# Biotech Daily

Monday February 19, 2024

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH EVEN: RESONANCE UP 8%; ACTINOGEN DOWN 10%**

*** COCHLEAR H1 REVENUE UP 25% TO $1.1b; PROFIT UP 35% TO $191m**

*** STARPHARMA LOSES FDA VIVAGEL BV APPEAL; MORE DATA REQUIRED**

*** REX, AO FOUNDATION ORTHOPAEDIC SCREW PARTNERSHIP**

*** PYC RECEIVES $4.5m FOR GOPOMELO, GOOGLE. DEAL**

*** LTR STARTS SPONTAN ERECTILE DYSFUNCTION TRIAL**

*** LITTLE GREEN WITHDRAWS UK RESET PSYCHEDELICS SPIN-OUT**

*** MELODIOL (CRESO) REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CYCLOPHARM APPOINTS JOHN WIGGLESWORTH DIRECTOR**

## MARKET REPORT

The Australian stock market edged up 0.09 percent on Monday February 19, 2024, with the ASX200 up 6.8 points to 7,665.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Resonance was the best, up 0.4 cents or 7.8 percent to 5.5 cents, with 271,857 shares traded, followed by Opthea up 7.7 percent to 63 cents, with one million shares traded.

Alcidion and Clinuvel climbed more than five percent; Micro-X and Neuren improved more than four percent; Atomo and Telix were up more than three percent; Immutep rose 2.9 percent; Clarity, Emvision, Next Science, Paradigm and Proteomics were up one percent or more; with Nanosonics, Pro Medicus and Volpara up by less than one percent.

Actinogen led the falls, down 0.5 cents or 10.4 percent to 4.3 cents, with 23.2 million shares traded. 4D Medical lost eight percent; Dimerix and Starpharma were down six percent or more; Orthocell and Prescient fell five percent or more; Amplia, Impedimed and Syntara (Pharmaxis) were down more than four percent; Avita was down 3.6 percent; Cochlear, Curvebeam, Cynata, Nova Eye, Percheron (Antisense) and Polynovo shed two percent or more; CSL, Genetic Signatures and Universal Biosensors were down more than one percent; with Resmed down by 0.9 percent.

## COCHLEAR

Cochlear says sales revenue for the six months to December 31, 2023 was up 24.7 percent to $1,113,400,000, with net profit after tax up 35.2 percent to $191,400,000.
Cochlear said that the record sales revenue was “driven by strong growth in cochlear implants and sound processer upgrades”.
The net profit after tax was the second largest half year profit in the company’s history, following the $236,200,000 for the six months to December 31, 2020 (BD: Feb 19, 2021).
The company said cochlear implant sales were up 26.4 percent to $648.5 million and service sales, including sound processor upgrades rose 34.9 percent to $348.9 million, with its acoustics division including bone conduction and acoustic implants falling 4.1 percent to $116.0 million.
Cochlear said that US sales rose 31.7 percent to $444.5 million, Europe, Middle East and Africa improved 22.95 percent to $352.5 million, with the Asia Pacific up 8.7 percent to $175.5 million.
The company said an interim dividend of $2.00 a share, franked at $1.40, for shareholders on the record date of March 22 would be paid on April 15, 2024, compared to a $1.55 interim dividend franked at 0.54 cents for the six months to December 31, 2022.
Cochlear said research and development spending was up 24.1 percent to $127,300,000 or 11.4 percent of total revenue.
The company said it expected “the positive momentum of the … [six months] to continue into the second half [of the year] … [and expects] profit growth to be driven by a combination of revenue growth and improved net profit margin”.
Earlier this month, Cochlear said it had increased its underlying net profit guidance for the year to June 30, 2024 to $385 million to $400 million, due to “better-than-expected growth” (BD: Feb 8, 2024).
The company said diluted earnings per share rose 35.3 percent to $2.913 with net tangible assets per share up 1.7 percent to $20.202, and it had cash and equivalents of $485,200,000 at December 31, 2023 compared to $521,700,000 at December 31, 2022.
Cochlear said that it had paused its up-to $75 million share buy-back given the “high interest rate environment” with $73 million in shares acquired (BD: Feb 15, 2023).
Cochlear fell $6.72 or two percent to $327.82 with 134,432 shares traded.

## STARPHARMA

Starpharma says the US Food and Drug Administration has refused its appeal to approve Vivagel BV, maintaining the need for “additional clinical efficacy data”.
In 2018, Starpharma said the FDA requested “confirmatory clinical data” to approve the use of Vivagel for bacterial vaginosis in the US; and in 2019, said it was awaiting a formal outcome of an approval path discussed with the FDA (BD: Jan 20, Apr 11, 2019).
Today, Starpharma said it had disputed the FDA’s position through “multiple submissions, meetings, detailed analyses, and the preparation of regulatory precedents”.
The company said the FDA raised “no approvability issues with the safety, toxicology, manufacturing or quality aspects” of Vivagel BV.
Starpharma said its FDA application remained open but that it was “not planning to pursue additional clinical studies for Vivagel BV on its own at this time”.
The company said it would pursue commercialization of Vivagel BV in the more than 45 markets where it was approved and the FDA’s decision did not alter its status.
Starpharma chief executive officer Cheryl Maley said “naturally, this is not the outcome Starpharma was hoping for”.
Starpharma fell one cent or 6.9 percent to 13.5 cents with 1.1 million shares traded.

## REX ORTHO PTY LTD

Perth's Rex Ortho says it has financial support from the Swiss AO Foundation for research, development and trials of its orthopaedic screw technologies.
Rex Ortho executive chair Ian Brown told Biotech Daily that the Biel-Bienne-based Arbeitsgemeinschaft für Osteosynthesefragen (AO) foundation had provided undisclosed funding for four to five years of research and development, clinical trials and US Food and Drug Administration applications for its removable orthoaedic screw systems.
Biotech Daily estimates that the total amount of funding is $3 million to $5 million.
The former chief executive officer of the ASX-listed Cordlife and entrepreneur in residence at the Fountainbleu, France-based Institut Européen d'Administration des Affaires (Insead), Mr Brown also worked at Milan's Instrumentation Laboratory and London's Bioceramics Therapeutics.
Mr Brown said that initial inventors of the first iteration of the removable screw system were Perth orthopaedic surgeons Dr Phil Hardcastle, Dr Markus Kuster and Dr Gabriel Lee.
Mr Brown said the company name was an acronym for "removable and expandable".
Mr Brown said that the system was taken to Perth's Curtin University and further developed by Dr Intan Oldakowska (now Rex chief scientific officer) and her spouse Dr Matt Oldakowski (now Rex chief technical officer).
A video on the company website shows the F-Rex screw system including inserting two leaves, or tulips, that expand within the neck of femur to hold a proximal fracture tight to the femur, with the screw able to be removed should later surgery require it.
Mr Brown said that the funding from the AO foundation would enable work to begin on a second screw system designed for spinal surgery.
A Rex media release said that the AO Foundation was "the world's leading orthopaedic surgeon network" and the collaboration would cover development costs and "invaluable access to key opinion-leading surgeon groups and expert consultants to guide prototyping, manufacturing, clinical trial [and] regulatory clearances".
Rex said that the goal was to produce a market-ready S-Rex spine screw (specifically a lumbar pedicle screw for the $US1billion global pedicle screw market.
The company said that its screw system had "the potential to solve the problem of screw loosening in osteoporotic bone".
In the media release Mr Brown said "the F-Rex hip screw delivers what surgeons have asked for - improved fixation, stability and removability all in one fixation screw".
Rex said it was preparing for an F-Rex clinical study with Dr Alicja Bojan at Gothenburg's Sahlgrenska University Hospital in Sweden.
The company said its technology was supported by a patent portfolio of five patent families including 24 granted patents, including two US patents.
Rex is a private company.

## PYC THERAPEUTICS

PYC says it has received the $4.5 million upfront fee from its artificial intelligence-based drug discovery collaboration with Gopomelo Pte Ltd and Google Cloud.
Last year, PYC said it would pay $10 million to develop an artificial intelligence-based drug development and discovery platform with Gopomelo and Google Cloud, and that it would receive $4.5 million for its data sets to execute the project, which would take 12 months (BD: Jan 21, 2024).
PYC was up 0.6 cents or 7.8 percent to 8.3 cents.

## LTR PHARMA

LTR Pharma says it has begun recruitment for its bio-equivalence trial of its Spontan nasal spray, which used vardenafil, or Levitra, for erectile disfunction.

Earlier this month, LTR Pharma said it had completed quality control milestones in the manufacturing of Spontan for the 18-healthy volunteer, randomized, open-label, single-dose bioequivalence study (BD: Feb 6, 2024).

Today, the company said the four-week trial would assess the relative "bio-availability" of vardenafil following administration of the Spontan nasal spray, containing 5mg of vardenafil in two 2.5mg nasal sprays, compared to oral delivery of 10mg vardenafil tablets.

LTR Pharma said contract research organization Southern Star Research would manage various aspects of the study, including monitoring, data management, safety and pharmacokinetic analysis.

The company said it hoped to use the data for its new drug application with the US Food and Drug Administration and the Australian Therapeutic Goods Administration.

LTR Pharma chair Lee Rodne said "commencing recruitment for our upcoming bioequivalence clinical study for our lead product, Spontan, is a significant achievement for our company and in keeping with the clearly mandated clinical and commercial milestones that we communicated during our recent [initial public offer]".

"This study will form a critical piece of the data package we plan to submit to the FDA and TGA, supporting our plans for expedited regulatory approval for Spontan in key initial markets," Mr Rodne said.

LTR was unchanged at 30 cents.

## LITTLE GREEN PHARMA

Little Green Pharma says it has withdrawn its prospectus to spin-out subsidiary Reset Mind Sciences as it is not eligible to list on the UK stock exchange.

In November, Little Green said its extraordinary general meeting would vote to approve the separation of its subsidiary Reset psychedelics business, and that the spin-out of the 3,4 methylene-dioxy-meth-amphetamine (MDMA or ecstasy) and mushroom-based psilocybin business was in order "to focus on its medical cannabis business" later extending the meeting date several times (BD: Nov 10, 2023).

In November, the company said Reset intended to make a public offering of 10,000,000 shares at 20 cents a share, to raise up to $2,000,000 with existing eligible Little Green shareholders having a priority for up-to 5,000,000 Reset shares.

Today, Little Green said the withdrawal was due to the London Stock Exchange's Alternative Investment Market decision that, since "psychedelic-assisted psychotherapy is not … permitted in the United Kingdom, UK funds cannot invest and Reset is not … capable of listing on a UK stock exchange".

The company said that while the news was "disappointing, … [it] believes that "with the rapid advance of psychedelics globally, [psychedelic-assisted psychotherapy] services will be legal in the UK in the near term at which time … [it] will re-engage with regulators".

Little Green was up half a cent or 3.7 percent to 14 cents.

## MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

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

Trading will resume on February 21, 2024, or on an earlier announcement.

Melodiol last traded at 1.4 cents.

## CYCLOPHARM

Cyclopharm says it has appointed John Wigglesworth as a non-executive director, effective from today.

Cyclopharm said Mr Wigglesworth had 37 years of experience, including about 25 years as a partner at Klynveld Peat Marwick Goerdeler, and has “held several previous board positions over the past decade including Atlas Arteria and also in public sector health entities”.

The company said Mr Wigglesworth’s “extensive experience will contribute significantly to the company’s strategic direction, governance, and overall success” following the US Food and Drug Administration approval of Technegas.

According to his Linkedin profile, Mr Wigglesworth held a Bachelor of Economics from Sydney’s Macquarie University.

Cyclopharm was unchanged at $1.85.