

# **Biotech** Daily

# Tuesday June 18, 2019

Daily news on ASX-listed biotechnology companies

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- \* EDITORIAL: BNYM & SUBSTANTIAL SHAREHOLDER NOTICES
- \* MEDLAB 2,000 PATIENT NANABIS 'OBSERVATIONAL' STUDY
- \* BARD1 PLACES \$5m, RIGHTS ISSUE FOR \$2.5m MORE
- \* RHYTHM SIGNS MONASH FOR COLOSTAT TRIAL
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- \* BOTANIX REQUESTS 'PSORIASIS PHASE Ib RESULTS' TRADING HALT
- \* BOTANIX 17m DIRECTORS OPTIONS, TERMINATION BENEFITS EGM
- \* MAX JOHNSTON, PHILIP POWEL REPLACE BARD1 BRETT MONTGOMERY

## \* GI DYNAMICS APPOINTS PROF STEVEN OPAL ADVISOR

#### MARKET REPORT

The Australian stock market was up 0.6 percent on Tuesday June 18, 2019, with the ASX200 up 39.1 points to 6,570.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and four were untraded. All three Big Caps were up.

Optiscan was the best, up half a cent or 11.9 percent to 4.7 cents, with 222,200 shares traded. Clinuvel climbed more than 6.1 percent; Benitec, Polynovo, Prescient and Proteomics improved five percent or more; Avita was up 4.2 percent; Paradigm rose 2.9 percent; with Cochlear, Compumedics, CSL, Cynata, Ellex, Pro Medicus, Resmed and Telix up one percent or more.

Impedimed led the falls, down 1.5 cents or 12.5 percent to 10.5 cents, with 2.1 million shares traded. Osprey lost 9.2 percent; Orthocell fell 6.45 percent; Oncosil retreated 5.1 percent; Alterity (Prana) and LBT were down more than three percent; Antisense, Kazia, Neuren, Opthea, Pharmaxis and Universal Biosensors shed two percent or more; Dimerix, Nanosonics and Volpara were down more than one percent; with Mesoblast and Starpharma down by less than one percent.

## **BIOTECH DAILY EDITORIAL: SUBSTANTIAL SHAREHOLDER NOTICES**

The filing of substantial shareholder notices by the Bank of New York Mellon on behalf of unnamed clients obscures the ownership of public companies.

But it is only defying the former spirit of the Corporations Act 2001, not the letter of the law.

The Australian Securities and Investments Commission (ASIC) previously published 'Regulatory Guide 159: Takeovers, compulsory acquisitions and substantial holding notices' which referred directly to the recommendations of the Cohen Committee:

"...the intention thereof is to enable a shareholder to know who [their] co-adventurers are and the public to find out who controls the business to which they are contemplating investment or to which they are considering granting credit": Report of the Committee on Company Law Amendment UK (1945) p39.'

The Guide has been withdrawn, this provision does not appear to have been replaced and there does not appear to be any law to support this principle.

Last month, the Bank of New York Mellon says it had become substantial in eight Australian biotechnology companies because it held the shares as American depository receipts (ADRs) (BD: May 8, 2019).

Several companies told Biotech Daily that the requirement for repeated, un-informative Bank of New York Mellon notices was recently implemented by ASIC.

The notices serve no purpose, other than to obscure the real share ownership of companies in the same way as "nominee companies". Biotech Daily was once told by a company director that the reason he hid his holding behind a nominee company was "because I don't want my wife or the Tax Office to know what I own".

It is time to change the Corporations Act to implement the previous intent to allow shareholders to know who their co-investors are. ASIC says the matter is one for the law of Trusts.

Along with ending the practice of allowing investors to hide behind nominee companies, where even the listed entity cannot find them, Biotech Daily believes the substantial shareholder level should be reduced from 5.0 percent to 1.0 percent, so we have a clearer picture of the major holders.

Finally, if the Bank of New York Mellon is deemed to be a substantial shareholder because it holds the ADRs, then surely Commsec, other trading platforms, all stock brokers and the ASX itself should be filing substantials as well.

Biotech Daily will no longer report Bank of New York Mellon filings on behalf of unnamed investors in biotechnology companies including: Alterity (Prana), Avita, Benitec. Clinuvel, Genetic Technologies, Immutep, Immuron and Kazia.

David Langsam Editor

#### MEDLAB CLINICAL

Medlab says it expects to begin a 2,000-patient, 12-month data collection "observational" study of its marijuana-based Nanabis for pain management.

Last year, Medlab said that a five-patient, phase I trial had shown Nanabis to be safe and it would proceed to a 25-patient phase II trial for cancer pain (BD: Oct 30, 2018).

In March, the company said the five phase I patients had shown a reduction in pain when administered Nanabis, with two patients ceasing use of all medication other than Nanabis after four days and one month, respectively (BD: Mar 14, 2019).

In a trial review at the Australian and New Zealand Clinical Trials Registry, Medlab said the study would include "patients who are about to start a therapy with or are already administering Nanabis for the management of cancer ... and non-cancer related pain". The trial details are available at: <u>https://bit.ly/2MUrmtj</u>.

Medlab chief executive officer Dr Sean Hall told Biotech Daily the company was "looking for publishable data for regulatory agency approval".

Dr Hall said the study would gather use and abuse data as well as evidence that Nanabis diminished the use of opioids or other drugs.

Dr Hall said Nanabis normally retailed at \$400 for a one to two-month supply and that subjects in the observational study would be entitled for a 50 percent discount.

In a media release Dr Hall said the study would allow Medlab "to leverage the Australian special access scheme, follow the patients closely, but more-so publish and use the forth-coming data to bolster all our regulatory efforts as it relates to Nanabis".

Medlab fell half a cent or 1.4 percent to 35.5 cents.

#### BARD1 LIFE SCIENCES

Bard1 says it has raised \$4.97 million in a placement at two cents a share and hopes to raise a further \$2.5 million in a rights issue, with \$200,000 underwritten.

Bard1 said it had a placement with the Perth, Western Australia-based Merchant Opportunities Fund, Kidder Williams principal David Williams and Jeffrey Emmanuel. The company said Mr Williams was the chairman of Medical Developments International, Polynovo and RMA Global.

Bard1 said Mr Emmanuel was a private investor and worked for the Hong Kong-based EFM Asset Management.

The company said that the record date for the rights issue was June 21, the offer would open on June 26 and close on July 5, 2019.

Bard1 said the funds would support its diagnostics pipeline, new research and development activities and working capital.

Bard 1 fell 0.4 cents or 16 percent to 2.1 cents with 42.9 million shares traded.

#### **RHYTHM BIOSCIENCES**

Rhythm says that Monash Health will join its 1,000 patient, multi-centre prospective clinical trial of its Colostat colorectal cancer detection blood test.

Rhythm said that the Melbourne-based Monash was the second hospital to join the trail and had recruited its first patients.

Earlier this year, the company said Adelaide's Lyell McEwin Hospital had joined the trial and recruited the first patient (BD: Feb 20; Mar 18, 2019).

Today, Rhythm said Monash Health head of clinical trials Prof Stephen Pianko had been appointed the principal investigator at the site.

Rhythm was up one cent or 6.7 percent to 16 cents.

## <u>CARDIEX</u>

Cardiex says its trading halt and suspension for "a material customer contract" is not material and it has resumed trading.

Yesterday, Cardiex has requested a voluntary suspension to follow the June 13 trading halt "pending an announcement regarding a material customer contract through Cardiex investment company Inhealth Medical Services" (BD: Jun 13; Jun 17, 2019).

Today the company said that due to its 7.7 percent holding in Inhealth that the contract with an electronics and medical device company was material to Inhealth but not to Cardiex.

Cardiex said the 7.7 percent holding was prior to the conversion of a tranche 2 convertible note, that would take its position to 41.03 percent prior to a tranche 3 option to increase the stake to 50.5 percent (BD: Feb 1, 2019)

Cardiex fell 0.4 cents or 11.4 percent to 3.1 cents with 12.3 million shares traded.

## **GI DYNAMICS**

GI Dynamics says it has removed the proposal to delist from the ASX from its initial proxy statement and notice of annual general meeting.

Earlier this month, GI Dynamics said it would consider delisting from the ASX due to the cost of compliance and inability to raise funds for its Endobarrier for obesity and type 2 diabetes (BD: Jun 4, 2019).

Today, the company said the delisting proposal would not be included as the board was "still considering the merits of a delisting".

GI Dynamics said the annual meeting was expected to be held at the June, 2019, but did not have a date set.

GI Dynamics was up 0.4 cents or 22.2 percent to 2.2 cents.

## **GENETIC TECHNOLOGIES**

The Bank of New York Mellon says it has reduced its substantial holding in Genetic Technologies from 1,726,989,661 shares (58.78%) to 1,696,945,861 shares (57.76%). The Bank of New York Mellow said that between June 12 and June 14, 2019, it transferred 30,043,800 shares for no price?

The substantial shareholder notice was signed by "attorney-in-fact" Ivan Arias on behalf of unnamed customers of the Bank.

Genetic Technologies was unchanged at 0.7 cents with 8.8 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt pending an "announcement in relation to its BTX1308 psoriasis phase lb study results".

Trading will resume on June 20, 2019 or on an earlier announcement. Botanix last traded at 13.5 cents.

## BOTANIX PHARMACEUTICALS

Botanix will vote to grant executive chairman Vincent Ippolito and director Michael Thurn 17,000,000 "incentive options" and "termination benefits" for Mr Ippolito.

Botanix said an extraordinary general meeting would vote to issue 12,000,000 incentive options to Mr Ippolito and 5,000,000 options to Mr Thurn, exercisable at the higher of the closing share price of the previous day's trading prior to grant or the seven-day weighted average price of shares before the grant date, and within four years.

In the explanatory memorandum to the notice of meeting, Botanix said that "if Mr Ippolito's employment agreement was terminated by the company without cause or by Mr Ippolito with good reason, the company will be required to provide Mr Ippolito with .... an amount equal to 12 months of Mr Ippolito's base salary [and] where Mr Ippolito works in his full-time capacity this would be \$571,429" along with other benefits.

In May, Botanix said it had appointed Vince Ippolito as executive chairman and president starting on \$400,000 a year (BD: May 20, 2019).

The company said at that time that Mr Ippolito had more than 30 years' experience in the pharmaceutical industry, including 20 years working in dermatology, and had developed and launched more than 20 dermatology products in the US.

The meeting will be held at Level 16, Brookfield Place Tower 2, 123 St Georges Terrace, Perth on July 18, 2019 at 9.30am (AWST).

## BARD1 LIFE SCIENCES

Bard1 says it has appointed Max Johnston and Philip Powel as directors with Brett Montgomery to resign, effective immediately.

Bard1 said Mr Johnston was Johnson & Johnson Pacific's chief executive officer for 11 years and previously worked for Daigeo and Unilever in Australia, Africa and Europe. The company said Mr Powel was currently chairman of Probiotec and a non-executive director of Medical Developments, Polynovo and Cannpal.

Bard1 said that Mr Powell was an accountant with experience in investment banking, capital raisings, initial public offerings, and mergers and acquisitions in financial services, pharmaceuticals and food and agriculture

#### **GI DYNAMICS**

GI Dynamics says it has appointed Prof Steven Opal to its scientific advisory board. GI Dynamics said Prof Opal was a clinical professor of medicine at the Providence, Rhode Island-based Brown University infectious disease division.

The company said Prof Opal held more than "more than 20 academic and hospital appointments" and had been a reviewer and/or presenter at five US Food and Drug Administration meetings including a pre-submission meeting with GI Dynamics for its 2018 investigational device exemption for its Endobarrier.

GI Dynamics said Prof Opal held a Doctor of Medicine from the Albany, New York-based Albany Medical College of Union University.