



# Biotech Daily

Wednesday May 23, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: IMMUTEP UP 14%; OPTISCAN DOWN 11%**
- \* **CDH SIRTEX BID, VARIAN WON'T MATCH; PROFIT WARNING**
- \* **ACTINOGEN \$15m PLACEMENT, \$2m SHARE PLAN; DSMB BACKS TRIAL**
- \* **UK NHS NOT NICE TO CLINUVEL SCENESSE REIMBURSEMENT**
- \* **PROTA PROBIOTIC, PEANUT IMMUNOTHERAPY TRIAL ENROLLED**
- \* **AUSTRALIA, US APPROVE \$502m MERCK VIRALYTICS ACQUISITION**
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- \* **ADHERIUM APPOINTS DAVID ALLINSON CFO**

## MARKET REPORT

The Australian stock market fell 0.16 percent on Wednesday May 23, 2018 with the ASX200 down 9.4 points to 6,032.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Immutep was the best, up 0.4 cents or 14.3 percent to 3.2 cents with 27.7 million shares traded. Factor Therapeutics climbed 5.4 percent; Actinogen, Compumedics and LBT were up four percent or more; Bionomics and Uscom improved more than three percent; Opthea and Prana rose more than two percent; Avita, Mesoblast, Pharmaxis and Volpara were up more than one percent; with Ellex and Viralytics up by less than one percent.

Optiscan led the falls for the second day in a row, down 0.7 cents or 11.1 percent to 5.6 cents with 635,000 shares traded. Impedimed lost 8.6 percent; Cynata, Dimerix, Neuren, Prescient, Telix and Universal Biosensors fell four percent or more; Oncosil and Osprey lost more than three percent; Airxpanders, Genetic Signatures, Pro Medicus and Sirtex shed two percent or more; with CSL and Orthocell down more than one percent.

## SIRTEX MEDICAL

Sirtex says China's CDH Investments has offered to buy it for \$33.60 less any dividend up to 30 cents a share, with Varian refusing to increase its \$28 a share proposal.

Earlier this month, CDH made an unsolicited, non-binding, indicative and conditional offer of \$33.60 a share, valuing Sirtex at \$1.87 billion, but the Sirtex board backed the Paolo-Alto, California-based Varian bid (BD: May 4, 2018).

In January, California's Varian Medical Systems offered \$28 a share to buy the company, valuing it at \$1.56 billion (BD: Jan 30, 31, 2018).

Last night, Sirtex said that CDH Genetech had made "an offer capable of acceptance" to acquire the company through a scheme of arrangement.

In a media release to the New York Stock Exchange, Varian said it would not submit a counterproposal and was committed to the terms of the current scheme of arrangement.

Sirtex said its board was considering the relative merits and risks of the CDH Proposal and the Varian Scheme, but "at this time, the directors of Sirtex continue to unanimously support and recommend the Varian scheme".

The company said the CDH proposal required shareholder and regulatory approvals.

Sirtex said that Varian had made an application to the Federal Court of Australia for the shareholder meeting to approve the Varian scheme be re-convened on May 31, the Court relisted proceeding for May 25, 2018 but the company said it was "premature to reconvene the shareholder meeting".

In its media release Varian said it "continues to believe that the Varian scheme is superior to the CDH proposal ... [because it had been] unanimously approved by both boards of directors, has fully committed financing and has received all necessary regulatory approvals" and Varian is ready to complete the acquisition following approvals. Varian said the CDH proposal was "highly uncertain [and] the financing of the CDH proposal is complex"

Varian said it was ready to close the transaction pending Sirtex shareholder approval "whereas the CDH proposal leaves open the prospect of shareholder approval being obtained as late as March 2019".

In its CDH-Varian announcement Sirtex said that SIR-Spheres dose sales for the six months to December 31, 2017 were "relatively flat, reflecting a 0.4 percent decline versus the prior corresponding period".

Sirtex said that through most of the three months to December 31, 2017 it had "positive momentum in dose sales [but] subsequent to the announcement of the Varian scheme, dose sales have not met internal expectations", with dose sales in the four months to April 30, 2018 down 10.6 percent compared to the previous corresponding period, and dose sales for the 10 months to April 30, 2018 were down 4.6 percent compared to the prior corresponding period.

Sirtex chief executive officer Andrew McLean said that "since the announcement of the Varian scheme, Sirtex has experienced uncertainty and distraction and this has contributed to dose sales being below expectations".

"As a result, our second half dose sales are expected to be relatively flat versus the first half," Mr McLean said. "We believe once the current process has been resolved, the recent growth initiatives implemented will drive positive momentum, and market growth rates are still favourable."

Sirtex said that earnings before interest, taxation, depreciation and amortization for the year to June 30, 2018 would be "at the lower end of the \$75 to \$85 million guidance previously issued", but it did not expect the trading update to have any impact on implementation of the Varian scheme or the CDH proposal.

Sirtex fell 83 cents or 2.8 percent to \$29.00 with 3.7 million shares traded.

## ACTINOGEN MEDICAL

Actinogen says it has raised \$15 million in a placement at five cents a share, hopes to raise a further \$2 million in a share plan and has approval to continue its Xanadu trial. Actinogen said the five cent placement price was a 13.4 percent premium to the 5-day volume-weighted average price, with a “cornerstone investment” \$10.5 million investment from the San Francisco-based Biotechnology Value Fund, along with support from Australian Ethical Investment and Platinum Investment Management.

The company said the funds would support its phase II Xanamem for Alzheimer’s disease program which had data safety monitoring board approval to continue unchanged.

Actinogen said the placement would be in two tranches with the second tranche requiring shareholder approval.

The company said that BVF would be its largest shareholder with 19.9 percent of the company prior to the share plan, which had a record date of May 22 and would close on July 11, 2018.

Actinogen said that the placement was led by Bell Potter Securities.

Actinogen was up 0.2 cents or 4.4 percent to 4.7 cents with 43.4 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says in its final decision, the English National Institute of Health and Care Excellence (NICE) failed to approve Scenesse for reimbursement.

Last year the Institute refused Clinuvel’s application for reimbursement for Scenesse (afamelanotide 16mg) for erythropoietic protoporphyria (EPP), subject to a final report expected this month (BD: Dec 21, 2017).

The company said Scenesse was the only approved treatment for EPP patients in Europe and had been reviewed as a highly specialized technology (HST) in England.

In December, Clinuvel said that Scenesse had been authorized by the European Commission and while not reimbursed in England had been adopted as the standard-of-care for adult EPP patients in surrounding European reference countries.

Today, the company said that the Institute advised the English National Health Service (NHS) whether a proposed therapy met its economic criteria for reimbursement or not.

Clinuvel said it would appeal the decision and discussions with NICE were ongoing.

The company said that the Highly Specialised Technologies committee of NICE maintained that Scenesse did not meet its health-economic criteria for reimbursement. Clinuvel said that NICE-recommended therapies must be made available under the NHS.

The company said it first engaged with NICE’s affiliated organisations from 2012, was participated in a workshop on EPP in March 2016 and was required to make a formal submission to NICE in 2017 and attended two public meetings of the HST committee.

Clinuvel said that during the second public HST committee meeting on February 20, representatives of NICE, Clinuvel and the committee discussed the alternative of a managed access agreement, in which patients would be given access to the product through a commercial agreement between Clinuvel and the NHS.

Clinuvel European general-manager Lachlan Hay said it was “most disappointing that English EPP patients will not have access to the only approved medication for a debilitating condition, one not well understood by authorities”.

“The length of time of the review by NICE is unacceptable, particularly in the context of this unique and rare disorder and it appears that EPP patients in England must endure at least one more year of isolation and anxiety while an increasing number in Europe are granted reimbursement for this medication,” Mr Hay said.

Clinuvel fell 10 cents or 0.8 percent to \$12.25.

### [PROTA THERAPEUTICS, MURDOCH CHILDREN'S RESEARCH INSTITUTE](#)

Prota says it has completed enrolment of the 200 patients in its phase IIb trial of its probiotic and peanut oral immunotherapy.

Prota said the probiotic and peanut oral immunotherapy technology (PPOIT) was licenced from the Murdoch Children's Research Institute at Melbourne's Royal Children's Hospital (BD: May 29, Aug 17, 2017).

The company said that the randomized and blinded PPOIT-003 study was designed to provide evidence of a longer-lasting tolerance to peanut in a larger number of patients and to compare probiotic and peanut oral immunotherapy with peanut oral immunotherapy alone, to assess the added effect of the probiotic.

Prota said that recruitment was completed ahead of schedule at sites in Melbourne, Adelaide and Perth, with top-line results expected by April 2020

Prota chief executive officer Dr Suzanne Lipe said enrolment was "a tremendous milestone in the advancement of PPOIT and another step towards the further validation necessary for commercialization".

"The rate of enrolment demonstrates both the demand and necessity for a treatment for peanut allergies, but also other food allergies more generally," Dr Lipe said.

Prota is a private company.

### [VIRALYTICS, MERCK SHARP & DOHME](#)

Viralytics says Merck Sharp & Dohme Australia has Australian Foreign Investment Review Board approval for the \$502 million acquisition (BD: Feb 22, 2018)

Viralytics said that Merck had informed it that there were no US objections and it expected the acquisition at \$1.75 a share to be completed on June 20, 2018.

Viralytics was up half a cent or 0.3 percent to \$1.735 with 1.1 million shares traded.

### [BIONOMICS](#)

Bionomics says it has recruited the first of up to 40 patients in a phase II trial of BNC210 for geriatric agitation.

Bionomics said that agitation in the elderly in hospitals and nursing home was "a rapid potential path to market for BNC210" with no currently approved treatments and a significant unmet medical need.

The company said that the randomized, double-blind, placebo-controlled trial was designed for rapid recruitment in specialist geriatric hospital wards across Australia, with a five-day treatment period and results expected by April 2019.

Bionomics said that current options for agitation included benzodiazepines and antipsychotics which could have "severe adverse effects in elderly patients including sedation, stroke and sudden death and hence their use is heavily restricted".

Bionomics chief executive officer Dr Deborah Rathjen said her company expected the results of two ongoing phase II trials in the near term.

"Agitation in the elderly, which has an underlying component of anxiety, has significant unmet treatment needs, with only approximately nine percent of patients suffering agitation receiving drug treatment," Dr Rathjen said.

"Last month, we completed recruitment into our BNC210 phase II clinical trial in patients suffering post-traumatic stress disorder," Dr Rathjen said.

Dr Rathjen said that data from the post-traumatic stress disorder trial was expected by the end of 2018.

Bionomics was up two cents or 3.6 percent to 57.5 cents.

## ADMEDUS

Admedus says it has filed three provisional patent applications in the US as part of its transcatheter aortic valve replacement (TAVR).

Admedus said the patent applications related to “additional embodiments of inventive valve replacement devices that reduce the French-size of the catheter required for delivery of the valve replacement device”.

The company said that some of the inventive concepts disclosed in the applications, provided improved reduction in regurgitation and additional means of control for a physician to recapture and reposition an, at least partially, deployed valve replacement device as needed during a procedure.

Admedus did not provide the patent titles, nor the expected coverage duration.

The company said that since the project’s inception in 2017, it had submitted “numerous provisional patent applications relating to the development of a unique [three-dimensional] single-piece moulded valve, sterile hydro-packaging, a reduced catheter French-size, components that deliver enhanced valve placement and positioning and a design element to reduce paravalvular leakage which can lead to higher morbidity and poor health outcomes for patients”.

Admedus was unchanged at 30 cents.

## MMJ PHYTOTECH, ESENSE LAB

MMJ says it has sold its Cannabis Wheaton Income Corp stock for \$C5.6 million (\$A5.8 million), realising a 2.2 multiple on its Dosecann investment (BD: Apr 5, May 18, 2018). MMJ said it sold its shares in Esense for \$200,000 making a 0.8 loss on the investments (BD: Nov 14, 2017).

MMJ chief executive officer Jason Conroy said the divestments were “in-line with our strategy to recycle capital to provide cash for further investments by MMJ in the global cannabis sector”.

“As a result, MMJ’s current unaudited corporate cash position will increase to approximately \$8.1 million,” Mr Conroy said.

MMJ was up 1.5 cents or 4.8 percent to 33 cents.

Esense was up 0.4 cents or 5.5 percent to 7.7 cents.

## QRX PHARMA

The ASX says QRX was removed from the Official List at the start of trading today, May 23, under Listing Rule 17.12.

The ASX said QRX securities had been suspended from trading for a continuous period of more than three years.

QRX listed on the ASX in May 25, 2007 to commercialize its Moxduo combination of morphine and oxycodone for pain, but following the failure to have Moxduo approved by the US Food and Drug Administration and a period of voluntary administration, the company creditors voted for a deed of company arrangement, returning the management and control to directors (BD: Aug 14, 2014; May 25, Dec 9, 2015).

QRX last told the ASX that its cash burn for the three months to March 31, 2018 was \$112,000 and all spent on administration and corporate costs, with \$331,000 in cash and cash equivalents at March 31, 2018.

QRX last traded at 2.8 cents.



### IMAGION BIOSYSTEMS

Imagion says principal collaborator, the MD Anderson Cancer Centre, will convert \$793,000 of the sponsored research program fees into shares.

Imagion said it had been working with the Houston, Texas-based MD Anderson Cancer Centre to develop and validate the magnetic relaxometry technology since 2014.

Imagion executive chairman Bob Proulx said the company was “delighted to welcome the MD Anderson Cancer Centre as a shareholder”.

The company said 10,529,053 shares would be issued to MD Anderson in lieu of about \$793,000 of \$848,795 research fees and would be subject to a three-month voluntary escrow period, pending shareholder approval.

Imagion was up 1.6 cents or 34.8 percent to 6.2 cents.

### ELLEX MEDICAL LASERS

Investors Mutual says it has increased its substantial shareholding in Ellex from 7,450,000 shares (5.21%) to 8,947,315 shares (6.23%).

The Sydney-based Investors Mutual said that between December 20, 2017 and May 18, 2018 it acquired 1,497,315 shares, with the single largest purchase 500,000 shares for \$315,000 or 63 cents a share.

Ellex was up half a cent or 0.8 percent to 66 cents.

### PATRYS

The Sydney-based Mason Stevens says it has become a substantial shareholder in Patrys with the acquisition of 58,823,529 shares (5.48%).

Mason Stevens director Ronald Erbos said the shares were acquired on May 22, 2018 for \$2,000,000 or 3.4 cents a share, the same price as the company’s recent placement which raised \$4.6 million (BD: May 16, 21, 2018).

Patrys was unchanged at 3.6 cents with 10.3 million shares traded.

### GENERA BIOSYSTEMS

JPS Distribution for the Raff Superannuation Fund says it has increased its substantial shareholding in Genera from 7,559,524 shares (7.6%) to 9,637,727 shares (8.97%).

JPS said that the Raff Superannuation Fund bought 2,078,203 shares for \$369,209 or 17.8 cents a share on May 18, 2018.

Dr John Raff is the former chief executive officer of Starpharma and the former chairman of the Bio-Melbourne Network.

Genera was up 1.5 cents or 8.3 percent to 19.5 cents.

### COMPUMEDICS

Compumedics says it has appointed Tucson Dunn as a director, effective immediately, subject to shareholder approval.

Compumedics said that the US-based Mr Dunn had “significant international experience in health care delivery”, in senior management roles, including as hospital chief executive officer in the US, as well as in Asia, Europe and the Middle East, and was currently employed by China healthcare investment company, the Fosun Group.

Compumedics was up 1.5 cents or 4.1 percent to 38 cents.

## [ADMEDUS](#)

Admedus says company secretary and chief financial officer Catherine Costello has been appointed as an interim executive director, effective immediately.

Admedus said the appointment followed the resignation of Mathew Ratty and fulfils the requirement to have two resident Australian directors (BD: May 21, 2018).

The company said it had begun a search for an Australian director to replace Mr Ratty.

## [ADHERIUM](#)

Adherium says it has appointed David Allinson as its chief financial officer, effective immediately.

Adherium said that Mr Allinson had more than 20 years' experience in finance, corporate development and transaction management, predominantly in the medical technology sector.

The company said that most recently, Mr Allinson was Augmedix chief financial officer and he was previously with GE Medical Systems, the Self Health Network, Mecon, Inc, and HCorp Inc.

Adherium said that Mr Allinson held a Bachelor of Science from California's San Jose State University

Adherium was up half a cent or 3.7 percent to 14 cents.