

# Biotech Daily



Tuesday November 22, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: IDT UP 8%, NEUREN DOWN 11%**
- \* **VOLPARA PLACEMENT RAISES \$7m, RIGHTS OFFER FOR \$3.7m MORE**
- \* **ZELDA OPENS UP 15% FOR MEDICAL MARIJUANA, CLOSES DOWN 8%**
- \* **MAYNE LAUNCHES IDT'S TEMOZOLOMIDE IN THE US**
- \* **ANATARA: 'PIG DETACH IN 2017; PROF TRACEY BROWN HUMAN HEALTH'**
- \* **HUNTER HALL TAKES 9.5% OF MACH7**
- \* **FACTOR THERAPEUTICS, MONASH UNI WOUND COLLABORATION**
- \* **SWEDEN APPROVALS PARADIGM PPS HAY FEVER TRIAL**
- \* **BIOTRON REMUNERATION REPORT FACES 18.1% DISSENT**
- \* **VIRALYTICS APPOINTS 4-PROFESSOR CLINICAL ADVISORY BOARD**
- \* **WEHI'S PROF JANE VISVADER, PROF GEOFF LINDEMAN WIN RAMACIOTTI**
- \* **RECCE LOSES DIRECTOR BERNADETTE MURDOCH AHEAD OF AGM**

## MARKET REPORT

The Australian stock market climbed 1.16 percent on Tuesday November 22, 2016 with the ASX200 up 62 points to 5,413.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell and eight traded unchanged. All three Big Caps were up.

IDT was the best, up 1.5 cents or 8.1 percent to 20 cents with 285,410 shares traded. Avita, Cellmid, Nanosonics, Polynovo and Pro Medicus climbed more than three percent; Admedus, Cochlear, Factor Therapeutics, Psivida and Sirtex rose two percent or more; Prana was up 1.7 percent; with CSL, Ellex, Resmed and Starpharma up less than one percent.

Neuren led the falls, down 0.7 cents or 10.6 percent to 5.9 cents with 646,521 shares traded. Osprey lost 7.6 percent; Atcor and Oncosil shed five percent or more; Actinogen, Benitec and Impedimed fell more than four percent; Airxpanders was down 3.85 percent; Anteo, Compumedics and Opthea shed two percent or more; Clinuvel, Cyclopharm, Living Cell, Medical Developments, Mesoblast and Universal Biosensors were down more than one percent; with Reva and Viralytics down by less than one percent.

### [VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says it has raised \$7 million in a placement at 60 cents a share and expects for raise \$3.7 million in a one-for-20 non-renounceable entitlement offer.

In April, Volpara raised \$10 million at 50 cents a share in its initial public offer, having initially sought to raise up to \$20 million to commercialize its mammography software (BD: Apr 18, 27, 2016).

Today, Volpara said that the 60 cents placement and rights offer price was a 28 percent discount to its last traded price of 83.5 cents a share, an 18 percent discount to its 30-day volume-weighted average price to November 17 and a three percent discount to its 90-day volume weighted average price (BD: Nov 18, 2016).

The company said the record date for the entitlement offer would be November 25, the offer would open on November 30 and close on December 15, 2016.

Volpara said the placement and rights offer was fully underwritten by Morgans Corporate. Volpara fell 3.5 cents or 4.2 percent to 80 cents.

### [ZELDA THERAPEUTICS \(FORMERLY GLENEAGLE GOLD\)](#)

The Perth-based Zelda opened on the ASX at 2.8 cents, a 15 percent premium to its initial public offer price of 2.5 cents, in which it raise \$4 million for medical marijuana.

Zelda said last week it would relist under the code ZLD to develop sublingual and topical marijuana treatments for insomnia, acne and glioblastoma having raised the \$4 million maximum allowed under its prospectus (BD: (BD: Aug 24, Nov 16, 2016).

Zelda said that the funds were to continue with pre-clinical research and development activities, fund human clinical trials and expand the management and advisory team.

Zelda closed down 0.2 cents or eight percent at 2.3 cents with six million shares traded.

### [IDT AUSTRALIA, MAYNE PHARMA GROUP](#)

Mayne says it has launched six doses of IDT's temozolomide capsules, or generic Temodar, for glioblastoma multiforme in the US.

IDT managing-director Dr Paul MacLeman said that the launch of IDT's first drug was "a significant moment in the company's history".

"It represents the culmination of several years of effort in delivering on our announced strategy for revenue and profit growth via the development and commercialisation of IDT's own drug portfolio," Dr MacLeman said. "Following on the back of last week's audit of IDT's manufacturing facility by the US Food and Drug Administration, temozolomide is the first of these products, with more to come."

Mayne said that the temozolomide capsules came in doses ranging from 5mg to 250mg and were indicated for adults with newly-diagnosed glioblastoma multiforme brain tumors, with radiotherapy and then as maintenance treatment.

The company said that temozolomide capsules had US sales of about \$US150 million for the 12 months to September 30, 2016.

Mayne said it would distribute the drug on behalf of IDT, which developed and manufactured the product.

Mayne chief executive officer Scott Richards said that "since entering the United States in 2012, Mayne Pharma has aggressively expanded its product portfolio, through internal product development, strategic acquisition, in-licencing and working collaboratively with partners like IDT".

IDT was up 1.5 cents or 8.1 percent to 20 cents.

Mayne was up 4.5 cents or 2.9 percent to \$1.58 with 5.4 million shares traded.

## ANATARA LIFESCIENCES

Anatara says it expects to launch Detach for piglet diarrhoea in 2017 and then focus on human health, led by former Alchemia executive Prof Tracey Brown.

In a Melbourne investor conference, Anatara executive chairman Dr Mel Bridges confirmed that Prof Brown had been appointed chief development officer to oversee the human trials of Detach for gastro-intestinal disease including irritable bowel syndrome, inflammatory bowel disease and travellers diarrhoea.

Dr Bridges said that the company could take Detach through either or both a pharmaceutical regulatory pathway or as an approved over-the-counter drug which could take two to three years.

Dr Bridges said that Prof Brown would have a laboratory in Parkville and development would be in collaboration with LaTrobe University.

Dr Bridges said that regulators wanted to see a reduction in antibiotic use in healthy animals and US regulations would see a three-year period to eliminate the use of antibiotics as growth promotion drugs.

He said that there was no existing alternative to promote rapid growth and although there might be competitors in development, Detach would be an early option for livestock producers.

Dr Bridges said that Anatara had a licence option for Detach for livestock with the Florham Park, New Jersey-based Zoetis Inc and had already earned its first milestone payment (BD: Jan 27, Apr 1, 2016).

In a media release to the ASX, Anatara said it had filed its application to the Australian Pesticides and Veterinary Medicines Authority for approval to sell and market the pineapple stem bromelain-derived Detach (BD: Oct 4, 2016).

Last year, Anatara said that a 560 weaner piglet trial showed that treatment with Detach reduced the number of pigs with diarrhoea by 41 percent and the severity by 45 percent (BD: Sep 16, 2016).

Dr Bridges said that with the application completed, the company's focus "will increasingly turn to applications for human health, particularly gut health and gastrointestinal disorders".

"There is significant opportunity for Anatara in this area," Dr Bridges said.

Anatara said there were about four billion episodes of diarrhoea in the world each year and it was a serious unmet medical need, with diarrhoea the second cause of death in children under five years of age and the leading cause of malnutrition.

Anatara chief scientific officer Dr Tracey Mynott said that the "anti-secretory and anti-inflammatory action of Detach actives open the way to treat human gastrointestinal conditions such as irritable bowel syndrome, inflammatory bowel disease and traveller's diarrhoea".

"These are significant areas of unmet medical need that are not addressed by current products," Dr Mynott said.

Anatara was up six cents or 5.5 percent to \$1.15.

## MACH7 TECHNOLOGIES

Hunter Hall Investment Management says it has become a substantial shareholder in Mach7 with the acquisition of 100,000,000 shares (9.48%).

The Sydney-based Hunter Hall said it acquired the 100,000,000 shares on November 18 for \$4,000,000 or four cents a share, the same price as Mach7's recent \$9 million placement (BD: Nov 16, 2016).

Mach7 was up half a cent or 11.6 percent to 4.8 cents with 3.2 million shares traded.

## FACTOR THERAPEUTICS

Factor Therapeutics says it has a collaboration and intellectual property option agreement with dermatology researchers at Melbourne's Monash University.

Factor Therapeutics said that the collaboration focused on "the immunology of wound healing, specifically anti-inflammatory pathways that appear to play a significant role in both lipid barrier skin diseases as well as chronic wounds".

The company said that the collaboration had two purposes, with the first that the combination of anti-inflammatory strategies and cell adhesion and proliferation might extend the use of its core wound treatment technology and might enable new strategies to broaden the indication for its vitronectin-targeting platform.

Factor Therapeutics said the second purpose was that the Monash group, led by Prof Ian Smyth had identified a library of anti-inflammatory small molecules that showed promise in targeting key inflammation pathways involved in regulating immune cell recruitment in skin healing.

The company said that several of the molecules were candidates for clinical evaluation including several high-value orphan disease indications such as Harlequin Ichthyosis and the lead program might be suitable for development under a US Food and Drug Administration 505(b)(2) new drug application approval process.

Factor Therapeutics said that the collaboration included the option to licence both background and foreground intellectual property within a two-year period under pre-negotiated, commercially competitive terms.

The company said that the cost of the collaboration was within its planned research and development expenditure for 2016-'17 and would not change finance requirements.

Factor Therapeutics said that both parties would use their "best efforts to access further non-dilutive funding to support the collaboration".

Factor Therapeutics chief executive officer Nigel Johnson said the collaboration had "the potential to not only yield a clinical strategy for several high-impact dermatology and wound care applications, but will help our company to further understand the nexus of anti-inflammatory processes and cellular differentiation in wound care".

Factor Therapeutics said that over the next 12 months, both parties would evaluate the safety and efficacy of clinical candidates in relevant pre-clinical models and the two parties could elect to pursue a further 12 months of collaboration for the purpose of building an investigational new drug application-enabling package.

Prof Smyth said that inflammatory processes were "a key part of wound healing and our data is highly supportive of clinical translation".

"To accomplish this goal we have elected to establish a commercially-directed collaboration for this promising technology," Prof Smyth said.

Monash University Innovation head Dr Alastair Hick said that Prof Smyth's team had "demonstrated some remarkable proof-of-concept data in pre-clinical models of ichthyosis, and it is now an appropriate juncture for us to establish the commercial relationships to help steer the technology toward the clinic where this technology potential to impact patient lives".

Factor Therapeutics executive director Dr Christian Behrenbruch said the company was "committed to broadening the indication potential and value of our wound care and dermatology portfolio".

"This collaboration enables us to explore an area of considerable commercial interest in a cost and operationally effective way," Dr Behrenbruch said.

Factor Therapeutics was up 0.2 cents or 2.6 percent to 7.8 cents.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says it has Swedish approval to begin a 40-patient, phase IIa trial of pentosan polysulfate sodium for allergic rhinitis trial or hay fever.

Paradigm said that with Swedish Medical Products Authority and ethics committee approval, screening and recruitment had begun and the first participant was scheduled to be treated in the double blind, placebo controlled, cross-over design challenge trial in December 2016.

The company said that treatment would take between two and three months, with results expected by October 2017.

Paradigm said the trial would be conducted at Skane University Hospital led by Prof Lennart Greiff.

Paradigm operations manager Dr Claire Kaufman said the challenge study would enable the company "to assess the nasal formulation of [pentosan polysulfate sodium] for the treatment of this disease in a controlled setting".

Paradigm chief executive officer Paul Rennie said the beginning of the phase IIa clinical trial was "the next step in the clinical development of Rhinosul following the successful non-clinical animal studies comparing Astra Zeneca's Rhinocort with Paradigm's Rhinosul, [the] intranasal toxicology study and the safety data from the phase I clinical trial".

The company said that the current market for hay fever was about \$US11 billion and was dominated by anti-histamines and corticosteroids with market surveys highlighting patient dissatisfaction and the need for effective therapy.

Paradigm was unchanged at 45 cents.

## BIOTRON

Biotron's very low turn-out annual general meeting saw 7,487,979 votes (18.1%) opposition to the remuneration report with 29,621,301 votes (71.7%) in favor.

The second resolution to re-elect director Dr Denis Wade was passed by a wider margin, with 4,193,925 undecided proxy votes for both resolutions.

The company's most recent Appendix 3B new issue announcement said that Biotron had 313,839,853 shares on issue, meaning that the votes against the share issue amounted to 2.4 percent of the company, not sufficient to requisition extraordinary general meetings. Biotron was unchanged at 4.9 cents.

## VIRALYTICS

Viralytics says it has appointed Prof Keith Flaherty, Prof Michael Boyer, Prof J Randolph Hecht and Prof Kurt Schalper as its clinical advisory board.

Viralytics said that the board would be chaired by Prof Flaherty who was a Harvard Medical School professor of medicine and Massachusetts General Hospital Cancer Center clinical research director and had previously served on its scientific advisory board. The company said that Prof Boyer was the University of Sydney's medical oncology professor and chief clinical officer of the Chris O'Brien Lifehouse.

Viralytics said that Prof Hecht was a University of California Los Angeles professor of clinical medicine and the director of the UCLA Gastrointestinal Oncology Program.

The company said that Prof Schalper was the Yale Medical School's assistant professor of pathology and the director of the Translational Immuno-oncology Laboratory at the Yale Cancer Center.

Viralytics fell one cent or 0.9 percent to \$1.15.

### [RAMACIOTTI FOUNDATIONS](#)

The Ramaciotti Foundations say that the Walter and Eliza Hall Institute's Prof Jane Visvader and Prof Geoff Lindeman are the joint winners of the 2016 Ramaciotti Medal. The Foundations said that Prof Visvader and Prof Lindeman would share a \$50,000 grant, with more than \$778,000 granted through its Health Investment Grants.

The Foundations said that Prof Visvader and Prof Lindeman won the medal "for their pioneering work in discovering new approaches for breast cancer treatment and prevention".

"Over the past decade the pair were instrumental in a series of ground-breaking discoveries, including the discovery of stem cell daughters, found to be the culprit cells that give rise to breast cancer in women who carry a faulty BRCA1 gene," the Foundations said.

"They have also discovered that an existing medication, denosumab, may have potential to prevent breast cancer from developing," the Foundations said.

The Foundations said that Ramaciotti health investment grants of up to \$150,000 each were awarded to five early career recipients undertaking biomedical research, including the University of New South Wales Dr Jane Kohlhoff, the Centre for Eye Research Australia's Prof Lyndell Lim, South Australian Health and Medical Research Institute's Prof Philippa Middleton, the Heart Research Institute's Dr Sanjay Patel and the University of New South Wales' Dr Mark Polizzotto.

### [RECCE](#)

Recce says that Bernadette Murdoch has notified the company of her resignation as a director with immediate effect.

Recce said that Ms Murdoch joined the company in May 2016.

The company said that the annual general meeting resolution to re-elect Ms Murdoch at today's meeting had been withdrawn.

Recce was unchanged at 16 cents.