



# Biotech Daily

Wednesday June 12, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: DIMERIX UP 8%; IMMUTEP DOWN 7%**
- \* **OPTHEA TO RAISE \$227m**
- \* **INOVIQ PLACEMENT RAISES \$7m; UP-TO \$2.4m SHARE PLAN TO GO**
- \* **BLUECHIIP PLACEMENT RAISES \$368k FOR 'STRATEGIC REVIEW'**
- \* **ATOMO 'BUDGETS' \$1.3m HIV SELF-TEST FEDERAL REVENUE**
- \* **BOTANIX FILES FINAL SOFDRA LABEL DETAILS TO FDA**
- \* **STARPHARMA: '20-30% OF DEP-HER2 REACHES TUMOR, IN MICE'**
- \* **INOVIQ: 'NEURO-NET ISOLATES ALZHEIMER'S BRAIN EXOSOMES, EX-VIVO'**
- \* **CARTHERICS AUSTRALIAN TAG-72 CAR STEM CELL PATENT**
- \* **EPSILON: GIANNOPOULOS, HUTCHINS IN; CUI, CAMERON OUT**

## MARKET REPORT

The Australian stock market fell 0.51 percent on Wednesday June 12, 2024, with the ASX200 down 39.9 points to 7,715.5 points.

Thirteen of the Biotech Daily Top 40 were up, 17 were down, nine traded unchanged and one was untraded.

Dimerix was the best, up 4.5 cents or 8.0 percent to 60.5 cents, with 12.75 million shares traded. Syntara climbed 4.35 percent; Atomo was up 3.6 percent; Amplia, Curvebeam, Orthocell and Starpharma rose more than two percent; Percheron, Polynovo, Pro Medicus and Universal Biosensors were up more than one percent; with Nanosonics, Resmed and SDI up by less than one percent.

Immutep led the falls, down three cents or seven percent to 40 cents, with 10.0 million shares traded. Prescient fell 4.35 percent; Genetic Signatures was down 3.4 percent; Alcidion, Clinuvel, Impedimed and Medical Developments shed more than two percent; CSL, Cyclopharm, Imugene, Neuren, Proteomics and Telix were down one percent or more; with 4D Medical, Avita, Clarity, Cochlear, Emvision and Mesoblast down by less than one percent.

## OPTHEA

Opthea says it hopes to raise up-to \$227.3 million at 40 cents a share in a \$10 million institutional placement and \$217.3 million, one-for-1.22, partially underwritten rights offer. Opthea said the issue price was a 33.9 percent discount to the 30-day volume weighted average price, or a 17.5 percent discount to the last closing price of 48.5 cents a share. The company said investors in the institutional placement and the institutional and retail components of the rights offer would receive one attaching option for every three shares issued, exercisable at \$1.00 each by June 30, 2026.

Opthea said the funds raised would be used to cover its costs until the release of the results from its phase III OPT-302, or sozinibercept, trial for wet-aged macular degeneration in 2025, as well as for manufacturing activities in preparation for a biologics licence application with the US Food and Drug Administration and general corporate purposes.

Opthea said that the topline data readout of the Coast trial was expected by July 2025, and topline data from the Shore trial in mid-2025.

Opthea chief executive officer Dr Fred Guerard said the capital raising would strengthen the cash position “and we expect to fund operations through the anticipated topline data readouts of both our pivotal trials, which have enrolled a total of 1,984 wet AMD patients”. “Opthea also plans to complete the manufacturing of the commercial-scale drug batches required for the BLA,” Dr Guerard said.

“We are excited about the potential for sozinibercept to become the first treatment in over 15 years to demonstrate superior vision outcomes in wet AMD when combined with standard-of-care anti-VEGF-A therapies,” Dr Guerard said.

The company said MST Financial Services was the lead manager, bookrunner and sole partial underwriter to the institutional entitlement offer, with Bell Potter co-manager.

Opthea said MST had agreed to fully underwrite the retail component of the entitlement offer and underwrite the institutional entitlement offer up-to \$30 million.

The company said the retail offer had a record date of June 14, would open on June 19 and close on July 10, 2024.

Opthea said it had requested to remain in a trading halt “pending completion and announcement of the placement and the institutional component of the entitlement offer”. Trading will resume on June 14, 2024, or on an earlier announcement.

Opthea last traded at 48.5 cents.

## INOVIQ

Inoviq says it has raised about \$7 million at 50 cents a share in a placement and hopes to raise up-to \$2.4 million in a share purchase plan at the same price.

Inoviq said the issue price was a 25.1 percent discount to the 10-day volume weighted average price of 66.8 cents a share, and an 11.5 percent discount to the last traded price. The company said investors in the placement and share plan would receive one option for every two shares issued, exercisable at \$1.00 each within 24 months.

Inoviq said \$1.4 million of the funds raised would be used for sales and marketing, \$6.4 million for research and development, \$400,000 for administrative costs and \$800,000 for costs associated with the raise.

The company said its board and management had agreed to take up 500,000 shares in the placement, with 250,000 attaching options, subject to shareholder approval.

Inoviq said the share plan had a record date of June 11, would open on June 19 and close on July 2, 2024; and aimed at raising \$2 million with up to \$400,000 in over-subscriptions.

Inoviq was up 10.5 cents or 18.6 percent to 67 cents with 2.5 million shares traded.

## BLUECHIIP

Bluechiip says it has raised \$367,600 at 0.44 cents a share in a placement “for working capital purposes while undertaking a strategic review”.

Biotech Daily calculates the issue price of 0.44 cents to be a 26.7 percent discount to the Bluechiip’s last closing price on June 6, 2024 of six cents a share.

The company said director Michael Ohanessian had agreed to subscribe for \$10,000 worth of the placement, subject to shareholder approval.

Bluechiip fell 0.05 cents or 9.1 percent to 0.5 cents with 6.3 million shares traded.

## ATOMO DIAGNOSTICS

Atomo says it expects revenue of \$1.3 million from orders of its HIV self-tests made by the Federally-funded National HIV self-test mail-out program in the next two years.

Atomo said the National HIV self-test mail-out program was run by the National Association of People with HIV Australia (NAPWHA) and aimed to improve testing rates among at-risk groups through the supply of free HIV self-tests in a mail-out program.

The company said the program had been successful in reaching key populations, with promotion of the program supported by the online dating site Grindr “to its users being particularly effective in improving program awareness and driving demand”.

Atomo said with funding committed by the Federal Government to expand the program and pricing agreed with the NAPWHA it was “budgeting, not forecasting, revenue from the program over the next two years of approximately \$1.3 million”.

In May, Atomo welcomed the Federal Budget’s \$43.9 million investment in HIV prevention, testing, workforce training and information and the Federal Government commitment to “eliminating HIV transmission by 2030” (BD: May 15, 16, 2024).

Today, Atomo said it supplied the only HIV self-test included on the Australian Register of Therapeutic Goods and had “been instrumental in the implementation of several pilot programs, now being funded directly by the Federal and State Governments”.

The company said the Federal funding would expand HIV self-test kit vending machines to every state and territory and would “see a sizable increase in access to free tests at key locations”, with the scale-up led by Thorne Harbour Health and a South Australian pilot program operating six vending machines increase to up-to 70 machines nationally.

Atomo said the program generated \$25,000 so far, this financial year, and it expected “an increase in sales as new machines coming online later this year are stocked with tests”.

The company said New South Wales Health had engaged it to supply tests for the ‘Mytest’ pilot project, providing free HIV self-test kits via vending machines for people at risk.

Atomo said ‘Mytest’ was “supporting people who have never been tested for HIV or those who infrequently test for HIV and are not engaged in primary care, as well as those who face barriers to regular sexual health testing due to ... insurance or Medicare ineligibility”.

The company said five vending machines had been installed for ‘Mytest’ with an initial order of tests procured by NSW Health to begin the program, with further machines “expected in the coming months”.

Atomo chief executive officer John Kelly said he was “encouraged to see the government now investing in HIV self-testing as a key tool in the public health response to ... HIV”.

“This follows on from widespread public health adoption of rapid testing during the Covid-19 pandemic ... [with] self-testing ... recognized by governments around the world as cost effective to deploy at scale and supporting improved and earlier detection,” Mr Kelly said.

“We anticipate seeing this trend continue with a broader range of infectious disease testing being funded for deployment at home,” Mr Kelly said.

Atomo was up 0.1 cents or 3.6 percent to 2.9 cents with two million shares traded.

## BOTANIX PHARMACEUTICALS

Botanix says it has submitted “the last label materials” to the US Food and Drug Administration for its new drug application of Sofdra for excessive underarm sweating. Last year, Botanix said it had resubmitted its new drug application for sofipironium bromide gel, or Sofdra, for excessive sweating, after the FDA had requested printed ‘instructions of use’ changes (BD: Sep 26, Dec 4, 21, 2023).

In January, the company said the FDA had accepted its resubmission which included revisions to its instruction leaflet and that it expected approval following a six-month review by “late June 2024” (BD: Jan 22, 2024).

Today, Botanix said label discussions were the final step before the expected FDA approval of Sofdra and had involved discussions with the FDA on product carton design and wording of information that was provided to patients and physicians about the product.

The company said the materials submitted today included the prescribing information and patient information, and that FDA-approval remained “on target for June 21, 2024”.

Botanix said “upon approval Sofdra will be the first new chemical entity approved for excessive underarm sweating, known as primary axillary hyperhidrosis”.

Botanix chief executive officer Dr Howie McKibbon said the company had “been highly focused on completing these last label components, well in advance of approval”.

“Our label and packaging materials are an important part of the materials that we will use to communicate important safety and efficacy information upon approval of Sofdra,” Dr McKibbon said.

Botanix was up one cent or 3.6 percent to 28.5 cents with 8.5 million shares traded.

## STARPHARMA HOLDINGS

Starpharma says its DEP-HER2 “achieved significant tumor accumulation, with 20-to-30 percent of the injected dose per gram localizing in tumor from day one-to-five”, in mice.

Previously, Starpharma has said that the dendrimer enhanced product (DEP) diagnostic was designed to diagnose, stage and monitor human epidermal growth factor receptor 2 (HER2) positive cancers with greater sensitivity” (BD: Jul 21, 2023).

Today, the company said the study, conducted with the University of Queensland, assessed its DEP-HER2 product in 25 mice from four hours to 12 days compared to mice dosed with trastuzumab, a HER2 antibody.

Starpharma said a poster of the data, titled ‘Dendrimer nanoparticles (DEP) enable targeted precision delivery and customized biodistribution for cancer radiotheranostics’ was presented at the Society of Nuclear Medicine and Molecular Imaging annual meeting in Toronto, Canada on June 11, 2024, and was available at: <https://bit.ly/4ejTKNN>.

The poster concluded that DEP-HER2 “achieved an optimal bio-distribution profile [versus] trastuzumab, with high levels of accumulation in tumor, low uptake in radio-sensitive organs, and fast clearance from circulation”.

The conclusion said that the results supported DEP-HER2 as a radio-diagnostic and as a radio-therapeutic using high energy radio-isotopes [for example] 177-lutetium chloride.

The poster said that DEP dendrimers were “a promising, versatile, multifunctional platform for customization of precision radio-theranostics for cancer imaging and therapeutic applications, bridging the gap between small molecules and large antibodies”.

The poster concluded that DEP dendrimers could “be employed with a wide range of targeting moieties and radio-therapeutic payloads to achieve customized bio-distribution and excretion profiles”.

Starpharma was up 0.2 cents or two percent to 10 cents.

## INOVIQ

Inoviq says “its Neuro-Net technology can isolate brain-derived exosomes in Alzheimer’s Disease”.

Inoviq said Neuro-Net captured exosomes secreted from various brain cells and that exosomes provided a “‘fingerprint’ of the health or disease status of the parent cell and can cross the ‘blood-brain barrier’, making them promising candidates as diagnostics for neurological diseases”.

The company said its Neuro-Net was “a magnetic bead-based exosome isolation system designed using multiple antibodies to capture surface proteins found on brain-derived exosomes” suitable for isolation from blood, saliva, cerebrospinal fluid and cell cultures. Inoviq said early studies showed exosomes isolated from blood using Neuro-Net contained proteins known to be expressed by brain cells and that Neuro-Net “was superior to other commercially-available methods tested in isolating brain-derived exosomes from blood”.

The company said the studies showed Neuro-Net identified “known Alzheimer’s biomarkers in exosomes that could not be detected by other methods” and that analysis of Neuro-Net-captured exosomes identified more than 200 proteins that were differentially expressed in Alzheimer’s patients when compared with healthy individuals”.

Inoviq said the results were further validated by a larger independent study of 48 cases and 44 controls conducted by the Walter and Eliza Hall Institute “confirming the differential expression of previously identified proteins”.

The company said “47 proteins were uniquely expressed in exosomes isolated from Alzheimer’s blood samples and provided robust discrimination between cases and controls”.

Inoviq chief executive officer Dr Learne Hinch said Neuro-Net was “an important addition to our exosome portfolio”.

“These results validate the ability of Neuro-Net to isolate exosomes from the brain and provide Inoviq with opportunities to collaborate with pharmaceutical [and] diagnostic companies and leading academic groups to develop and validate new diagnostic tests using novel and informative biomarkers for brain cancer, neuropsychiatric disorders and neurodegenerative diseases,” Dr Hinch said.

Inoviq chair David Williams said that “brain-derived exosomes hold enormous potential for the diagnosis and treatment of neurological diseases like Alzheimer’s and Parkinson’s”.

## CARTHERICS PTY LTD

Cartherics says Intellectual Property Australia has granted a patent for its chimeric antigen receptor (CAR) stem cells targeting the tumor-associated glycoprotein-72 (TAG-72).

Cartherics said the patent was titled ‘Genetically modified cells and uses thereof’ and would protect Cartherics’ intellectual property until November 23, 2036.

The company said the Australian patent was “part of a broader patent family, with applications for similar protection filed in key jurisdictions such as the US, Japan, and Europe”.

Cartherics said it had “filed a divisional application covering other aspects of this invention”.

Cartherics’ chief executive officer Prof Alan Trounson said the patent strengthened the company’s “global position in cancer therapy and potentially other intractable disease conditions”.

Cartherics is a private company.

## EPSILON HEALTHCARE

Epsilon administrator Ian Purchas says Josh Cui and Stuart Cameron have been removed as directors with Peter Giannopoulos and Zoe Hutchins appointed directors.

Last week, SV Partners' Ian Purchas said the final creditors meeting resolved to adopt a deed of company arrangement proposed by founder Alan Beasley (BD: Jun 5, 2024).

Epsilon was in a suspension and last traded at 2.4 cents.