



Biotech Daily

Monday May 28, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTISCAN UP 10%; LBT DOWN 8%**
- * **IMMUTEP IMP321 MELANOMA INTERIM SAFETY, EFFICACY RESULTS**
- * **SIRTEX SCHEME MEETING DELAYED UNTIL JULY**
- * **TGA APPROVES NOVITA'S TALI TRAIN FOR ATTENTION DISORDERS**
- * **PROTEOMICS SIGNS PRISMHEALTHDX FOR US PROMARKERD LAUNCH**
- * **RHINOMED SIGNS UNNAMED US PHARMACY RETAILER FOR MUTE**
- * **PHARMAUST: 'BRI MONEPANTEL PALATABLE FOR DOGS, HUMANS'**
- * **CYNATA REQUESTS 'PLACEMENT' TRADING HALT**
- * **JCP INCREASES TO 9.4% OF NANOSONICS**
- * **CVC TAKES 5.6% OF UNIVERSAL BIOSENSORS**
- * **DR DAX MARCUS CALDER DILUTED TO 11% OF PATRYS**
- * **MACQUARIE GROUP TAKES 5% OF PATRYS**
- * **DR WARWICK TONG, CANCER CRC TAKE 11% OF INNATE**
- * **INNATE APPOINTS DR WARWICK TONG CHAIRMAN**
- * **USCOM: TERESA GUO CHINA HEAD, CURT GROSSE NTH AMERICA SALES**
- * **SIMON MOORE REPLACED TPI CHAIRMAN PETER ROBINSON ON MAY 1**

MARKET REPORT

The Australian stock market fell 0.48 percent on Monday May 28, 2018 with the ASX200 down 28.8 points to 6,004.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and three were untraded. All three Big Caps fell.

Optiscan was the best, up 0.6 cents or 10.3 percent to 6.4 cents with 256,500 shares traded. Volpara climbed 8.2 percent; Benitec, Ellex, Oncosil and Starpharma improved more than three percent; Cynata and Factor Therapeutics rose more than two percent; Orthocell and Pharmaxis were up more than one percent; with Bionomics, Medical Developments and Nanosonics up by less than one percent.

LBT led the falls, down one cent or 7.7 percent to 12 cents with 480,000 shares traded. Telix lost 7.35 percent; Immutep and Osprey fell more than six percent; Airxlanders and Reva retreated five percent or more; Mesoblast and Opthea fell more than four percent; Avita and Compumedics were down more than three percent; Dimerix, Impedimed, Polynovo and Prana shed more than two percent; with Neuren, Pro Medicus and Sirtex down more than one percent.

IMMUTEP

Immutep says its IMP321 with Keytruda trial for melanoma has shown the combination to be safe and with six of 18 patients (33%) showing an overall response.

The company published 'Two ACTIVE Immunotherapies In Melanoma (TACTI-mel): Results Of A Phase I Trial With Metastatic Melanoma Patients Treated With A Soluble LAG-3 Receptor (LAG-3lg Or Eftilagimod Alpha) As An Antigen Presenting (APC) Activator Combined With Pembrolizumab' by chief scientific officer and chief medical officer Dr Frédéric Triebel following its presentation at the Advances in Immuno-oncology Congress in London on Friday, May 25 2018, ahead of detailed results to be discussed in a teleconference on Wednesday May 30, 2018.

One slide detailed that of the 18 patients in the dose-escalation phase of the 24-patient trial, the best overall response rate was six of 18 (33%), while nine patients (50%) had tumor shrinkage, with two patients having "complete disappearance of all target lesions". Immutep fell 0.2 cents or 6.1 percent to 3.1 cents with 15.2 million shares traded.

SIRTEX MEDICAL

Sirtex says the Federal Court will relist proceedings concerning the Varian scheme of arrangement on July 3, 2018 to consider a supplementary disclosure to shareholders. In January, the Palo Alto, California-based Varian Medical Systems offered \$28 a share for Sirtex valuing the company at \$1.56 billion, but shortly before the shareholder meeting to approve the Varian scheme, China's CDH Investments offered \$33.60 a share valuing the company at \$1.87 billion, with the board supporting Varian (BD: Jan 31, May 4, 2018). Today, the company said that Varian sought orders that the shareholder meeting be re-convened on May 31, 2018 and the Court expected to make orders "consistent with the indicative timetable submitted by Sirtex", which included relisting the proceedings on July 3, 2018 to consider the approval of a supplementary disclosure to shareholders.

The company said that, if approved, a date would be set "later in July" for the scheme meeting and "at this time, the directors of Sirtex continue to unanimously support and recommend the Varian scheme", with the new timetable allowing time for the board to assess the formal offer received from CDH Genetech (BD: May 23, 2018).

Sirtex fell 42 cents or 1.4 percent to \$29.08 with 347,441 shares traded.

NOVITA HEALTHCARE

Novita says the Australian Therapeutic Goods Administration has approved its Tali Train attention training device as a class 1 medical device.

Novita said that wholly-owned subsidiary Tali Health Pty Ltd had been issued with an Australian Register of Therapeutic Goods certificate allowing the sale of the system.

Novita managing-director Glenn Smith said the inclusion of Tali Train as a medical device was "a regulatory milestone as it supports the broader healthcare sector adoption of Tali Train across Australia and is an important step in the ... regulatory process for Tali Train".

"This announcement follows Tali Health's approval as a registered provider under the National Disability Insurance Scheme and strengthens our competitive advantage as we continue to roll out the commercial release of Tali Train," Mr Smith said.

Novita said that Tali Train was a game-based training program used to treat and monitor childhood difficulties and was designed for the needs of children with development disorders such as autism spectrum disorder, attention deficit hyperactivity disorder, Down syndrome and non-specific intellectual disability.

Novita was untraded at 3.3 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has signed Prismhealthdx Inc to launch its Promarkerd predictive test for diabetic kidney disease in the US.

Proteomics said that the Austin, Texas-based would launch its Promarkerd test across the US “with a major marketing campaign” aimed at the more than 30 million Americans living with diabetes.

The company said that licencing discussions were ongoing in Mexico, Australia, China, Japan, and Europe.

Prismhealthdx chief executive officer Jim Canfield said that the Promarkerd was a “revolutionary technology [which would] complement [our] existing portfolio to create the leading diabetes test offering in the country”.

“It will save lives and improve the quality of life for diabetes sufferers, all while reducing the cost to the healthcare system,” Mr Canfield said.

Proteomics said that Prismhealthdx would develop and commercialize the Promarkerd mass spectrometry laboratory-developed test (LDT) in its certified laboratories.

The company said that a laboratory-developed test permitted “fast adoption of a new test in advanced markets” with first sales expected in four to six months.

Proteomics said it would receive a royalty on all tests sold.

Proteomics was up half a cent or 2.2 percent to 23 cents.

RHINOMED

Rhinomed says it has signed an unnamed US retailer for its Mute anti-snoring nasal dilators with an initial order for 6,000 units from the retailer.

Rhinomed said that the unnamed retailer was “one of America's largest pharmacy retailers” and the purchase orders meant that Mute would be stocked at an additional 3,000 pharmacies across the US, taking its availability to more than 10,000 shops on three continents.

The company said that the retailer’s identity would be announced in line when stock appeared on shelves July or August, with revenue not expected until the end of 2018.

Rhinomed was up one cent or 9.1 percent to 12 cents.

PHARMAUST

Pharmaust says it has reformulated monepantel into a tablet suitable for canine clinical trials, expected to begin by the end of 2018.

Pharmaust said that the Vancouver, British Columbia BRI Pharmaceutical Research produced a dry tablet-based formulation, using “micronized” monepantel, which met the company’s requirements for palatability and dosing for a clinical trial in dogs.

Since 2016 the company had been attempting to make the compound, originally designed for worms in sheep, to be palatable for dogs and humans (BD: Jul 11, 2016).

Today, the company said it would scale production of the tablets using monepantel sourced from animal health company Elanco.

Pharmaust said it expected to begin a pharmacokinetic study directed to refining and optimizing the use of the new formulation in dogs later in 2018, before moving onto phase II clinical trials.

Pharmaust executive chairman Dr Roger Aston said the company was “pleased the BRI collaboration has identified a new tablet-based formulation that clears the path for us to re-initiate clinical trials in late 2018”.

Pharmaust was up 0.1 cents or 2.1 percent to 4.9 cents.

CYNATA THERAPEUTICS

Cynata has requested a trading halt “pending an announcement in relation to a placement to an institutional investor”.

Trading will resume on May 30, 2018 or on an earlier announcement.

Cynata last traded up three cents or 2.5 percent to \$1.25.

NANOSONICS

JCP Investment Partners says it has increased its substantial shareholding in Nanosonics from 25,005,980 shares (8.40%) to 28,210,101 shares (9.42%).

JCP said that between July 25, 2017 and May 24, 2018 it bought, sold and “transferred” shares, with the largest purchase 680,357 shares for \$1,670,276 or \$2.455 a share, matched by the sale of the same number of shares for the same price, while the single largest sale was 868,320 shares for \$2,611,687 or \$3.01 a share.

JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.

Nanosonics was up one cent or 0.4 percent to \$2.64 with 1.1 million shares traded.

UNIVERSAL BIOSENSORS

The Sydney-based CVC says it has become substantial in Universal Biosensors with 9,919,409 shares (5.6%).

The substantial shareholder notice said that between January 25 and May 25, 2018 CVC acquired 3,745,410 shares for \$929,962 or an average price of 24.8 cents a share.

Universal Biosensors was untraded at 25 cents.

PATRYS

Dr Dax Marcus Calder has increased his substantial shareholding in Patrys but has been diluted from 118,000,004 shares (12.67%) to 120,117,634 shares (11.19%).

The substantial shareholder notice said that the West Perth, Western Australia-based Dr Calder bought and sold shares directly and with Staffwear Pty Ltd between May 9 and 21, 2018 and acquired shares in the placement at 3.4 cents a share, which raised \$4.6 million (BD: May 21, 2018).

Patrys was up half a cent or 13.2 percent to 4.3 cents with 13.95 million shares traded.

PATRYS

The Macquarie Group says it and its controlled entities have become substantial shareholders in Patrys with 55,637,703 shares or 5.18 percent.

The Sydney-based Macquarie said that the registered holder was Bond Street Custodians and named a large number of companies as controlled entities.

The company said that between February 16 and May 23, 2018 it “transferred into admin” bought shares primarily at three cents but on several occasions at four cents, with one transfer at zero cents and most transfers on May 23, 2018.

INNATE IMMUNOTHERAPEUTICS

The Cancer CRC (co-operative research centre) says it has become substantial shareholder in Innate with 4,514,468 shares or 11.00 percent.

In a substantial shareholder notice signed by CTXT Pty Ltd director and Innate chairman Dr Warwick Tong the companies said they acquired the shares on May 4, 2018 at a deemed price of 2.1 cents a share as consideration for shares in Amplia Therapeutics, acquired by Innate (BD: Oct 24, 2016; Mar 23, Apr 26, 2018).

In 2016, Amplia said it licenced two early-stage oncology drug candidates from London's Cancer Research Technology, first developed by the Australian Cancer Therapeutics co-operative research centre (CTX) (BD: Oct 24, 2016).

Innate was up one cent or 2.4 percent to 43 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says that Dr Warwick Tong has been appointed chairman of its board of directors. Innate said that Dr Tong had 20 years of clinical, commercial and drug development leadership experience in both the pharmaceutical and biotechnology industries and was appointed a director on May 4, 2018, following the acquisition of Amplia Therapeutics (BD: Oct 24, 2016; Mar 23, Apr 26, 2018).

The company said that Dr Tong was previously the Cancer Research UK appointed director to the board of Amplia, with Cancer Research UK the licensor of the focal adhesion kinase (FAK) program acquired from Amplia, thereby becoming a shareholder. The company said that from 2011 until April 2018, Dr Tong was chief executive officer of the Cancer Therapeutics Cooperative Research Centre (CTx) and continued as director of the CTx commercialization company (CTxONE).

Innate said that prior to CTx Dr Tong was the head of development for the Boston, Massachusetts-based Surface Logix Inc and worked for Glaxosmithkline in "country, regional and global roles in medical affairs, business development" and was the head of commercial strategy for its infectious diseases division.

The company said Dr Tong worked in primary care medicine for 14 years, founding two clinics in New Zealand and held a Medicinae Baccalaureus and Baccalaureus Chirurgiae (Bachelor of Medicine and Bachelor of Surgery) from the University of Auckland and a Masters of Public Policy from the Wellington, New Zealand-based Victoria University.

USCOM

Uscom says it has appointed Teresa Guo director of China operations and Curt Grosse as head of North American sales.

Uscom said the Beijing-based Ms Guo was most recently Bayer Healthcare Beijing medical communications officer and previously was the Sihuan Pharmaceutical Holdings business assistant and product specialist for project management and quality analysis.

Uscom said that Ms Guo had experience in project management, regulatory affairs, China patents and trademarking, marketing and distribution, medical affairs and business development.

The company said that Ms Guo held a Master of Science from University College London. Uscom said that the North Carolina-based Mr Grosse had more than 20 years' experience in medical device and capital equipment sales, having worked with Edwards Lifesciences, Covidien, Olympus, US Surgical Corp and Cheetah Medical and held a Bachelor of Science and Bachelor of Business Administration.

Uscom was unchanged at 18 cents.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI filed a late Appendix 3Z today saying that chairman Peter Robinson had resigned from the company on May 1, 2018.

On April 30, TPI filed its notice of annual general meeting and annual report, in which Mr Robinson was described as the chairman at that time.

After the market closed on April 30, TPI posted an announcement to the ASX, titled 'TPE Investor Update', which said in the final paragraph on the fourth page of the four-page announcement that Mr Robinson would retire effective from May 1, 2018.

TPI said that Mr Robinson had been a director for seven years "and his contributions will be missed".

"His position as chairman will be taken by [director] Simon Moore," the company said.

Today, TPI said that "due to an administrative oversight, the enclosed Appendix 3Z was not lodged within the required time frame".

The ASX has published Guidance Note 8 and Guidance Note 14 referring to announcements that contain market sensitive information, requiring "a header that clearly conveys this fact".

"ASX has had issues with announcements that have headers that convey an impression that they are not market sensitive when they have embedded within them market sensitive information," the ASX said.

"Alternatively and preferably, market sensitive announcements should be made on a stand-alone basis and not embedded in other announcements that may not be market sensitive," the ASX said.

The ASX Listing Rule 3.1 on transparency says that market sensitive information is what "a reasonable person" would expect a company to disclose.

TPI was unchanged at \$1.43.