



# Biotech Daily

Friday May 19, 2017

*Daily news on ASX-listed biotechnology companies*

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- \* **CRYOSITE LOSES CEO ANDREW SHINE, JOB OPEN**

## MARKET REPORT

The Australian stock market fell 0.19 percent on Friday May 19, 2017 with the ASX200 down 10.9 points to 5,727.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and three were untraded.

Dimerix was the best, up 0.15 cents or 20 percent to 0.9 cents with 14.0 million shares traded, followed by Sirtex recovering 9.5 percent to \$11.77 with 3.15 million shares traded.

Compumedics climbed 6.8 percent; Factor Therapeutics and Opthea were up more than three percent; Avita, Cyclopharm and Mesoblast rose more than two percent; Ellex, Neuren and Osprey were up more than one percent; with Airxpanders, Clinuvel, Cochlear, CSL, ITL, Nanosonics and Pro Medicus up by less than one percent.

IDT led the falls, down one cent or 7.7 percent to 12 cents with 665,618 shares traded.

Atcor lost 6.8 percent; Bionomics and Living Cell fell more than four percent; Medical Developments, Orthocell and Viralytics were down more than three percent; Impedimed, Polynovo and Psivida shed more than two percent; Acrux lost 1.9 percent; with Resmed down 0.44 percent.

## DR BOREHAM'S CRUCIBLE: MEDICAL DEVELOPMENTS INTERNATIONAL

By TIM BOREHAM

**ASX Code:** MVP

**Market cap:** \$273 million

**Share price:** \$4.62

**Shares on issue:** 58.98 million

**Chief executive officer:** John Sharman

**Board:** David Williams (chairman), Max Johnston, Allan McCallum, Dr Harry Oxler, Leon Hoare, Philip Powell.

**Financials (December half 2016):** revenue \$8.05 million (up 34%), net profit \$410,000 (up 74%), Ebit \$540,000 (up 70%), earnings per share 0.71 cents (up 73%), interim dividend 2 cents per share (steady), cash \$5.5 million (down 42%).

**Major shareholders:** David Williams 30.3%, HSBC Custody Nominees 5.75%, JP Morgan Nominees 5.08%, RBC investor Services 3.2%, Dr Russell Kay Hancock 2.5%

If there's ever a more stunning case of an Australian biotech commercialising an old technology, please write in on a parchment with an old-fashioned fountain pen.

More commonly known as the Green Whistle, Medical Developments' lead product Pentrox has been used in ambulances here since 1975, when Gough still ruled the land (okay, only just).

What's changed is that as medical authorities have become more averse to opioids given the addiction issues, there's more appetite for the fast acting non-narcotic analgesic that the Green Whistle is.

The story to date is that Medical Developments has penetrated the UK and Irish markets, where it has product approval and a distribution tie-up with the pharma giant Galen.

In March, Galen lodged a re-order which, while unquantified, was meaty enough for the company to be "buoyed by the size of the order and its timing".

The company also began selling in France and Belgium in February this year.

In April, the company then signed up JSC Lancet to distribute Pentrox in Russia. The deal involves a \$2.3 million milestone payment and Lancet bears the regulatory approval costs -- which is nyet bad at all.

Lancet estimates sales of two million units among a populace of 143 million. And don't the Rusks know pain ...

The company aims to sell Pentrox into 40 countries by 2019, including the similarly pain-ridden Iraq, Iran and Jordan.

But the next major step is to launch in the US, where the denizens are coping with a different pain (the one in the White House\*). Further trials are likely to be needed to affirm Pentrox's street cred.

Apart from geographic expansion, there's also wider scope for the use of Pentrox in minor surgical procedures, military use, the home first-aid kit and developing world aid programs.

The company recently chirped that Galen achieved record sales in the UK in January, with 38 hospitals ordering or using Pentrox. A number of ambulance trusts are also appraising Pentrox, but it's interesting that more demand is coming from the centres of healing rather than what our American friends would term the 'first responders'.

While Pentrox is non-addictive and fast active, ambulance sources tell us it has one bizarre side effect: a temporary boost to the libido of female (but not male) patients.

One can only ponder the potential for off-label use as a female version of Viagra in which case the company should be worth \$275 billion and not \$275 million.

### **Asthma pumps up the story**

So as not to be accused of being a one trick pony, Medical Developments has also rolled out a number of asthma pumps to improve the delivery of asthma and chronic obstructive pulmonary disease medications.

The core product, Space Chamber, recently won US FDA approval. What's more, US retailers Walmart, Kmart and Costco have agreed to stock the product in their drugstores, as well as the chemist chains Independent Pharmacy Group and Price Chopper.

Collectively these deals provide reach to more than 8,000 outlets, bearing in mind that chemist ownership rules are more liberal over there.

### **Hockey stick growth**

Medical Developments recorded half-year revenue of \$8.05 million, up 34 percent with earnings rising 74 percent to \$410,000.

The company has been profitable every year since listing in 2003, when John Howard ruled the land (and Peter Costello wished he could have a turn).

Pentrox delivered sales of \$4.03 million, up 24 percent on the year while the asthma devices contributed \$2.84 million (up 103%). The company earned \$886,000 in milestone and licence payments as well as \$294,000 in veterinary anaesthesia and spacers.

But for the time being at least, Pentrox delivers most of the profits: earnings before interest taxation depreciation and amortization (Ebitda) of \$2.237 million, compared with \$54,000 for the devices.

Despite the overseas push, 66 percent of revenue still derives from Australia but this was down from 75 percent a year ago.

While management doesn't regard the asthma devices as second string products, Pentrox will drive short-term financial performance.

Bell Potter estimates the devices will chip in \$1.3 million of the company's forecast Ebitda of \$5.2 million in 2016-'17, increasing to \$2.9 million of \$7.7 million in 2017-'18.

The company received \$18.5 million in milestones and up-fronts from its various partners over the last 15 months and expects a further \$7 million to be received over the next 18 months.

The banks must hate Medical Developments, because it has cash of around \$5 million and negligible debt.

### **Dr Boreham's prognosis:**

The stock has run hard, from \$2 two years ago to peak at \$6.85 last May. The current valuation puts the company on an earnings multiple of well over 100 times.

Unusually, the company paid a 4 cents a share dividend in 2015-'16 and should do again this year after paying out 2 cents a share as an interim dividend.

Bell Potter estimates peak net sales of \$248 million in Europe (excluding Russia), assuming 30 percent penetration and forecasts peak sales of \$332 million in the US, also with 30 percent market share but ascribes only a 50 percent chance of success.

"Progress of development on Pentrox towards launch in the US may lead to an upside in our valuation," says Bell Potter.

We reckon the company needs a successful US launch to justify its valuation, while asthma spacer sales also need to leave investors gasping with delight.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort.***

***\*Political comment contained within is spoken and authorised by a no-liability company created for negative gearing purposes.***

## AUSCANN GROUP HOLDINGS

Auscann says it has raised \$12 million in a placement at 50 cents a share to institutional and high net worth investors

Auscann said the placement, managed by Merchant Corporate Advisory, was at a 16 percent discount to the 5-day volume-weighted average price.

The company said that strategic partner, the Smiths Falls, Ontario-based Canopy Growth Corp, participated in the placement maintaining its holding at about 11 percent, with “strong interest from a range of other institutional investors including ... Australian fund manager Tribeca Investment Partners”.

Auscann said the funds would support its partnership with Tasmanian Alkaloids, progress development of its Western Australia cultivation facility and advance development of its activities in Chile with joint venture partner Dayacann and expand its outreach activities to the Australian medical community.

Auscann fell half a cent or 0.9 percent to 57.5 cents with 1.1 million shares traded.

## MEMPHASYS

Memphasys says it has engaged the Melbourne-based Hydrix as its Spermsep device partner to develop prototype cartridges for the next generation device.

Memphasys said that the prototype miniaturised cartridges were redesigned with new bio-compatible Memphasys membranes with reformulated, disposable buffers and a new, simplified and cheaper flow configuration for improved viable sperm harvest.

The company said the cartridges would process greater volumes of semen to 1.8ml, a three-fold increase from the current processing volumes, providing a larger quantity of viable sperm, for a range of assisted reproductive treatments including in-vitro fertilisation and intra cytoplasmic sperm injection as well as and potentially for the large untapped intra uterine insertion market.

Memphasys said that five reusable cartridges would be produced for this next developmental stage to enable multiple testing at minimum cost.

The company said that the membranes, buffers and semen samples would be changed between uses and the prototypes were expected by August, 2018.

Memphasys said that following internal testing, the cartridges would be tested by its scientific research and commercialization collaborators including the University of Newcastle, Monash IVF, Westmead IVF and the University of New South Wales, with feedback expected by October 2017, to refine the final product.

University of Newcastle head of reproductive medicine and Memphasys advisory board Prof John Aitken said that with the engagement of Hydrix “we are now in an extremely powerful position to develop prototype instruments for clinical assessment by the [assisted reproductive treatments] industry”.

“This constitutes a giant leap forward in our capacity to bring this novel cell separation technology to market,” Prof Aitken said.

Memphasys said that it was applying the same technology to animal reproduction and would use one of the cartridges, with some modifications, for testing on fresh bovine and equine semen in collaboration with the University of Newcastle.

The company said that development of the first five cartridges would be “a crucial step towards development of the final, fully disposable cartridges”.

Memphasys said that Hydrix would be issued up to 5,000,000 shares, pending shareholder approval and it was pursuing patent protection for the new cartridge design and the membrane.

Memphasys was unchanged at 0.2 cents with 1.3 million shares traded.

## BOTANIX PHARMACEUTICALS

Botanix says it has completed the second tranche of its \$7.4 million placement at 5.5 cents a share (BD: Apr 5, 2017).

Botanix said the first tranche raised \$5.4 million, with the second tranche approved by shareholders and raising \$2 million.

The company said the funds would be used for its product development programs, commercialization of the Permetrex delivery technology, to accelerate its US phase II cannabis acne dermatology program and advance products in dermatitis and psoriasis. Botanix was unchanged at five cents.

## TBG DIAGNOSTICS

TBG says the American Society for Histocompatibility and Immunogenetics has accredited its Xiamen, Fujian, China facility.

TBG said that the Society accreditation was specific to transplant laboratories and the reports could be accepted internationally and its Taiwan facility already had the approval. The company said that accreditation ensured that the Xiamen facility produced results recognized as high-quality.

TBD said that the accreditation followed a program evaluating personnel, procedures, facility presentation and clinical services and supported its aim to be the leading supplier of human leukocyte antigen (HLA) products and services in Asia.

The company said that Xiamen was one of China's five special economic development zones and a key industry area to showcase Chinese technology

TBG said the Xiamen facility opened in July 2016 and was building on its core technologies of in-vitro diagnostic-related nucleic acid testing kits to include infectious diseases, oncology, blood screening and genetic testing.

TBG was untraded at 16 cents.

## PHARMAUST

Pharmaust says that three of four dogs in its 10-dog trial of monepantel (PPL-1) for lymphoma "achieved stable disease and reduction in tumor size" of 11 percent.

Pharmaust said the result was "the first evidence that [monepantel] is directly active against tumors in dogs, and is consistent with outcomes observed in a recent phase I human trial" (BD: Jul 23, 2015).

The company said the primary objective of the dog trial was the efficacy of monepantel as a first line therapy in dogs diagnosed with lymphoma that had no previous chemotherapy. Pharmaust said the dogs were treated for two weeks with daily doses of monepantel as first-line therapy before conventional chemotherapy.

The company said that it expected final results by October 2017.

Pharmaust principal investigator Dr Angela Frimberger said the drug was "well-tolerated and biologically active in terms of its ability to reduce expression of clinically-relevant biomarkers".

"The dogs treated in earlier studies had late-stage cancers that had already failed standard of care treatments, which made it a challenge to try [to] interpret the clinical benefits from those earlier trials," Dr Frimberger said. "To address this, the current trial uses [monepantel] as first-line therapy in dogs diagnosed with lymphoma."

Pharmaust said that tumor volume was reduced by two to 19 percent with an average 11 percent reduction across all three dogs

Pharmaust fell 0.2 cents or 2.9 percent to 7.1 cents.

## RECCE

Recce says it has conducted a chemical analysis and structural confirmation of its lead antibiotic candidate Recce 327, including animal blood micro-detection.

Recce said the data would support its investigational new drug application to the US Food and Drug Administration.

Recce executive chairman Dr Graham Melrose said the positive micro-analysis and verification of the chemical structure and stability of its lead compound gave further support to the company's clinical strategy and moved it closer to completing the documentation required for its investigational new drug application.

The company said the tests confirmed the compound's structure, chemical stability and mode of action as outlined in its patents and manufacturing process

Dr Melrose said the next step would be to assess a toxicity study in rats.

Recce was up 1.5 cents or 7.5 percent to 21.5 cents.

## NUHEARA

Nuheara investors will vote to issue up to 20,000,000 options to Fosters Stockbroking and Hunter Capital Advisors for investor relations and corporate advisory services.

Nuheara said the options would vest on November 2, and were exercisable at 7.8 cents by November 2, 2019.

The company said that other resolutions included the ratification of placements of 83,073,383 shares and 55,000,000 shares

The extraordinary general meeting will be held in the Broderick Room, Rosie O'Grady's Irish Pub, 205 James Street, Northbridge, Perth, Western Australia on June 20, 2017 at 11am (AWST).

Nuheara fell 0.1 cents or 1.3 percent to 7.7 cents with 1.6 million shares traded.

## REPRODUCTIVE HEALTH SCIENCE

Rod Gibson says that two of his companies have increased their holding in Reproductive Health from 9,000,000 shares (11.36%) to 10,800,000 shares (13.635%).

The Redesdale, Victoria-based Mr Gibson said that Rosherville and Endeavour River bought the 1,800,000 shares on-market for \$192,987 or 10.7 cents a share.

Reproductive Health was unchanged at 15 cents.

## CRYOSITE

Cryosite says that chief executive officer Andrew Shine has tendered his resignation but will work his three month notice period to support the business and transition.

Cryosite said it would begin a search for a new chief executive officer.

Cryosite was untraded at 18 cents.