



# Biotech Daily

Monday May 22, 2017

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: PSIVIDA UP 13%, IMPEDIMED DOWN 7.5%**
- \* **REGENEUS CLAIMS KNEE OSTEOARTHRITIS SAFETY, EFFICACY**
- \* **PARADIGM READY FOR PHASE II PPS ROSS RIVER VIRUS TRIAL**
- \* **HYDROPONICS \$8m IPO, 12<sup>th</sup> FOR MEDICAL MARIJUANA, EQUIPMENT**
- \* **VICTORIA \$450k FOR HEALTH ACCELERATOR, APPLICATIONS OPEN**
- \* **INVITROCUE, MUNDIPHARMA TAKE ASSAYS TO SKIN, WOUND HEALING**
- \* **G MEDICAL CHINA MOBILE HEALTH JOINT VENTURE**
- \* **NEUROTECH SIGNS VDT FOR MENTE AUTISM GERMANY, SWITZERLAND**
- \* **BNP, UNISUPER, QUEST BELOW 5% IN VIRALYTICS**
- \* **FACTOR THERAPEUTICS CEO DR ROSALIND WILSON STARTS ON \$275k**
- \* **FEDERAL GOVERNMENT ENTREPRENEURS' SEMINAR**

## MARKET REPORT

The Australian stock market was up 0.76 percent on Monday May 22, 2017 with the ASX200 up 43.8 points to 5,771.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and three were untraded.

Psivida was the best, up 36 cents or 12.8 percent to \$3.18 with 3,890 shares traded, followed by Dimerix up 11.1 percent to one cent with 27.3 million shares traded.

ITL climbed 5.3 percent; Living Cell improved 4.35 percent; Viralytics was up 3.8 percent; Universal Biosensors rose 2.3 percent; Bionomics and Pharmaxis were up more than one percent; with Airxpanders, Medical Developments, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Impedimed led the falls, down 5.5 cents or 7.5 percent to 67.5 cents with 1.4 million shares traded. Avita, Mesoblast, Opthea and Orthocell were down three percent or more; Actinogen, Atcor, Compumedics, Osprey, Polynovo and Uscom shed more than two percent; Acrux, Admedus, Ellex, Neuren, Reva and Starpharma fell one percent or more; with CSL and Sirtex down by less than one percent.

## REGENEUS

Regeneus says its 20-patient phase I trial for mild or moderate knee osteoarthritis shows allogeneic, fat-derived Progenza stem cells are safety, tolerated and reduce pain.

Regeneus said a single knee injection of either 3.9 million or 6.7 million Progenza cells was safe and well-tolerated and “showed durable and clinically meaningful pain relief”.

The company said its first clinical trial of Progenza was double-blinded, placebo-controlled and randomized the patients into two dose cohorts to receive intra-articular knee injections of 3.9 million cells or placebo in cohort 1, or 6.7 million cells or placebo in cohort 2, with 16 patients receiving a single dose of Progenza and four receiving placebo.

Regeneus said patients were monitored for 12 months, with no serious adverse events and the majority of adverse events mild and similar in both active and placebo groups.

The company said there were “no trends or findings of concern” identified from the data collected from patients’ blood tests, physical examinations, electrocardiograms or other safety measurements.

Regeneus said secondary efficacy endpoints included pain measured by the Western Ontario and McMaster Universities arthritis index (Womac) and visual analogue scale.

The company said that patients treated at either dose of Progenza showed a statistically significant within-group reduction in Womac pain ( $p < 0.001$ ) and the placebo group showed no statistically significant reduction in pain, with visual analogue pain showing “very similar findings”.

Regeneus said that examination of knee joint structure by magnetic resonance imaging showed a statistically significant improvement in lateral tibial cartilage volume for patients treated with 3.9 million cells compared to a worsening in placebo patients ( $p = 0.028$ ).

The principal investigator, Sydney sports medicine specialist Dr Donald Kuah, said the study “confirms a benign safety profile for Progenza ... as an intra-articular injection”.

“Progenza significantly reduced pain and in the majority of patients, Progenza alleviated pain to clinically meaningful levels, defined as 30 percent or more reduction from baseline,” Dr Kuah said. “The same pain reduction was not seen in the placebo group.”

“The beneficial effect of Progenza on the knee structure reinforces Progenza preclinical findings and may offer the potential for disease modification,” Dr Kuah said.

Regeneus chief executive officer John Martin said the company was “very pleased” with the results and the initial efficacy effects relating to the reduction of pain, preservation of cartilage and potential for disease modification were most encouraging.

“We will use these results to advance our licencing discussions for Progenza in Japan and inform future clinical study designs for [osteoarthritis],” Mr Martin said.

Regeneus was up half a cent or 3.85 percent to 13.5 cents.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for its 24-patient, phase II alphavirus trial of the pentosan polysulfate sodium (PPS) for Ross River virus.

Paradigm said it expected to dose the first patient in the randomized, double-blinded, placebo-controlled, trial at the Brisbane-based Mater Research clinical trial site “in the coming weeks” along with ethics approval for a Geelong, Victoria trial site.

The company said that patients with Ross River virus-induced arthralgia, or painful joints, would be evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections, with results expected in mid-2018.

Paradigm chief executive officer Paul Rennie said there was “no effective way to treat patients with Ross River virus”.

Paradigm was up 1.5 cents or 2.3 percent to 66.5 cents.

## THE HYDROPONICS COMPANY

Australia's twelfth marijuana company to list on the ASX, the Hydroponics Company, raised \$8,000,000 at 20 cents a share and listed up 65 percent, on May 4, 2017.

Hydroponics said it had sought the issue of 47,100,000 shares and 23,550,000 options exercisable at 40 cents each by December 31, 2019.

Hydroponics opened up 65 percent at 33 cents, climbed as much as 107.5 percent to 41.5 cents before closing up 102.5 percent at 40.5 cents with 25,816,736 shares traded.

The company said it aimed "to be a leading, global cannabis business, a leader in the development and delivery of medicinal cannabis, worldwide manufacturer and distributor of hydroponics equipment, materials and nutrients, and large-scale hydroponic greenhouse design and construction".

Hydroponics said its chairman was Alan Beasley, with chief executive officer Hamish MacDonald and directors Ian Mutton, Mary Verschuer, Peter Wallace and John Hall.

The company said the chief financial officer was Francis Choy, with company secretary Henry Kinstlinger and executives Dr Andrew Beehag, Jason Colquhoun and Jim Barlow.

Hydroponics said its corporate advisor was the MMR Corporate Services Pty Ltd, with joint lead managers Gleneagle Securities (Aust) Pty Ltd and Red Leaf Securities Pty Ltd. Today, Hydroponics was up one cent or 3.1 percent to 33 cents.

## VICTORIA GOVERNMENT

The Victoria Government says its Public Sector Innovation Fund will provide \$450,000 for the Melbourne Health Accelerator program, with applications open for other grants.

In a media release Victoria's Special Minister of State Gavin Jennings said the Melbourne Health Accelerator project intended "to make the most of our world-class medical research so that we can make that next new breakthrough to improve patient care".

"Australia produces world class medical research, but we need to do more to realize the commercial and social benefit that flows from it, including better healthcare and new jobs," Mr Jennings said.

"[The Melbourne Health Accelerator] will help fill that gap by putting all the key players together to boost patient outcomes and create jobs," Mr Jennings said.

The Government said the program built on a 2016 project at the Royal Melbourne Hospital in which 40 hospital staff and 15 health technology start-ups identified applications for their digital education platform in neurosurgery and chronic disease management.

The Government said that a range of grants had been provided through the \$11 million Public Sector Innovation Fund, of which the Melbourne Health Accelerator was one.

The media release said that applications for the Public Sector Innovation Fund were open and more information was at: at [www.publicsectorinnovation.vic.gov.au](http://www.publicsectorinnovation.vic.gov.au) .

## INVITROCUE

Invitrocue says an agreement with Mundipharma Manufacturing Pte Ltd will expand its cell based assaying business into skin and wound healing.

Invitrocue said the agreement would develop "robust and easy-to-use in-vitro assays to assess the safety and effectiveness of consumer antiseptics and over-the-counter wound dressing products.

Invitrocue executive director Dr Steven Fang said the assays would help position

Invitrocue "as a competitive basin for our customers as current technology and know-how are implemented in the [over-the-counter] and consumer health market".

Invitrocue was up half a cent or 6.25 percent to 8.5 cents.

### G (GEVA) MEDICAL INNOVATIONS

The Cayman Islands-based G Medical says it has a joint venture with the Guangzhou Sino-Israel Bioindustry Investment Fund to provide its products and services.

In February, G Medical said it had a term sheet with the Guangzhou Fund to distribute its mobile telephone electronic health devices, had completed trials of the technology and expected Conformité Européenne (CE) mark approval by July 2017 and US Food and Drug Administration approval by the end of the year (BD: Feb 20, 2017).

Today G Medical said the Guangzhou Fund would invest \$US5 million or around June 18, 2017 in the joint venture, for a 30 percent interest in the subsidiary and use best efforts to facilitate \$US10 million of additional future government grant or loan funding.

G Medical said that its operations in the People's Republic of China, Hong Kong and Macau would be through the joint venture, which would have three Guangzhou Fund directors and four G Medical directors and a general manager appointed by G Medical. The company said that Guangzhou Fund would have a right, at its discretion to list the Chinese Subsidiary at no less than \$US50 million.

G Medical fell two cents or 10.5 percent to 17 cents with 3.7 million shares traded.

### NEUROTECH INTERNATIONAL

The Malta-based Neurotech says that VDT Psychologie & Medizinvertrieb will market and distribute its Mente Autism product in Germany and Switzerland.

Neurotech said that the Göttingen, Germany-based VDT was "one of the German-speaking world's oldest and most experienced providers of professional products for biofeedback, neurofeedback and other products for the health care and medicine market". The company said that training of the local distributor's sales teams and medical experts had begun, with marketing initiatives underway.

Neurotech previously said that Mente Autism was an electro-encephalogram (EEG) based system designed to provide feedback and training for children on the autism spectrum (BD: Nov 4, 2016).

Neurotech fell half a cent or two percent to 24.5 cents.

### VIRALYTICS

The Sydney-based BNP Paribas Nominees Pty Ltd says it has reduced below five percent in Viralytics.

In March, the Melbourne-based Unisuper said it had become a substantial shareholder in Viralytics with 14,312,957 shares or 5.96 percent (BD: Mar 6, 2017).

Unisuper said that between November 14, 2016 and March 2, 2017, Quest Asset Partners Pty Ltd acquired 5,326,849 shares for \$5,075,102 or 95.3 cents a share.

The Unisuper substantial shareholder notice said that the shares were held by the Sydney-based BNP Paribas Nominees as its custodian and that "various fund managers hold the shares as investment manager for Unisuper".

Today, BNP Paribas said that on March 27 and May 19, 2017, it sold 3,884,240 shares for \$4,285,188 or \$1.103.

Viralytics was up four cents or 3.8 percent to \$1.10.

## FEDERAL GOVERNMENT

The Federal Department of Industry, Innovation and Science says it will hold a seminar “on the rewards and challenges of developing successful businesses”.

The Department said that free seminar and question and answer session on June 20 was part of its Entrepreneurs Program and aimed at small and medium sized businesses in the life sciences sector.

The Department said the event would include a panel of industry experts in a conversation on successful businesses in the sector, including Vaxxas founder Prof Mark Kendall, Mimetica chief executive officer Dr Michael Thurn former Anatomics chief executive officer Andrew Batty and Clever Culture Systems chair and Bio-Melbourne Network interim chief executive officer Lusia Guthrie.

The Department said that the seminar would be held at the office of Deloitte, Level 10, 550 Bourke Street, Melbourne on June 20, 2017 at 9.30am.

To register go to: [https://eple140\\_pharmamedtechstories.eventbrite.com.au/](https://eple140_pharmamedtechstories.eventbrite.com.au/).

## FACTOR THERAPEUTICS

Factor Therapeutics says it has appointed Dr Rosalind Wilson as chief executive officer, effective from June 19, 2017, starting on \$275,000 a year.

Factor Therapeutics said that interim chief executive officer Nigel Johnson would return to chief operating officer and executive director Dr Christian Behrenbruch would become a non-executive director.

The company said that Dr Wilson was previously an executive or advisor with Nucleusx and F Hoffman-LaRoche, or Roche Australia, UK and Switzerland.

Factor Therapeutics said that Dr Wilson led the Roche team that developed pertuzumab, marketed as Perjeta, in HER2-overexpressing breast cancer and was lifecycle leader for the orlistat franchise, marketed as Xenical.

The company said that Dr Wilson held a Bachelor of Medicine and Bachelor of Surgery from Monash University and a Master of Business Administration from the London Business School.

Factor chairman Dr Cherrell Hirst said that the board wanted to acknowledge the efforts of Mr Johnson who stepped into the role of interim chief executive officer from April 2015.

“I draw attention to the significant impact of Nigel’s leadership during our period of corporate turnaround and launch of current clinical activities,” Dr Hirst said.

Factor Therapeutics said that Dr Wilson would receive a base annual salary of \$275,000 inclusive of statutory superannuation and eligibility to receive a short-term incentive bonus of up to 25 percent of annual salary based on agreed key performance indicators, as well as a grant of options to the value of 2.5 percent of the company’s outstanding shares, vesting over three years and exercisable at 11 cents within five years.

Factor Therapeutics was unchanged at 6.1 cents.