Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Memphasys

By Tim BOREHAM

ASX code: MEM

Share price: 1.6 cents

Market cap: $15.4 million

Shares on issue: 959,520,382

Financials (half year to December 31 2022): revenue $4,271 (down 68.5%), grant income $224,109 (down 19.3%), net loss $1.18 million (previous $937,000 loss), cash $2.095 million (up 68%)

Chief executive officer: Alison Coutts

Board: Robert Cooke (chair), Ms Coutts, Andrew Goodall, Paul Wright

Major shareholders: Peters Investments (Bob Peters) 27.2%, Andrew Goodall 17.7%, Alison Coutts 8.8%.

What's wrong with our tadpoles, gentlemen?

According to local fertility expert Prof John Aitken, sperm counts have roughly halved over the last 50 years and about 20 percent of men shoot blanks.

No-one's sure why, but possible reasons include exposure to toxins, pesticides, poor diet or even chronic stress.

In any event, 86 percent of sperm have deficiencies such as double heads, short tails or bent necks.

So, when it comes to artificial reproduction, selecting the best sperm in the first place is crucial to maximizing the chances of success.

Enter Memphasys, which has been beavering away on a device to separate the best sperm from the duds, for in-vitro fertilization (IVF).

The device - Felix - is proven to work, but the company has faced regulatory and reimbursement issues in two of its target markets, India and Japan.

Howzat! moment spurs Memphasys

Felix evolved from Prof Aitken's knowledge of the ASX-listed Gradipore, which was developing a device to separate molecules using electrical charge.

Prof Aitken pondered whether the sperm could be separated with that technique, given healthy sperm have a strong negative charge.

Gradipore morphed into Nusep, which then listed in May 2007, as a spin-off from blood products group Life Therapeutics.

Like most sperm, Nusep didn't last the journey and it was rescued by Alison Coutts and Andrew Goodall.

Ms Coutts was a biotech corporate adviser who co-founded the ASX-listed, mobile x-ray machine developer Micro-X. Mr Goodall founded a plant nursery in New Zealand, before successfully dabbling in property investment.

In 2021, the company took delivery of its perfected prototype units.

In September 2018, Memphasys struck a collaboration with the ASX-listed Monash IVF that includes an ongoing trial.

Distinguished Emeritus Laureate Prof Aitken recently retired from New South Wales' University of Newcastle, but remains closely involved with developing Felix.

Indeed, the work is by way of a collaboration with the Novocastrian learning institution.

Prof Aitken was an academic at the University of Edinburgh when he was offered the University of Newcastle position.

"I thought they meant the Newcastle University on Tyne, just up the road," he says. But he came anyway, if only to watch a Test match at the Sydney Cricket Ground.

What's the problem?

The most common sperm separation technique - density gradient centrifugation (DGC) - risks accentuating cell damage because of the powerful forces involved.

Another method, swim-up - aka 'survival of the fittest' - is also not ideal. As its name suggests, the tadpoles that survive the arduous journey up the fallopian tubes are considered the fittest. But they may still be damaged.

The gentle Felix process does not involve chemicals or shearing forces and takes about five minutes, compared with about one hour for the conventional methods.

Sydney's Westmead Hospital tested a prototype device, which was found to be just as effective as the current techniques based on a small sample.

The pandemic meant that key opinion leaders (that is, IVF practitioners) across eight countries were unable to complete their assessments. But activity fired-up in the second half of 2022.

Earlier, Felix engineering flaws were identified and eventually rectified, with the ASX-listed device manufacturer Hydrix paying $650,000 to Memphasys in a settlement.

The birds and the bees

The Melbourne in-vitro fertilization trial with Monash IVF recruited slower than expected, because of an apparent post-pandemic hangover and blokes "failing to meet stringent entry criteria".

Early results have been "encouraging with respect to fertility rates and embryo utilization rates".

The sperm is for use in intra-cytoplasmic sperm injection (ICSI) - a.k.a. 'playing god' - which involves embryologists selecting the best-looking sperm from the beauty parade of tadpoles. The tail of the winning sperm is broken so it can't swim away and it is fused to the egg (hopefully resulting in fertilization).

The double-blinded study involves 104 couples (54 women) providing their eggs for density gradient centrifugation (DGC) or 'swim-up'.

The primary success measure is the number of embryos good enough for use at the time, or for freezing.

Secondary measures are pregnancy rates (duh!) and other factors including sperm count, motilities, DNA fragmentation (the lower the better) and morphology (cell abnormalities).

The DGC arm is well behind, but the 'swim up' comparison should be done within three months.

Fertile opportunities in India …

The trial is likely to assist with Australian Therapeutic Goods Administration (TGA) approval, paving the way for use in the smallish local market and some Asian countries. But Ms Coutts doesn't want all her eggs in the TGA basket and more fertile markets abound elsewhere.

In India, sales of Felix were going swimmingly - excuse the pun - until the country's Central Drugs Standard Control Organisation tightened regulation of the IVF industry.

Ms Coutts assumed that because Felix had the requisite International Standard Organisation certification the company would be okay - but that wasn't the case. The company plans to circumvent the problems by manufacturing the Felix devices and cartridges in India. "We already have a site and are going down that path rapidly."

Ahead of the regulatory clampdown, the clinic that produced the first 'Felix baby' had already re-ordered the cartridges. "They have been absolutely delighted and they are asking when they can get more," Ms Coutts says.

Japan …

In Japan, a change to insurance funding rules meant the company lost the interest of a number of high-end clinics who didn't want to do out-of-pocket work.

"But then out of the blue we got an order from a clinic and so we have made our first sale in Japan," Ms Coutts says. "It's an introductory offer and a small number to begin with, but we still make a profit out of it."

Ms Coutts says other sites are interested despite the lack of insurance, bearing in mind that the cost of the test (under $200) pales into that of an IVF cycle there (around $6,000). In Japan - and elsewhere - the company is likely to give away the consoles and an introductory pack of cartridges to speed up sales.

… and China

In China, the company hopes for so-called 'green channel' fast-track approval, with a decision on the express route expected shortly. Memphasys is partnered in China with in-vitro fertilization equipment supplier Diagens.

"They have introduced us to various clinics who have tested the device and really like it," Ms Coutts says.

With China projected to be overtaken by India as the most populous nation, China's rescinded one-child policy is being supplanted by former Australia Treasurer Peter Costello's doctrine of 'have one for Mum, one for Dad and one for the country'.

Highlighting the pregnant potential, one Shanghai hospital carries out more in-vitro fertilization procedures a year than the whole of Australia.

Giving beasts a helping hand

Reflecting Memphasys' animal artificial insemination potential, the company's biggest shareholder is Perth horse-breeder Bob Peters.

Despite locker room boasts to the contrary, the average stallion ejaculates 100 times more sperm than the average guy - but the hard-working beasts (the stallions that is) still need a helping hand.

Students of the turf would know that artificially inseminating thoroughbreds is illegal, but this ban does not apply to equine variants such as polo ponies and harness racing.

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.

The company's immediate animal hopes lie not with Felix but with AI (artificial insemination) Port, a device for storing and transporting livestock semen at ambient temperature, for up to four days. This avoids the harmful freezing of the specimens.

The company plans a field trial at a beef stud property near Scone in New South Wales' Hunter Valley (not too far from the Australian University of Newcastle). A herd of 20-30 cows will be inseminated either with sperm kept at 'room' temperature, or frozen samples. Ms Coutts says that up to half the sperm die in the freezing process and even a five percent increase in pregnancies would be highly significant.

Coming up …

The company's most advanced product under development is a point-of-care device called Rosa, as in Rapid Oxidative Stress Assay.

Rosa assesses oxidative stress in a semen or blood sample. Oxidative stress is an underlying factor in conditions including Alzheimer's diseases, diabetes and heart disease. It is also inked to - drum roll - male infertility, as well as pre-eclamptic placental failure, pre-term births and miscarriages. "There are known ways of measuring oxidative stress, but it takes hours in a lab and we have reduced it to five minutes," Ms Coutts says.

Finances and performance

Memphasys reported a loss of $1.18 million in the December 2022 half compared with a $937,865 deficit previously, despite administration costs being shaved by 56 percent.

In August 2022, the company raised $3.36 million in a $1.6 million placement and $1.76 million rights issue, both at two cents a share (a whopping 50 percent discount). The placement was underwritten by broker Canaccord.

Memphasys had cash of $2.09 million at December 31, 2022 but has postponed plans for another capital raising in favor of a potential loan from Mr Goodall, or borrowing against a $1.7 million Federal Research and Development Tax Incentive due in September 2023.

If Memphasys shares were sperm they would be flushed down the sink, having lost almost 80 percent of their value over the last 12 months.

The shares traded at a 12-month high of eight cents in March 2022 and at an all-time low of one cent in early January this year. The stock hit a record high of 15 cents in August 2020. According to Commsec data Nusep hit 66 cents in mid-2007.

Dr Boreham's diagnosis:

When we last covered Memphasys in December 2019: Ms Coutts said she was feeling the investor love after a few barren years.

As the Righteous Brothers aptly crooned, that lovin' feeling has gone, gone, gone … baby baby baby …

Ms Coutts says the current share price flies in the face of the many positive developments.

"Brokers are yet to be convinced that Felix [will] be commercial," she says. "I shake my head because we have given them so much evidence."

Indeed, Felix has the potential to play a leading role in staunching global infertility - and the spectre of Western countries being dominated by unproductive 'oldies'.

While Felix is the lead - and most advanced - product in the Memphasys stable, the market for AI-Port could be worth much more.

Memphasys can be one of the surviving 'swimmers', but it needs to hasten its commercial plans and assure investors from where its next funding dollar is coming.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. When it comes to his sickly share portfolio, he is down on his knees and has certainly lost that lovin' feeling.