

Biotech Daily

Friday November 23, 2018

Daily news on ASX-listed biotechnology companies

* ASX UP, BIOTECH DOWN: CYCLOPHARM UP 11%; ITL DOWN 39%

* DR BOREHAM'S CRUCIBLE: MEMPHASYS

- * ITL TO DELIST IN FEBRUARY: 'LOW SHARE PRICE, LIQUIDITY'
- * BOTANIX RECEIVES \$4.6m FEDERAL R&D TAX INCENTIVE
- * RECCE TAKES RADIUM \$256k R&D TAX INCENTIVE ADVANCE
- * MARK KERR TAKES 11% OF PHOSPHAGENICS

MARKET REPORT

The Australian stock market was up 0.44 percent on Friday November 23, 2018 with the ASX200 up 24.9 points to 5,716.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and three were untraded.

Cyclopharm was the best, up 11 cents or 11.1 percent to \$1.10, with 18,736 shares traded.

LBT climbed 7.1 percent; Prescient was up 5.4 percent; Neuren and Paradigm improved more than three percent; Immutep rose 2.6 percent; Avita, Compumedics, Pharmaxis, Telix and Volpara were up more than one percent; with Cochlear, Compumedics and Resmed up by less than one percent.

ITL led the falls (see below), down 5.8 cents or 38.7 percent to 9.2 cents with 557,056 shares traded.

Optiscan and Reva lost more than nine percent; Orthocell shed 8.7 percent; Airxpanders was down 7.3 percent; Imugene fell 4.2 percent; Impedimed was down 3.3 percent; Dimerix shed two percent; Benitec, CSL and Pro Medicus were down more than one percent; with Clinuvel, Medical Developments and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: MEMPHASYS

By TIM BOREHAM

ASX code: MEM

Share price: 3.9 cents; Market cap: \$14.2 million; Shares on issue: 363,922,478

Financials (year to June 30 2018): revenue nil, income \$66,000* (down 19%), loss \$401,159 (previously \$1.9 million)**, cash of \$201,807 (previously \$2,349)

* Grant income; ** Improvement largely reflects reduction in legal fees from \$953,809 to \$95,111 and net abnormal gain of \$896,322 relating to legal settlement.

Executive chair: Alison Coutts

Board: Alison Coutts, Andrew Goodall, Marjan Mikel

Identifiable major shareholders: Andrew Goodall 24%, Alison Coutts 16%, Peters investments 18.3%

Like a sperm competing with millions of others in the Great Procreation Race to the fallopian tubes, the odds have been against Memphasys lasting for a decade as a listed entity. But it has.

In that time, the developer of a sperm separation device for IVF purposes has had numerous legal disputes, a revolving door of CEOs, an enforceable undertaking with the regulator (pertaining to former directors) and a failed attempt at acquiring an erectile dysfunction company.

Financially, Memphasys has led a hand-to-mouth existence with just enough money flowing from directors' loans, convertible notes and other parties to keep the lab lights on.

Against the odds, Memphasys remains on track to commercialize its flagship device, Felix. Derived from the Latin for 'joy', Felix uses alternative methods to sort gently the best sperm to be used for IVF insemination.

With the quality of sperm declining because of lifestyle and other factors, couples need the best tadpoles available and that means eliminating the DNA-damaged ones. Felix is in prototype stage and is expected to be tested by a number of IVF clinics, with planned commercialization next year.

About Memphasys

Some deviations aside, the Memphasys emphasis remains on sperm selection. This is the same remit the company had when it listed as Nusep - a spin off from the blood products group Life Therapeutics - in May 2007.

The driving forces behind Memphasys are 16 percent shareholder Alison Coutts and fellow director and 24 percent holder Andrew Goodall.

Ms Coutts became involved of what was a complete mess four years ago, in the role of executive chairman. She was a biotech corporate adviser who co-founded Micro-X (ASX code MX1), which is developing a lightweight mobile x-ray machine. Mr Goodall is an entrepreneur with New Zealand commercial property interests.

"We have had a very funny chequered history," Ms Coutts says. "We fought to stay alive. I have had to put my own money in and remortgage the house [but] it was well worth saving because the technology is excellent."

Under previous management in March 2009, Nusep announced a \$5 million raising to acquire an entity called Nxgen, which sold a range of remedies for premature ejaculation, erectile dysfunction and women's sexual dysfunction.

Unhelpfully, Nxgen was linked to the controversial Advanced Medical Institute, owned by the now bankrupt Jack Vaisman after numerous run-ins with the consumer regulator.

AIM was famed for its garish yellow roadside billboards spruiking the message 'want longer lasting sex' or the even blunter 'Bonk Longer'. Nusep protested that AMI was only a minor customer of Nxgen. But by June of that year the deal - along with a plan to spin-off the rest of Nusep as Prime Biologics - was dead anyway. Prime was spun-out in 2016 and moved to Singapore.

Nusep made a \$90,000 profit in the six months to December 31, 2009, but like Mr Vaisman's long-lasting erections, the black ink was short-lived.

Nusep changed its name to Memphasys in July 2016.

Sorting the swimmers from the floaters

Felix works on pretty much the same principle as Nusep's original Sperm Sorter, but with some crucial design flaws ironed out. For example, a salt solution used as a buffer material in the old device could not be changed between uses, raising the danger of a virus transmission.

Felix replaces the laboratory-based methods for sperm sorting - such as density grading centrifuging - which is labor-intensive, costly and can contribute to sperm DNA damage.

The Felix process takes less than five minutes, compared with 30 to 40 minutes for the lab techniques. It is based on a membrane to sort quality by size and electrical separation – the good sperm has a negative charge.

Don't bother getting out the magnifying glass, but bad sperm are distinguishable because of a double head or tail, a short tail, a bent neck or a misshaped head.

The technology was developed in league with fertility specialist Prof John Aitken of the University of New South Wales, who remains involved with the company.

'Nespresso' business model

Memphasys intends to sell the Felixes on the "Nespresso pod" principle of providing a cheap machine and making money out of the consumables. In this case, the consumables are the single-use cartridges housing the sperm sample and - not surprisingly - they can only be used for one in-vitro fertilization (IVF) cycle.

Management is yet to decide on pricing, but Ms Coutts envisages a price of around \$100 per cartridge - a small component of the typical \$10,000 cost of an IVF cycle.

On average, women undergo 2.2 cycles for a 70 percent chance of success. With six million IVF cycles globally each year, that makes for a potential \$600 million market.

There's also a second market of a similar size known as intra-uterine insemination, in which the egg is left in the uterus and the sperm is introduced. Once again, only the best tiddlers are required and because it's cheaper than in-vitro fertilization, the procedure is common in India and China.

Horses for courses

Memphasys also has its hand in the equine semen market, with a University of Newcastlebased program to develop a similar product - provisionally named Far Lap - for horses.

This is not about breeding the next Winx, or Phar Lap, as thoroughbred artificial insemination is illegal. Rather, the company is eyeing the market for harness racing, show ponies, polo ponies and such.

One wee issue is that as stallions ejaculate about 100 times more sperm than even the most virile bloke, the device will have to be bigger than the Felix. "We don't have any foals yet, but we know it works," Ms Coutts says.

Path to commercialization

Until recently, the company's key activity has been litigation, including disputes with financiers, partners and a former CEO. All actions have been finalized.

In mid-September, Memphasys announced a collaboration with Monash IVF, by which Monash IVF's clinicians and researchers provide advice on designing and operating Felix. Monash IVF gets first dibs on the instruments, which are expected to be marketed to IVF clinics globally. It is expected that 10 to 15 IVF clinics globally will adopt the device.

The company expects pre-production of the Felixes to start by December, with delivery to the clinical parties for in-vitro testing by the end of March 2019.

Management has held initial meeting with European Union regulators, in view of applying for approval as a class II B medical device.

This should be followed swiftly by an application to the Australian Therapeutic Goods Administration, with an entreaty to the US Food and Drug Administration some time down the track.

Finances and performance

Memphasys has been a hand-to-mouth existence and its end-of-year cash balance of \$201,000 is a tad on the tight side, to put it mildly.

But the resolution of the legal issues slashed the reported full-year loss by 80 percent, to \$401,000.

In the six months to December 2018, operations were funded by \$251,000 of director loans from Ms Coutts and Mr Goodall, a loan against a \$310,000 Federal Research and Development Tax Incentive and a \$300,000 convertible note (since converted to equity).

In May, Western Australia horse owner and breeder Bob Peters invested \$1 million in two tranches.

"The cupboard is a little bit bare and we will need to raise money," Ms Coutts says.

In August this year, the company consolidated its 5.458 billion shares on issue on a 15:1 basis.

Meanwhile, the stock has returned to investor favor, soaring from 1.4 cents to 5.8 cents a share in mid to late October and prompting two 'please explain' notices from the ASX.

Dr Boreham's diagnosis:

We reckon the cleaned-up Memphasys has a good chance of reaching its potential, given the evident need for the product and its relative simplicity.

The equine side should not be overlooked as a potential money spinner. It's just the company needs to raise decent enough funds to last the distance to the finishing post of regulatory approval and then first sales.

Reflecting its past woes, the company has \$37.7 million of accumulated losses, which could come in handy if it can turn a profit.

Memphasys, by the way, is a name made up in the shower by Ms Coutts, drawing from the words 'emphasis' and 'membrane'.

It's had to be named something, we guess ...

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Given Victoria's weekend plebiscite and with polls due federally and in New South Wales early next year, Australia has no problems with longer-lasting elections.

ITL HEALTH GROUP

ITL says it has applied to the ASX to de-list in February 2019, citing poor valuations and thin trading.

Executive chairman Bill Mobbs told Biotech Daily he expected the company to hold an extraordinary general meeting in January to approve the de-listing.

The company said that "the prices of the securities that are trading on the ASX are significantly and materially lower than the underlying value of the group and also of the net assets that these securities represent".

In September ITL said its revenue for the 12 months to June 30, 2018 fell 30.2 percent to \$24,309,000 with net profit after tax down 11.9 percent to \$3,022,000 (BD Sep 3, 2018). Last night, when the company's share price closed at 14 cents its market capitalization was \$12.8 million, but following today's 38.7 percent fall with 557,056 shares traded, it closed at \$7.9 million.

ITL said that the liquidity of the shares was "insufficient to provide security holders an avenue to redeem their shares now, or in the future ... [and] the financial, administrative and compliance obligations and costs associated with maintaining an ASX listing can no longer be justified".

"This is particularly the case given the low levels of trading in the security [and] there are a large number of unmarketable holdings parcels held, indicating a limited market for trading of the securities," the company said.

ITL said it intended to conduct an unmarketable parcels buy-back program before delisting and also to participate in on-market buybacks in order to assist shareholders who may wish to sell their securities before de-listing.

ITL fell 5.8 cents or 38.7 percent to 9.2 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has received \$4,616,539 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Botanix said the rebate related to research and development expenditure for the year to June 30, 2018.

Botanix was up half a cent or 6.5 percent to 8.2 cents.

RECCE PHARMACEUTICALS

Recce says it has received a \$256,000 advance payment from Radium Capital against its 2018-'19 future Research and Development Tax Incentive.

Recce chief executive officer James Graham told Biotech Daily that the \$256,000 was 80 percent of its expected Tax Incentive and followed the repayment of a previous advance from Radium for the 2017-'18 Tax Incentive. (BD: Sep 13, 2018).

The company said it would pay Radium a small upfront fee and "a reduced 1.16 percent per month carry rate on funds received".

Recce said the funds would be used to advance its antibiotic development program. Recce was untraded at 18 cents.

PHOSPHAGENICS

Mark Kerr says he and associated entities have increased their substantial holding in Phosphagenics from 109,083,634 shares (7.341%) to 169,583,634 shares (10.725%). The Melbourne-based Mr Kerr said the associates were Lindmark Inv Staff

Superannuation Fund with Linda Kerr, Berkeley Consultants and Paradyce.

Mr Kerr said that the group bought and transferred shares on May 18 at 1.5 cents and acquired shares from November 15 to 22, 2018, at prices ranging from 0.2 cents to 0.3 cents a share.

Phosphagenics was unchanged at 0.3 cents with 24.0 million shares traded.