# Biotech Daily

Friday April 7, 2017

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market edged up 0.11 percent on Friday April 7, 2017 with the ASX200 up 6.2 points to 5,862.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and two were untraded.

Actinogen was the best, up 0.6 cents or 9.4 percent to seven cents with 2.8 million shares traded.

Both Dimerix and Oncosil climbed 8.3 percent; Psivida was up 4.5 percent; Cellmid improved 3.2 percent; Opthea and Uscom rose more than two percent; Atcor, Medical Developments, Pharmaxis, Pro Medicus and Reva were up more than one percent; with Cochlear, CSL and Ellex up by less than one percent.

Factor Therapeutics led the falls, down 0.6 cents or 8.8 percent to 6.2 cents with 922,482 shares traded.

Benitec, Bionomics, Orthocell and Prana fell four percent or more; Avita, Cyclopharm, Living Cell and Mesoblast were down more than three percent; Impedimed shed 2.6 percent; Acrux, Admedus, Airxpanders, Nanosonics, Sirtex and Viralytics were down more than one percent; with Resmed down 0.5 percent.

# DR BOREHAM'S CRUCIBLE: OPTHEA

By TIM BOREHAM

**ASX code:** OPT

**Market cap:** $235 million***; Share price:** $1.175; **Shares on issue:** 200,045,175*****

**CEO:** Dr Megan Baldwin

**Board:** Geoff Kempler (chairman), Dr Megan Baldwin, Michael Sistenich

**Financials** (2016-'17 first half):** revenue $179,731 (up 65%), loss $2.297 million (up 32%), cash $13.14 million (down 9%)

**Shareholders**:** Biotech Value Fund 18%, Baker Brothers NY 9%, Packer & Co 8.5% (but ceased being substantial holder this month)

***** Including this week's $42 million institutional raising, but not the $3 million retail offer.
****** Not including this week's capital raise

When the eye diseases house entered its trading halt last Thursday, management hinted at positive clinical results by also flagging a "potential" capital raising.

As it happened, the hint understated the outstanding success of the phase I/IIa results for Opthea's ophthalmic disease therapy, OPT-302. We don't use the superlative "outstanding" lightly because that's what the market - the ultimate arbiter - thought of the outcome.

Seizing the day, the company passed around the fedora for around $45 million, $42 million by way of an institutional placement and entitlement offer and an estimated $3 million through a retail raising.

The offer was priced at 93 cents, a 15 percent premium to the closing price ahead of last Thursday's trading halt. Resuming trade on Wednesday this week, the shares bounded 34 percent (to $1.09) - an unusual reaction to an equity raising.

So what's all the fuss about?

A so-called vascular endothelial growth factor (VEGF) receptor, OPT-302 binds on to the VEGF proteins that cause wet age-related macular degeneration (wet AMD).

A leading cause of blindness globally, wet AMD is loss of vision caused by degeneration of the central part of the retina (the macula). This is caused by abnormal growth of blood vessels and leakage of fluid and protein from the vessels.
OPT-302 is a soluble form of the receptor VEGFR-3, which inhibits VEGF C and D.

The two current drugs Eylea and Lucentis tackle the troublesome VEGF-A, but not the variants VEGF-C and VEGF-D.

“Our plan is to address the unmet medical need that remains for wet AMD patients,” Opthea says. “Approximately half of the people receiving the existing therapies do not experience a significant gain in vision and/or have persistent fluid in the back of the eye.”

But if OPT-302 is combined with Lucentis, the results appear much more effective.

**Trial and (little) error:**

The trial, across 14 US sites, enrolled 51 patients (49 of which were assessable as two died for unrelated reasons), including difficult to treat and untreated, or naïve, patients.

Of the patients, 37 were treated with the OPT-302-Lucentis combo, with 12 treated with OPT-302 alone. Overall, 44 patients gained or maintained vision after 12 weeks.

That’s a pass rate of 90 percent, which in Dr Boreham’s schooldays was enough for an elephant stamp.

Of the 19 previously treated patients, all of them gained or maintained vision.

That’s dux of the biotech class stuff.

Among the 12 monotherapy patients, nine gained or maintained vision.

That’s 75 percent, or enough to be spared the cane for a week or so.

Sadly, five patients (10%) recorded further loss of vision.

They’re the students told by the posh school their educational outcomes would be enhanced in a more practical learning environment (the local tech).

The improvement was measured by “visual acuity outcomes”, which in Malcolm Turnbull’s pub test terms meant the patients could read smaller letters on an eye chart than previously.

**Coming up:**

According to Opthea, the dosh raised will fund three more studies and fund the company until mid-2020.

The biggest by far is a $35 million randomised 350-patient phase IIb wet AMD study, comparing the Lucentis plus OPT-302 combo with Lucentis alone. Another study with yet to be defined parameters will enrol only previously-treated wet AMD patients.

Surprisingly, Opthea is also launching a 90-patient study on the use of OPT-302 for diabetic macular oedema (DME), a condition that also involved retinal leakage.

Dr Baldwin says DME affects a younger, working age demographic and is about half to two-thirds the size of the wet AMD market.

**A chequered history:**

Did you know that Opthea is the renamed iteration of Circadian Technologies, which is the oldest ASX-listed biotech, founded by bio-doyen Leon Serry AO?

It has been described as “an incubator”, investing in companies including the Victoria State-founded Amrad, later renamed Zenyth and sold to CSL, chief scientist Dr Alan Finkel’s Axon, sold to California’s Molecular Devices for $140 million in 2004, along with Antisense, Avexa, Metabolic, Optiscan and Syngene.

Save that one for the school quiz night.

Circadian dabbled in a number of applications, including melatonin for jet-lag (hence the name), drugs for Alzheimer’s and cancer and cancer diagnostics, before deciding to focus on eye ailments.

After a board cleanout in 2015 that saw the departure of three long-serving directors, Opthea boasts a tight three-person board which is sure to save costs and ensure debate is wrapped up by recess time.

Opthea is a well-owned biotech: before the raising the top 10 holders accounted for 69 percent of the register while institutions owned 79 percent of the stock.

**Dr Boreham’s diagnosis:**

As a guide to the size of the prize, Lucentis and Eylea turn over $US8.5 billion globally.

The cancer drug Avastin, used as an off-label cheaper alternative, accounts for even more than that.

There’s a healthy precedent in that Psivida (ASX: PVA) successfully licenced its delivery treatment for DME and posterior uveitis (nothing to do with bottoms but an inflammatory eye disease and also a leading cause of blindness).

Top-line results from the wet AMD trial are due in 2010 and the DME results by 2018, which is a nanosecond in the context of the planet’s evolution.

While it’s nice to see Opthea with a sharp focus on the one drug, there’s little for the company to fall back on if OPT-302 fails to shine.

We’ll “see”.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is a true visionary when he can find his glasses, which is not often.***

## SUDA

Suda says it has raised $1.5 million through an underwritten “oversubscribed” placement at two cents a share.
Suda said the funds would be used to develop and commercialize its Oromist drug delivery technology, its pipeline of oral sprays, including Zolpimist for insomnia, a proof-of-concept trial of SUD-003 sildenafil oral spray for erectile dysfunction and working capital.
The company said that the Perth Western Australian RM Corporate Finance was the lead manager and underwriter to the placement.
Suda fell 0.1 cents or 4.35 percent to 2.2 cents with 3.6 million shares traded.

## FACTOR THERAPEUTICS

Factor Therapeutics says that recruitment is underway in its 168-patient, randomized, double-blinded, placebo-controlled, US phase II trial of VF001 for venous leg ulcers.
Factor Therapeutics said that 29 patients had be recruited so far, with 22 patients recruited since March 1, with enrolment expected to be completed by October 2017.
The company said that all 26 trial sites had been contracted by it and its partner contract research organization, Parexel International, with 21 of the specialty clinics and academic and opinion leader sites actively screening patients and the remaining five sites due to begin screening following site initiation visits by Parexel expected by mid-April.
Factor Therapeutics said that the ‘VF00102’ trial design had strict inclusion and exclusion criteria along with a screening process that built into the trial protocol.
The company said that where there was evidence of spontaneous healing or severe deterioration during the screening period, the patient did not proceed in the study.
Factor Therapeutics said there was “very little competition for patients across our trial network and many sites are reporting healthy numbers of patients in backlog”.
Factor Therapeutics chief executive officer Nigel Johnson said his company and Parexel had “has worked tirelessly over the last quarter to get 26 sites active”.
“While a handful of sites to date have contributed the majority of patients to the study, this is expected to change as we complete the remaining [site initiation visits] this month,” Mr Johnson said.
Factor Therapeutics fell 0.6 cents or 8.8 percent to 6.2 cents.

## AVITA MEDICAL

Avita says the US Food and Drug Administration had allowed 20 more compassionate use program patients for its Recell wound injury treatment.
Avita said the FDA had approved the fourth and largest expansion of the compassionate use program allowing treatment of up to 68 patients with insufficient healthy skin for standard skin grafting treatment and increasing the number of hospitals from 15 to 18.
Last year, the FDA provided several compassionate use expansions allowing up to 48 patients at 15 hospitals under the continued access protocol for the Recell spray-on skin autologous cell harvesting treatment (BD: Oct 19, 2016).
Avita chief executive officer Adam Kelliher said the company was “pleased to receive this compassionate use expansion, which we think underscores both the necessity of our product for treating life-threatening burns and the growing interest within the US burns community”.
Avita said it expected to submit its clinical and non-clinical data package in mid-2017, with an anticipated FDA approval by July 2018.
Avita fell 0.3 cents or 3.1 percent to 9.5 cents with 1.8 million shares traded.

## MACH7 TECHNOLOGIES

Mach7 says it has completed its unmarketable parcel sale facility with 1,370 investors holding 308,608 shares selling their shares at 28 cents a share.
Mach7 said that prior to the conclusion of the facility it had 3,050 shareholders and following settlement would have 1,670 shareholders.
The company said that its shareholder base had been reduced by almost half, significantly reducing administrative costs.
Mach7 was up two cents or 7.1 percent to 30 cents.

## SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster (STC) says Victoria start-up Hemideina has won the $40,000 Medtech's Got Talent competition for its an internalised hearing device.
STC said that Hemideina's Elizabeth Williams and Kate Lomas developed "the first major innovation to the cochlear implant in decades, achieving internalisation that dramatically improves patient quality of life" using research spun-out from New Zealand's University of Auckland.
STC said that from more than 100 applicants, Hemideina was selected as the most investible team.
STC said that by internalising the hearing device, Hemideina would remove existing lifestyle restrictions and aimed to produce a lower cost cochlear implant and was preparing to enter clinical testing.
STC said that Medtech's Got Talent was primarily supported by the Victorian Government through the Department of Economic Development, Jobs, Transport and Resources, with assistance from the Federal Government's Department of Industry, Innovation, and Science, MTP Connect, Medtronic, Minifab and Johnson & Johnson.

## MEDICAL TECHNOLOGIES AND PHARMACEUTICALS GROWTH CENTRE

MTP Connect says Australia's National Digital Health Initiative will "facilitate and support the development and commercialization of clinically validated digital health".
The Medical Technologies and Pharmaceuticals Industry Growth Centre, or MTP Connect, said that the Initiative, to be known as AND Health, would be an industry body for companies working in digital and connected medical technologies and was funded through the MTP Connect Project Fund Program.
MTP Connect said that AND Health was established by a consortium of commercial partners, led by the Murdoch Children's Research Institute.
MTP Connect said that Bioscience Managers executive and former Adherium head of commercial development and company secretary Bronwyn Le Grice had been appointed AND Health managing director (BD: Apr 22, 2016).
"AND Health has been created to foster innovation and commercialization … by working with mid-stage digital health projects on proof-of-concept and pivotal clinical trials and validation, investment readiness and market entry, with a specific focus on regulated digital health technologies which have a clear impact on clinical outcomes for patients," Ms Le Grice said.
MTP Connect said that AND Health would expand its team and run a one-day digital health summit with Ausbiotech on May 23, 2017.
MTP Connect said that there would be a call for projects at the end of May and for more information go to: www.andhealth.com.au.

## IMMURON

Immuron says it has appointed Prof Ravi Savarirayan as a non-executive director, effective from April 1, 2017.

Immuron said that Prof Savarirayan was a consultant clinical geneticist at the Victorian Clinical Genetics Services, as well as professor and research group leader at the Murdoch Children's Research Institute both located at Melbourne's Royal Children's Hospital.

The company said that Prof Savarirayan was a founding member of the Skeletal Dysplasia Management Consortium and had been the chair of the Royal Australasian College of Physicians specialist advisory committee in clinical genetics since 2009 and president of the International Skeletal Dysplasia Society from 2009 to 2011.

Immuron said that Prof Savarirayan's primary research focus was on inherited disorders of the skeleton causing short stature, arthritis and osteoporosis and had published more than 150 peer-reviewed articles and was on the editorial board of Human Mutation, European Journal of Human Genetics, American Journal of Medical Genetics and the Journal of Medical Genetics.

The company said that Prof Savarirayan held a Bachelor of Medicine and a Bachelor of Surgery from the University of Adelaide and a Doctorate in Medicine from the University of Melbourne.

Immuron was up one cent or 2.5 percent to 40.5 cents.