

# **Biotech Daily**

# Thursday August 17, 2017

Daily news on ASX-listed biotechnology companies

\* ASX DOWN, BIOTECH UP: COCHLEAR UP 7%, DIMERIX DOWN 9%

\* 4-YEAR DATA BACKS PROTA, MCRI PEANUT IMMUNOTHERAPY

\* COCHLEAR REVENUE UP 7% TO \$1,240m, PROFIT UP 18% to \$224m

- \* ALLEGRA TO DEVELOP KANGAROO FOR TENDON, LIGAMENT REPAIR
- \* MICRO-X TAKES OVER XINRAY'S CARBON X-RAY TUBE PRODUCTION
- \* ANATARA REQUESTS 'ZOETIS LICENCE' TRADING HALT
- \* BOTANIX REQUESTS 'ACNE TRIAL ETHICS APPROVAL' TRADING HALT

# MARKET REPORT

The Australian stock market slipped 0.1 percent on Thursday August 17, 2017 with the ASX200 down 5.9 points to 5,770.2 points.

Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and six were untraded.

Cochlear was best on what one analyst called "super stellar growth in the US", up \$10.24 or 7.2 percent to \$153.02 with 410,478 shares traded (see article below).

Avita climbed 6.9 percent; Uscom was up 5.6 percent; Acrux, Bionomics, Neuren, Orthocell and Viralytics were up more than three percent; Polynovo and Starpharma rose more than two percent; Compumedics, CSL, Medical Developments, Mesoblast, Pharmaxis and Pro Medicus were up one percent or more; with Ellex, Nanosonics and Sirtex up by less than one percent.

Yesterday's best, Dimerix, again led the falls, down 0.1 cents or 9.1 percent to one cent with 2.4 million shares traded.

Cellmid lost eight percent; Airxpanders and Prima fell more than four percent; LBT and Opthea were down more than three percent; Osprey shed 2.2 percent; Clinuvel and Psivida were down more than one percent; with Resmed down 0.2 percent.

# PROTA THERAPEUTICS, MURDOCH CHILDRENS RESEARCH INSTITUTE

Prota says that four-year follow-up data of a 48-patient study of a probiotic and peanut immunotherapy treatment shows "long-lasting tolerance effects of treatment". Prota said that it licenced the technology from Melbourne's Murdoch Children's Research Institute at the Royal Children's Hospital and last year received \$15 million in funding led by Oneventures (BD: Sep 29, 2016).

The company said that at the end of the 2013 trial, 20 of 24 children (83.3%) who received the probiotic and peanut immunotherapy were deemed tolerant to peanuts and four years later, 80 percent of the 20 children who had initially developed tolerance to peanut were still consuming peanut as part of their normal diet and 70 percent passed a further challenge test confirming long-term tolerance to peanut.

The research article, entitled 'Long-term clinical and immunological effects of probiotic and peanut oral immunotherapy after treatment cessation: 4-year follow-up of a randomised, double-blind, placebo-controlled trial' was published in The Lancet, Child and Adolescent Health and the full article is available at:

http://thelancet.com/journals/lanchi/article/PIIS2352-4642(17)30041-X/fulltext.

Prota said that the follow-up study data provided "the strongest evidence yet that a cure may be possible for peanut allergy and holds important implications for attacking the modern food allergy epidemic".

The company said peanut allergy was the most common cause of anaphylaxis and one of the most common causes of death from food allergy.

Prota said that 48 children in the original randomized trial were given either a combination of the probiotic, Lactobacillus rhamnosus, together with peanut protein in increasing amounts, or a placebo, for 18 months to assess whether they would become tolerant to peanut.

Prota said that 19 children (79.2%) who received the combination probiotic peanut oral immunotherapy treatment were able to tolerate peanut at the end of the trial, compared to one child (4.2%) in the placebo group.

Prota chief scientific officer and lead researcher Prof Mimi Tang pioneered the treatment and said the study showed that the majority of treated children who tolerated peanut at the end of the original trial were still eating peanut essentially without reactions four years later.

"These children had been eating peanut freely in their diet without having to follow any particular program of peanut intake in the years after treatment was completed," Prof Tang said. "Over half were consuming moderate to large amounts of peanut on a regular basis, others were only eating peanut infrequently."

"The importance of this finding is that these children were able to eat peanut like children who don't have peanut allergy and still maintain their tolerant state, protected against reactions to peanut," Prof Tang said.

Prota said that among the few that reported allergic reactions to peanut following intentional peanut intake since stopping treatment, none reported anaphylaxis.

Prota said the follow-up study was conducted by the MCRI with contributory funding from the MCRI and Australian Food Allergy Foundation.

Oneventures managing-partner Dr Paul Kelly said the Lancet publication "further validates the quality and rigor of Prof Tang's work and its potential".

Prota chief executive officer Dr Suzanne Lipe told Biotech Daily that an up-to 200-patient, multi-centre, phase II trial was underway in Australia with results expected in 2020, and an up-to 500-patient, pivotal, phase III, US regulatory-directed trial was being planned to start in 2019.

Prota is a private company.

#### **COCHLEAR**

Cochlear says total revenue for the 12 months to June 30, 2017 was up 7.0 percent to \$1,239,700,000 with net profit after tax up 18.4 percent to \$223,600,000.

Last year, Cochlear reported total sales revenue of \$1,158,100,000 with a \$27,500,000 foreign exchange loss providing \$1,130,600,000 in "total revenue" (BD: Aug 9, 2016). This year, the company changed its presentation to remove other income of \$4,500,000 and a foreign exchange gain of \$14,100,000, implying total revenue of \$1,258,300,000, 11.3 percent compared to last year's "total revenue".

Cochlear chief executive officer Chris Smith told a teleconference that along with an increase in sales and revenue in all regions, net profit after tax for the year to June 30, 2018 was expected to be \$240 million to \$250 million, with research and development expenditure expected to be \$160 million to \$170 million.

In a media release, Cochlear said that revenue from the Americas was up 14 percent, with the Europe, Middle East and Africa up 0.14 percent and the Asia-Pacific up three percent. Cochlear chief financial officer Brent Cubis told Biotech Daily that unit sales in India were up by 40 percent and unit sales to private payers in China increased by 30 percent. Cochlear's incoming chief executive officer Dig Howitt said there were four elements to its growth strategy: demand generation through awareness of products and access to them; technology leadership with the new Kanso sound processor rolling-out and the Nucleus 7 sound processor to launch in September; the services business including upgrades and accessories; and a focus on emerging markets over the coming 10 to 20 years.

Cochlear said that investment in research and development was up 4.7 percent from \$145.1 million last year to \$151.9 million or 13.4 percent of total revenue, for the year to June 30, 2017.

The company said the final fully-franked dividend was up 16.7 percent to \$1.40 to be paid on October 11, 2017, for a record date of September 20, taking the full year dividend to \$2.70 compared to the previous year's \$2.30.

Cochlear said that basic earnings per share climbed 17.8 percent to \$3.90, compared to the previous year's \$3.31, but last year the company cited diluted earnings per share of \$3.30, which was absent from this year's report.

The company said net debt was up \$11.5 million to \$129.4 million and it had cash and cash equivalents of \$89.5 million at June 30, 2017, compared to \$75.4 million last year. Cochlear climbed \$10.24 or 7.2 percent to \$153.02 with 410,478 shares traded.

# ALLEGRA ORTHOPAEDICS

Allegra says it will collaborate with Bone Ligament Tendon Pty Ltd to commercialize a tendon and ligament reconstruction product derived from kangaroos.

Allegra said that orthopaedic surgeons undertaking ligament or tendon reconstruction needed a reliable graft, with no donor site issues and restoration of function.

The company said that kangaroo had a reputation for strength and kangaroo Achilles tendon had "impressive biomechanical abilities", with initial studies at the University of Sydney showing that kangaroo tendon was three times stronger than and twice as stiff as the human anterior cruciate ligament tendon, with morphology, collagen architecture and arrangement, and composition typical of human tendons.

Allegra said the collaboration to provide an off-the-shelf tendon to repair torn or ruptured anterior and posterior cruciate ligaments of the knee, rotator cuffs of the shoulder,

collateral ligaments of the elbow, tendons in the hands and feet.

Allegra was unchanged at 12.5 cents.

# MICRO-X

Micro-X says it will take over carbon x-ray tube production from its partner Xinray Systems for its DRX Revolution Nano product.

In June, Micro-X said the US Food and Drug Administration had approved the marketing of the DRX Revolution Nano x-ray technology (BD: Jun 26, 2017).

Today, the company said that the Morrisville, near Raleigh, North Carolina-based Xinray was its partner for carbon nano tube x-ray technology.

Micro-X managing-director Peter Rowland said that his company would "directly manage tube production in North Carolina under its ISO13485 accredited quality system and implement improvements in manufacturing processes and supply-chain management".

"Our former [General Motors] Holden production team provide the ideal skills and experience for these tasks," Mr Rowlands said.

"This is effectively a vertical integration move for Micro-X to have x-ray tube manufacturing in Raleigh directly managed as part of the overall Micro-X production operation," Mr Rowlands said.

"We expect these changes to drive reduced costs due to rationalisations in the supply chain, productivity improvements and reduced cycle times," Mr Rowlands said.

Micro-X said that production manager Adam Williams would relocate to North Carolina for a period to provide hands-on leadership of a change management team.

The company said it had negotiated an option for its investment in plant and equipment that would be made under the agreement to be exchanged in the future for additional equity that to increase its ownership of Xinray.

"The market response to the first showings of ... the DRX Revolution Nano has been enormously positive and this is leading us to plan for significant higher production volumes," Mr Rowland said.

Micro-X was up 1.5 cents or 3.6 percent to 43 cents.

# ANATARA LIFESCIENCES

Anatara has requested a trading halt "pending an announcement regarding the evaluation and licence option agreement with animal health company Zoetis Inc for Detach". Trading will resume on August 21, 2017 or on an earlier announcement. Anatara last traded at 95 cents.

# **BOTANIX**

Botanix has requested a trading halt pending "an announcement regarding ethics approval for its BTX 1503 acne patient study".

Trading will resume on August 21, 2017or on an earlier announcement. Botanix last traded at 5.3 cents.