# Biotech Daily

Thursday March 29, 2018

*Daily news on ASX-listed biotechnology companies*

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*** IDT LOSES DIRECTOR REO SHIGENO**

## MARKET REPORT

The Australian stock market fell 0.52 percent on Thursday March 29, 2018, with the ASX200 down 30.1 points to 5,759.4 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, 12 traded unchanged and one was untraded. All three Big Caps fell.

ITL was the best, up 1.5 cents or five percent to 31.5 cents with 15,873 shares traded. Oncosil climbed four percent; LBT and Pharmaxis were up more than three percent; Starpharma rose two percent; Clinuvel and Polynovo were up more than one percent; with Pro Medicus and Psivida up by less than one percent.

Airxpanders led the falls, down 2.5 cents or 5.6 percent to 42.5 cents with 53,634 shares traded. Dimerix, Medical Developments and Telix fell more than four percent; Bionomics and Genetic Signatures were down more than three percent; Actinogen, Factor, Opthea and Prana shed more than two percent; with Avita, CSL, Ellex, Impedimed, Mesoblast, Nanosonics and Resmed down more than one percent.

# DR BOREHAM'S CRUCIBLE: PATRYS

**By TIM BOREHAM**

**ASX code:** PAB

**Share price:** 4.1 cents

**Market cap:** $38.2 million

**Shares on issue:** 931,622,801

**Chief executive officer:** Dr James Campbell

Board: John Read (chairman), Michael Stork, Suzy Jones, Dr James Campbell

**Financials (December half):** revenue $224,760*****, loss of $994,326, cash $911,779******, estimated current quarter cash burn $760,000

*****includes R&D Tax Incentive of $199,713

******ahead of $2.8 million rights raising in January

**Major holders:** Dr Dax Marcus Carter 12.67%, Stork Holdings (Michael Stork) 10.7%, Oncomab GmBH 2.19%, Marginata Pty Ltd (Roy Bolton) 2.17%, Yale University 1.75 percent.

Like the four-minute mile before fleet-of-foot medical student Roger Bannister cracked it in 1954, the blood-brain barrier has proved a stubborn obstacle for drug administration.

And like most bodily engineering, the brain is well-designed with a protective layer of cells allowing only certain molecules to transit from the blood to the cerebro-spinal fluid surrounding the noggin.

Is Patrys' antibody cancer treatment PAT-DX1 one such molecule?

The Melbourne-based entity seems to think so, hailing Yale University research showing the injected compound "crossed the blood-brain barrier to significantly reduce tumor size".

Sir Roger, who died last month, would be proud.

For investors it was a case of off-to-the-races as well, with Patrys shares more than doubling on the day.

"The blood-brain barrier is a really good layer of cells that stops bacteria, viruses and chemicals," says Patrys chief Dr James Campbell.

"Few antibodies have managed to cross this barrier."

## Germanic roots

Patrys sounds like a Greek village or a 1970s orange juice brand. In fact, the company was formed in December 2006 to consolidate human antibody technology from Germany's University of Wurzburg, German biotech Oncomab and Acceptys Inc (a US company commercializing Columbia Uni know-how).

The company listed in July 2007, having raised $25 million at 40 cents apiece.

Patrys' original work related to immunoglobin M (IgM) antibodies, which are bigger and more complex than the immunoglobin B antibodies used in most therapies.

In 2013, the company raised funds for a phase II trial, but it was curtailed because of manufacturing issues.

Dr Campbell, who has a background in biochemistry and venture capitalism, started as part-time chief executive officer in April 2015 and moved to full-time in March last year.

When he was appointed the board told Dr Campbell to see what he could do with the existing assets, but he might have to bring in something new.

Dr Campbell did just that, with the company licencing the relevant technology from Yale University in 2016.

A Chinese party has licenced the Chinese rights to a gastric cancer application for its old technology. Otherwise, the old assets are on the books but dormant.

## The lowdown on PAT-DX1

Patrys is a player in the art of DNA damage repair (DDR) therapeutics with a program called PAT-DX1.

PAT-DX1 is a humanized and smaller version of deoxymab 3E10 (D3E10), a DNA damage repair antibody first identified in the inflammatory immune disorder lupus.

While most antibodies bind to the surface of cells, D3E10 nanoparticles penetrate them and transport the agent across the protective plasma membrane. Rather like Omo on those tough stains. It then binds to DNA and kills deficient or mutant cells.

Dr Campbell said the PAT-DX1 mechanism of action was "very different" to that of other antibody therapies.

"This antibody is particularly cool because it localizes in the tumor, crosses all membranes and binds to the DNA of the cell and stops the DNA repair enzymes."

True, treatments known as poly-ADP-ribose polymerase (PARP) inhibitors block these enzymes as well. But like Omo Plus, PAT-DX1 is the all new and improved version.

In December, Patrys said it worked effectively with olaparib, the first approved PARP inhibitor. In 2014, the US Food and Drug Administration approved Lynparza, Astrazeneca's branded version of olaparib, for use in breast and ovarian cancer.

Patrys thus believes PAT-DX1 is likely to be used in other DDR therapeutics including with PARP inhibitors, as well as a vehicle to improve the delivery of chemotherapy and radiotherapy.

**Multiple possibilities**

PAT-DX1 has been shown to be effective in pre-clinical work on colon cancer cells and triple negative breast cancer (those lacking the three receptors that current drugs target).

In January, the company confirmed it worked in a similar localized manner for triple-negative breast cancers (the ones not showing the three usual markers).

Patrys also believes PAT-DX1 may be relevant for melanomas, prostate, pancreatic and ovarian cancers.

"We will go for glioblastoma first but there's no reason not to think it will work in a broad range of other cancers," Dr Campbell says.

The company hopes to start human trials within two years and has started the drudge work to enable this.

**.. but it's early days**

The Yale tests showed the glioblastomas - highly malignant cancers characterized by rapid cell reproduction - were 40 percent smaller in the treated mice relative to the control rodents.

Putting the Yale results in perspective, they derived from orthotopic rodent models of glioblastoma using human tumor explants.

Under the orthotopic model, cells from human tumors are inserted in the brains of the mice.

Sceptics note that the tests pertain to mice and not men (with apologies to John Steinbeck there).

"There are models and there are models," Dr Campbell says. "People will say 'what's the point in curing cancer in mice' but ours is a very sophisticated model."

Yale's parallel study to evaluate the comparative survival of mice with glioblastoma treated with PAT-DX1, relative to untreated mice, showed a 21 percent survival increase.

**Financials**

At the end of December, Patrys' coffers needed replenishing and a $2.4 million rights raising at 1.7 cents a share did just that.

The two-for-11 rights issue raised a net $2.4 million and was kindly underwritten by Somers & Partners.

As it happened the corporate financier didn't need to do much for its fee, because the offer - struck at a 19 percent discount - was 45 percent over-subscribed.

These investors were on the money: Patrys shares doubled to 4.4c after February's blood-brain breakthrough and last time we looked they were holding that level.

Over time, the shares have traded as high as 32 cents in March 2008 and as low as half a cent last August.

"I'm delighted the share price is starting to reflect the true value of the company," Dr Campbell says.

Patrys investors include Mike Stork, of the Canadian tech investor Stork Holdings and Dr Dax Marcus Calder - a Perth periodontist with a passion for immunology who has supported the company since its early days.

**Dr Boreham's diagnosis:**

It's well-known in big bad biotech land that only a fraction of early clinical programs get anywhere near commercialization.

Thus, the $40 million market cap has to be seen as a funny money bet and we wouldn't advise hanging around for a short-term dividend.

That said, the prawns are running M&A wise.

Late last year Johnson & Johnson bought antibody play Zymeworks for $US282 million, while in July 2016 Celgene acquired the early-stage Jounce for $US2.6 billion.

After Merck's $500 million offer for our own mid-stage immuno-oncology play, Viralytics, anything can happen.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Given Patrys actually means 'partridge' in Afrikaans, he can only assume it's a grouse company.***

# BIOTECH DAILY EDITORIAL: SOMETHING IS ROTTEN IN OPTISCAN

To lose one senior management team member could be seen as an accident, but to lose six, including the key inventor and head of research and development as well as the chief executive officer who apparently turned the company around, does appear to be carelessness (apologies again to Oscar Wilde).

Biotech Daily has never seen a staff revolt against a board (except for one director) in 12 years of publication.

For the board to claim that it's business as usual, having loss its entire top shelf is like a whiskey bar claiming the same.

Could I have a Glenmorangie?

We have Carlton Light.

How about that Tasmanian whiskey?

We have Boag's Light.

What about … oh don't bother.

Given that the Ian Mann group, which has called for the removal of all four other directors says on its www.saveoptiscan.com website that it has the support of both the senior management team and the major customer Carl Zeiss, the logical thing would be for the other four directors: chairman Alan Hoffman and directors Peter Frances, Dr Ian Griffiths and Dr Philip Currie to take note of the writing on the wall and resign.

Biotech Daily is not aware of the root cause of the management revolt, but it is clear that there is a very serious problem. One that the board should have disclosed.

We believe that Optiscan has one of, if not the, best confocal microscopes with a vast range of applications. We didn't promote the company into the Top 40 lightly.

The Dr Boreham Crucible describes the journey the company has made from biotech doyen Leon Serry discovering inventor Peter Delaney to the Archie Fraser recovery.

We were shocked by Mr Fraser's sudden departure in January and moreso at developments this month.

We are unaware of the history of the second group of dissenting shareholders associated with Graeme Mutton, but that group does not appear to have the support of the senior management team and the major customer.

If readers will pardon a sports analogy, when the team walks off the field because they can't work with the coach and his or her assistants, one might consider replacing the coach rather than the team.

**David Langsam, Editor**

## PSIVIDA

Psivida says it expects to raise $US65 million, take a loan of $US20 million, buy Icon Bioscience for its Dexycu, rebrand as Eyepoint Pharmaceuticals and delist from the ASX.
Psivida said it would acquire the Newark, California-based Icon Bioscience for its dexamethasone intraocular suspension, or Dexycu, which was the first long acting intraocular product approved by the US Food and Drug Administration for the treatment of post-operative inflammation in the eye.
The company said the Palo Alto, California-based Essex Woodlands Healthcare Partners and an unnamed investor would invest up to $US60.5 million ($A78.95 million) and the Dallas, Texas-based SWK Holdings would provide up to $US20 million ($A26.1 million) in debt financing.
Psivida said the funds would be used for the Icon acquisition and the US launches of Dexycu and, pending approval, Psivida's Durasert micro-insert for treatment of non-infectious posterior segment uveitis, expected by July 2019.
Psivida chief executive officer Nancy Lurker said the change of name to Eyepoint Pharmaceuticals would "reflect the tremendous progress we've made and embody the momentum at Eyepoint".
Psivida said that its ASX shares would be suspended from April 30 and delisted and removed from the ASX on May 7, 2018 because of a "significant decrease in the proportion of the company's common stock held by Australian shareholders, low trading activity and the costs of maintaining the listing".
The company said Essex Woodlands director Ron Eastman had been appointed as a Psivida director.
Ms Lurker said that "today's announcements significantly accelerate the transformation of Psivida into a specialty biopharmaceutical company with the potential to launch two ophthalmic products in the first half of 2019".
"Our goal is to establish Eyepoint Pharmaceuticals as a leader in developing and launching innovative ophthalmic products in indications with high unmet medical need to improve the lives of patients with serious eye disorders," Ms Lurker said.
Psivida said MTS Health Partners was its financial advisor, Toreo Partners was its debt advisor, Hogan Lovells was its legal advisor and Danforth Advisors was its corporate finance advisor.
Psivida was up one cent or 0.6 percent to $1.61.

## CYCLOPHARM

Cyclopharm says it has recruited and imaged the first 40 of up to 240 patients in its phase III trial of Technegas for lung imaging.
The company said the trial for US Food and Drug Administration approval to market and sell Technegas in the US would be conducted at 10 to 15 locations in the US.
In 2016, Cyclopharm said the FDA had approved a special protocol assessment for a phase III trial comparing Technegas with Xenon-133 (BD: Nov 23, 2016).
Cyclopharm director James McBrayer said the achievement was a "significant milestone, in line with our previously announced timeline [and] demonstrates that we remain on track to submit our first 40 patient interim study to the US FDA in the current half year".
"This first 40 patient interim study was agreed to by the FDA to establish the trial's effectiveness… [and] will also provide Cyclopharm the opportunity to engage with the FDA to review, refine and improve the trial's protocol which may accelerate the overall rate of recruitment," Mr McBrayer said.
Cyclopharm fell half a cent or 0.4 percent to $1.185.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION
BHP BILLITON FOUNDATION
THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Commonwealth Scientific and Industrial Research Organisation says the Walter and Eliza Hall Institute's Dr Misty Jenkins has won a $20,000 indigenous STEM award.

The CSIRO said that the awards were funded by the BHP Billiton Foundation and delivered by CSIRO, recognizing the achievements of Aboriginal and Torres Strait Islander students, teachers and scientists, with a view to inspiring more Aboriginal and Torres Strait Islander student participation in science, technology, engineering and mathematics (STEM) studies and careers.

The Organisation said that Dr Jenkins won the $20,000 Professional Career Achievement Award.

CSIRO said that Dr Jenkins was a cancer researcher and Gunditjmara woman and was the first indigenous Australian to attend Oxford and Cambridge Universities as a postdoctoral fellow.

The Organisation said that Dr Jenkins was "a passionate advocate for building the STEM literacy of Aboriginal and Torres Strait Islander students".

"It is important to have role models because you can't be what you can't see," Dr Jenkins said.

"By being visible, you are showing students that STEM is a viable career and that you can discover things that have never been discovered before," Dr Jenkins said.

"I see a lack of indigenous voices at the table across the industry and I want to see more Aboriginal and Torres Strait Islander people involved," Dr Jenkins said.

""It is essential to have an Aboriginal and Torres Strait Islander cultural lens applied to western science, just like it is important to have others with diverse backgrounds and genders in senior positions in our workplaces," Dr Jenkins said.

"This breadth and depth of diversity is what is going to drive innovation," Dr Jenkins said.

CSIRO said that Kamilaroi man and founder of Brisbane's Barayamal, Dean Foley, won the $20,000 Early Career Professional Award.

The Organisation said that Barayamal was an indigenous-owned and managed charity that assists Aboriginal and Torres Strait Islander entrepreneurs through coding programs for young people, mentoring and workshops.

The CSIRO said that the $5,000 Tertiary Undergraduate Student Award was won by the University of Western Australia's Shailyn Isaac;

the Secondary Student Awards of a trip to the US for the International Science and Engineering Fair went to Kayla Pattel at Tullawong State High School, Caboolture and Jessica Storrar at Gungahlin College, Canberra;

the $10,000 School Award was given to Wiluna Remote Community School in Western Australia;

the $5,000 Teacher Award was won by Camila Zuniga-Greve of the Heatley State School in Townsville;

the $5,000 STEM Champion Award was given to Fifi Harris of Leonora District High School, Leonora, Western Australia;

the Aboriginal and Torres Strait Islander Student Science Award worth $1,250 each was won by Boyden George of Leonora District High School and Willow Wells of Thuringowa State High School, Townsville, Queensland;

and the $1,250 Aboriginal and Torres Strait Islander Student Maths Award was won by Angela Barely and Russell Sands of Innisfail State College, Innisfail.

## MESOBLAST

Mesoblast says it has completed enrolment in its 404-patient phase III trial of MPC-06-ID in patients with chronic low back pain due to degenerative disc disease.

Mesoblast said that in the randomized, placebo-controlled trial, patients received a single intra-discal injection of its mesenchymal precursor cell product MPC-06-ID to determine whether it could alleviate pain and improve function in patients who did not receive adequate relief from current standard of care therapies such as non-steroidal anti-inflammatory drugs, epidural steroid injections or opioids.

The company said the US Food and Drug Administration-agreed primary endpoint specified the use of a composite measurement showing significant clinical improvement in pain and function at 12 months and 24 months, pre-specified thresholds for determining significant improvement in pain, with patients who had additional interventions at the treated level considered treatment failures.

Mesoblast said that a 100-patient, phase II trial showed that a single intra-discal injection of MPC-06-ID alleviated pain and improved function for up to three years in patients whose symptoms were not adequately treated with current standard of care therapies (BD: Mar 15, 2017).

Mesoblast fell two cents or 1.3 percent to $1.49 with 1.5 million shares traded.

## KAZIA

Kazia says it has begun its phase II trial of GDC-0084 for patients newly-diagnosed with glioblastoma multiforme or brain cancer, with a focus on dose optimization.

Kazia said the study's first site was the Stephenson Cancer Center at the University of Oklahoma and that screening of patients would begin after the Easter holiday.

The company bought GDC-0084 from Genentech in 2016 and in 2017 the then Novogen said it planned to recruit 200 patients (BD: Oct 31, 2016; Apr 10, 2017)

Kazia was up 1.5 cents or two percent to 75 cents.

## SUDA PHARMACEUTICALS

Suda says a German court has dismissed its appeal regarding a judgement in its case against HC Berlin Pharma AG.

Suda said that there were no written findings from the court and that its directors were not in a position to "finalize the next step in the process" until the written judgement and legal clarification had been received.

The company said it anticipated that a further appeal would be lodged.

In 2016, Suda said it had rejected a $6.15 million statement of claim in relation to a lawsuit against HC Berlin Pharma AG (BD: Jun 3, 2016).

Suda fell 0.1 cents or 6.7 percent to 1.4 cents with 8.6 million shares traded.

## INVION

Invion 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 186.7 percent from 1.5 cents on March 15 to 4.3 cents today, March 29, 2018 and noted a "significant increase" in the volume of the company's shares traded.

Invion closed up 0.4 cents or 12.5 percent to 3.6 cents with 89.1 million shares traded.

## MGC PHARMACEUTICALS

MGC says that with interim good manufacturing practice (GMP) certification, it has begun European production of its first batch of Cannepil for epilepsy.
Last year, MGC said it had a cannabis extraction facility in Solevnia (BD: Apr 10, 2017).
Today, the company said the first batch of Cannepil was “a major milestone” with analysis and validation to follow within a few weeks.
MGC said that once full certification was granted full-scale commercial production of Cannepil would begin and it would be able to produce additional pharmaceutical grade medical cannabis for use in clinical studies, research pipelines and additional medical products licenced for distribution.
The company said it expected to generate revenue of more than $1 million a year from fewer than 100 registered Australian patients or more than $10,000 per course per year.
MGC was up 0.2 cents or 2.4 percent to 8.6 cents with 8.0 million shares traded.

## ESENSE LAB

In answering a series of ASX queries, Esense says that its general operations, including research, development, sales and marketing, have continued.
Esense told the ASX that despite Dr Brendan de Kauwe being able to veto payments, it had reached an agreement with him and the National Australia Bank to “pay a specified amount based on a payment list … [including] salaries and wages up to March 2018”.
The board told the ASX that it had ordered a change to the finance signatories which it claimed Dr de Kauwe ignored.
The company said it had a total of $US2.425 million ($A3.169 million) in various company bank accounts, of which $US2.075 million ($A2.712 million) was held in its NAB account and $US165,192 ($A215,915) in a security deposit in an Israeli bank account.
Esense said it had outstanding creditors which it was “hoping to pay” after today’s annual general meeting and extraordinary general meeting when its board was finalized and Dr de Kauwe was removed as a signatory on the company’s NAB bank account.
The ASX asked if Esense had reported the allegations against Dr de Kauwe and Dr de Kauwe’s allegations against the board to the relevant corporate regulator in Israel.
The company said that it was “not a ‘reporting company’ under Israeli laws and was not required to make any report or announcement to any regulatory body in Israel.
In a separate final director’s interest notice today, Esense said that director Quentin Megson had ceased to be a director as of March 29, 2018.
In a response to a second ASX query, the company said that auditors BDO Israel would prepare a report that would be provided to ASX on the outcome of the voting at the annual general meeting and the extraordinary general meeting today.
Esense was in an ASX suspension and last traded at 16.5 cents.

## MAYNE PHARMA

Investors Mutual says it has increased its substantial holding in Mayne from 113,984,705 shares (7.44%) to 129,178,674 shares (8.47%).
Investors mutual said that registered holders included Sandhurst Trustees, Citicorp Nominees, JP Morgan State Super, State Street and RBC Global Services Australia.
The company said it bought and sold shares between August 18, 2017 and March 26, 2018, with the single largest purchase on December 7, 2017 of 1,410,000 shares for $891,261 or 63.21 cents a share.
Mayne fell half a cent or 0.7 percent to 74 cents with 8.5 million shares traded.

## MEDLAB CLINICAL

Mitsubishi UFJ Financial and Morgan Stanley say they have become substantial shareholders in Medlab with 12,466,662 shares (5.99%).
The Tokyo, Japan-based Mitsubishi UFJ Financial and New York and Sydney-based Morgan Stanley filed similar substantial share-holder announcements saying that in a large number of trades between November 29, 2017 and March 26, 2018 they bought shares and received collateral, with the single largest purchase 6,384,903 shares for $4,054,413 or 63.5 cents a share.
Medlab fell three cents or 4.8 percent to 60 cents.

## RHINOMED

Melbourne-based Dr John McBain says he has become a substantial shareholder in Rhinomed with 6,450,667 shares (5.48%).
The substantial shareholder notice, in the name of Thirty-Fifth Celebration and signed by director Dr McBain, said that between January 30 and March 23, 2018 it bought 2,450,667 shares for $251,935 or 10.28 cents a share.
Rhinomed was up one cent or 8.3 percent to 13 cents.

## ONCOSIL MEDICAL

The Brisbane-based Webinvest says it has been diluted in the recent Oncosil from 28,600,000 shares (6.11%) to 31,100,000 shares (4.62%).
In the substantial shareholder notice, Webinvest director Otto Buttula said that he had made commitments on March 28, 2018 to purchase 2,500,000 shares for $300,000 or 12 cents a share in a share purchase plan, and had been diluted below the five percent substantial shareholder level “due to [the] placement size.
Oncosil was up half a cent or four percent to 13 cents.

## IDT AUSTRALIA

IDT says that director Reo Shigeno will resign as a non-executive director, effective from March 31, 2018.
IDT was up 0.1 cents or 1.3 percent to eight cents.