

Biotech Daily

Tuesday May 30, 2017

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: DIMERIX UP 7%, IMPEDIMED DOWN 5.5%
- * IP GROUP \$200m FOR AUSTRALIA, NZ COMMERCIALIZATION
- * ORTHOCELL: 'ORTHO-ACI 1st CARTILAGE CELL THERAPY ON ARTG'
- * ELLEX TO PAY \$3m FOR ITRACK ROYALTIES
- * CANN EXPECTS AUGUST MARIJUANA HARVEST
- * RESAPP: 'TRIAL RESULTS IN JULY'
- * NUHEARA SHIPS \$1.8m IQBUDS
- * OVENTUS SIGNS HONG KONG MODERN DENTAL MANUFACTURING
- * RESPIRI CLAIMS DRAFT CHINA PARTNERSHIP DEAL
- * ACORN TAKES 8.6% OF FACTOR THERAPEUTICS
- * IMMURON REQUESTS 'NASDAQ LISTING' TRADING HALT'

MARKET REPORT

The Australian stock market was up 0.19 percent on Tuesday May 30, 2017 with the ASX200 up 10.8 points to 5,717.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and four were untraded.

Dimerix was the best, up 0.05 cents or 7.1 percent to 0.75 cents, with 1,165 shares traded. Orthocell climbed 5.4 percent; Living Cell improved 4.34 percent; Admedus was up 3.6 percent; Acrux, Actinogen, Polynovo and Viralytics rose more than two percent; Bionomics and Starpharma were up more than one percent; with Resmed and Sirtex up by less than one percent.

Impedimed led the falls, down 3.5 cents or 5.5 percent to 60.5 cents with 1.2 million shares traded. Uscom lost 5.1 percent; IDT, Oncosil, Opthea and Prana fell four percent or more; Neuren and Pharmaxis were down more than three percent; Compumedics and Pro Medicus shed more than two percent; Ellex, ITL and Nanosonics were down one percent or more; with Clinuvel, Cochlear, CSL and Mesoblast down less than one percent.

IP GROUP PLC

London's IP Group PLC says it has committed at least \$200 million for developing spin-out companies from nine Australia and New Zealand universities.

The IP Group said the commercialization agreements were signed with the University of Adelaide, the Australian National University, the University of Melbourne, Monash University, University of New South Wales, the University of Queensland, the University of Sydney, the University of Western Australia and the University of Auckland.

The IP Group website says the company was founded by stockbroking firm Beeson Gregory in 2001 through the transfer of a December 2000 agreement with the University of Oxford's Chemistry Department, with Beeson Gregory acquired by Evolution Group PLC.

The website said that the IP Group was floated on the London Alternative Investment Market (AIM) in October 2003 and Evolution sold 22 percent of its holding in May 2004 and the remaining 18 percent in March 2005.

Today, the IP Group said it would invest "at least \$200 million over a 10-year period to fund investments in spin-out companies based on the intellectual property developed by academics at the nine universities, generated from research in areas such as digital medicine, new medical therapies and quantum computing".

The company said that the investment was supported by a capital raising, with new shareholders, Telstra Super Pty Ltd, Singapore's Temasek and M&G Investments participating, along with existing shareholders Invesco, Woodford and Lansdowne. The IP Group said the nine universities were "a significant source of world-class and potentially disruptive research".

The company said that the agreements with each university were for an initial 20-year term and would support "the best and brightest researchers to translate their findings into new and innovative ways to improve the economic and social wellbeing of Australasians". IP Group chief executive Alan Aubrey said that the business model being used was "similar to the model IP Group has used successfully in the UK and the US, providing business-building expertise, capital, networks, recruitment and business support". "We believe the model is ideally suited to the Australian and New Zealand markets and represents a significant commercial opportunity for all those involved," Mr Aubrey said. The University of Queensland vice-chancellor Prof Peter Høj and chair of the co-ordinating body for the eight Australian universities, known as the Group of Eight said the investment was "a massive vote of confidence from global capital markets in the quality and impact of

"We know IP Group is constantly approached to fund university research," Prof Høj said. "It could have placed this \$200 million anywhere in what has become a highly competitive arena," Prof Høj said.

research and innovation by the Group of Eight and the University of Auckland".

"That it sought out the [Group of Eight] and was also able to attract Australian co-investors cannot be downplayed," Prof Høj said.

"It is a significant recognition of Australia's leading research-intensive universities and the \$6 billion a year of research which they undertake," Prof Høj said.

The IP Group announcement was welcomed in media releases from Monash University, the University of Melbourne and Uniquest, the commercialization arm of the University of Queensland.

Monash University deputy vice-chancellor for enterprise Ken Sloan said the IP Group would provide access to additional investment capital as well as significant in-kind support for early stage investee companies.

Uniquest chief executive officer Dr Dean Moss said the investment would provide preseed and seed funding to develop innovative discoveries into commercial opportunities.

ORTHOCELL

Orthocell says its Ortho-ACI for knee and ankle cartilage repair is the first cell therapy to for cartilage repair to be included on the Australian Register of Therapeutic Goods. Orthocell managing-director Paul Anderson told Biotech Daily that the inclusion of the company's autologous chondrocyte implantation (Ortho-ACI) by the Australian Therapeutic Goods Administration on the Register was possibly the first cell therapy of any sort to be included, but definitely the first for cartilage repair on Register. Mr Anderson said that the Ortho-ACI procedure costs \$6,500 per treatment and the TGA approval was "an important step towards reimbursement".

In a media release to the ASX, Orthocell said Ortho-ACI was the only Australian Register of Therapeutic Goods (ARTG) approved intervention to repair damaged or degenerate cartilage in the knee or ankle joint without damage to the sub-chondral bone.

The company said that the Ortho-ACI had been approved for sale in Australia under a TGA manufacturing licence, but to maintain regulatory approval for commercial sales it had applied for approval and inclusion on the ARTG.

Orthocell said that inclusion on the ARTG was "a significant milestone" enabling the start of the process for reimbursement and the wider sale and distribution of Ortho-ACI in Australia and the treatment of patients in other countries such as Hong Kong, Singapore and New Zealand.

The company said that Ortho-ACI was "the gold standard intervention for symptomatic defects of the articulating cartilage of the joints, predominately the knee and ankle". Orthocell said that damage to articular cartilage could occur through injury or normal wear and tear and when damaged, it did not repair itself effectively like other tissues, leading to increased joint pain and impaired mobility, which affected daily activities.

Orthocell said that the defects were a difficult clinical problem and if left untreated could lead to osteoarthritis.

The company said that Ortho-ACI provided "the opportunity for the body to regenerate its own cartilage and provide a functional and durable outcome".

Orthocell said it had treated patients in Australia, Hong Kong and Singapore, with Ortho-ACI indicated as a pre-arthritis cell therapy designed to treat the localized defects in the knee, patella and ankle that could lead to osteoarthritis and cartilage degeneration. Mr Anderson said the inclusion of Ortho-ACI on the ARTG was "a significant milestone for the company and enables the continued pathway towards reimbursement".

Orthocell was up two cents or 5.4 percent to 39 cents.

ELLEX MEDICAL LASERS

Ellex says it will pay Itrack vendor ISCI Holdings \$US2.15 million (\$A2.89 million) for the all future Itrack royalties.

Ellex said the payment included an initial payment of \$US650,000 made on May 25, 2016 and the second instalment of \$US1.5 million will be made on September 15, 2017. Last year, the company said that Itrack was a single-use, minimally invasive glaucoma surgery (MIGS) device used to restore the natural outflow pathways in open-angle glaucoma patients no longer responding to selective laser trabeculoplasty or pharmaceuticals (BD: Nov 10, 2016).

Today, Ellex said that the acquisition price was good value as it prepared to accelerate sales and marketing of Itrack.

Ellex said that the acquisition removed all financial imposts for the Itrack and would be made from its cash reserves.

Ellex fell one cent or one percent to \$1.00.

CANN GROUP

Cann says that with permits from the Federal Office of Drug Control it expects to receive its first plant material and start cultivation of medicinal cannabis.

Cann said it had been issued with one medicinal cannabis permit and two cannabis research permits, with the first crop to be harvested "by early August".

The company said the permits would facilitate the establishment of breeding plants for propagation purposes, a research program with the Commonwealth Scientific and Industrial Research Organisation to develop cannabis extracts and the supply of plant material for manufacturing into medicinal cannabis products for patient use.

Cann said that marijuana cultivated under the medicinal cannabis permit would be supplied under a commercial agreement, the terms of which, including manufacturer details, volume and price were confidential.

Cann chief executive officer Peter Crock said the company had arrangements to produce medicinal cannabis for manufacturing into a final product that could be accessed by patients in clinical trials or through the Australian Therapeutic Goods Administration's authorised prescriber or special access scheme.

"We will start cultivation at our southern facility, while work continues on preparing our northern facility, also in Melbourne, which will have a larger cultivation and production capacity," Mr Crock said.

"When the facility modification is complete towards the end of this year, we will apply for our licences and permits to be extended to that facility," Mr Crock said.

"We now have the necessary funding to complete our expansion program and continue with evaluation of strains for production and our breeding program and other development activities," Mr Crock said.

"Securing these permits is another significant milestone in the execution of our business plan," Mr Crock said.

Cann fell three cents or 5.4 percent to 53 cents.

RESAPP HEALTH

Resapp says that with 1,157 patients enrolled in its Smartcough-C trial the initial phase of the trial of its respiratory diagnostic "is nearing completion".

Resapp said it had reached its target recruitment numbers for all study endpoints, including those for pneumonia, upper respiratory tract infection, lower respiratory tract involvement, croup, asthma and reactive airways disease and bronchiolitis.

The company said that principal investigators at the hospital sites and the managing clinical research organization, the Raleigh, North Carolina-based INC Research, required two weeks until June 16, 2017 to close recruitment before final data verification began. Resapp chief executive officer Dr Tony Keating said that recruiting 1,157 paediatric patients in less than five months was "a significant achievement and ... span a broad spectrum of childhood respiratory disease".

The company said that clinical and radiologic adjudication would be conducted for the remaining patients and final source data verification site visits would be performed by INC Research.

Resapp said that the analysis team would prepare the top-line results, which were expected in July, while in parallel it would finalize the US Food and Drug Administration de novo submission with its regulatory consultants.

Resapp fell half a cent or 1.5 percent to 33.5 cents with 1.3 million shares traded.

NUHEARA

Nuheara says it has completed shipping of about 6,000 lqbuds non-retail pre-orders at an average unit sales price of \$307 each.

Nuheara said that manufacturing was "maintaining high yields and the volumes necessary to exceed our initial shipment orders to major distribution and retail partners around the globe".

Last year, Nuheara said its Iqbuds pre-order campaign has passed \$1,000,000 for 3,632 sets of its sound filtering and device ear buds (BD: Jun 9, 2016).

Nuheara fell 0.3 cents or 3.8 percent to 7.6 cents with four million shares traded.

OVENTUS MEDICAL

Oventus says it has entered a manufacturing agreement with the Hong Kong-based Modern Dental Group for its O2Vent anti-snoring mouth-guard products.

Oventus said that Modern Dental had expertise in the manufacture of dental appliances, held quality management certifications for medical device manufacture and was registered as a contract manufacturer with the US Food and Drug Administration.

The company said that the non-exclusive agreement included set pricing for the applicable manufacturing steps.

Oventus said it would continue to design and print its airway components.

Oventus chief executive officer Neil Anderson said the agreement allowed the company "to focus on the manufacture of our unique differentiating feature, the Oventus airway technology that distinguishes us from all other appliances".

"Our strategy is to commercialise a range of oral appliances with our proprietary airway design that have the various lower jaw advancement mechanisms," Mr Anderson said. "Modern Dental will be able to manufacture the volumes required to meet the future demand for our products and at relatively short notice," Mr Anderson said.

Oventus said the agreement started immediately and would be for small volumes for Australia before starting to manufacture for the US later in 2017.

Oventus was unchanged at 40 cents.

RESPIRI

Respiri says it has "a written, commercial-in-confidence, draft proposal to establish a partnership vehicle to manufacture and market an updated Airsonea in China". Respiri said that China was "a significant opportunity" with asthma education and management control poor and the country had "the world's highest mortality rate from this chronic disease" with about 100 million people with asthma.

The company said it had a product "to address the unmet need of regular monitoring, the key to asthma control in children and parental peace of mind".

In April, Respiri said the Airsonea at-home monitoring device was granted class IIa Conformité Européenne (CE) mark approval, which followed the 2013 Australian Therapeutic Goods Administration approval for the original Airsonea wheeze detection monitor (BD: Aug 6, Sep 4, 23, 2013; Apr 12, 2017).

Last year the company said air pollution in China and India causing asthma and respiratory diseases made them "a major opportunity for Respiri's wheeze monitoring products" (BD: Jun 9, 2016).

Respiri fell 0.6 cents or 10.5 percent to 5.1 cents with 2.3 million shares traded.

FACTOR THERAPEUTICS

Acorn Capital says it has increased its substantial shareholding in Factor Therapeutics from 54,611,542 shares (7.54%) to 62,814,562 shares (8.60%).

The substantial shareholder notice said that the Melbourne-based Acorn bought and sold shares between August 15, 2016 and May 29, 2017 with the single largest purchase 2,850,000 shares for \$143,284 or an average price of 5.0 cents a share.

Last year, Acorn became substantial in Factor with 54,611,542 shares or 7.54 percent acquiring the shares at an average price of 3.5 cents a share (BD: May 6, 2016). Factor was unchanged at 6.2 cents.

IMMURON

Immuron has requested a trading halt pending "an announcement to the market in respect of a proposed US Nasdaq initial public offer".

Trading will resume on June 1, 2017 or on an earlier announcement. Immuron last traded at 50 cents.