# Biotech Daily

Tuesday March 27, 2018

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: POLYNOVO UP 10%; PHARMAXIS DOWN 5%**

*** PROTAGONIST FALLS 57% ON PTG-100 COLITIS TRIAL 'FUTILITY'**

*** OPTISCAN LOSES FOUNDER PETER DELANEY, MORE TO GO; 2nd SPILL CALL**

*** FOREIGN INVESTMENT REVIEW BOARD CLEARS VARIAN SIRTEX BID**

*** VICTORIA LAUNCHES $300k J&J QUICKFIRE DEVICE CHALLENGE**

*** KERRYN MOORE WINS $20k VICTORIA GONGS**

*** MEDICAL DEVELOPMENTS ADDS 4 EURO PENTHROX APPROVALS**

*** OPTHEA DOSES OPT-302 WET AMD PATIENTS IN EUROPE, ISRAEL**

*** PAINCHEK, HEALTH METRICS COLLABORATE FOR AGED CARE**

*** MAYNE US QUARTETTE ORAL CONTRACEPTIVE LAUNCH**

*** FDA OK FOR ADHERIUM O-T-C SMARTINHALER FOR SYMBICORT**

*** MERCHANT REDUCES TO 7.7% OF POLYNOVO**

*** ALEXANDER BEARD, CVC, STINOC TAKE 9% OF PROBIOTEC**

*** DIRECTOR ANDREW KROGER TAKES 37% OF CRYOSITE**

*** DIMERIX APPOINTS PROF DAVID PACKHAM CMO**

## MARKET REPORT

The Australian stock market recovered 0.72 percent on Tuesday March 27, 2018, with the ASX200 up 41.8 points to 5,832.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and two were untraded. All three Big Caps were up.

Polynovo was the best, up five cents or 10.4 percent to 53 cents with 1.85 million shares traded. Clinuvel climbed 4.2 percent; Avita and Starpharma were up more than three percent; Impedimed and Resmed rose two percent or more; Admedus, Airxpanders, CSL and Volpara were up more than one percent; with Cochlear, Mesoblast, Nanosonics, Opthea, Pro Medicus, Sirtex and Telix up by less than one percent.

Pharmaxis led the falls, down 1.5 cents or 4.6 percent to 31 cents with 111,526 shares traded. Optiscan lost 4.2 percent; Dimerix and ITL were down more than three percent; Factor Therapeutics shed 2.4 percent; Bionomics, Compumedics, Neuren, Reva and Universal Biosensors were down more than one percent; with Medical Developments down 0.7 percent.

PROTAGONIST

Protagonist fell 56.8 percent on the Nasdaq, following the close of its phase IIb trial of PTG-100 for ulcerative colitis.

Protagonist said the independent data monitoring committee reviewed unblinded efficacy and safety data from the first 65 patients in the planned 240-patient trial who had completed the 12-week treatment.

The company said that the committee “deemed the trial to be futile based on an analysis of the primary endpoint of clinical remission”.

Protagonist said that no safety concerns were noted.

In 2016, the University of Queensland spin-out Protagonist said it raised $US90 million ($A117.1 million) in a Nasdaq initial public offer at $US12.00 a share to develop peptide drugs (BD: Aug 12, 2016).

Protagonist said its product candidates PTG-100 and PTG-200 had “the potential to transform the existing treatment paradigm” for irritable bowel disease a gastro-intestinal disease consisting primarily of ulcerative colitis and Crohn’s disease.

Today, Protagonist said it was discontinuing the phase IIb Propel study of PTG-100, its investigational oral gastro-intestinal-restricted alpha-4-beta-7 integrin antagonist peptide, in patients with moderate to severe ulcerative colitis.

The company said that the data monitoring committee used pre-specified criteria in the planned interim analysis.

“Based on the [committee’s] recommendation received after the market close on Friday and while further review of the data is being conducted, Protagonist is notifying Propel trial investigators that randomization of potential participants and further treatment of patients currently in the study will be discontinued”.

Protagonist said it would postpone its decision about the initiation of a phase II/III clinical trial of PTG-100 in chronic pouchitis until after its full review of the interim data from the Propel study.

Protagonist chief executive officer Dr Dinesh Patel said the company was “very disappointed with this futility-based outcome which was also accompanied by an unexpectedly high placebo rate”.

“We will conduct an extensive review of the complete dataset on the totality of patients enrolled in the trial before making any further decisions about the future development of PTG-100," Dr Patel said.

“Protagonist remains committed to progressing its other peptide-based assets currently in clinical development, PTG-200 and PTG-300, and to discovering new peptide-based therapeutic entities to address significant unmet medical needs," Dr Patel said.

Protagonist said the phase IIb Propel trial was a randomized, double-blind, placebo-controlled, two-stage adaptive clinical trial to assess the safety, efficacy, and dose-optimization of 150mg, 300mg, or 900mg of PTG-100 compared to placebo for 12 weeks in patients with moderate to severe ulcerative colitis.

The company said that the primary efficacy endpoint was the proportion of patients who achieve clinical remission as defined by rectal bleeding, stool frequency, and endoscopic sub-scores of the Mayo score.

In January, Protagonist reached a peak closing share price of $US22.86 and a market capitalization of $US482 million ($A601 million).

Overnight on the Nasdaq, Protagonist closed down $US11.61 or 56.8 percent to $US8.82 ($A11.39) with 4,366,574 shares traded.

## OPTISCAN IMAGING

Optiscan founder Peter Delaney says he has resigned and expects the rest of the senior management team to follow, with a counter-spill meeting called by other shareholders.
Earlier this month, Optiscan said it received a board spill call from shareholders including director Ian Mann, former chief executive officer Archie Fraser and the inventor of the company's confocal microscope technology and former director Mr Delaney, who, with others, held 57,817,204 shares or 13.41 percent of the company (BD: Mar 16, 19, 2018).
The notice said the group wanted to remove chairman Alan Hoffman and directors Peter Francis, Dr Ian Griffiths and Dr Philip Currie, to be replaced by Mr Fraser and Ron Grey.
Today, Mr Delaney told Biotech Daily that he formally resigned two weeks ago but had a three-month notice period to serve.
"It appears the entire senior management will resign, representing decades of knowledge and understanding of the technology and the business," Mr Delaney said.
"They are resigning because the information around the resignation of Archie Fraser was not adequate," Mr Delaney said.
A spokesperson for the ASX told Biotech Daily that the ASX required companies to notify changes of director, chief executive officer and company secretary but not other staff.
"Beyond that, companies have a general obligation to disclose to the market any potential material development which might include the movement of senior executives," the ASX spokesperson said. "That would be for the company to assess."
"In addition, the ASX will monitor for any unusual share price movements," the ASX spokesperson said.
Last night, Optiscan said that a group of shareholders with a combined holding of 61,273,214 shares or 14.21 percent called for a second extraordinary general meeting to remove director Ian Mann and elect as directors Darren Lurie and Graeme Mutton.
Optiscan chairman Alan Hoffman told Biotech Daily that the people and companies calling for the second meeting were unrelated to existing directors.
"The board is focussed on an outcome which seeks to avoid the company committing resources and time to the holding of a general meeting," Mr Hoffman said.
Biotech Daily calculates from previous Appendix 3Y director interests' statements that the directors, not including Ian Mann, held a further unrelated 17,625,000 shares or 4.09 percent, along with 3,750,000 options.
The signatories to the second meeting call were Semblance Pty Ltd which is related to Graeme Mutton; Harech Pty Ltd (Porter Superfund); Susy Munro; Stewart W Brash Pty Ltd and S W Brash Pty Ltd; Numeruno Superannuation Fund Pty Ltd which was related to Gregory Allen and Kaye Allen and Canadex Unit Account; Chris Graham and Diane Graham; Sash Pty Ltd which was related to Knezevic Super Fund and Wally Knezevic; Project Management Pty Ltd which was related to D & K Corps Family Superfund; and two companies believed to be Perth-based but with no names associated with them, Kebin Nominees Pty Ltd and Jongila Nominees Pty Ltd.
Optiscan closed at 10.0 cents on January 22, 2018, when Mr Fraser resigned, and today fell 0.3 cents or 4.2 percent to 6.9 cents.

## SIRTEX MEDICAL

Sirtex says that the Australian Foreign Investment Review Board has decided that it has no objection to Varian Medical Systems acquiring the company.
Sirtex said the clearance was a key condition to implementation of the scheme.
In January, Varian offered $28 a share to acquire the company (BD: Jan 31, 2018).
Sirtex was up 10 cents or 0.4 percent to $27.71 with 476,463 shares traded.

## VICTORIA GOVERNMENT, JOHNSON & JOHNSON

Victoria Innovation Minister Philip Dalidakis has formally launched the $300,000 Victoria Johnson & Johnson Quickfire Challenge: 'Driving Device Innovation'.
In February, the Health Minister Jill Hennessy foreshadowed the Challenge saying that three finalists would share a cash prize of $300,000 as well as receive mentoring and support from Johnson & Johnson.
A media release at that time said the Victoria Quickfire Challenge aimed "to help kick-off the search for new medical device innovation".
For information and to apply, go to: https://jlabs.jnjinnovation.com/quickfire-challenges.

## VICTORIA GOVERNMENT

The Victoria Government says that the Monash Children's Research Institute's Kerryn Moore has won both the $15,000 Excellence Award and the $5,000 Public Health Award.
A media release form Victoria Health Minister Jill Hennessy said that Ms Moore won the awards for her research into the impact of malaria in pregnancy on birth outcomes in Asia.
The Government said that Ms Moore was formerly with the University of Melbourne, Burnet Institute and the Shoklo Malaria Research Unit and was currently working now working for the Monash Children's Research Institute based in Laos at the Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit.
"This research is making a real difference across the globe, influencing World Health Organisation guidelines on the treatment, control and prevention of malaria in pregnancy in Asia," the media release said.
The State Government said that the $5,000 Basic Science Researcher Award was jointly awarded to the University of Melbourne and Peter Doherty Institute for Infection and Immunity's Dr Hui-Fern Koay for 'How our Mucosal Associated Invariant T (MAIT) cells develop' and the University of Melbourne and Walter and Eliza Hall Institute of Medical Research's Dr Tan Nguyen for 'Love thy neighbour: how uninfected cells help combat viral infection'.
The media release said that the $5,000 Clinical Researcher Award went to the University of Melbourne and Peter MacCallum Cancer Centre's Dr Benjamin Teh for 'Improving the care of infections in patients with blood cancer multiple myeloma treated with new generation therapies'.
The Government said that the $5,000 Health Services Researcher Award was won by the Peter MacCallum Cancer Centre and the University of Melbourne' Dr Gabrielle Haeusler for 'Improving the quality of research and the delivery of care for one of the most common complications of cancer treatment in children'.
The media release said that the awards, in their twenty-fourth year, "honor the outstanding work and discoveries of up-and-coming health and medical researchers in the early stages of their career and continue to affirm Victoria's reputation as a world leader in health and medical research".

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that its Penthrox inhaled methoxyflurane analgesic has been approved for sale in Sweden, Norway, Croatia and Poland.
Medical Developments chief executive officer John Sharman said the marketing authorizations meant the company had 15 European approvals with a number of key countries including Germany and Finland "expected soon".
Medical Developments fell five cents or 0.7 percent to $7.40.

## OPTHEA

Opthea says it has dosed the first patients in Europe and Israel in its 351-patient, phase IIb trial of OPT-302 for wet age-related macular degeneration (AMD).
In December, Opthea said it began dosing US patients in the randomized, controlled trial of the vascular endothelial growth factor-C (VEGF-C) and VEGF-D OPT-302, in combination with ranibizumab, marketed as Lucentis, for wet age-related macular degeneration (BD: Jan 21, 2018).
Opthea chief executive officer Dr Megan Baldwin said that the activation of trial sites in Europe and Israel was "significant progress in our phase IIb trial".
"It expands patient recruitment for the study into another nine countries and follows a successful investigators' meeting held in Barcelona, Spain, on March 16," Dr Baldwin said.
The company said that the trial was enrolling patients from more than 50 US sites and was due to open six sites in Israel and more than 50 sites in the UK, France, Poland, Hungary, Spain, Latvia, Italy and the Czech Republic.
Opthea said the trial would investigate whether the addition of OPT-302 to Lucentis therapy over a six-month dosing period improved visual acuity and anatomical parameters of wet age-related macular degeneration lesions as assessed by imaging techniques.
The company said that the primary analysis was expected in early 2020.
Opthea was up half a cent or 0.9 percent to 58.5 cents.

## PAINCHEK

Painchek says it has signed an agreement with Melbourne software firm Health Metrics for access to aged care facilities.
Painchek said it would use Health Metrics Ecase management software system and the two companies would collaborate to market the Painchek application to customers of Health Metrics in Australia.
The company said its software application provided caregivers point-of-care diagnostic information to detect facial expressions indicating pain.
Painchek said that Health Metrics owns operated and licenced access to its Ecase software designed to document clinical data and improve the efficiency of healthcare providers including the residential aged care market.
Painchek chief executive officer Philip Daffas said the integration of the systems would "provide consumers with easy access to Painchek and the benefit of full automation and integration of pain assessment results within their clinical management systems".
Painchek said it expected the integration of the two systems to be available by July 2018.
Painchek was unchanged at 7.9 cents with two million shares traded.

## MAYNE PHARMA GROUP

Mayne says it has launched an authorized generic of the oral contraceptive Quartette, or levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets in the US.
Mayne chief executive officer Scott Richards said that generic Quartette "adds to our women's health portfolio of 22 marketed products including oral contraceptives, hormone replacement therapy and breast cancer products".
"Mayne Pharma is the second largest supplier of oral contraceptives in the US and continues to invest in growing its pipeline of women's health products with high value, complex formulations such as generic Nuvaring, an intra-vaginal hormonal contraceptive delivery device which was recently accepted for filing by the US FDA," Mr Richards said.
Mayne was up one cent or 1.3 percent to 78 cents with 7.3 million shares traded.

## ADHERIUM

Adherium says the US Food and Drug Administration has granted 510(k) clearance for over-the-counter sales of its Smartinhaler for Astrazeneca's Symbicort asthma inhaler.
Adherium said that the Smartinhaler sensor attached to an inhaler to monitor and promote asthma and chronic obstructive pulmonary disease medication adherence as part of a self-management plan.
The company said that the FDA clearance meant its Smartinhaler Smarttouch for Symbicort could be sold directly to consumers in the US.
Adherium chief executive officer Arik Anderson said that over-the-counter sales would make "adherence to personal management plans easier".
"We are now well positioned to launch in the US, following successes in Europe and Australia," Mr Anderson said.
The company said that the Smartinhaler sensor recorded the date and time the inhaler was used and transmitted the information to the patient's mobile phone or computer tablet, allowing doctors to review and help make decisions.
Adherium was up 6.5 cents or 54.2 percent to 18.5 cents with 12.1 million shares traded.

## POLYNOVO

Merchant Funds Management says it has reduced its substantial shareholding in Polynovo from 60,500,000 shares (9.29%) to 50,000,000 shares (7.65%).
Last year, the Perth-based Merchant Funds reduced its holding in Polynovo from 62,897,664 shares (11.29%) to 60,500,000 shares (9.29%) (BD: Nov 3, 2017).
Today, Merchant Capital said that on March 26, 2018 it sold 10,500,000 shares for $4,591,808 or 43.7 cents a share.
Polynovo was up five cents or 10.4 percent to 53 cents with 1.85 million shares traded.

## PROBIOTEC

Alexander Beard, CVC and Stinoc say they have increased their substantial holding in Probiotec from 4,772,515 shares (7.85%) to 5,502,806 shares (9.05%).
The Sydney-based CVC said that between November 2, 2017 and February 27, 2018 it acquired 730,291 shares for $612,124 or an average price of 83.8 cents a share.
Probiotec was up 2.5 cents or three percent to 87 cents.

## CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding from 16,642,791 shares (35.52%) to 17,315,291 shares (36.95%).
Mr Kroger said the shares were bought off-market on March 22, 2018 at 11 cents a share.
Mr Kroger said that the shares were held directly and through Austen Bay Pty Ltd acting for the Andrew Kroger superannuation fund, SHR Pty Ltd and Process Wastewater Technologies Pty Ltd.
Cryosite was up half a cent or 4.55 percent to 11.5 cents.

## DIMERIX

Dimerix says it has appointed chronic kidney disease specialist and major shareholder Prof David Packham as chief medical officer to drive the DMX-200 programmes.

Dimerix said that Prof Packham would responsible for the identification and engagement of clinical trial sites in Australia and help define and identify patient populations, particularly with respect to focal segmental glomerulosclerosis, a rare disease which caused nephrotic syndrome in children and adolescents and was a leading cause of kidney failure in adults.

The company said that Prof Packham would lead communications with key opinion leaders.

Dimerix said that Prof Packham was one of the principal investigators on its phase IIa trial of DMX-200 for chronic kidney disease, which concluded in 2017 (BD: Jul 12, 2017).

The company said that Prof Packham held a Bachelor of Medicine and Bachelor of Surgery from the University of London and a Doctorate of Medicine from the University of Melbourne.

Dimerix fell half a cent or 3.85 percent to 12.5 cents.