



# Biotech Daily

Friday December 6, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: ANTISENSE UP 8%; PRESCIENT DOWN 9%**
- \* **DR BOREHAM'S CRUCIBLE: MEMPHASYS**
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- \* **AUSTRALIAN ETHICAL TAKES 6% OF PALLA PHARMA**
- \* **PETERS TAKES 10% OF PAINCHEK**

## MARKET REPORT

The Australian stock market was up 0.36 percent on Friday December 6, 2019, with the ASX200 up 24.0 points to 6,707.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and four were untraded. All three Big Caps were up.

Antisense was the best, up 0.7 cents or 7.9 percent to 9.6 cents, with 1.45 million shares traded. LBT and Pharmaxis climbed six percent or more; Dimerix and Immutep were up six percent or more; Dimerix and Immutep improved more than four percent; Avita and Telix were up more than three percent; Imugene, Medical Developments, Mesoblast and Nanosonics rose more than two percent; Compumedics and CSL were up more than one percent; with Cochlear, Polynovo and Resmed up by less than one percent.

Prescient led the falls, down one cent or 9.1 percent to 10 cents, with 13.2 million shares traded. Optiscan and Pro Medicus Imugene lost five percent or more; Cynata, Next Science and Uscom fell four percent or more; Genetic Signatures, Impedimed and Neuren were down more than three percent; Actinogen, Clinuvel, Oncosil, Opthea, Osprey and Paradigm shed two percent or more; with Orthocell, Starpharma and Volpara down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: MEMPHASYS](#)

**By Tim BOREHAM**

**ASX code:** MEM

**Share price:** 5.1 cents

**Market cap:** \$37.8 million

**Shares on issue:** 740,742,415

**Financials (year to June 30 2019):** revenue \$86,612\*, loss of \$1.04 million, cash of \$873,573\*\*

**Executive chair:** Alison Coutts

**Board:** Alison Coutts, Andrew Goodall, Marjan Mikel, Shane Hartwig

**Major shareholders:** Peters Investments (Bob Peters) 27.9%, Andrew Goodall 23.4%, Alison Coutts 10.85%.

\* consists of grant and interest income

\*\* pre \$4.2 million placement

Did you know that a hard-working stallion ejaculates 100 times more sperm than the average bloke?

Given a virile, but weary, thoroughbred can service hundreds of mares in a breeding season, that's just as well.

But even the most virile of these breeders can do with a helping hand when it comes to selecting the very best of the tiddlers.

Enter Memphasys, which is commercializing a novel sperm separation device called Felix to replace the current techniques that can damage the tadpoles rather than enhance the gene pool.

The equine program bears the cute title of Far Lap, but that's a bit of a misnomer because thoroughbred artificial insemination is illegal (technically at least).

The Memphasys program is actually pitched at show horses and polo ponies, harness nags and the like.

"People pay handsomely for that sort of thing," says executive chair Alison Coutts.

The company is also working on cattle breeding and there's enough promise on the veterinary side to attract West Australian horse owner and breeder Bob Peters as a major shareholder.

"We also want to expand to other aspects of animal fertility. There are some interesting programs going on," Ms Coutts says, enigmatically.

Mr Peters says the market is probably bigger for food production animals than for humans. He notes that with cattle and sheep, natural conception is successful only around 80 percent of the time. With race horses, there's also scope for using Felix to test sperm for imperfections.

But for the time being the Memphasys emphasis is on the two-legged side of things: sperm selection for human in-vitro fertilization (IVF) procedures.

With male sperm quality declining alarmingly - one in three blokes aged over 40 are shooting blanks - humanity needs all the help it can get.

### **Not every sperm is sacred**

Formerly known as Nusep, Memphasys is getting to the pointy end of commercializing Felix, which uses electrical separation and a membrane to sort the sperm by quality and size.

'Good' sperm - the tiddlers without a double head, short tail, bent neck and other flaws - has a negative charge. The membranes work by clearing "unwanted debris" such as white blood cells.

The technology was developed in league with fertility specialist Prof John Aitken, of the University of Newcastle.

The Felix devices consist of a unit in which a cartridge containing the sample is placed.

Felix intends to replace two current sperm sorting methods. One is density grading centrifuging, which is labor intensive and costly and can cause DNA damage.

The other is a laborious process called 'swim up', which involves the strongest sperm demonstrating that they can break out of the seminal plasma and emerge as a swimmer rather than a floater.

If it all sounds rather Darwinian, you're right ...

### **A tortured path to gestation**

Originally known as Sperm Sorter, the device has gone through several iterations.

But the company's remit is basically the same since Nusep listed in May 2007 as a spin off from blood products group Life Therapeutics.

"Along the way, we have had to do a lot of engineering of the original device," Ms Coutts says.

"Some were pure economic reasons. The electrodes were platinumized titanium which cost \$40 a pair. We have replaced it with carbon printed on to a plastic."

The big difference between Sperm Sorter and Felix relates more to the company itself, with Nusep becoming a basket case after a promising start.

Five years ago, the company was rescued by Alison Coutts and Andrew Goodall.

The company's executive chair, Ms Coutts was a biotech corporate adviser who co-founded the ASX-listed mobile x-ray machine developer Micro-X.

Director Andrew Goodall left school early and founded a plant nursery in New Zealand, before successfully dabbling in property investment. "He has a sharp eye for understanding competitive advantage," Ms Coutts says.

Both are major shareholders, having tipped plenty of their own hard-earned into the company.

## **The path to approval**

Memphasys recently took delivery of the first Felix units, manufactured by WNS Plastics (the biggest maker of plastic injected moulds in New South Wales, the company also supplies Resmed).

The units are being sent to key opinion leaders - a.k.a. IVF specialists - for appraisal.

In September last year, Memphasys struck a collaboration with the ASX-listed Monash IVF, along the lines of Monash clinicians test-driving the device and providing advice.

Melbourne's Monash IVF has already suggested that the optimal sample size is one millilitre rather than 1.8 millilitres, while the cartridge should be loaded with a single rather than dual pipetting method.

Monash IVF also has first dibs on any approved and commercial instrument.

On that note, the company plans to front the local Therapeutic Goods Administration early next year with its plans for a clinical trial to support an approval application.

"We are working with Monash IVF to do a substantial number of in-vitro tests to compare with the current process," says Ms Coutts, adding the exact parameters of the trial are yet to be decided.

If the TGA says OK, Europe is next ... or maybe. Ms Coutts says the European approval process is “a bit of a menace” because of the Continent’s push to tighten device approval requirements following some mishaps with faulty breast implants.

“Even devices that are already approved need to be re-certified,” Ms Coutts says.

### **China and India need more babies ...**

But does Memphasys really need approval from fuddy-duddy regulators?

Ms Coutts confides that the company is eyeing other markets where registration may not be required at all, because the units are treated as a laboratory device in the same way a test tube is.

Ms Coutts is not letting on which countries the company has in mind. “You would be surprised,” she teases.

One aspect to this surprise is that the US is not the biggest potential market, because a lack of reimbursement means IVF procedures are stratified between the rich (NY, Boston, California) and the poor (Trump’s battlers).

The biggest markets are Japan, China and Europe (notably Germany, France and Spain).

We didn’t think the Middle Kingdom was in urgent need of more babies but China is “going gangbusters”. The company’s reference institution, Shanghai’s prosaically titled Number 9 Hospital, carries out more IVF procedures a year than the whole of Australia.

IVF procedures in China are cheaper - \$2,000 to \$3,000 a year - but are always paid out of pocket (having spent decades mandating one child only, the government doesn’t exactly shower patients with subsidies).

Japan - which has an urgent need to re-stock - is also an interesting market, if only because of the nuances ensuing from a belief that life begins only at birth.

There’s also a massive need in India, where egg donation is popular. “People really want families but they are not as particular about their genetic material,” Ms Coutts says.

A key feature of Felix is a six-minute run time, compared with at least half an hour for the standard methods. “It’s dead easy, so you don’t need an embryologist to do it.”

### **Financials and performance**

The Memphasys coffers are pregnant with cash after a \$4.2 million placement, supported by the aforementioned Messrs Goodall and Peters.

“The good thing is we have raised enough money to develop the device and get it to the key opinion leaders and make some progress on registration,” Ms Coutts says.

“It will see us through to some meaningful milestones in future.”

Earlier, the company raised \$3.64 million in a rights issue, also supported by family and friends.

With the raisings struck at 2.3 cents and 2 cents, respectively, the supporters have broad smiles on their faces given the shares have since traded as high as 9.2 cents (on October 14).

For its efforts, Monash IVF was issued with two million Memphasys shares in August 2019, at a nominal price of two cents.

In August last year, the company underwent a 15-to-one share consolidation.

### **Dr Boreham’s diagnosis:**

Ms Coutts says she’s now feeling the investor love after a few barren years when most of the company’s progress was behind the scenes.

“I knew way back then that we had a valuable technology,” she says. “I was frustrated it wasn’t being understood and covered. I knew it was a matter of time before the market cottoned on.”

The fortunes of Memphasys are aligned to the IVF industry, which in turn is linked to the availability or otherwise of reimbursement.

In Australia, a standard cycle costs \$10,000 to \$12,000 and is partly subsidized by Medicare (budget offerings without certain add-ons are also available).

Of that cost component, sperm preparation accounts for only around \$100. So, moving to a deluxe separation method won’t break the (sperm) bank, especially if it leads to an improved success rate for notoriously unreliable IVF procedures.

Ms Coutts says the company hasn’t worked out its exact pricing model, but in the case of big orders it’s likely to provide the units for nothing in the hoping of making money from the consumables (membranes, electrodes, other paraphernalia).

“Pricing will depend very much on results,” she says. “We know we will have to be competitive, but the price will come down as we automate and obtain scale.”

Oh baby! This one could be a winner.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He knows a few stallions who should be gelded - and he’s not talking about horses.***

## [OPTHEA](#)

Opthea says it has completed a \$50 million private placement at \$2.65 a share to sophisticated and institutional investors in Australia and the UK.

On Monday, Opthea said it hoped to raise \$50 million in a placement and would use the funds to support the late-stage clinical development of OPT-302 for wet age-related macular degeneration, including the manufacture of clinical grade OPT-302 for phase III clinical development, and to begin two concurrent phase III pivotal registration trials (BD: Dec 2, 2019).

Opthea fell eight cents or 2.6 percent to \$2.95.

## [SIENNA CANCER DIAGNOSTICS](#)

Sienna says it has raised \$1,657,186 in a placement to institutional and sophisticated investors at 3.5 cents a share, rights issue for \$2.5 million more.

Last month, Sienna said it hoped to raise up to \$4.2 million through a \$1.7 million placement and a one-for-four, rights issue (BD: Nov 29, 2019).

The company said the funds would be used to commercialize Sien-Net, fund co-development expenditure for a pancreatic cancer diagnostic test with Minomic International and an exosome-based therapeutic for critical limb ischemia with Viva Zome, to evaluate acquisition or licensing opportunities and to provide additional working capital. Sienna was untraded at three cents.

## [MEDICAL DEVELOPMENTS INTERNATIONAL](#)

Medical Developments says the Russian Ministry of Health has accepted for review its marketing authorization application for Pentrox for trauma pain.

Medical Developments said it had been advised that no further clinical work was required in Russia and the Ministry of Health intended to review the clinical, safety and efficacy data used for European Pentrox approval.

The company said it expected final approval in Russia within 15 months and in Kazahhstan, Armenia and Kyrgyzstan within two years.

Medical Developments chief executive officer John Sharman said the acceptance was “a significant achievement and pointer to our future in Europe”.

Medical Developments was up 15 cents or 2.1 percent to \$7.24.

## [ELIXINOL GLOBAL](#)

Elixinol says a yet-to-be served class action alleges its US parent company Elixinol LLC's products are mislabelled as dietary supplements and may be misleading.

Elixinol said the class action suit was filed in the US District Court for the Northern District of California, but was yet to be served.

The company said it believed that its products were accurately labelled, that the claims were without merit and that it intended to defend itself against any suits.

Elixinol said it believed the plaintiffs were the same as reports of other proposed class actions, which were related to the same claim subject matter, against hemp-derived cannabidiol (CBD) brands Charlotte's Web and Infinite Products Co.

Elixinol fell eight cents or 8.4 percent to 87 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says data from its pre-clinical study of Emtin-B for Alzheimer's disease is mostly inconclusive and statistically non-significant in CVN mice.

Neuroscientific said it compared a wild type mice vehicle, a CVN mice vehicle, CVN mice administered with 5.0 milligrams (mg)/kilogram of Emtin-B and CVN mice administered 20mg/kg of Emtin-B to assess the potential neuroprotective and neuroinflammatory mechanism of action of Emtin-B for Alzheimer's.

The company said it assessed increases in choline metabolite levels, including choline (CHO), phosphorylcholine (PCH) and glycerophosphocholine (GPC), as well as decreases in acetylcholine (ACH) levels, which were positively correlated with cognitive impairment. Neuroscientific said CVN mice treated with Emtin-B showed a reversal of the increase in all choline metabolites to the levels of wild-type animals, but CHO was the only statistically significant change.

The company said this data suggested that Emtin-B showed patterns of reversing neurodegeneration, resulting in better neurotransmission.

Neuroscientific said it assessed gamma amino-butyric acid (GABA) levels, the main inhibitory neurotransmitter in mammal cerebral cortexes.

The company said Emtin-B was not statistically significant but did cause remodelling of GABA neurotransmission as a compensatory response to neurodegeneration and a diminished number of active neurons.

Neuroscientific said there glutamine levels were not reduced.

The company said it found a statistically significant increase in the Tau protein, found in most Alzheimer's disease patients, in CVN mice compared to wild type mice.

Neuroscientific said treatment with Emtin-B showed a dose dependent decrease in Tau brain markers in CVN mice, indicating a neuroprotective effect.

The company said it compared the levels of lymphocyte common antigen (CD45) and glial fibrillary acidic protein (GFAP) inflammatory markers in the brain.

Neuroscientific said there was a strong phenotypic difference between wild type and CVN mice in CD45 and GFAP markers, but no changes were observed following treatment of Emtin-B in the cortex and hippocampus.

The company said this suggested that the neuroprotective properties of Emtin-B were not associated with its ability to modulate inflammatory responses in the brain.

Neuroscientific said it assessed radial arm water maze measurements and found a trend towards phenotypic differences in cognitive impairment between wild type and CVN animals but did not achieve statistical significance.

Neuroscientific chief executive officer Matthew Liddelov said that "while the cognitive data set appears inconclusive, we are pleased with the results on the whole as it builds our deeper understanding of this unique molecule and its correct application in the neuroscience field," Mr Liddelov said.

Neuroscientific chairman Brian Leedman said that "given this new set of data enhances our view of Emtin-B as a potent neuroprotective drug, we are looking forward to receiving the data from our glaucoma pig model by the end of the calendar year".

Neuroscientific fell 8.5 cents or 28.8 percent to 21 cents with 1.6 million shares traded.

## HERAMED

Heramed has requested a trading halt "pending an announcement regarding a capital raising".

Trading will resume on December 10, 2019 or on an earlier announcement.

Heramed last traded at 17 cents.



## VICTORIA GOVERNMENT

The Victoria Government says the Barrie, Canada-based Medipharm Labs has opened the State's first commercial medicinal marijuana processing facility in Wonthaggi.

A media release from Victoria Premier Daniel Andrews said the facility would process up to 75,000 kilograms of cannabis into resin every year for use in medicinal products.

The Government said the facility would create up to 60 new jobs in Gippsland, in Eastern Victoria, and would support local agriculture and business.

The media release said Medipharm Labs would partner with more than 50 Australian agricultural growers, including 30 from Victoria, as the first independent global manufacturing company to enter Victoria's medicinal cannabis industry.

Medipharm Labs chief executive officer Warren Everitt said that this company was "proud to be opening the first specialized cannabis manufacturing facility in the state of Victoria, setting the gold standard for this new and exciting industry".

"Building this state-of-the-art facility is a tremendous achievement for Medipharm Labs," Mr Everitt said.

"We are thankful for the strong support from traditional landowners, government and from the Therapeutic Goods Administration," Mr Everitt said.

The Government said Victoria's emerging medicinal marijuana industry would provide manufacturing, agricultural and pharmaceutical opportunities, attract investment and create new high-tech jobs.

The Government said its Medicinal Cannabis Industry Development Plan would aim to supply half of Australia's medicinal cannabis by 2028, which would create 500 Victoria jobs.

The media release said Victoria had attracted investment from the Cronos Group and Canopy Growth Corp and both established their Asia-Pacific headquarters and research facilities in Victoria.

The Government said Victoria was the first state to legalize medicinal marijuana for patients in exceptional circumstances in 2016 and the Federal Government allowed doctors to prescribe medicinal cannabis to anyone who needed it.

Mr Andrews said the facility would "give more people access to life-changing treatment and [will] create regional jobs".

"No one should have to choose between watching their children suffer and breaking the law - that's why we legalized access to medicinal cannabis and why we're backing a local industry right here in Victoria," Mr Andrews said.

## LIFESPOT HEALTH

Lifespot says its Medihale medical marijuana vaporizer system and Seng Vital medical marijuana software application are being evaluated by unnamed marijuana companies. Lifespot said the devices and accompanying software would be evaluated with a number of medical marijuana companies to progress programs for vaporizing for diseases including chronic pain, chemotherapy, induced nausea and vomiting and post-traumatic stress disorder.

The company said it had completed development of a refillable flower cartridge for its Medihale system, which would be available in February 2020, and which would allow the supply of the vaporizer by licenced cannabis producers and dispense of the flower cartridge by doctors and dispensaries.

Lifespot said it had added a temperature control function to its Seng Vital application so that patients could control vaping temperature.

Lifespot was unchanged at 3.5 cents.

### [PALLA PHARMA \(FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES\)](#)

Australian Ethical Investment says it has become a substantial shareholder in Palla Pharma with 7,987,076 shares or 6.34 percent.

The Sydney-based Australian Ethical said that it bought the shares between October 25 and December 5, 2019 with the single largest correctly notified purchase 1,641,787 shares for \$1,357,454 or 82.7 cents a share.

Palla was unchanged at 82 cents.

### [PAINCHEK](#)

Peters Investments says it became substantial in Painchek in 2016 and has increased its holding from 55,000,000 shares (11.99%) to 100,000,000 shares (9.66%).

In two separate substantial shareholder notices, the Perth-based Peters said it first became substantial on September 26, 2016, buying 55,000,000 shares for \$1,100,000 or 2.0 cents a share and acquired a further 45,000,000 shares between September 21, 2017 and November 27, 2019.

Peters said that it increased its holding in two placements to acquire 23,793,103 shares for \$2,500,000 at 5.0 and 14.5 cents a share, through the exercise of 10,000,000 options at 2.25 cents each share and in on market purchases of 6,858,756 shares for \$1,320,779 or an average of 19.3 cents a share (BD: Sep 18, 2017; Jun 19, 2019).

Painchek was unchanged at 20 cents with 4.6 million shares traded.