

Biotech Daily

Wednesday June 28, 2017

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: SIRTEX UP 17%, DIMERIX DOWN 11%
- * MINISTER LAUNDY LAUNCHES CSIRO DATA61: 'SHIFT HAPPENS'
- * ONDEK RAISES \$3.6m
- * VICTORIA-JIANGSU FUND \$400k FOR BURNET LAB, CHINA'S BOINT
- * SIRTEX CUTS 15% STAFF, LOSES CMO DR DAVID CADE, RESTRUCTURE
- * CYCLOPHARM RAISES \$7m
- * REVA: 1st FANTOM COMMERCIAL SALE
- * ITL, MYHEALTHTEST WIN \$2.6m CRC GRANT
- * OPTISCAN APPOINTS SCINTICA NORTH AMERICA DISTRIBUTOR
- * BEST BUYS EXTENDS NUHEARA IQBUDS DISTRIBUTION
- * NEUREN PLEADS SCHULTZ TO ASX 38% QUERY
- * PARADIGM M-D PAUL RENNIE, KZEE, EAR, TAKE 22%

MARKET REPORT

The Australian stock market was up 0.73 percent on Wednesday June 28, 2017 with the ASX200 up 41.5 points to 5,755.7 points. Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, 11 traded unchanged and two were untraded.

Sirtex was the best, up \$2.31 or 17.1 percent to \$15.80 with 2.8 million shares traded.

ITL climbed 8.3 percent; Universal Biosensors was up 7.8 percent; both Bionomics and Genetic Signatures were up 5.3 percent; Benitec, Impedimed and Osprey were up more than three percent; Clinuvel, Ellex, Oncosil, Opthea, Pharmaxis and Starpharma rose more than two percent; Factor Therapeutics, Mesoblast and Reva were up more than one percent; with Acrux, Cochlear and Pro Medicus up by less than one percent.

Dimerix led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 2.5 million shares traded. Actinogen, Medical Developments, Prima and Psivida lost more than three percent; Admedus, Avita, Compumedics and Resmed were down one percent or more; with CSL down 0.2 percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Federal Assistant Minister for Industry, Innovation and Science Craig Laundy has opened the CSIRO Data61+ Live 2017 to promote big data awareness.

The CSIRO said that the Melbourne conference, meeting and exhibition was entitled: 'Shift Happens: how can Australian organizations adapt to disruption'.

The Organisation said that Data61 would address the challenge of how to create a "datadriven future with science and technology by partnering with industry, government and universities to deliver economic, societal and environment outcomes".

The CSIRO said that Data61's capabilities ranged from cyber security, confidential computing, the internet of things, robotics, machine learning and analytics, software and programing to behavioral sciences.

Opening the meeting, Social Science co-founder and former Bio-Melbourne Network chief executive officer Michelle Gallaher told Biotech Daily that understanding data and being able to use data would have a major impact on the life sciences industry.

"Biotech is a data-rich environment and is increasingly so," Ms Gallagher said.

"Our ability to apply a systems approach to drug discovery is at the heart of the future of the healthcare industry," Ms Gallaher said.

CSIRO chief executive Dr Larry Marshall paid tribute to the traditional owners of the land at the Docklands venue, the Wurundjeri people of the Kulin nation and said that history had an "impact on where we are and where we are going".

Dr Marshall said that the CSIRO had 100 years' experience in "taming an arid land" to produce better cotton, wool and minerals and 60 years in medical related research. Dr Marshall said that adversity inspired fear or determination and "determination drives innovation".

"When the shift hits the fan you had better duck," Dr Marshall said, "and you can either blame someone else or invent your way around it, so it doesn't have an impact."

Dr Marshall said Australia needed to "stop selling raw resources and value add", so instead of exporting mineral sands they could be converted to ink for three-dimensional printers to produce a sternum implant, a working jet engine and horseshoes.

Mr Laundy said Data61 was "a real hidden jewel" and urged people to visit the Expert Connect (https://expertconnect.data61.csiro.au) and Ribit (https://ribit.net) websites.

Mr Laundy said that last year there were 47 visitors to the Expert Connect site, but last month there were more than 10,000 visits.

Mr Laundy said that there needed to be far greater connections between research institutions and small and medium sized businesses.

He said that cutting red tape and reducing regulation was "just a slogan" because there was a need for regulation, but using data effectively through a digital revolution between government and business could increase efficiency.

Mr Laundy cited the National Business Simplification Initiative, a "beta" project connecting local, state and federal governments for business approvals and gave as an example a bar or restaurant wanting to open in Parramatta, New South Wales which had to deal with the three tiers of government.

Through a connected business and government approach approval times could be cut from 18 months to three months, providing 15 months of additional business and revenue both to the business and through taxation to governments.

Mr Laundy said that he wanted to see the Federal Government website www.business.gov.au operating like the Health and Social Security site https://mygov.au "so we can instantly have a two-way dialog".

"We can evaluate your rent and wage rates in your area and have a granular understanding of your business," Mr Laundy said.

ONDEK

Ondek says it has raised \$3.59 million in equity funding from professional and high-networth investors for pre-clinical studies of Immbalance for alergies.

Ondek said the funds would be used to exploit the human microbiome to develop a new immunotherapy based on the bacterium Helicobacter pylori.

The company said it was founded by Prof Barry Marshall and had patented a derivative of Helicobacter pylori to be developed as an immunotherapy named Immbalance.

Ondek said that the first Immbalance target indication was childhood eczema because the product was likely to be most effective during development of the immune system. The company said that Immbalance would be tested against existing allergies and other chronic inflammatory diseases in adults.

Ondek chief executive officer Dr Jenny Harry said the funds raised would be "deployed to scale up manufacturing of the new drug compound and generate pre-clinical safety and efficacy data ahead of a meeting with the US Food and Drug Administration later next year to seek guidance and permission to start regulatory toxicology studies and human trials".

The company said it had received a National Health and Medical Research Council development grant of \$919,596 to support clinical trials.

Ondek said that investors included Dymocks chairman John Forsyth and the founder of construction and property company ABN Group, Dale Alcock.

Ondek chairman Peter Hammond said that there had been "a dramatic rise in the prevalence of allergic diseases".

"An estimated 30 percent to 40 percent of the global population suffered from some form of allergic condition in 2011," Mr Hammond said.

Prof Marshall said that "the wider medical community is recognizing the important role of the microbiome in regulating the immune system".

"[Helicobacter] pylori is a unique member of the natural gut microbiome and has a potent immune regulatory function," Prof Marshall said. "I am very excited to be able to exploit this natural immune modulatory trait of [Helicobacter] pylori to shape the potential of future treatments for allergy."

Ondek is a private company.

BURNET INSTITUTE

The Burnet says the Victoria-Jiangsu Innovation and Technology Fund has awarded \$400,000 to its health diagnostics laboratory and China's Boint Biotechnology.

The Burnet said the first round of grants from the Victoria-Jiangsu Innovation and Technology Research and Development Fund would provide about \$200,000 over two years for each partner to support collaborative research and development to develop new laboratory reagents and novel diagnostic tests for a range of infectious diseases.

The Institute said that the work built on its patented 'chimeric secretory component' technology and infectious disease expertize and Boint's expertize in development and industrial-scale purification of monoclonal antibodies.

Burnet deputy director Prof David Anderson said the research institute was "delighted to have the opportunity to expand our collaboration with Boint Biotech".

"Dr Brian Cao and his team at Boint Biotech in Nanjing are leaders in the field of antibody development and production in China," Prof Anderson said.

"The new reagents will enable us to fully capitalise on our patented innovation in immunoglobulin A and M antibody technology, supporting the development of some priority infectious disease diagnostics," Prof Anderson said.

SIRTEX MEDICAL

Sirtex says it will cut a further 15 percent of its staff including chief medical officer Dr David Cade and write off assets in an organizational restructure.

Sirtex said the measures were intended to reset the company's "profitable core business for further global expansion".

Sirtex chief executive officer Andrew McLean said that financial results supported the long-term growth potential of core operations, while at the same time it was important to take additional steps to improve the underlying profitability of the business.

"Sirtex's core business, based on selective internal radiation therapy (SIRT) with targeted doses of SIR-Spheres Y-90 resin microspheres into the liver is clinically proven technology with regulatory approvals across key global markets, which produces positive outcomes for patients with liver cancer," Mr McLean said.

"Our goal is to achieve expanded use within our existing markets which covers over 40 countries globally and gaining utilisation in new geographies," Mr McLean said.

"While the reduction in headcount across a number of business functions is regrettable, it must be noted that these structural changes in the business are designed to optimize the way we engage with our key clinician stakeholders and more effectively target new users, while ensuring as many patients receive our innovative therapy through new or expanded reimbursement," Mr McLean said.

Sirtex said that dose sales for the year to the end of June 2017 were up 5.5 percent to 12,590 doses, with underlying constant currency earnings before tax, interest, depreciation and amortization expected to be about \$72 million, with both within previous guidance.

The company said that the intangible clinical and research and development assets written off in non-cash, pre-tax, had an impairment charge of about \$90 million in the six months to June 30, 2017, removing future amortization.

Sirtex said it expected dose sales increases of 4.7 percent in the Americas, 5.9 percent in Europe the Middle East and Africa and 11.3 percent in the Asia Pacific.

The company said that the 15 percent staff reduction would cost about \$5.3 million.

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CYCLOPHARM

Cyclopharm says its fully underwritten one-for-6.8 share entitlement issue has raised \$6,947,814 with valid acceptances for 90 percent of total entitlements.

Cyclopharm said that investors applied for 7,809,366 shares worth \$6,247,493, leaving a shortfall of 875,402 shares, to be taken up by sub-underwriter Australian Ethical.

The company said that Bell Potter was the manager and underwriter.

Cyclopharm managing-director James McBrayer said he was "delighted with the outcome of the entitlement offer and particularly pleased by Australian Ethical's support and that so many shareholders opted to take up the company's offer to acquire additional new shares".

"The funds raised will allow us to complete clinical trial recruitment and file for [US Food and Drug Administration] approval whilst continuing to invest in research and development and other growth opportunities," Mr McBrayer said.

Mr McBrayer said the fund would be used to complete of recruitment of the 240 patients required for the US phase III Technegas 3 trial, with the clinical trial process expected to be completed by October 2018.

Cyclopharm was unchanged at 84 cents.

REVA MEDICAL

Reva says it has its first commercial sales contract for the Fantom bio-resorbable coronary scaffold from the Universitätsklinikum Schleswig-Holstein.

Reva said the Kiel, Germany hospital was expected to receive the first order in early July. Reva chief executive officer Dr Reggie Groves said that "after years of development and dedication to building a best in class bio-resorbable scaffold, we are extremely pleased to achieve the milestone of securing our first commercial customer and formally making the transition from a purely research and development organization to a full service corporation".

Reva said its Fantom launch was focused on hospitals which had experience with bioresorbable scaffolds and it was finalizing additional contracts.

Reva was up 1.5 cents or 1.8 percent to 84.5 cents.

ITL HEALTH GROUP

ITL says pathology test subsidiary Myhealthtest has won a \$2.6 million co-operative research centre project grant for health testing using dried blood spots.

ITL said that the Federal Department of Industry, Innovation and Science grant would support a three-year collaborative project with industry and academic partners, including Agilent Technologies Australia, the University of Canberra and the ANZAC Institute's Prof David Handelsman.

The company said that the project would begin immediately and would help Myhealthtest develop and bring to market a wider range of tests, including tests for vitamins and hormones, at a reduced cost.

ITL executive chairman Bill Mobbs said the grant was "an endorsement of the hard work [Myhealthtest] has carried out to expand its portfolio of tests".

"The company has been working with University of Canberra for some time and their shared expertise should see the acceleration of new products coming to market," Mr Mobbs said.

Myhealthtest general-manager Dr Nick Cerneaz said that by the end of 2017 the company would be selling test services for diabetes, cholesterol, prostate cancer and thyroid cancer and the grant would ensure the pipeline could be "aggressively accelerated".

ITL was up four cents or 8.3 percent to 52 cents.

<u>OPTISCAN IMAGING</u>

Optiscan says it has appointed the London, Ontario-based Scintica Instrumentation as its North America distributor for its Preclinical Research system, Viewnvivo.

Optiscan said the agreement was for an initial three years with the option to extend for a further two years.

Optiscan chief executive officer Archie Fraser said the appointment was "a significant step ... [and] a further endorsement of the return of Optiscan as a global player and acceptance that Viewnvivo represents world leading technology".

Optiscan said that Scintica was jointly owned by the Houston, Texas-based, Indus Instruments and the London, Ontario-based ONS Projects Inc.

The company said that Indus was "a well-established high tech engineering and manufacturing company" and ONS Projects was an investment, marketing, sales and distribution company in the scientific, preclinical and medical equipment field. responsible for the sales and marketing for Indus Instruments.

Optiscan was up 0.3 cents or 3.2 percent to 9.8 cents.

NUHEARA

Nuheara says that the Minneapolis, Minnesota-based Best Buy would stock Iqbuds hearing and device ear buds in 210 of its shops.

Nuheara said the expansion followed an initial 90 days of sales through the Best Buys online store and at their Ignite shop where sales and consumer sentiment were closely monitored.

Nuheara was up 0.6 cents or eight percent to 8.1 cents with 7.4 million shares traded.

NEUREN PHARMACEUTICALS

Neuren has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 38.2 percent from 5.5 cents on June 19 to 7.6 cents on June 27, 2017, and noted a significant increase in the trading volume. Neuren was in a trading halt for a capital raise and last traded at 7.6 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm managing-director Paul Rennie says he has increased his holding in the company from 22,104,543 shares (21.78%) to 22,389,543 shares (22.06%). The Adelaide-based Mr Rennie said that the investment was with Kzee Pty Ltd and Ear Investments and he acquired 285,000 shares for \$100,619 or 35.3 cents a share. Paradigm fell three cents or 9.2 percent to 29.5 cents.