



Biotech Daily

Friday May 11, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AIRXPANDERS, USCOM UP 8%; OSPREY DOWN 5%**
- * **DR BOREHAM'S CRUCIBLE: PRESCIENT THERAPEUTICS**
- * **MRFF \$215m INVESTMENTS THIS YEAR, \$20b FUND BY 2021, \$80m 'FEES'**
- * **OPTISCAN EGM: MUTTON GROUP WINS, DIRECTOR IAN MANN OUT**
- * **BIOTRON PLEADS SCHULTZ TO ASX 35% QUERY**
- * **BIOTRON TELLS ASX: \$1.5m RIGHTS ISSUE WILL COVER COSTS**
- * **KATHY CONNELL WINS BIO-MELBOURNE WOMEN IN LEADERSHIP GONG**
- * **PROF IAIN MCGREGOR DINES ON MEDICAL CANNABIS WITH RACI**
- * **DR CHRISTIAN BEHRENBRUCH, ELK RIVER TAKE 6% OF INNATE**
- * **GI DYNAMICS' DAVE BRUCE APPOINTED COMPANY SECRETARY**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Friday May 11, 2018 with the ASX200 down 2.5 points to 6,116.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and four were untraded.

Airxpanders and Uscom were the best, both up 8.3 percent to 13 cents and 19.5 cents, respectively, with 444,896 shares and 44,089 shares traded, respectively.

Telix climbed 6.9 percent; Compumedics was up 5.3 percent; Immutep, Prescient, Universal Biosensors and Volpara improved four percent or more; Ellex and Factor Therapeutics rose more than two percent; Cochlear, Opthea and Resmed were up more than one percent; with Cynata and Sirtex up by less than one percent.

Yesterday's best, Osprey, led the falls, down one cent or 5.3 percent to 18 cents with 417,654 shares traded.

Admedus lost 4.8 percent; Impedimed, Pharmaxis and Starpharma were down more than three percent; Benitec and ITL shed two percent or more; Avita, Mesoblast, Nanosonics, Polynovo and Pro Medicus were down more than one percent; with Bionomics, Clinuvel, CSL, Medical Developments and Neuren down by less than one percent.

DR BOREHAM'S CRUCIBLE: PRESCIENT THERAPEUTICS

By TIM BOREHAM

ASX code: PTX

Share price: 13 cents

Market cap: \$27.5 million

Shares on issue: 211,508,374

Financials (March quarter)*: revenue nil, cash used \$282,000, cash on hand \$6.29 million, estimated current quarter cash outflows \$1.43 million

* During the quarter the company received a \$1.06 million R&D Tax Incentive

Chief executive officer: Steven Yatomi-Clarke

Board: Steven Engle (chairman), Steven Yatomi-Clarke, Paul Hopper, Dr James Campbell

Identifiable major shareholders: Australian Ethical Investments (12.96%), Regal Funds Management (8.78%), Retzos Executive Pty Ltd (Chris and Susie Retzos) (6.12%), Andrew Morrison Stewart (3.2%), Armada Trading (4.81%), Margaret Khoo (2.12%), One Managed Investment (2.89%) Wigtown Pty Ltd (2.61%).

Now's the time for a targeted oncology therapy company to be loud and proud, given Merck's \$502 million swoop on Viralytics - which is still the talk of the sector.

Not that investors are entirely uncritical about the cancer wonder drug theme.

On April 10, Prescient announced what looked like okay clinical results for its early-stage breast cancer drug trial, but investors sent the stock down by two cents, or 14 percent, to 12 cents.

"It baffles me when you produce encouraging data - albeit early stage - and the company is worth less on the other side (of the announcement)," says CEO Steven Yatomi-Clarke.

Bear in mind that the shares had rallied from six cents in early March in anticipation of the results.

Banker's prescient move

Prescient evolved from oncology house Virax Holdings, which acquired the current portfolio with the acquisition of Aktivite Therapeutics in October 2014.

Virax paid \$300,000 cash and 234 million of its own shares at one cent (\$2.34 million), with 100 million shares up-front and the remainder subject to milestones.

Virax then undertook a one-for-20 share consolidation and changed its name to Prescient.

Current chief executive officer Steven Yatomi-Clarke succeeded Rob Crombie in February 2016.

Mr Yatomi-Clarke was corporate finance director at Paterson Securities. As a biotech specialist he was involved in a number of big-ticket deals in the sector, including Halcyon's acquisition of the former Faulding operations (the precursor to Mayne Pharma).

Mr Yatomi-Clarke is a scientist by training with a Melbourne University honors degree in biochemistry and molecular biology, as well as a commerce degree. He describes himself as an "acquired taste", fitting the famous Jimmy Barnes descriptor of "a simple man with a heart of gold".

"I worked with so many companies that I learnt how to do things and not to do things," he says.

One example was dealing with regulators. "I saw companies getting defensive with the FDA and digging their heels in. That never ends well."

He engineered Prescient's last capital raising himself, "which annoyed a few brokers around town".

Prescient shares DNA with Viralytics, in that Viralytics chair Paul Hopper is a Prescient director. Mr Hopper also chairs immuno-oncology play Imugene, which also enjoyed a share price romp after the Merck-Viralytics deal.

Pressing the right buttons

Prescient's lead drug PTX-200 inhibits the tumor survival pathway Akt, which is linked with breast and ovarian cancer and leukaemia.

A company presentation illustrates this mechanism of action with an on-off button. When the aberrant Akt is stuck 'on', the cancer cells are ordered to grow.

When it's 'off', they're not - and the cancer cells die.

It's actually more complex than that. Suffice to say, PTX-200 is touted as a novel mechanism-of-action that will inhibit Akt while being comparatively safer and better targeted than existing non-specific kinase inhibitors.

Prescient's second drug candidate is PTX-100, which has the ability to block the cancer growth enzyme geranylgeranyl transferase. Yes, that's right. Yes, that's right.

It works in a similar switch mechanism to PTX-200, albeit on a different cancer 'button' - PTX-100 addresses the Ras and Rho mutations.

To date, \$US20 million has been sunk into developing the drugs by owners' past and present.

In the clinic

In the company's "most significant clinical milestone to date", Prescient reported the early-stage results of a PTX-200 breast cancer trial on April 10.

Overall, the US based trial treated 28 patients, focusing on women who did not display some or all of the receptors commonly found on cancer cells: oestrogen, progesterone and HER2-negative.

The patients had locally advanced or metastatic HER2-negative cancer and received a hit of both PTX-200 and paclitaxel (chemotherapy). Ten patients were evaluable for efficacy.

Of the five with the locally advanced disease, a 100 percent overall response rate was achieved with two showing a complete response (i.e. the cancer was banished). This is especially important as it's the focus of the current phase II study.

Of the 10 patients, five - or 50 percent - had an overall response rate, compared with the 25 percent the industry would expect from paclitaxel alone.

Mr Yatomi-Clarke said he was very pleased the best responses were in patients with the oestrogen-positive form of the disease, "which is especially difficult to treat and with poor expected outcomes from current chemotherapy regimens alone".

The trial (with 26 patients) is now in phase II, with five of the phase Ib patients participating.

If the overseers observe three partial or complete responses among the first 11 patients, the trial expands to another 15 patients.

The timing of this achievement can't be pinned down, because the desired response might be in the first or last patient treated.

The trial is at the New York-based Albert Einstein College of Medicine's Montefiore Medical Centre, and the Tampa, Florida-based H Lee Moffitt Cancer Centre.

Other events the punters will be awaiting are the results of earlier stage trials of PTX-200 for ovarian cancer and acute myeloid leukaemia (AML). PTX-200 is now envisaged as a combination drug to be used with the standard-of-care chemotherapy treatment.

This program is overseen by Prof Jeff Lancet of the Moffitt Centre. As well as having the best name in the medical game, he is a world-leading leukaemia expert.

The company expects initial results from ovarian cancer by the end of 2018 and AML results by around the middle of this year.

Wait! There's more ...

Let's not forget PTX-100, which in phase I trials was well-tolerated and achieved stable disease status for advanced solid tumors.

Now it's back to the clinic, but this time the company is targeting a range of cancers harboring mutations in cancer switches called Ras and Rho.

PTX100 inhibits the activation of Rho, Rac and Ral circuits in cancer cells, which are key pathways to blocking tumor growth.

The PTX-100 study will focus on Ras and Rho-A mutant malignancies, "including Rho-A mutant lymphomas".

Dr Boreham's diagnosis:

Prescient compares its approach to the Nasdaq-listed Loxo Oncology, which has followed a similar development path.

Loxo, which has two mid-stage candidates, recently entered a deal with Bayer involving \$US400 million of up-front payments and a total potential value of \$US1.55 billion.

With only phase II data, Loxo has applied to the FDA for investigational new drug status to treat a range of solid tumor patients.

"We will try to follow a similar development path," Mr Yatomi- Clarke says.

He reckons the \$6 million is enough to last the company well into 2019.

But old banker that he is, he adds: "You don't wait until the petrol tank is empty until you pull into the servo."

Prescient shares may not have saluted on the occasion, but ultimately clinical data is the truth serum for any biotech.

In a year or so we'll know whether Prescient should be worth Loxo's \$US4 billion market cap - or somewhat south of that.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is just a working class man trying hard to make a living.

MEDICAL RESEARCH FUTURE FUND

The Federal Budget papers say that the Medical Research Future Fund had \$7,055,724,000 at June 30, 2018 and is expected to triple to \$20 billion in three years. According to the Finance Portfolio 2018-'19 Budget Statements, the expected disbursement from the fund for the year 2018-'19 would be \$214,913,000.

The Budget Statements said the Government expects the fund to increase from \$7.0 billion this year to \$9.47 billion by June 30, 2019 and then nearly double to \$17.59 billion by June 30, 2020, exceeding the targeted \$20 billion by June 30, 2021.

The Statements said that the MRFF expected to provide funding of \$214.9 million in the 12 months to June 30, 2019, rising to \$386.4 million the following year, \$642.9 million in 2020-'21 and \$645.95 million when fully-funded in 2021-'22.

The 2018-'19 Portfolio Budget Statements said that "management fees" would more than double from \$40.0 million in the current year to \$85.8 million by 2020-'21.

The detailed Federal government Finance Portfolio Budget Statements are available at: <https://www.finance.gov.au/publications/portfolio-budget-statements/18-19/> .

Biotech Daily asked the Finance Department how the MRFF would increase to \$20 billion and who was receiving the "management fees" but at the time of publication had not received a response.

OPTISCAN IMAGING

Optiscan says shareholders voted to remove director Ian Mann and elect Darren Lurie and Graeme Mutton as directors at its extraordinary general meeting on May 10, 2018.

Optiscan said resolutions to remove Dr Phillip Currie and appoint Archie Fraser and Ron Grey were not passed.

In March, the company said the group aligned with director Mr Mann, former chief executive officer Archie Fraser and founder Peter Delaney called for the removal of Dr Currie as well as chairman Alan Hoffman and directors Peter Francis and Dr Ian Griffiths and the appointment of Mr Fraser and Mr Grey as directors, while a group aligned with Mr Mutton called for the removal of Mr Mann and the appointment of Darren Lurie and Mr Mutton (BD: Mar 16, 19, 27, 29, 2018).

In April, Optiscan said that former chairman Mr Hoffman and directors Mr Francis and Dr Griffiths had resigned (BD: Apr 18, 23, 2018).

The company said the Mutton resolutions were supported by about 190 million votes, while the Mann resolutions were supported by more than 116 million votes.

According to the company's most recent Appendix 3B new share issue announcement, Optiscan had 431,178,800 shares on offer, meaning that strongest Mann vote, to remove director Dr Currie, with 118,993,093 votes, amounted to 27.6 percent of the company, sufficient to requisition meetings and defeat remuneration reports.

Optiscan was unchanged at 6.8 cents.

BIOTRON

Biotron has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 34.8 percent from 2.3 cents on May 2 to 3.1 cents on May 8, 2018 and noted an increase in the trading volume.

Biotron said it was analyzing samples from its phase II trial of BIT225 for HIV-1 infection and the results were a "key outcome" for potential partners (BD: Jul 27, 2017).

Biotron was up 0.4 cents or 16 percent to 2.9 cents with 1.3 million shares traded.

[BIOTRON](#)

In a response to an ASX Appendix 4C Query, Biotron says it has a partially underwritten renounceable rights issue to raise up to \$1.47 million (BD: Apr 26, 2018).

The ASX noted that Biotron had a cash burn of \$886,000 for the three months to March 31, 2018, had \$672,000 in cash at that date and expected to spend \$475,000 in the three months to June 30, 2018.

The ASX asked how Biotron expected “to able to continue its operations and to meet its business objectives and if so on what basis?”

The company said the rights issue hoped to raise \$1.47 million, of which \$800,000 was underwritten by the Perth-based CPS Capital Group.

[BIO-MELBOURNE NETWORK](#)

Bio-Melbourne Network says that Johnson & Johnson Innovation executive Kathy Connell has won the 2018 Women in Leadership award.

Bio-Melbourne said that Victoria’s chief scientist Dr Amanda Caples won the Most Valuable Women in Leadership award with Australia’s National Digital Health Initiative’s director Grace Lethlean awarded the Emerging Women in Leadership prize.

The Network said the awards were launched in 2015 “to recognize and champion women at different stages of their careers who had made outstanding contributions to advancing the biotechnology, medical technology and pharmaceutical sector, and to inspire more women to pursue leadership roles”.

Bio-Melbourne Network said the 2018 awards would be presented by the Victorian State Government’s Parliamentary Secretary for Industry and Employment Vicki Ward at a ceremony hosted today by the State Government.

[ROYAL AUSTRALIAN CHEMICAL INSTITUTE](#)

Lambert Initiative academic director Prof Iain McGregor will discuss medical cannabis at the Royal Australian Chemical Institute dinner next week.

The Institute said that the University of Sydney’s Lambert Initiative Cannabinoid Therapeutics aimed “to fast-track research into the therapeutic benefits of cannabinoids in conditions such as epilepsy, anxiety, pain and cancer” and that Prof McGregor would share insights from his 20 years of research into cannabinoids.

The Institute said Prof McGregor’s work focused on the effects of drugs on the brain and behavior and involved development of medications for diseases using cellular assays and pre-clinical animal models of disease as well as human trials.

RACI said Prof McGregor was a co-founder of Kinosis Therapeutics, a company developing an oxytocin-derived drug called SOC-1 for the treatment of addictions, social anxiety and autism.

The Institute said that Prof McGregor’s talk was titled ‘Medical cannabis in Australia: the view from the Lambert Initiative’.

RACI said the dinner would be hosted by its Bioactive Discovery and Development Group with support from law firm Davies Collison Cave at the Pumphouse Hotel, 128 Nicholson Street Fitzroy on Wednesday, May 16, 2018.

For more information, go to <https://www.raci.org.au/document/item/3262> and to register, go to <http://www.ivvy.com.au/event/VBG806>.

[INNATE IMMUNOTHERAPEUTICS](#)

Innate director Dr Christian Behrenbruch says he has become a substantial shareholder in Innate with 2,492,142 shares or 6.07 percent of the company.

The Melbourne-based Dr Behrenbruch said that he held the shares through Elk River Holdings and 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.

Innate was unchanged at 39 cents.

[GI DYNAMICS](#)

GI Dynamics says principal accounting and financial officer Dave Bruce has been appointed company secretary.

In April, GI Dynamics said it had appointed Mr Bruce as the principal accounting and financial officer following the termination of chief compliance officer Brian Callahan and finance and accounting head Houry Youssoufian (BD: Apr 20, 2018).

The company said Mr Bruce was previously the general accounting manager, having been employed with the company since October 2016.

GI Dynamics was unchanged at 3.5 cents.