



# Biotech Daily

Tuesday May 16, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: PATRYS UP 8%; CYNATA DOWN 10%**
- \* **PRO MEDICUS \$20m GUNDERSEN VISAGE CONTRACT**
- \* **HYDRIX TO DISTRIBUTE IMPLICIT HEART MONITORS; AVERTIX NASDAQ**
- \* **CHINA INCLUDES TRUSCREEN CERVICAL CANCER SCREENING**
- \* **IMMUTEP: 'FDA RESPONSE TAKES EFTI CLOSER TO PIVOTAL NSCLC TRIAL'**
- \* **ISLAND: 'FDA LIFTS ISLA-101 CLINICAL HOLD, APPROVES TRIAL'**
- \* **OSTEOPORE OSTEOMESH SOUTH AFRICA REIMBURSEMENT**
- \* **VITURA, RELEAF MARIJUANA JOINT VENTURE**
- \* **INCANNEX FORMS PSYCHEDELIC SUBSIDIARY PSYCHENNEX**
- \* **CRESO UP-TO 47% OPPOSE BLUMENTHAL, EVERBLU OPTIONS**
- \* **CYCLOPHARM POTENTIAL UP-TO 25% SHARE BUY-BACK**
- \* **FIDELITY REDUCES TO 7.3% OF MEDICAL DEVELOPMENTS**
- \* **MARK KERR DILUTED TO 11.52% IN AVECHO**
- \* **GZ FAMILY TAKES 8% OF ATOMO**
- \* **FORMER CHAIR DR JOHN CULLITY DILUTED BELOW 5% IN RACE**
- \* **BCAL APPOINTS DAVID DARLING ADVISER**

## MARKET REPORT

The Australian stock market fell 0.45 percent on Tuesday May 16, 2023, with the ASX200 down 32.4 points to 7,234.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Patrys was the best, up 0.1 cents or 8.3 percent to 1.3 cents, with 3.2 million shares traded. Mesoblast climbed six percent; Immutep improved 4.4 percent; Opthea was up three percent; Nanosonics, Telix and Universal Biosensors rose more than two percent; Antisense, Avita, Emvision, Prescient and Starpharma were up more than one percent; with Neuren up by 0.7 percent.

Cynata led the falls, down 1.5 cents or 10.3 percent to 13 cents, with 946,943 shares traded. Nova Eye lost 6.25 percent; Amplia, Impedimed, Kazia and Micro-X fell five percent or more; Medical Developments was down 3.9 percent; Alcidion, Clinuvel, Dimerix, Next Science, Orthocell and Volpara shed two percent or more; Actinogen, CSL, Genetic Signature, Polynovo, Proteomics and Resmed were down one percent or more; with Cochlear, Paradigm and Pro Medicus down by less than one percent.

## PRO MEDICUS

Pro Medicus says it has a \$20 million, seven-year, contract with Gundersen Health System for its Visage 7 imaging platform, archive and workflow modules.

Pro Medicus said the La Crosse, Wisconsin-based Gundersen was a non-for-profit integrated delivery network (IDN) comprising seven hospitals and 65 clinics in Wisconsin, Minnesota and Iowa.

The company said the rollout of Visage 7 was planned immediately and would be based on its internet cloud implantation process, expected to be operational by the end of 2023.

Pro Medicus chief executive officer Dr Sam Hupert said that integrated delivery networks were “the largest market segment in North America and ... this our fifth material IDN contract in the last 12 months ... making our total addressable market very significant”.

“[The internet] cloud is a key differentiator for us with all our implementations in North America over the past two and a half years being cloud-deployed,” Dr Hupert said.

“The other emerging trend is the growing number of clients like Gundersen opting for ‘full-stack’- all three Visage 7 products namely Viewer, Open Archive and Workflow, a trend we see continuing,” Dr Hupert said.

Pro Medicus fell 38 cents or 0.6 percent to \$59.82 with 220,433 shares traded.

## HYDRIX

Hydrix says it will distribute Implicity’s cardiac remote monitoring platform technology and Avertix Medical, formerly Angel Medical, has applied to be listed on the Nasdaq.

Hydrix said the four-year agreement with the Cambridge, Massachusetts-based Implicity included the rights to market and sell its cardiac implantable electronic devices on a software-as-a-service basis to cardiologists in Australia, New Zealand and Singapore.

The company said that an undisclosed, one-time, upfront installation fee and an annual subscription fee would be paid to Implicity.

Earlier this month, Hydrix said Angel Medical Systems would merge with Bioplus Acquisition Corp to be Avertix Medical, valued at \$US195 million and its one million Angel shares would be about 29 percent of the merged company (BD: May 4, 2023).

Today, Hydrix said Avertix had filed a registration statement with the US Securities Exchange Commission to list on the Nasdaq.

The company said it had a distribution agreement for Avertix’s Guardian heart device, its portfolio would increase from \$1.15 million to \$6.0 million once Avertix had listed with a share price of \$US10.00 and it was eligible for a further \$2.5 million pending milestones.

Hydrix was unchanged at 3.5 cents.

## TRUSCREEN GROUP

Truscreen says the Chinese Society for Colposcopy and Cervical Pathology (CSCCP) has endorsed its optical-electric cervical cancer screening technology.

Truscreen said the CSCCP endorsement was the first national medical guideline to recommend its technology.

The company said the CSCCP guideline was a clinical standard for doctors and other healthcare providers as well as government bodies, with the recommendation expected to drive sales in China.

Truscreen chief executive officer Dr Beata Edling said the decision “paves the way for the case of effective screening technologies, such as Truscreen, in the drive to eradicate cervical cancer”.

Truscreen was unchanged at 2.8 cents.

## IMMUTEP

Immutep says it has “positive feedback” from the US Food and Drug Administration for eftilagimod alpha, or efti, for first line non-small cell lung cancer.

Last year, Immutep said its 114-patient, Tacti-002 phase II trial of efti, formerly IMP321, with pembrolizumab for non-small cell lung cancer had an “encouraging” overall response rate of 40.4 percent (BD: Nov 11, 2022).

Today, the company said the FDA was “supportive of a registrational trial” to evaluate efti in combination with an anti-programmed cell death-ligand-1 (PD-L1) therapy, regardless of the level of PD-L1 expression, based on the data from its phase II trial.

Immutep chief executive officer Marc Voigt said the meeting was a “critical step” in the late-stage development process of efti.

Immutep chief scientific officer Dr Frédéric Triebel said the FDA’s feedback was “an important milestone within Immutep’s three main clinical programs targeting cancers [...and positioned] efti to make a significant impact”.

Immutep was up one cent or 4.4 percent to 23.5 cents.

## ISLAND PHARMACEUTICALS

Island says it has US Food and Drug Administration approval for a single-ascending dose study of its ISLA-101 for dengue fever and mosquito borne diseases.

In February, Island said the FDA had placed a “clinical hold” on its investigational new drug application for ISLA-101 and required a further “small” trial as well as protocol amendments; and last month, it said it had filed a response (BD: Feb 1, Apr 17, 2023).

Today, the company said the FDA had lifted the hold and would allow it to proceed with the requested study, which was expected to be held in Australia.

Island said it intended to open further dialogue with the FDA to determine next steps for the development program.

The company said that the single ascending dose study aimed to determine the dose levels to “safely achieve blood concentrations of ISLA-101 that are predicated to be effective against the dengue virus”.

Island chief executive officer Dr David Foster said that with the clinical hold lifted, the company could take ISLA-101 to the clinic through a single ascending dose study.

“We anticipate being able to optimize and potentially streamline protocols for subsequent studies using input from the single ascending dose study,” Dr Foster said.

Island was up one cent or 10 percent to 11 cents.

## OSTEOPORE

Osteopore says Discovery Health Medical Scheme will reimburse the cost of its Osteomesh cranial maxillofacial bone substitute mesh in South Africa.

Osteopore said the Johannesburg-based Discovery Health was the most prominent medical scheme in South Africa and held a 57 percent market share.

The company said its Osteomesh had already been approved for sale by South African Health Products Regulatory Authority and it had appointed Chronos Medical Pty Ltd as a distributor to support marketing and sales efforts.

Osteopore did not disclose the price of its Osteomesh product, or the material terms of the reimbursement scheme.

Osteopore executive chairman Mark Leong said the approval was a “positive development ...expected to remove barriers to the patients who require [Osteomesh] implants”.

Osteopore was up 0.55 cents or 7.2 percent to 8.15 cents.

### VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says it has an unincorporated joint venture with Melbourne's Releaf Group to prescribe medical cannabis through a Releaf-branded version of its Canview platform. Vitura said the venture was expected to increase the number of medical marijuana products prescribed and distributed through its Canview online marketplace platform.

The company said Releaf provided in-person and telehealth consultations at four clinics in Melbourne and Queensland, with 10 more expected by the end of 2023.

The company said that the venture included a Releaf-branded version of Vitura's Canview to prescribe and dispense medical cannabis.

Vitura chief executive officer Rodney Cocks said since launch of the prescriber and patient functionality of the Canview platform earlier in the year the company was "excited to see the Canview platform being favoured as the complete end-to-end technology solution within our industry".

Vitura was up two cents or 5.7 percent to 37 cents.

### INCANNEX HEALTHCARE

Incannex says it has formed a wholly owned subsidiary Psychennex Pty Ltd to hold its "psychedelic assets to facilitate coordinated management and [a] potential future exit.

Incannex said Psychennex would be the holding company for its intellectual property, psychedelic product development, distribution contracts and clinic subsidiaries.

The company said director Peter Widdows would lead the Psychennex businesses.

Incannex was unchanged at 10 cents with 6.96 million shares traded.

### CRESO PHARMA

Creso's extraordinary general meeting faced up to 47.38 percent opposition to the issue of options to former chair Adam Blumenthal and his company Everblu Capital.

Last month, Creso said it would vote on 21 resolutions relating to the issue of more than 130,831,574 shares, 752,021,794 options and \$2,777,750 in convertible notes, including options to Mr Blumenthal and Everblu (BD: Apr 17, 2023).

Last night after the market closed, the company said the strongest opposition was against the issue of investor options to Mr Blumenthal which passed with 65,934,280 votes (52.62%) in favor and 59,368,041 votes (47.38%) against.

Creso said that two other resolutions to issue options to Everblu were passed 45.9 percent opposition.

The company said that the remaining 18 resolutions faced opposition between 6.74 percent and 13.81 percent dissent.

According to Creso's most recent filing there were currently 2,137,040,695 shares on issue, meaning the vote against Mr Blumenthal's options amounted to 2.78 percent of shares on issue, not sufficient to requisition extraordinary general meetings.

Creso fell 0.1 cents or 5.9 percent to 1.6 cents with 14.6 million shares traded.

### CYCLOPHARM

Cyclopharm says it has the potential for an on-market buy-back of up-to 25 percent of the 93,696,326 shares on issue, at the time of the notice, over the next 12 months.

Cyclopharm did not disclose whether it would conduct a buy-back not a minimum or maximum number of shares to be bought back or the price per share.

Cyclopharm last traded at \$2.14.

### MEDICAL DEVELOPMENTS INTERNATIONAL

Fidelity Investments Ltd says it has reduced its substantial shareholding in Medical Developments from 7,069,520 shares (8.71%) to 6,331,871 shares (7.31%).

Fidelity said that between August 16, 2022 and May 11, 2023 it bought and sold shares in more than 90 transactions, at prices ranging from 80.95 cents to \$1.9971 a share.

Medical Developments fell three cents or 3.9 percent to 74.5 cents.

### AVECHO BIOTECHNOLOGY

Mark Kerr and associates say their substantial shareholding of 249,133,188 shares in Avecho has been diluted from 15.79 percent to 11.52 percent.

Last week, Avecho said it had raised about \$2 million of a hoped-for \$11 million in a rights offer at 0.6 cents a share (BD: May 9, 2023).

Avecho was unchanged at 0.4 cents.

### ATOMO DIAGNOSTICS

GZ Family Holdings Pty Ltd says it has increased its substantial holding in Atomo from 29,118,147 shares (5.10%) to 45,987,536 shares (8.06%).

The Sydney-based GZ said it bought shares between April 14 and May 15, 2023, with the single largest purchase 9,738,920 shares off-market for \$322,358, or 3.31 cents a share.

Atomo was unchanged at 3.3 cents with one million shares traded.

### RACE ONCOLOGY

Dr John Cullity says he has ceased his substantial holding in Race after being diluted by the exercise of options and conversion of performance rights.

Last year, Dr Cullity said he became a substantial shareholder in Race with 8,402,194 shares or 5.62 percent of the company (BD: Apr 11, 2022).

In an appendix 3Y Director's Interest Notice in January 2022, Dr Cullity said he had sold 300,000 "to cover personal and tax commitments".

Biotech Daily calculates that Dr Cullity holds 8,102,194 shares (4.97%) of the company.

Race fell 2.5 cents or 1.4 percent to \$1.72.

### BCAL DIAGNOSTICS

Bcal says it has appointed former Pacific Edge chief executive officer David Darling as an adviser.

The company said Mr Darling was previously the Pacific Edge chief executive officer for 19 years and before that held management positions at the New Zealand-based construction company Fletcher Challenge.

Bcal executive chair Jayne Shaw said Mr Darling's counsel would be of great value as the company moved towards commercializing the company's blood test for breast cancer, initially as an adjunct to mammography".

Bcal was up 0.3 cents or 3.45 percent to nine cents.