



Biotech Daily

Friday August 30, 2019

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: OPTHEA UP 8%; OSPREY DOWN 9%
- * DR BOREHAM'S CRUCIBLE: ANATARA LIFESCIENCES
- * MESOBLAST REVENUE DOWN 3.6% TO \$25m, LOSS UP 155% TO \$134m
- * AVITA REVENUE UP 50% TO \$17m, LOSS UP 110% TO \$34.6m
- * AVECHO H1 REVENUE UP 409% TO \$4.2m, LOSS TO \$2.3m PROFIT
- * MEDLAB REVENUE UP 41% TO \$6.1m, LOSS UP 72% TO \$8.2m
- * ALLEGRA REVENUE DOWN 15% TO \$4m, LOSS UP 38% TO \$836k
- * DORSAVI REVENUE DOWN 27% TO \$3.2m, LOSS UP 8% TO \$4.0m
- * ADHERIUM REVENUE DOWN 53% TO \$2.8m, LOSS UP 26% TO \$11.8m
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- * ORTHOCELL REVENUE UP 26% TO \$1.2m, LOSS UP 2% TO \$5.9m
- * SUDA REVENUE UP 186% TO \$1.2m, LOSS UP 29% TO \$7.8m
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- * MACH7 M-D MIKE LAMPRON STARTS ON \$410k A YEAR

MARKET REPORT

The Australian stock market was up 1.49 percent on Friday August 30, with the ASX200 up 96.8 points to 6,604.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Opthea was the best, up 24 cents or 7.7 percent to \$3.35, with 1.1 million shares traded. Oncosil and Universal Biosensors climbed more than seven percent; Antisense was up 6.4 percent; Clinuvel climbed 5.8 percent; Amplia, Nanosonics and Uscom improved more than four percent; Compumedics was up 3.6 percent; Cochlear, CSL, Kazia and Next Science rose more than two percent; Genetic Signatures, Medical Developments, Orthocell, Paradigm and Resmed were up one percent or more; with Ellex and Neuren up by less than one percent.

Osprey led the falls, down 0.5 cents or 9.4 percent to 4.8 cents with 1.5 million shares traded. Avita and Optiscan lost more than six percent; Actinogen was down 5.9 percent; Resonance fell 4.35 percent; Alterity, Impedimed and Polynovo were down more than three percent; Cynata and Mesoblast shed more than two percent; Dimerix, Telix and Volpara were down one percent or more; with Pro Medicus down 0.7 percent.

DR BOREHAM'S CRUCIBLE: ANATARA LIFESCIENCES

By TIM BOREHAM

ASX code: ANR

Share price: 22 cents; **Shares on issue:** 49,413,236; **Market cap:** \$10.9 million

Chief executive officer: Steve Lydeamore

Board: Sue MacLeman (chair), Dr Jane Ryan, Dr Tracie Ramsdale, Dr David Brookes

Financials (year to June 30, 2019): customer revenue (licencing fees) \$663,405 (previously \$6,467), other income* \$877,573 (\$1.34m), loss of \$2.87 million (previous loss of \$3.6 million), cash balance \$5.4 million (\$7.65 million).

* mainly \$840,932 Federal R&D Tax Incentive

Identifiable holders: Parma Corp (Mel Bridges) 11.95%, RTL Group (Lederer family) 10.07%, Myeng Pty Ltd (Dr Tracey Mynott) 8.89%, Tiga Trading (Thorney Investments) 5.64%.

Logically, shares in the two-legged and four-legged gut health play should have surged after animal health giant Zoetis walked away from a partnering deal in June this year for "portfolio reasons".

At the time of the May 2018 partnership, Anatara said it could not have had a better partner in the US-based Zoetis, which assumed the rights for all livestock and equine applications.

But after that supposed feel-good event, Anatara shares tumbled 40 percent because the terms weren't as lucrative as investors expected.

Having now regained its rights to Detach, in theory the company can execute a better deal with one of the other potential partners. Instead, investors were spooked by Zoetis's lack of interest and excised a further 43 percent from the share price.

Anatara maintains its faith in its lead product Detach, which is approved locally as a treatment for scour (diarrhoea) in piglets.

And no, it's not an oink-ment, but an oral drench.

"It came as a surprise and a disappointment," Anatara CEO Steve Lydeamore says of Zoetis's brusque termination. "But in some ways, it presents an opportunity."

Anatara's greater prospects lie with human health, as a remedy for the common but difficult-to-treat afflictions of irritable bowel syndrome and inflammatory bowel disease (ulcerative colitis and Crohn's disease).

Mr Lydeamore notes that gut health is "very topical", which is an understatement given the range of digestion-related 'wellness' products purveyed by the likes of Blackmores and Suisse.

"If you do a Google search on the topic you will get more than 400 million hits," he says.

He's right: your columnist's rigorous cross-checking of this claim reveals 530 million online references.

The problem bugging all of us

Detach is an alternative for antibiotics which are being banned from the food chain as microbial resistance builds. The active ingredient, bromelain, is derived from the stems of pineapples, of all things.

Describing antimicrobial resistance as "one of the most urgent health issues of our time", the World Health Organisation projects up to 10 million people will die annually by 2050 if nothing is done.

Mr Lydeamore says 70 percent of bacteria are resistant in one form or another to antibiotics.

Across the world, 70 percent of antibiotics are used in meat production but the Europeans have set the trend by banning them from the food chain. A soil pollutant, zinc oxide will also be outlawed on the Continent from 2022.

Mr Lydeamore says US surveys also show that US consumers think antibiotic-free meat is better for their health - although they have no problem with guns which also tend to be injurious to their wellbeing. "So there is a push from consumers - not just governments and regulators - to reduce the use of antibiotics," he says.

Anatara's evolving story

Like a trots-afflicted traveller, Anatara has undergone a board room, management and strategic purge since we last covered the stock in August last year.

In December Mr Lydeamore became CEO, with interim CEO Dr Tracie Ramsdale returning to non-executive director duties. Mr Lydeamore has 26 years of global healthcare experience, mainly at Apotex (Canada's biggest drug company) and FH Faulding (now Mayne Pharma).

Anatara chairman and industry legend Mel Bridges retired in May last year, to be replaced by Sue MacLeman (who is also on the boards of Palla Pharma, Novita Healthcare, Oventus Medical and industry body MTP Connect).

Anatara's advisory board includes Monash University gastro-enterologist Prof Peter Gibson, who shares fame with Messrs Atkins and Pritikin and Ms Paltrow for inventing a diet: FODMAP.

More of an anti-FODMAP regimen, FODMAP seeks to avoid fermentable carbohydrates that are thought to exacerbate irritable bowel diseases. (For those remotely interested, FODMAP stands for fermentable oligosaccharides, disaccharides, monosaccharides and polyols).

Steering clear of diarrhoea

An enzyme extract, bromelain blocks the receptor sites in the gut that the parasites attach to (thus causing diarrhoea). But Anatara has veered away from its original idea of treating diarrhoea alone, after deciding the market is not that attractive.

Mr Lydeamore notes that sales of the two key travellers' diarrhoea products - including the ASX-listed Immuron's Travelan - have been modest.

"It turns out people aren't willing to take a product prophylactically for what you may or may not get on holiday," he says. "They tend to deal with it after the fact with products such as Imodium [loperamide]." And close proximity to a bathroom at all times.

A three pronged approach to bug busting

Management's focus has turned from developing Detach as a diarrhoea treatment to a three-pronged curative for irritable bowel syndrome and inflammatory bowel disease.

With symptoms similar to overindulging at a Christmas lunch, irritable bowel syndrome afflicts 11 percent of the population and one in five at any one time.

While irritable bowel syndrome is a collection of symptoms, inflammatory bowel disease is a more specific disorder causing elevated white cell counts, bleeding, fever pain and diarrhoea.

Between 30 to 50 percent of sufferers of both afflictions turn to dietary supplements or complementary healthcare.

With its prospective GASTROintestinal Repositioning Product, or Garp, Anantara's remedy aims to restore normal microbial functions, treat inflammation and repair mucosal damage. (It has nothing to do with dying ball-turret gunners, unfortunate accidents in driveways or John Irving.)

In its natural state, the body has trillions of microbiomes, which outnumber human cells by about 100 to one. About 95 percent of these desirous bugs are in the gut, which is also the source of about 90 percent of diseases.

Microbiome therapeutics is a trendy field of research but it was perfected about 1,700 years ago by the Chinese with a treatment called "yellow soup" - not a hearty pumpkin broth but a serve of watered down faeces donated by a healthy patient to boost the immunity of a sick one.

Anantara's more palatable curative is expected to be developed as an over-the-counter alternative to existing treatments such as probiotics, which are largely unproven. The over-the-counter approach presents fewer regulatory barriers and faster speed to market.

"Because the products are natural and safe, we could put a product on the market now as a dietary supplement," Mr Lydeamore says. "But we would like a product to have evidence that it actually works."

Can't argue with that.

Detach clings through the ages

Detach has a long - but interrupted - history with animal health, having been marketed in Australia in the 1990s under a different name.

The product achieved a 40 percent market share, despite there being no imperative at the time to remove antibiotics from the food chain. However, then owner Ciba-Geigy was taken over by Novartis, which preferred to focus on human health.

One of the co-inventors of the original Detach, Dr Tracey Mynott worked on a reformulation and Anantara listed in October 2014 after raising \$7 million at 50 cents apiece.

(In 2006, Dr Bridges, Dr Ramsdale and Dr Mynott launched Incitive on the ASX to develop bromelain as a cancer treatment, but it was not to be.)

Ms Mynott resigned as Anantara's chief scientific officer in August last year, but has retained the rights to develop Detach as a diarrhoea treatment for the third world.

In 2017, the US Food and Drug Administration confirmed bromelain's 'generally regarded as safe' status. In October last year, the Australian Pesticides and Medical Veterinary Authority granted Detach approval as a scour treatment.

The local assent paves the way for Detach to be approved in South East Asia, which is not exactly short of piggeries and poultry farms.

What's next?

The company is conducting preclinical (proof-of-concept) trials for inflammatory bowel disease, with data expected later this year.

Preclinical activity is also underway for a human irritable bowel syndrome trial, expected to start recruiting early next year.

The trial is likely to involve 100 patients. "We shouldn't have too much trouble recruiting them," Mr Lydeamore says.

The company also expects partnering discussions for the human program to continue next year, with animal health discussions underway.

Mr Lydeamore says that rather than handing the rights to one party holus bolus - an approach that proved unpopular with investors with Zoetis - the rights could go to multiples partners based on species or geographies (or both).

Finances and performance

As of June 30, Anantara had \$5.4 million in the kitty - enough to fund the irritable bowel syndrome trial.

This dosh includes a \$US2.5 million (\$3.7 million) upfront payment from Zoetis, which Anantara pocketed as a consolation prize.

Anantara shares soared from 50 cents at listing to a December 2017 peak of \$1.80, ascribing a \$90 million market valuation.

The current price - close to the record low of 20c a share after Zoetis walked away - values the company at \$11 million.

Despite its re-emphasis on the two-legged species, Anantara still boasts the Lederer family (owner of Primo Smallgoods) as a 10 percent shareholder.

Although he's left the building, Dr Bridges remains the biggest holder on just under 12 percent.

Dr Boreham's diagnosis:

Anatara is setting itself up to play in the expansive market for over-the-counter gastrointestinal and digestive products, estimated to be worth \$US25 billion (\$37 billion) and growing to \$US36 billion by 2021.

There's a lot of snake oil out there, so a product with genuine clinical claims should enjoy a key advantage in the global market.

Between 15 and 20 percent of piglets die before weaning because of conditions such as scour.

Despite the Zoetis setback, the animal health market still looks worthwhile, but investors need to re-set expectations about the dollar rewards a partnership could bring.

With human health Anatara needs to firm up its clinical evidence and sign some decent partnerships, or else its proposals will be little more than - dare we say it - loose motions.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he likes to think he has the runs on the board.

MESOBLAST

Mesoblast says revenue for the year to June 30, 2019 was down 3.6 percent to \$US16,722,000 (\$A24,918,623) with net loss after tax up 154.5 percent to \$US89,799,000 (\$A133,815,776).

Mesoblast said milestone revenue was \$US11 million and included \$US10 million from Tasly Pharmaceutical Group for the development, manufacture and commercialization of its allogenic MPC products, MPC-150-IM and MPC-25-IC in China, and \$US1 million for its licence with JCR Pharmaceuticals for net Japan sales milestones of Temcell for graft versus host disease.

The company said it had commercialization revenue of \$US5,003,000 from sales of Temcell in Japan by JCR and interest revenue of \$US719,000.

Mesoblast said that research and development expenditure fell 9.3 percent to \$US59,815,000, with manufacturing costs up 178.8 percent to \$US15,358,000 and administration costs down 1.3 percent to \$US21,625,000.

The company said that net tangible asset backing per share fell from 4.88 US cents to negative 8.71 US cents, with diluted loss per share up 139.6 percent to 18.16 US cents.

Mesoblast said it had cash and cash equivalents of \$US50,426,000 at June 30, 2019 compared to \$US37,763,000 at June 30, 2018.

Mesoblast fell 3.5 cents or 2.4 percent to \$1.435.

AVITA MEDICAL

Avita says revenue for the year to June 30, 2018 was up 49.8 percent to \$17,031,918, with net loss after tax up 109.5 percent to \$34,603,141.

Avita said that Recell wound care sales was up 542.7 percent to \$7,705,398 with US Biomedical Advanced Research and Development Authority (BARDA) contract revenue down 18.4 percent to \$8,259,152.

Avita chief financial officer Tim Rooney told Biotech Daily the revenue figures were adjusted following the adoption of International Financial Reporting Standards guidelines reclassifying Recell revenue from the BARDA contract from sale of goods to other income. The company said diluted loss per share was up 54.2 percent to 2.73 cents, with net tangible asset backing per share up 8.05 percent to 1.61 cents, and cash and equivalents of \$28,983,491 at June 30, 2018 compared to \$14,825,532 at June 30, 2017.

Avita fell three cents or 6.2 percent to 45.5 cents with 9.3 million shares traded.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS).

Avecho says revenue for the six months to June 30, 2019 was up 409.4 percent to \$4,176,196 with net loss after tax turned to a profit of \$2,305,152.

Avecho said revenue was from royalties and licence fees, with \$3,571,429 from Ashland's rights to its Vital ET and tocopheryl phosphate mixture (TPM) vitamin E products.

The company said net tangible asset backing per share rose 88.2 percent to 0.32 cents and a previous diluted loss per share of 0.12 cents turned to earnings of 0.15 cents for the six months to June 30, 2019, and had cash and cash equivalents of \$4,689,777 at June 30, 2019 compared to \$2,111,171 at June 30, 2018.

Avecho was up 0.1 cents or 25 percent to 0.5 cents with 8.0 million shares traded

MEDLAB CLINICAL

Medlab says revenue for the year to June 30, 2019 was up 40.8 percent to \$6,059,584 with net loss after tax up 71.7 percent to \$8,168,811.

Medlab said sales of its probiotics and food additives rose 47.0 percent to \$6,074,834 and the increased loss was due to costs for production of food additives for pharmacies.

The company said diluted loss per share rose 64.7 percent to 3.82 cents, with cash and equivalents of \$11,441,975 at June 30, 2019 compared to \$20,332,694 at June 30, 2018.

Medlab fell 1.5 cents or 3.1 percent to 46.5 cents

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the year to June 30, 2019, fell 14.9 percent to \$3,992,859 with net loss after tax up 38.3 percent to \$835,508.

Allegra said revenue came from sales of orthopaedic products and fell due to lower demand of its primary knee systems and clavicle fracture system, along with the Federal Government's 10.5 percent compulsory benefits reduction of prosthesis rebates.

The company it aimed to improve sales and distribution of products, and would commercialize its Sr-HT-Gahnite bone substitute material in the next financial year.

The company said diluted loss per share was up 31.3 percent to 0.84 cents, with net tangible assets per share down 12.6 percent to compared to 6.27 cents at June 30, 2018.

Allegra said it had cash and cash equivalents of \$1,076,425 at June 30, 2019, compared to \$1,614,937 at June 30, 2018.

Allegra was untraded at 11 cents.

DORSAVI

Dorsavi says revenue for the year to June 30, 2019 was down 26.6 percent to \$3,223,869 with net loss after tax up 7.9 percent to \$4,020,751.

Dorsavi said sales revenue was down 26.7 percent to \$2,514,992, including \$1,336,817 for clinical income from its wearable sensors for physical therapy patient assessments and \$956,624 for workplace income from wearable devices and its Myvisafe product in the US, the UK and Australia.

The company said net tangible asset backing per share was down 56.7 percent to 1.43 cents, diluted loss per share was down 3.2 percent to 2.15 cents and it had cash and cash equivalents of \$2,766,419 at June 30, 2019 compared to \$3,966,857 at June 30, 2018. Dorsavi was untraded at six cents.

ADHERIUM

Adherium says revenue for the year to June 30, 2019 was down 52.6 percent to \$2,779,000, with net loss after tax up 26.3 percent to \$11,794,000.

Adherium said the reduction in revenue was due to a significantly large product design and engineering service revenue the previous year, as well as costs related to promotional pricing this year.

The company said that diluted loss per share rose 25.9 percent from 5.4 cents in the previous year to 6.8 cents for the year to June 30, 2019.

Adherium said that net tangible asset backing per share was down 94.4 percent from 7.2 cents at June 30, 2018 to 0.4 cents at June 30, 2019.

The company said it had cash and cash equivalents of \$12,118,000 at June 30, 2019, compared to \$763,000 at June 30, 2018.

Adherium fell 0.1 cents or 3.6 percent to 2.7 cents

TOTAL BRAIN

Total Brain says revenue for the year to June 30, 2019 was down 0.5 percent to \$2,602,137 with net loss after tax down 62.9 percent to \$8,570,754.

Total Brain said revenue was from fees from customers to access its software platform for mental health.

The company said net tangible assets per share fell 49.3 percent to 0.68 cents, diluted loss per share fell 77.3 percent to 1.45 cents and it had cash and cash equivalents of \$5,214,802 at June 30, 2019 compared to \$6,615,972 at June 30, 2018.

Total Brain was up 0.1 cents or 2.9 percent to 3.6 cents with 12.2 million shares traded

NUHEARA

Nuheara says revenue for the year to June 30, 2019 was down 41.1 percent to \$2,429,365 with net loss after tax up 35.2 percent to \$10,027,238.

Nuheara said revenue was from sales of its hearing products and net loss increased due to staff growth, research and development, new hardware and software products and infrastructure to support a new sales channel of its hearing healthcare products.

Nuheara said that net tangible asset backing per share rose from 0.5 cents to 1.0 cent, diluted loss per share rose 22.9 percent to 1.02 cents and it had cash and cash equivalents of \$3,220,079 at June 30, 2019 compared to \$8,345,698 at June 30, 2018.

Nuheara was unchanged at 2.6 cents with 4.1 million shares traded.

MICRO-X

Micro-X says revenue for the year to June 30, 2019 was up 20.2 percent to \$1,931,000 with net loss after tax down 40.7 percent to \$9,834,000.

Micro-X said revenue came from the first sales of its DXR Revolution Nano mobile x-ray for bedside imaging in hospital wards and intensive care units.

The company said it expected future sales of its Nano mobile x-ray to increase through partner Carestream Health, with the Rover mobile military x-ray system launch in 2021.

The company said that diluted loss per share fell 42.3 percent to 6.63 cents and net tangible assets per share increased 50.2 percent to negative 3.08 cents compared to negative 2.05 cents at June 30, 2018.

Micro-X said it had cash and cash equivalents of \$1,606,000 in at June 30, 2019 compared to \$4,068,000 at June 30, 2018.

Micro-X was up 2.5 cents or 7.35 percent to 36.5 cents with 1.2 million shares traded

TBG DIAGNOSTICS

TBG says revenue for the six months to June 30, 2019 was up 21.2 percent to \$1,558,390 with net loss after tax turned to a profit of \$10,468,540.

TBG said revenue was from invitro diagnostics sales and the net profit was “primarily due to a gain on discontinued operations relating to the disposal of the China group, TBG Xiamen” and the early settlement of deferred consideration of PG500 assets sold in 2016.

The company said net tangible asset backing per share was up 54.7 percent to 8.2 cents, diluted loss per share of 1.02 cents was turned to a diluted earnings per share of 4.88 cents for the six months to June 30, 2019 and it had cash and cash equivalents of \$6,920,214 at June 30, 2019 compared to \$6,452,172 at June 30, 2018.

TBG was untraded at 3.1 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says revenue for the year to June 30, 2019 was up 24.8 percent to \$1,468,076, with net loss after tax up 44.4 percent to \$2,080,275.

Proteomics said revenue was from analytical services and licencing fees, with expenditure focused on the commercialization of its Promarkerd diabetic kidney disease test.

The company said that basic loss per share rose 50.0 percent from 2.0 cents in the previous year to 3.0 cents for the year to June 30, 2019.

Proteomics said that net tangible asset backing per share was down 50.0 percent from 8.0 cents at June 30, 2018 to 4.0 cents at June 30, 2019, and it had cash and cash equivalents of \$1,511,430 at June 30, 2019, compared to \$2,316,781 at June 30, 2018.

Proteomics was unchanged at 27.5 cents.

ORTHOCELL

Orthocell said revenue for the year to June 30, 2019 was up 26.1 percent to \$1,239,371 with net loss after tax up 1.65 percent to \$5,852,214.

Orthocell said revenue was from its Ortho-autologous tenocyte implantation cell therapy for chronic tendon injuries and its Celgro dental bone collagen regeneration device.

The company said diluted loss per share fell 10.9 percent to 4.9 cents and it had cash and cash equivalents of \$11,236,299 at June 30, 2019 compared to \$2,910,233 at June 30, 2018.

Orthocell was up half a cent or 1.2 percent to 41 cents.

SUDA PHARMACEUTICALS

Suda says revenue for the year to June 30, 2019 was up 186.3 percent to \$1,219,083 with net loss after tax up 29.2 percent to \$7,795,039.

Suda said revenue increased with its development, licence and supply agreement with Strides for its Oromist oral spray version of sumatriptan for migraine, a supply and licence agreement with Mitsubishi Tanabe Pharma Singapore for Zolpimist and a feasibility agreement with Zelda Therapeutics.

The company said the net loss was primarily due to the impairment of its Artimist project for \$6,276,758.

Suda said net tangible asset backing per share rose from negative 0.32 cents to 0.10 cents for the year to June 30, 2019 and diluted loss per share fell 28.9 percent to 0.32 cents.

The company said it had cash and cash equivalents of \$4,313,562 at June 30, 2019 compared to \$98,125 at June 30, 2018.

Suda was unchanged at 0.4 cents with 4.1 million shares traded.

OPTISCAN IMAGING

Optiscan says revenue for the year to June 30, 2019 was down 52.3 percent to \$1,041,679 with net loss after tax up 15.2 percent to \$2,344,119.

Optiscan said revenue was from the development and commercialization of its confocal microscopes, system rentals and the provision of services.

The company said net tangible assets per share fell 18.9 percent to 0.60 cents, diluted loss per share rose 10.2 percent to 0.54 cents and it had cash and cash equivalents of \$1,752,440 at June 30, 2019 compared to \$1,562,494 at June 30, 2018.

Optiscan fell 0.3 cents or 6.5 percent to 4.3 cents.

NOVITA HEALTHCARE

Novita says it has raised \$1.09 million in a shortfall placement of 109,000,000 shares at one cent each, taking the total raised to \$1.575 million.

Earlier this week, Novita said its five-for-11 rights issue raised \$485,796 of a hoped-for \$2 million, its Detect and Train products, along with associated capital expenditures, operating costs and working capital (BD: Aug 27, 2019).

Today, the company said that directors had the right to place the remaining shortfall shares at their discretion within three months of the closing date of the rights offer.

Novita was up 0.2 cents or 20 percent to 1.2 cents.

REGENEUS

Regeneus says it has raised \$620,157 of a hoped for \$3.2 million in its one-for-six rights issue at eight cents a share.

Earlier this month, Regeneus said rights issue was partially underwritten by directors, with \$1.4 million in directors' loans to be converted into equity and \$400,000 to be contributed by directors Barry Sechos and Glen Richards (BD: Aug 1, 2019).

Today, Regeneus said the \$1.4 million in directors' loans and \$400,000 in cash would be converted into 17.5 million shares and 5.0 million shares.

The company said it had a shortfall of 9,437,872 shares and the directors had the right to place any shortfall shares within three months of the closing date.

Regeneus fell 1.4 cents or 16.7 percent to seven cents.

TELIX PHARMACEUTICALS

Telix says it will begin a 40-patient, phase I/II study of TLX250-CDx, or 89-zirconium-girentuximab, for renal cancer imaging in Japan.

Telix said the trial would be a bridge to the company's international Zircon 250-patient phase III study of TLX250 which began in October 2018 and would include at least 15 sites in Europe, Australia and the US (BD: Oct 23, 2018).

The company said the phase I part of the Japan trial would be a single-site study to evaluate "an initial cohort of patients to confirm that pharmacology [and] dosimetry is equivalent in Japanese subjects".

Telix said the phase II part would be a multi-centre study that would operate under a protocol that would be "effectively identical to the Zircon trial".

The company said the trial was the first of its kind in Japan and it would begin after receiving approval from the Japanese Pharmaceutical and Medical Devices Agency.

Telix said it expected enrolment to begin in 60 days and the trial would take "six to nine months to complete".

Telix Pharmaceuticals Japan KK president Dr Shintaro Nishimura said the trial was "the first formal clinical trial for a zirconium-labeled [positron-emission tomography] imaging agent in Japan".

"TLX250-CDx has tremendous potential to deliver benefit to Japanese cancer patients," Dr Nishimura said.

Telix fell two cents or 1.4 percent to \$1.365 with 1.2 million shares traded

NOVITA HEALTHCARE

Novita says it has received Conformité Européene (CE) mark approval for its Tali Train mobile software for attention training in children between the ages of three and eight.

Novita said attention deficit hyperactivity disorder (ADHD) and other attention related issues affected five percent of school aged children across Europe and inattention was the number one globally reported childhood issue.

The company said Tali Train was a mobile and tablet application software which aimed to improve attention as a cognitive skill by targeting the "core underlying issues" of attention problems".

Novita said Tali Train could be used as an alternative to psychostimulants and other behavioral training, or as a complimentary program to other treatment.

The company said the CE mark approval was supported by data collected in multiple randomized control clinical trials at Melbourne's Monash University.

ELIXINOL GLOBAL

Elixinol says it has a five-year exclusive distribution agreement with 25th Group for its Elixinol branded hemp and cannabidiol products in Belgium and Luxembourg

Elixinol said the agreement with the Brussels-based 25th Group was "based on achievement of minimum annual sales targets".

The company said that the 25th Group would be a co-distributor for the Netherlands and Switzerland, but did not provide details of the minimum sales targets.

Elixinol chief executive officer Stratos Karousos said the agreement would allow "Elixinol to establish a dominant position across central Europe and launch Elixinol branded products throughout retail channels in Benelux and Switzerland".

Elixinol was up two cents or 0.9 percent to \$2.31 with 654,469 shares traded.

MEDIBIO

Medibio says it has a fourth agreement with Compass Group PLC to trial its Illumen for mental health on up to 150 defense division employees.

Medibio said it would provide the Chertsey, England-based Compass' UK employees access its Illumen mobile and internet applications to screen for early symptoms of mental health issues including depression, anxiety and stress.

The company said users would be provided with a "well-being snapshot" to monitor and make improvements over time and Compass would receive anonymous aggregate data to support and manage the mental health of its 600,000 employees.

Last month, Medibio signed its first three trial agreements with Compass, including the study of Compass UK offshore and remote division employees and Compass Group Australia employees (BD: Jul 1; Jul 19; Jul 30, 2019).

Medibio was up 0.1 cents or 8.3 percent to 1.3 cents with 41.0 million shares traded

MEDIBIO

The London-based Chelodina Master Fund says it has become a substantial shareholder in Medibio with 25,000,000 shares or 8.81 percent of the company.

In a substantial shareholder notice, Chelodina said that on August 9, 2019 it purchased all 25,000,000 shares for \$250,000 or one cent each through the London-based Marble Bar Asset Management LLP, who was the beneficial holder of the shares.

Last week Medibio said it had completed an "oversubscribed" share plan offer at one cent a share, raising \$1,210,000.

ALCIDION GROUP

Alcidion says that director Rebecca Wilson will replace chairman Ray Blight from today, with Mr Blight continuing as a non-executive director.

Alcidion said that Mr Blight co-founded Alcidion in 2000 with Dr Malcolm Pradhan and was group chief executive officer and executive chairman until the acquisitions of MKM Health and Patientrack in July (BD: Apr 24, 2018).

Ms Wilson told Biotech Daily that "the succession plan has been discussed for some months and is unrelated to yesterday's director's interest statement".

Ms Wilson said that Mr Blight led the succession planning which began in January 2019 when he stepped down from executive duties and became the non-executive chairman.

Alcidion said that Ms Wilson had more than 20 years' experience working with public companies in health, technology and life sciences sectors, and has provided advice to boards and executive teams on mergers and acquisitions, issues management, investor and corporate relations and capital raisings.

Ms Wilson is investor and public relations company WE Buchan's head of region for Australia and Singapore.

Alcidion was unchanged at 17 cents with 1.25 million shares traded.

COGSTATE

Cogstate says Ingrid Player will replace director Jane McAloon, who will retire following the annual general meeting on October 21, 2019.

Cogstate said Ms Player was a senior executive at Melbourne's Healthscope and held a Bachelor of Economics and a Bachelor of Laws from Monash University.

Cogstate fell half a cent or 2.4 percent to 20.5 cents.

[MACH7 TECHNOLOGIES](#)

Mach7 says its Burlington, Vermont-based managing director Mike Lampron will receive a base salary of \$US275,000 (\$A409,814) from July 1, 2019.

Mach7 said Mr Lampron was appointed in June (BD: Jun 20, 2019).

The company said he would receive short-term incentives of up to \$US75,000 (\$A111,767), subject to filing a positive earnings before interest, tax, depreciation and amortization (Ebitda) report at June 30, 2020.

The company said Mr Lampron would be eligible for long-term incentives of up to 750,000 options in three groups of 250,000 options vesting respectively on July 1, 2020, July 1 2021, and July 1, 2022, exercisable at the higher of the five-day volume weighted average price at grant date or 80 cents, 95 cents, or \$1.10 a share, respectively, all expiring within five years of the grant date.

Mach7 said Mr Lampron would receive \$US20,000 (\$A29,804) for his role as interim chief executive officer earlier this year, which he will use to buy Mach7 shares.

Mach7 fell 1.5 cents or 2.05 percent to 71.5 cents.