Biotech Daily

Friday March 31, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYCLOPHARM UP 11%; PATRYS DOWN 24%**

*** DR BOREHAM'S CRUCIBLE: MEMPHASYS**

*** NOVA EYE: ITRACK ADVANCE WINS FDA 510(k) APPROVAL**

*** ALLEGRA FILES SPINAL CAGE FDA 510(k) APPLICATION**

*** PACIFIC EDGE COMPLETES CXBLADDER KAISER INTEGRATION TESTS**

*** QBIOTICS DOSES 1st EBC-46 PHASE II HEAD, NECK CANCER PATIENT**

*** PATRYS PHASE I PAT-DX1 TRIAL DELAYED**

*** OSTEOPORE ACQUIRES SOUTH KOREAN DISTRIBUTORS**

*** PARADIGM REQUESTS 'CLINICAL DATA' TRADING HALT**

*** W WHITNEY GEORGE TAKES 40.4% OF RHINOMED**

*** RYDER INCREASES, DILUTED TO 6.8% IN LUMOS**

*** RESMED TO LOSE COUNSEL, CAO, CO SEC DAVID PENDARVIS**

*** BIONICS INSTITUTE 'MEASURING INNOVATION' LECTURE**

MARKET REPORT

The Australian stock market was up 0.78 percent on Friday March 31, 2023, with the ASX200 up 55.5 points to 7,177.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and five were untraded. All three Big Caps were up.

Cyclopharm was the best, up 18 cents or 11.0 percent to $1.82, with 102,456 shares traded. Cynata and Nova Eye climbed more than five percent; Dimerix, Imugene and Prescient improved four percent or more; Actinogen and Polynovo were up more than three percent; Cochlear and Nanosonics rose more than two percent; Clinuvel, CSL, Orthocell, Resonance, Universal Biosensors and Volpara were up one percent or more; with Emvision, Neuren, Resmed and Telix up by less than one percent.

Patrys led the falls (see below), down 0.5 cents or 23.8 percent to 1.6 cents, with 52.0 million shares traded. Pharmaxis lost 6.1 percent; Antisense shed 5.3 percent; Atomo and Impedimed fell more than four percent; Genetic Signatures shed 2.6 percent; Avita, Immutep, Mesoblast, Pro Medicus and Starpharma were down one percent or more; with Medical Developments, Opthea and Proteomics down by less than one percent.

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, engineering flaws in the Felix device 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 the end of December 2022. The company 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.

NOVA EYE MEDICAL

Nova Eye says it has US Food and Drug Administration approval for its Itrack Advance canaloplasty device for canal-based glaucoma surgery.

Nova Eye said Itrack Advance was similar to the original micro-catheter, which enabled canal surgery for glaucoma using visco-elastic fluid to clear blockages but had an extended feature set that was expected to appeal to cataract and comprehensive surgeons as well.

The company said it would begin marketing and sales of the device with a product launch planned for the American Society of Cataract and Refractive Surgery meeting in San Diego on May 5 to 8, 2023.

Nova Eey said that the original Itrack was “the pioneering canaloplasty device that first established canal surgery for glaucoma” and to date about 120,000 surgeries have been performed by surgeons with an “outstanding clinical efficacy and safety profile”.

The company said that the Itrack microcatheter was “the only product that is indicated for canal surgery to treat glaucoma with visco-dilation alone”.

Nova Eye managing director Tom Spurling said the company was “well positioned to materially penetrate the expanding canal surgery market with Itrack Advance.”

The University of Oklahoma Dean McGee Eye Institute chair Prof Mahmoud Khaimi said “we’ve taken the original Itrack device and incorporated it into an ergonomic handpiece that allows surgeons to easily advance and retract the micro-catheter through the canal”.

“With this new design we have streamlined the canaloplasty procedure and made it efficient and very ergonomic for the surgeon,” Prof Khaimi said.

“I am confident that surgeons will adopt this device into their treatment algorithm, either as an adjunct to cataract surgery or as a standalone procedure,” Prof Khaimi said.

Nova Eye was up 1.5 cents or 5.4 percent to 29.5 cents with 4.4 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has submitted a 510(k) application to the US Food and Drug Administration for its Sr-Ht-Gahnite spinal cage device for bone healing.

Allegra previously said Sr-Ht-gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, 2016).

Last month, the company said the spinal cage showed a bone healing response “indicative of a fused spinal level” as well as biocompatibility, in sheep (BD: Feb 22, 2023).

Today, Allegra said the FDA submission followed a range of studies with successful outcomes and included extensive laboratory and pre-clinical investigation and anticipated feedback within 90-days.

The company said that the studies showed the product's mechanical strength, physical properties, safety, and efficacy in cervical fusion, with sterilization and biocompatibility evaluations providing further evidence of its biological safety and readiness for clinical settings.

Allegra said the submission was a milestone in the innovation of its 3D-printed bio-ceramic spinal fusion cage which began in 2014.

Allegra chief executive officer Jenny Swain said the submission “could not have been achieved without our committed team of engineers diligently working on this project to achieve this crucial milestone”.

“I would also like to gratefully acknowledge the universities, suppliers, and test facilities that provided support in generating the results supporting this submission,” Ms Swain said.

Allegra was untraded at 5.5 cents.

PACIFIC EDGE

Pacific Edge says it has completed integration testing of its Cxbladder non-invasive, urine-based, cancer test with the electronic medical record system Kaiser Permanente.
Pacific Edge said that after completing the necessary administrative and review processes it would take the project live, with continued updates until it is completed.
Last year, the company said the Oakland California-based Kaiser Permanente would incorporate its Cxbladder tests in its electronic medical records (EMR) system so that clinicians would be able to order Cxbladder tests and view results directly within their clinical workflow, rather than relying on a manual ordering system (BD: Jun 1, 2022).
Today, Pacific Edge said Kaiser Permanente was the largest integrated healthcare provider in the US, with 12.6 million members, about 3.7 percent of the population.
Pacific Edge chief executive officer Dr Peter Meintjes said the completed development and integration testing were “important technical milestones ... [which had] significantly de-risked the project”.
Pacific Edge was untraded at 38 cents.

QBIOTICS GROUP

Qbiotics says it has dosed the first of up-to 37 patients in its phase II, single-arm, open-label trial of intra-tumoral tigilanol tiglate, formerly EBC-46, for head and neck cancer.
In 2020, Qbiotics said it had dosed the first of up-to 40-patients in its phase I/II trial evaluating the dose and safety of tigilanol tiglate for head and neck squamous cell carcinoma (BD: Jul 22, 2020).
Today, the company said the phase I/II trial aimed to evaluate tumor ablation, or local tumor control, following injections of tigilanol tiglate and to evaluate the efficacy and safety of the treatment.
Qbiotics managing-director Dr Victoria Gordon said treating the first patient in the phase II trial was “an important milestone … as it builds on our overall development approach for tigilanol tiglate, which is exploring the drug’s potential against a range of tumor types”.
“We are hoping that results from this trial may eventually lead to providing a new solution for patients with this difficult to treat disease,” Dr Gordon said.
Qbiotics is a public unlisted company.

PATRYS

Patrys says its phase I trial of its deoxymab antibody PAT-DX1 for cancerous tumors has been delayed from this year to 2024.
Last year, Patrys said its contract development manufacturing organisation completed PAT-DX1 testing and expected to start the phase I trial in 2023 (BD: Aug 30, 2022).
Today, the company said the delay was due a “sporadic issue” related to the cell line used to produce PAT-DX1.
Patrys managing-director Dr James Campbell said the company was confident that once the issue was resolved “the manufacturing and purification process developed and tested for PAT-DX1 can provide the material required to initiate the first human clinical trial of a deoxymab antibody”.
“In the meantime, we look forward to completing the remaining, non-clinical … toxicology studies of PAT-DX1 in May, as scheduled,” Dr Campbell said.
“Work on our full-sized [immunoglobulin G] deoxymab, PAT-DX3, is progressing well and we expect to provide an update on this program in coming weeks,” Dr Campbell said.
Patrys fell half a cent or 23.8 percent to 1.6 cents with 52.0 million shares traded.

OSTEOPORE

Osteopore says it has completed the acquisition of the South Korean distributing company Target Businesses for the agreed $2.1 million in cash and scrip.
In January, Osteopore said it would buy multiple medical distribution businesses for $2,050,000 in cash and scrip to control manufacturing and marketing and move to direct retail sales (BD: Jan 23, 2023).
Today, the company said the medical distribution businesses would comprise about 40 percent to 45 percent of total sales.
Osteopore was up 0.1 cents or 1.2 percent to 8.6 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has requested a trading halt to analyze “biomarker, structural and clinical data relating to its phase II … trial” of pentosane polysulphate sodium (PPS).
Trading resume April 4, 2023, or on an earlier announcement.
Paradigm last traded at $1.435.

RHINOMED

W Whitney George says he has increased his substantial holding in Rhinomed from 112,089,721 shares (39.23%) to 115,366,276 shares (40.38%).
The Darien, Connecticut-based Mr George said between November 16, 2022 and March 24, 2023 he bought 3,276,555 shares for $US247,115 ($AU368,225), or an average price of 11.2 cents a share.
Rhinomed was untraded at nine cents.

LUMOS DIAGNOSTICS

Ryder Capital says it has increased and been diluted in its substantial holding in Lumos from 16,643,032 shares (7.93%) to 17,393,032 shares (6.81%).
The Sydney-based Ryder said that on October 13, 2022 it bought 750,000 shares for $39,039, or 5.2 cents a share, and on March 17, 2023 was diluted in a conversion agreement between Lumos and Lind Global Fund II LP of 7,758,621 shares at 2.9 cents a share.
Lumos was unchanged at 2.7 cents with 1.6 million shares traded.

RESMED

Resmed says general counsel, chief administrative officer and company secretary David Pendarvis will retire, effective from June 30 and consult until December 31, 2023.
Resmed chief executive officer Mick Farrell said Mr Pendarvis had been with the company for 20 years and helped “guide the company through its transformation from the pioneer of sleep apnoea treatment to a $US30 billion-plus global leader in digital health and cloud-connected medical devices.
“I want to thank [Mr Pendarvis] for his two decades of dedicated service and exemplary leadership,” Mr Farrell said.
The company said it appointed communications and investor relations head Amy Wakeham as chief communications and investor relations officer, to replace Mr Pendarvis’ role in corporate public affairs and had begun an internal search for a successor.
Resmed was up 21 cents or 0.65 percent to $32.39 with 676,805 shares traded.

BIONICS INSTITUTE

The Bionics Institute says its annual innovation lecture will explore the measurement of innovation to enhance the medical technology sector.

The Institute said the lecture would feature addresses from 4D Medical chief executive officer Dr Andreas Fouras and Australian Academy of Technological Sciences and Engineering chief executive officer Kylie Walker.

The Institute said the free event would host medical technology leaders, researchers, entrepreneurs, government agencies and investors.

The Bionics Institute said the event would "explore how Australia can accurately measure innovation and boost the [medical technology] ecosystem" in a panel discussion with the former general manager of the government's Innovation Metrics Review, Christine Williams and Commonwealth Scientific and Industrial Research Organisation deputy chief scientist Dr Jill Freyne.

The Bionics Institute said the event would be held at the Royal Auto Club of Victoria (RACV) City Club at 501 Bourke Street, Melbourne on Wednesday, May 17, 2023 from 5:45pm-9:45pm (AEST), with networking drinks to follow the lectures.

Register at: https://www.bionicsinstitute.org/news-and-events/innovation-lecture-2023/.