



# Biotech Daily

Monday October 24, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: NOVA EYE UP 9%; KAZIA DOWN 9%**
- \* **FEDERAL \$1.5m FOR LBT APAS COMPACT**
- \* **MEMPHASYS JAPAN, CANADA FELIX HUMAN SPERM SEPARATION STUDIES**
- \* **BIOXYNE SELLS 49% OF ASIA DISTRIBUTOR FOR \$2m CASH, SCRIP**
- \* **NOVA EYE RECRUITS PIVOTAL 2RT FOR AMD STUDY**
- \* **DORSAVI EXTENDS MEDTRONIC PARTNERSHIP 9 MONTHS, \$189k**
- \* **INVEX OPENS 1st AUSTRALIAN, UK 'EVOLVE' PRESENDIN TRIAL SITES**
- \* **MESOBLAST 4.9m DIRECTOR OPTIONS AGM**
- \* **CANN GROUP RECEIVES \$4.3m FEDERAL R&D TAX INCENTIVE**
- \* **OPTISCAN RECEIVES \$942k FEDERAL R&D TAX INCENTIVE**
- \* **ONCOSIL RECEIVES \$832k FEDERAL R&D TAX INCENTIVE**
- \* **IMPEDIMED WITHDRAWS 10% PLACEMENT FACILITY AGM VOTE**
- \* **SANDON TAKES 13.6% OF IDT**
- \* **CARL CHARALAMBOUS TAKES 11% OF EXOPHARM**
- \* **ONCOSIL LOSES DIRECTOR DR MARTIN CROSS, WITHDRAWS 2 AGM VOTES**
- \* **CANN GROUP TO LOSE 6-YEAR CEO PETER CROCK**
- \* **NUHEARA LOSES CFO, CO-SEC JEAN MARIE RUDD; NEW CFO WANTED**

## MARKET REPORT

The Australian stock market was up 1.54 percent on Monday October 24, 2022, with the ASX200 up 102.6 points to 6,779.4 points. Eighteen of the Biotech Daily Top 40 were up, 14 fell and eight traded unchanged. All three Big Caps were up.

Nova Eye was the best, up two cents or 8.9 percent to 24.5 cents, with 1,771 shares traded. Micro-X and Resonance climbed more than seven percent; Polynovo improved 4.7 percent; Alcidion and Telix were up more than three percent; CSL, Impedimed, Nanosonics, Neuren and Pharmaxis rose more than two percent; Avita, Clinuvel, Cochlear, Emvision, Immutep, Opthea, Proteomics, Pro Medicus and Resmed were up more than one percent; with Medical Developments up 0.3 percent.

Kazia led the falls, down 1.5 cents or 8.8 percent to 15.5 cents, with 256,556 shares traded, followed by Universal Biosensors down 8.5 percent to 27 cents, with 293,572 shares traded. Compumedics lost 6.25 percent; Starpharma shed five percent; Actinogen and Antisense fell more than four percent; Genetic Signatures was down 3.75 percent; Mesoblast and Prescient shed more than two percent; Cynata, Next Science and Orthocell were down more than one percent; with Cyclopharm and Paradigm down by less than one percent.

## LBT INNOVATIONS

LBT says it has a \$1.5 million grant from the Federal Government Medical Research Future Fund to develop a compact version of its Apas instruments.

Last week, the Federal Government said it would provide \$13.9 million through two MTP Connect programs, including LBT Innovations' Apas automated plate assessment system instrument (BD: Oct 21, 2022).

Today, the company said the funding, through the Clinical Translation and Commercialisation Medical Technology program, would allow it to develop Apas Compact, an "automated culture plate reader, designed specifically for smaller or remote laboratories".

LBT said that the first phase of the project was estimated to cost \$50,000, expected to finish by March 2023 and would leverage its core Apas intellectual property by "re-using the existing imaging analysis hardware and software from the Apas Independence" to minimize costs and 'de-risk' the project.

LBT managing-director Brent Barnes said there was "a significant opportunity to disrupt microbiology and introduce automation at scale to optimize the culture plate workflow".

"This ... funding accelerates delivery of a key component of the company's product pipeline strategy by adding a smaller, lower cost Apas instrument that means we are able to offer digital microbiology solutions that meet the needs of all laboratories globally," Mr Barnes said.

LBT fell 0.2 cents or 2.7 percent to 7.3 cents.

## MEMPHASYS

Memphasys says its Felix sperm separation device will be trialled in human studies in Japan and Canada and is preparing regulatory submissions to India, China and the US. Memphasys said that due to changes in Japan's in-vitro fertilization (IVF) insurance market, it chose to work with sites which only treated self-funded patients, and that its 'key opinion leader partner' would conduct a small-scale study to compare its Felix system with Japan's standard sperm separation procedure.

The company said that its 'Canadian key opinion leader' had "indicated a willingness to undertake a small in-vivo study".

Memphasys said that India's Central Drugs Standard Control Organisation had recently amended the regulation of medical devices and assisted reproductive technology sold in India, which "may have a short-term bearing on the Felix system's sales, but would ultimately bring more certainty and greater clarity around market governance to one of the world's largest and most rapidly growing IVF markets".

The company said that executive chair Alison Coutts would meet with Indian key opinion leaders to determine which of the opportunities presented by the new regime offered the best commercial outcome.

Memphasys said that it was preparing two applications to China's National Medical Products Administration, for device classification for Felix and a fast-tracked 'Green Channel' regulatory pathway for "innovative medical products".

The company said it had filed a pre-submission meeting request to the US Food and Drug Administration, with feedback expected in "early 2023".

Memphasys said that its Monash IVF Group 104-couple study of its Felix device had "encouraging" initial results with respect to fertilization rates and embryo use but participation rates had been lower than expected post-Covid-19 (BD: Jun 28, 2022).

Memphasys said the completion of the trial was likely to be "pushed back into 2023".

Memphasys fell 0.05 cents or 2.7 percent to 1.8 cents.

## BIOXYNE

Bioxyne says it will sell its 49 percent interest in its direct selling companies to Singapore's Paramount Star Investments for \$1 million cash and \$1 million in shares.

Bioxyne said that it held "direct selling licences in Malaysia and Indonesia and currently sells into other Asian countries through third party distributors".

The company said the \$1,000,000 placement of 25,000,000 shares was at four cents a share.

Bioxyne chair Tony Ho said the sale was "a significant opportunity for Bioxyne to grow our direct selling business just as economic conditions are normalizing in Asia".

"We have maintained our presence and goodwill of our direct selling business in our Asian markets during the past two Covid years... [and] now is the time to invigorate the business," Mr Ho said.

Bioxyne was up 0.1 cents or four percent to 2.6 cents.

## NOVA EYE MEDICAL

Nova Eye says it has recruited the investigator sites for its confirmatory pivotal study of its retinal rejuvenation therapy (2RT) laser for age-related macular degeneration.

In May, Nova Eye said it had a defined US clinical study plan and approval pathway for its 2RT laser for intermediate age-related macular degeneration (BD: May 3, 2022).

At that time, the company said its wholly-owned subsidiary Alpharet would start the confirmatory pivotal study at sites in Australia, Canada and Europe, but in accordance with the study protocol reviewed by the US Food and Drug Administration.

Today, Nova Eye said that 28 researchers in Europe, Canada and Australia had confirmed their participation, including Prof Robert Finger, a "leading authority in age-related macular degeneration research" at the University of Bonn, Germany.

Nova Eye said Alpharet was in discussion with equity partners to fund the completion of the pivotal study.

Nova Eye was up two cents or 8.9 percent to 24.5 cents.

## DORSAVI

Dorsavi says it has extended its partnership with Medtronic for an additional nine months, in a contract worth about \$US129,000 (\$A189,111).

In August 2021, Dorsavi said it had extended its deal with the Dublin-based Medtronic for six months, in a contract worth about \$US171,000 (\$A231,260), an extension beyond the \$US330,000 master service agreement with Medtronic to test its wearable sensors for patients undergoing surgical evaluation (BD: Dec 9, 2020; Mar 30, Aug 5, 2021).

Today, the company said that with Medtronic, it had developed "the first beta version of a new sensor application for the assessment of movement quality in patients with various spinal conditions" and that testing was underway at a clinical site in the US.

Dorsavi chief executive officer Dr Andrew Ronchi said he was "delighted" to announce the release of the beta sensor application for use in clinical studies.

"The project is the result of over one and a half years of collaboration between Dorsavi and Medtronic where our cutting-edge sensor technology and proprietary [artificial intelligence] algorithms have helped make the project possible," Dr Ronchi said.

Dorsavi was up 0.3 cents or 25 percent to 1.5 cents.

## INVEX THERAPEUTICS

Invex says it has “activated” its first Australia and UK sites in its 240-patient ‘Evolve’ phase III trial of Presendin for idiopathic intracranial hypertension.

Last month, Invex said it had ethics approval for three additional sites of its up-to 40 sites trial (BD: Sep 30, 2022).

In July, the company said the randomized, placebo-controlled, double-blind trial would test the safety and efficacy of Presendin, or sustained release Exenatide, once weekly over 24 weeks (BD: Jul 4, 2022).

Today, Invex said the Australian site was at Vision SA in Adelaide and the UK site was at University Hospital in Birmingham and both allowed for immediate recruitment.

Invex was up two cents or 3.4 percent to 61 cents.

## MESOBLAST

Mesoblast says its annual general meeting will vote to issue 4,875,000 options to directors, exercisable at prices ranging from 85 cents to \$1.03 each.

Mesoblast said shareholders would vote to issue 2,325,000 milestone-based options to managing-director Prof Silviu Itescu, and 900,000 options to chief medical officer Dr Eric Rose as part of their remuneration packages, worth about \$1,578,000 and \$US378,000 (\$A597,452) respectively, exercisable at \$1.03 an option, within seven years, vesting on performance milestones.

The company said the meeting proposed to issue 1,250,000 options to Dr Rose, exercisable at \$1.03 an option, 200,000 options to director Dr Philip Krause, exercisable at \$1.01 each and 200,000 options to director Jane Bell, exercisable at 85 cents each, expiring after seven years.

Mesoblast said shareholders would vote to elect directors Dr Krause, Ms Bell, Dr Rose and Mr William Burns, ratify a prior placement, approve an employee share option plan, and adopt the remuneration report.

The meeting will be held at Minter Ellison, Collins Arch, Level 20, 447 Collins Street, Melbourne on November 23, 2022 at 11am (AEDT), and shareholders could watch the meeting but not vote, at: <https://meetings.linkgroup.com/msb22>.

Mesoblast fell two cents or 2.1 percent to 94.5 cents.

## CANN GROUP

Cann Group says it has received \$4,348,528 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cann Group said the rebate related to research and development expenditure for the year to June 30, 2022.

Cann Group was unchanged at 27 cents.

## OPTISCAN IMAGING

Optiscan says it has received \$941,790 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Optiscan said the rebate related to expenditure for the year to June 30, 2022.

Optiscan was up 1.5 cents or 12 percent to 14 cents.

### ONCOSIL MEDICAL

Oncosil says it has received \$831,599 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Oncosil said the rebate related to research and development expenditure for the year to June 30, 2022.

Oncosil was unchanged at 4.8 cents.

### IMPEDIMED

Impedimed says it has withdrawn the annual general meeting resolution to refresh the 10 percent placement facility for its meeting on Wednesday, October 26, 2022.

Impedimed said the withdrawal was “based on feedback from shareholders” and that chair Don Williams and interim chief executive officer Dave Anderson had been “conducting face to face meetings with shareholders since arriving in Australia this past week”.

The company said “a discussion was held with certain shareholders regarding the need for the resolution ... given the strong cash position of the company” and the board agreed that the company had adequate cash to reach cash flow breakeven.

Last month, Impedimed said shareholders would vote to issue 60 percent of Mr Anderson’s annual salary of \$US360,000 (\$A543,583) in shares, to accept the remuneration report, to elect directors Dr Robert Graham and Janet West, to approve the 10 percent placement capacity and adopt the executive share plan (BD: Sep 23, 2022).

Impedimed was up 0.2 cents or 2.6 percent to 7.9 cents with two million shares traded.

### IDT AUSTRALIA

Sandon Capital Pty Ltd says it has increased its substantial holding in IDT from 29,219,292 shares (12.2%) to 32,774,525 shares (13.6%).

The Sydney-based Sandon said that between March 8 and October 19, it bought 3,555,233 shares for \$467,019 or an average of 13.1 cents a share.

IDT fell 0.1 cents or one percent to 9.9 cents.

### EXOPHARM

Carl Charalambous says he has increased his substantial holding in Exopharm from 15,468,243 shares (9.84%) to 17,216,270 shares (10.95%).

The Brisbane-based Mr Charalambous said that between May 31 and October 21, 2022 he bought 1,748,027 shares for \$256,998 or an average of 14.7 cents a share.

Exopharm fell half a cent or 4.55 percent to 10.5 cents.

### ONCOSIL MEDICAL

Oncosil says 5.5-year non-executive director Dr Martin Cross has resigned, with two resolutions to be withdrawn from tomorrow’s annual general meeting.

In September, Oncosil said that investors would vote to issue directors 20 million options exercisable at 12 cents each within five years and re-elect directors Dr Cross, Prof Ricky Sharma and Brian Leedman (BD: Sep 26, 2022).

Today, the company said that Dr Cross’s resignation would “take effect immediately and furthers the renewal of the board, over the past 15 months”.

Oncosil said that as a result of the resignation the resolutions relating to his re-election and option issue had been withdrawn.

## CANN GROUP

Cann Group says chief executive officer Peter Crock will resign, but will remain with the company until a replacement was found.

Cann Group said Mr Crock was appointed as chief executive officer in April 2016 and it would begin the search for his replacement “immediately”.

Mr Crock said it was “time for fresh leadership to guide the company through its next phase of growth”.

“Much has been achieved over recent years, with the establishment of our state-of-the-art manufacturing operations, key regulatory approvals, the development of our Satipharm delivery technology and a world class plant breeding and genetics program,” Mr Crock said.

## NUHEARA

Nuheara says Jean-Marie Rudd has resigned as chief financial officer and joint company secretary, effective from October 21, 2022.

Nuheara said Susan Park would continue as sole company secretary, and a search for a new chief financial officer would begin shortly.

Nuheara fell half a cent or 2.8 percent to 17.5 cents.