS was established by Edward Sugar in 2008 and had a track record of success in exposing ASX-listed companies to US investors and industry partners.

The company said it reported strong sales growth of its Évolis FGF5 inhibitor hair growth product and was well-placed to replicate this strategy in the US, where the hair care market reached \$US11.6 billion in sales in 2014.

Cellmid was unchanged at 3.3 cents with 10.1 million shares traded.

RESAPP HEALTH

Resapp says the Princess Margaret Hospital is the second site to approve the trial of its telephone applications for the diagnosis and management of respiratory disease. Resapp said that the Perth, Western Australia-based hospital has approved the first patient at the paediatric facility.

The company said that the study would gather data from patients with a variety of respiratory conditions to further optimize the Resapp algorithms for pneumonia and asthma as well as broadening the validation to other common respiratory conditions such as bronchitis, bronchiolitis and upper respiratory tract conditions.

Resapp said that the study was underway at Joondalup Health Campus, which had enrolled more than 150 patients and the company planned to enrol about 400 patients by the end of 2015.

Resapp fell 0.3 cents or 13.0 percent to two cents with 7.45 million shares traded.

ISONEA

Isonea says its second generation Airsonea Wheeze Monitor will be trialled at an unnamed American university to expedite US Food and Drug Administration approval. Isonea said that the unnamed principal investigator was "a renowned respiratory physician".

The company said that recruitment of patients would start "towards the end of September and the trial should be completed by the end of December 2015". Isonea fell half a cent or 8.3 percent to 5.5 cents.

<u>ACRUX</u>

The Singapore-based UBS AG and related bodies corporate have reduced their holding in Acrux from 12,493,473 shares (7.50%) to 10,648,889 shares (6.39%).

UBS AG said that between August 5 and 7, 2015, in more than 60 mainly very small trades, it bought, sold, borrowed and returned shares for institutions, including Citibank, Citigroup, JP Morgan Chase Bank, Macquarie Bank, Morgan Stanley, the Northern Trust Company, Brown Brothers Harriman, BMO Capital Markets Corp and State Street Bank & Trust Co.

UBS AG has previously said that the shares were held for Warbont Nominees and various custodians and were held with the "power to control disposal over shares pursuant to stock borrowing and lending activities" (BD: Dec 19, 2012; Nov 21, 2013).

Acrux has been reported as one of the most heavily 'short-sold' stocks in the Australian biotechnology sector.

Acrux was up three cents or 4.7 percent to 67 cents.

ACTINOGEN MEDICAL

Actinogen says that completing its phase I trials of Xanamem for Alzheimer's disease triggers the vesting of 3,000,000 employee shares to director Dr Jason Loveridge. Yesterday, Actinogen said the three-part trials involving 40 healthy volunteers were completed "on-time and on-budget" (BD: Aug 11, 2015).

Today, the company said that Dr Loveridge would receive 3,000,000 employee share plan shares for the milestone.

Actinogen fell 0.2 cents or 3.1 percent to 6.3 cents with 1.2 million shares traded.

NUSEP HOLDINGS

Nusep says Mark Studd has been appointed company secretary replacing Boardroom Pty Ltd colleague Elissa Hansen, ensuring a seamless transition.

Nusep said that Mr Studd was an experienced company secretary and holds a Masters of Business Administration as well as a Graduate Diploma of Applied Corporate Governance with Governance Institute of Australia.

Nusep was untraded at 3.2 cents.