



Biotech Daily

Tuesday February 21, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: COMPUMEDICS, OPTHEA UP 7%
- VIRALYTICS DOWN 6%**
- * **TAKEOVER PANEL REASONS FOR INNATE CHRIS COLLINS DECISION**
- * **ANALYTICA: 'PERICOACH IMPROVES SEX, PELVIC FLOOR STRENGTH'**
- * **CANN CLAIMS FIRST AUSTRALIAN MEDICINAL MARIJUANA LICENCE**
- * **CMAX SALE TAKES IDT H1 REVENUE UP TO \$5m, LOSS TO \$12m PROFIT**
- * **POLYNOVO REVENUE UP 328% to \$2m, LOSS DOWN 14% TO \$2m**
- * **BIOXYNE APPOINTS QUALITY BRANDS CHINA DISTRIBUTOR**
- * **NUHEARA BEST BUY US LAUNCH, GOOGLE PLAY DOWNLOAD**
- * **ADALTA INAUGURAL INVESTOR FIBROSIS R&D DAY**
- * **HONG KONG'S SENRIGAN TAKES 14.5% OF REVA**
- * **YODAMBAO INCREASES, DILUTED TO 5% OF DIMERIX**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Tuesday February 21, 2017 with the ASX200 down 4.1 points to 5,791.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded.

Compumedics was the best, up five cents or 7.35 percent to 73 cents with 36,325 shares traded, followed by Opthea up 7.32 percent to 88 cents with 78,556 shares traded. Prana climbed 5.6 percent; Bionomics, Cellmid and Factor Therapeutics were up more than three percent; Atcor rose 2.9 percent; Admedus, Orthocell and Pharmaxis were up more than one percent; with Mesoblast and Pro Medicus up less than one percent.

Viralytics led the falls, down six cents or 5.8 percent to 97 cents with 116,980 shares traded, followed by Airxpanders down 5.4 percent to 87 cents with 349,702 shares traded. Living Cell, Medical Developments and Nanosonics fell more than four percent; Actinogen, Clinuvel, IDT and Impedimed were down more than three percent; Benitec shed 2.6 percent; Acrux, Ellex, Oncosil, Osprey and Sirtex were down more than one percent; with Cochlear, CSL and Psivida down by less than one percent.

INNATE IMMUNOTHERAPEUTICS

The Takeovers Panel says that although the combined Collins family holding in Innate is more than 20 percent an association has not been established.

Yesterday, the Panel rejected an application from Sydney barrister and investor James Wheeldon into holdings associated with Innate's largest shareholder and director and US Republican Representative Chris Collins, alleging that Mr Collins might be associated with family members and other shareholders in contravention of section 606 of the Corporations Act 2001 (BD: Feb 15, 20, 2017).

Today, in delivering its reasons for rejecting the application, the Panel said Mr Collins held 17.06 percent of the company while his 26-year-old daughter Caitlin Collins and 24-year-old son Cameron Collins each held 2.34 percent.

The Panel said that Mr Wheeldon submitted that 18 recipients of shares in placements were either employees of, financial donors to, or otherwise had close ties to Mr Collins and many had businesses in Buffalo, New York, in Mr Collins' congressional district.

The Panel said Mr Wheeldon submitted that "it strains credulity to suggest that these intimate allies would not accede to Mr Collins' wishes and instructions should a matter be put to a vote ... of this company located on the other side of the world", particularly given that the investors acquired the discounted shares at his invitation.

But the Panel said "the applicant has not provided sufficient material to justify us making further enquiries as to the alleged association between Mr Collins and these investors".

The Panel said "there must be a sufficient body of material demonstrated by the applicant, which together with inferences ... support ... proceedings".

"It may be that these investors have business or political ties to Mr Collins, but this falls short of establishing an association," the Panel said. "The applicant also presented no material to support his submission that any of the investors would accede to Mr Collins' instructions should a matter be put to a vote ... we view this as supposition."

The Panel said family relationships were a possible indicator of association, with a spousal relationship a strong indicator, but relationships between siblings less so and between parent and child would depend on the child's age and other circumstances.

"There is material suggesting that Caitlin and Cameron Collins have some independence from their father," the Panel said and quoted Mr Collins saying his children "own their Innate shares free and clear of any control or involvement by me, they can buy and/or sell at their own discretion" and neither had lived at home for more than six years.

The Panel said that Mr Wheeldon alleged that, to his knowledge, Innate had never told the market that Caitlin and Cameron Collins were the children of Mr Collins, but this was disclosed in Innate's prospectus of November 25, 2013 as well as in the notice of annual general meeting for October 30, 2015.

The Panel said that given the disclosure and the time elapsed since and the small amount by which the collective holding exceeded 20 percent, it considered the justification for investigating the concerns raised to be greatly reduced.

The Panel said there was no control transaction or proposed changes to the board, the applicant did not point to any specific circumstance in which Mr Collins and his children would have been likely to want or need to act together as associates, but rather, the concern appeared to be that they were likely to act as associates, should the need arise and "if they do so, of course, it will be open to any person affected to make a further application to the Panel at that time".

"We do not consider that there is any reasonable prospect that we would make a declaration of unacceptable circumstances [and] accordingly, we have decided not to conduct proceedings," the Panel said.

Innate fell 9.5 cents or 12.2 percent to 68.5 cents with 1.2 million shares traded.

ANALYTICA

Analytica says a 47-patient trial of its intra-vaginal Pericoach shows improvements in sexual function, urinary incontinence and pelvic floor strength.

Analytica said that the post-approval, randomized clinical trial was held by an independent contract research organization at five Australian continence clinics.

The company said the trial studied women undergoing clinician-guided pelvic floor rehabilitation and women engaged in clinician guided pelvic floor rehabilitation with Pericoach to support home exercise between visits.

Analytica said that the study included women with predominantly stress urinary incontinence and required eight visits to the clinician study site over 20 weeks.

The company said that the level of clinical intervention in both groups exceeded that of a normal urinary incontinence sufferer seeking treatment, but the level of oversight was necessary to independently collect data.

Analytica said that quality of life measurements showed statistically significant superior results ($p = 0.015$) for the Pericoach group over the control group.

The company said the Pericoach group had higher scores at baseline and maintained higher scores throughout the trial which supported the thesis that effective bio-feedback provided positive reinforcement between clinical visits during treatment.

Analytica said that to analyze incontinence, a 24-hour pad weight test was used and pelvic floor strength was assessed through the Oxford scale with digital examination by clinicians, but pad weight reduction was not statistically significant ($p = 0.8034$).

The company said pelvic floor strength data was in favour of the Pericoach group, with participants twice more likely to have a 30 percent or better reduction in pad weight, which was considered a large change.

Analytica said that sexual satisfaction among sexually active participants was highly significant ($p = 0.0061$), with the Pericoach group increasing significantly while the control group worsened over the 20 weeks.

The company said that areas around emotional state during sexual activity showed improved shame and fear scores and reduced scores with relation to fear of urine leakage during sexual activity.

Analytica said that based on the findings during the interim analysis, a final data review was completed and enrolment concluded at 47 of the initial target of 90 patients.

The company said that the trial demonstrated the efficacy of Pericoach in the core areas for pelvic floor rehabilitation.

Analytica said its Pericoach version 3 had significant improvements over the version 2 product used in the study.

The company said that Pericoach 3 had a patent-pending accelero-meter and gyroscope which, in combination with the force-sensors allowed the system to identify whether or not a woman is performing her exercises correctly.

Analytica said about 50 percent of women did not perform their pelvic floor exercises correctly, with several different incorrect techniques and the version 3 would be capable of providing real-time feedback to a woman on whether she was exercising correctly.

The company said that the version 3 had superior quality-of-life monitoring features and a more structured exercise program, which could gather real-world data at a similar level of rigour to that in the clinical trial.

Analytica chief executive officer Geoff Daly said the trial was "originally designed to provide evidence to drive clinical acceptance of the Pericoach".

"We met this objective and now look to additional studies with the new version 3 which engage the everyday consumer," Mr Daly said.

Analytica was up 0.1 cents or 16.7 percent to 0.7 cents with 9.6 million shares traded.

CANN GROUP

The public unlisted Melbourne Cann Group says it has the first Australian Office of Drug Control licence to grow medicinal cannabis.

In a media release Cann said that the research licence was issued by the Federal Office of Drug Control to legally cultivate medicinal cannabis and conduct research on the use of cannabis for medicinal purposes.

The company said it had submitted an application for a cultivation licence and was confident of securing this in the near future.

Cann said that its research and development facilities had operated under an authority for low-tetrahydrocannabinol (low-THC) issued by the Victorian Government, authorizing cultivation of low-THC cannabis for research and non-therapeutic purposes.

The company said that the research program had focused on evaluating optimal conditions, processes and equipment for cultivating cannabis.

Cann chairman Allan McCallum said receiving the first Federal Government research licence "validates the significant investment made by the company in establishing facilities and protocols that meet the strict criteria required for a licence approval".

"This is an important milestone in the medicinal cannabis sector in Australia, but also for Cann Group and the development of our business plan," Mr McCallum said.

"The licence allows us to apply for a permit to progress our research and development programs, which are particularly focused on the breeding, cultivation, extraction and characterisation of cannabinoids," Mr McCallum said.

"It will also mean we can further discussions we have underway with a number of leading Australian research and technology organisations to access additional expertise and resources," Mr McCallum said.

Cann said its objective was to be recognized as the leading developer and supplier of regulated medicinal cannabis in Australia.

IDT AUSTRALIA

IDT says revenue for the six months to December 31, 2016 was up 62.1 percent to \$4,892,000 with the CMax sale taking last year's loss to a net profit after taxation to \$11,729,000.

Last year, IDT reported revenue for the six months to December 31, 2015 of \$6,450,000 with a net loss after taxation of \$3,538,000 (BD: Feb 19, 2016).

Today, the company said that following the divestment of the CMax clinical trials business, its operations had been re-categorized as a discontinued operation and a one-time profit on disposal of the \$14.4 million business recognized.

IDT said that as a discontinued operation, CMax revenues and profits were excluded from reported revenue and profit from ordinary operations for both the half year ended December 31, 2016 and the comparative period ended December 31, 2015.

The company said it received an initial cash payment of \$10 million for the first 61 percent of the CMax business with a second payment of \$4 million plus an additional balance receivable should forecasted revenues be achieved over the year to June 30, 2017, due in the next 12 months for the remaining 39 percent of the CMax business.

IDT said that diluted loss per share fell 38.9 percent from 1.8 cents in the previous year to 1.1 cents for the six months to December 31, 2016, with net tangible asset per security up 36.4 percent to 15 cents.

The company said it had cash and cash equivalents of \$9,443,000 at December 31, 2016, compared to \$4,982,000 at December 31, 2015.

IDT fell half a cent or three percent to 16 cents.

POLYNOVO

Polynovo says that revenue for the six months to December 31, 2016, was up 327.9 percent to \$2,091,162 reducing net loss after tax 14.0 percent to \$1,965,277.

Polynovo said that revenue primarily came from its US Biomedical Advanced Research and Development Authority (BARDA) contract supplemented by initial sales of its bio-degradable temporizing matrix (BTM) wound treatment.

The company said that diluted loss per share fell 10.3 percent from 0.39 cents in the previous year to 0.35 cents for the six months to December 31, 2016, with net tangible assets per share down 13.0 percent to 2.0 cents.

Polynovo said it had cash and cash equivalents of \$9,783,318 at December 31, 2016, compared to \$13,404,223 at December 31, 2015.

Polynovo was unchanged at 25.5 cents.

BIOXYNE

Bioxyne says it has an agreement with Melbourne's Quality Brands International Direct to supply and market its Progastrim and Protract probiotic products in China.

Bioxyne said that Progastrim targeted gastrointestinal and immune health and Protract was used for atopic dermatitis or eczema.

The company said that Quality Brands would distribute the products in through the on-line platform JD.com starting by July 2017, but the terms of the deal were confidential.

Bioxyne said that JD.com had 155 million active customer accounts and was headquartered in Beijing.

The company said that Quality Brands would provide translation of its marketing materials, engage with customers through a range of media channels, handle logistics and meet regulatory requirements.

Bioxyne chairman Tony Ho said that China was "clearly an important market for us".

"The demand for dietary supplements, including probiotics, is growing rapidly there," Mr Ho said.

"Bioxyne's entry into the Chinese market is a major milestone in our strategy to develop and market our own range of products to consumers," Mr Ho said.

Bioxyne said it would supply up to five products that would be marketed through the Quality Brands online portal at JD.com, with the initial products Progastrim and Protract registered with the Australian Therapeutic Goods Administration launched last year (BD: Nov 2, 2016).

The company said it was in the process of developing further products based on its proprietary probiotic PCC for launch in Australia and China in 2017.

Bioxyne was up 0.2 cents or 10.5 percent to 2.1 cents.

NUHEARA

Nuheara says it will launch its Iqbuds sound filtering and device ear buds in the US through Best Buy and its android version is available through Google Play.

Nuheara said that Best Buy was a leading consumer electronics retailer in North America with more than 1,400 shops in the US and a further 200 in Canada and Mexico.

The company said that the android version of the Iqbuds mobile telephone application was available for download on Google Play.

Nuheara was up half a cent or 4.8 percent to 11 cents with 8.6 million shares traded.

ADALTA

Adalta has held its inaugural research and development fibrosis briefing for analysts and investors in Melbourne.

Adalta said in a media release that the briefing included a keynote presentation by its US-based director Dr Robert Peach providing “a roadmap of how investment into an early stage [research and development] company addressing a significant market with a novel biological drug can provide exciting returns for investors”.

Dr Peach said that antibody drug discovery company Receptos Inc was sold to Celgene Corp for \$US7.2 billion.

Adalta chief executive officer Samantha Cobb said her company was “on-track to meet its stated clinical development milestones and initiating a phase I human clinical trial for its lead drug candidate by early 2018”.

“Our focus is to advance AD-114 into phase I clinical studies for idiopathic pulmonary fibrosis and secure a global licencing deal for this lead candidate,” Ms Cobb said.

The company said it had recently announced pre-clinical data for AD-114 and received orphan drug designation from the US Food and Drug Administration.

Adalta said the briefing provided investors and analysts with details of the potential commercial and clinical applications of its Australian-developed technology platform for common fibrotic diseases of the kidney, eyes and liver.

“Our aim with this briefing was to provide investors and analysts with more detail and color on the exciting opportunity that our I-body technology platform and lead drug candidate presents,” Ms Cobb said.

Adalta said that founding scientist Dr Michael Foley reviewed the research and development program in fibrosis and other speakers included the Alfred Hospital’s Dr Glen Westall discussing idiopathic pulmonary fibrosis, the Kolling Institute’s Dr Muh Geot Wong on renal fibrosis and chronic kidney disease and the University of Melbourne’s Prof Erica Fletcher who presented on eye fibrosis, causes, diseases and treatments.

Adalta was up three cents or 15 percent to 23 cents.

REVA MEDICAL

Reva says the Senrigan Master Fund has increased its holding from the equivalent to 57,652,301 Chess depository instruments (13.6%) to 62,192,706 CDIs (14.5%).

Reva and the Central, Hong Kong-based Senrigan did not provide a contact name or address for Senrigan and failed to disclose the cost of the shares.

Reva was untraded at \$1.045.

DIMERIX

Yodambao says it has increased its substantial shareholding in Dimerix and been diluted from 85,674,817 shares (6.13%) to 93,463,437 shares (5.11%).

The Dalkeith, Western Australia-based Yodambao Pty Ltd substantial notice, signed by director Tracy Blake, said that the increase followed the conversion of performance shares for nil consideration and dilution in a placement.

Dimerix was unchanged at 0.8 cents with 3.6 million shares traded.