Biotech Daily

Wednesday August 2, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 8%; ACTINOGEN DOWN 22%**

*** BCAL BREAST CANCER TEST: '90% SENSITIVITY, 85.5% SPECIFICITY'**

*** NOVA EYE: UNAUDITED US JULY QUARTER SALES UP 32% TO $3.3m**

*** ACTINOGEN 1-FOR-4.54 RIGHTS ISSUE TO RAISE $10m**

*** AMPLIA DOSES PHASE Ib/IIa AMP945 PANCREATIC CANCER TRIAL**

*** ECHO IQ: US STUDY COMPLETES ENROLMENT**

*** TRUSCREEN: CHINA JOURNAL INCLUDES CERVICAL CANCER TEST**

*** PYC: FDA FAST TRACKS VP-001 FOR RETINITIS PIGMENTOSA TYPE-11**

*** RESONANCE, ACUITY CAPITAL FACILITY EXPIRES**

*** MESOBLAST REQUESTS 'FDA REVIEW' TRADING HALT**

*** PETERS TAKES 24% OPTISCAN**

*** ORCHID CAPITAL TAKES 18.6% OF OPTISCAN**

*** ACADIA PARK, ASSOCIATES TAKE 8% OF IMPEDIMED**

*** ALLIANZ TAKES 11.8% OF STARPHARMA**

*** DR JOHN TARRANT, BALMAIN, CADEX TAKE 16.8% OF HEXIMA**

*** GEN JOHN MONASH FOUNDATION APPOINTS PAUL RAMADGE CEO**

MARKET REPORT

The Australian stock market fell 1.29 percent on Wednesday August 2, 2023, with the ASX200 down 96.1 points to 7,354.6 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and three were untraded.

Dimerix was the best, up 0.6 cents or 8.3 percent to 7.8 cents, with 488,014 shares traded. Patrys climbed five percent; Atomo, Cynata, Pro Medicus, Proteomics and SDI improved three percent or more; Nova Eye rose two percent; Prescient and Resmed were up more than one percent; with Cyclopharm up by 0.4 percent.

Actinogen led the falls, down 0.8 cents or 21.6 percent to 2.9 cents, with 8.5 million shares traded. Alcidion, Next Science, Telix and Universal Biosensors fell four percent or more; Clinuvel, Imugene, Neuren and Pharmaxis lost three percent or more; Avita, Nanosonics, Opthea and Orthocell shed more than two percent; Emvision and Resonance were down more than one percent; with 4D Medical, Antisense, Cochlear, CSL, Polynovo and Volpara down by less than one percent.

BCAL DIAGNOSTICS

Bcal says a 656-patient trial of its blood-based breast cancer diagnostic in North Carolina has shown 90.0 percent sensitivity and 85.5 percent specificity.

In 2022, Bcal said it had an agreement with the Morrisville, North Carolina-based Precion Inc for the development of its breast cancer test (BD: Jun 28, 2022).

Today, the company said the results increased "confidence" that its breast cancer test would be available for sale, in conjunction with mammograms, by January 2025.

Bcal said the results meant the test should be capable of being replicated not only in its dedicated laboratory in Australia but in commercial laboratories throughout the world.

The company said the results were a "very significant development and vindication of the efforts of the Bcal team over the past 10 years".

Bcal chair Jayne Shaw said the results were a "step towards making our test broadly available to patients and clinicians … and we will continue to work closely with leading scientists and doctors as our science team further optimizes the test to make it more cost-effective when it is launched as a patient friendly blood test for … breast cancer".

Bcal chief executive officer Dr John Hurrell said the study "shows the robustness of the Bcal breast cancer plasma lipid signature and the transferability of the test between laboratories and instrument types".

"The initial Bcal research was conducted with high sensitivity research instrumentation while the Precion results were obtained with instrumentation and procedures in routine use in clinical laboratories," Dr Hurrell said. "This is a major step towards making our test broadly available to patients and clinicians," Dr Hurrell said.

Bcal was up four cents or 50 percent to 12 cents with 7.1 million shares traded.

NOVA EYE MEDICAL

Nova Eye says unaudited US sales of its Itrack device for the three months to July 31, 2023 were up 32 percent to $US2.2 million ($A3.27 million), compared to the prior period.

Nova Eye said the record sales for its canaloplasty device for glaucoma followed clearance from the US Food and Drug Administration in April 2023.

The company said it had appointed additional sales personal to increase US sales, had expanded its Fremont, California-based production facility and expected to release audited results for the year to June 30, 2023 in the week of August 25, 2023.

Nova Eye chief executive officer Tom Spurling said the staged launch of Itrack Advance in the US was "providing promising early signs of the growth we expect to … achieve".

"We will ramp up our manufacturing capabilities to meet this expected significant lift in sales demand," Mr Spurling said.

Nova Eye was up half a cent or two percent to 25.5 cents.

ACTINOGEN MEDICAL

Actinogen says it hopes to raise about $10 million through a one-for-4.54, non-renounceable rights issue offer at 2.5 cents a share, to progress its clinical trials.

Actinogen said shareholders would receive one option for every two shares issued, exercisable at 3.75 cents within 36 months of issue.

The company said the rights issue had a record date of August 14, would open on August 17 and close on September 4, 2023.

Actinogen said chief executive officer Dr Steven Gourlay would take up his entitlement of $102,000, with directors to do the same for about $66,000.

Actinogen fell 0.8 cents or 21.6 percent to 2.9 cents with 8.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has begun dosing the final patient in cohort three of its phase Ib/IIa trial of AMP945 for pancreatic cancer, identifying a dose for the phase IIa stage.
In 2022, Amplia said it had dosed the first of 12 patients in the open-label trial, studying the pharmaco-kinetics, safety and efficacy of AMP945 in combination with nab-paclitaxel (Abraxane) and gemcitabine for pancreatic cancer (BD: Aug 2, 2022).
In May, the company said it had enroled the third cohort of patients in the phase Ib/IIa, ascending dose trial (BD: May 9, 2023).
Today, Amplia said it had dosed 12 patients across the three cohorts and they had completed their first full, 28-day cycle of treatment, with all patients electing to stay on the study drug after completing the first cycle of treatment.
Amplia chief executive officer Dr Chris Burns said that “while the cohort expansion has resulted in a delay for the complete data from this cohort to be reviewed by the safety committee, we continue to be encouraged by the data reported from all trial sites”.
Amplia was unchanged at 8.7 cents.

ECHO IQ

Echo IQ says it has completed enrolment for a study of its Echosolv heart disease detection technology in support of a US Food and Drug Administration application.
Echo IQ said the study, at an unnamed US hospital would evaluate the performance and effectiveness of its Echosolv artificial intelligence heart test for aortic stenosis.
The company said it expected results in about 80 days that would form part of its final FDA 510(k) application, and on FDA clearance, it would prioritize obtaining new technology add-on payment (NTAP) designation from the US Centers for Medicare and Medicaid Services, allowing its customers to reimburse their usage costs.
Echo IQ fell half a cent or 3.2 percent to 15 cents.

TRUSCREEN GROUP

Truscreen says the Chinese Society for Colposcopy and Cervical Pathology has included its Truscreen cervical tissue opto-electrical diagnostic in a journal.
Truscreen says its technology was published in the China Cervical Cancer Screening Guideline, based on evidence supporting Truscreen clinical use gathered in China and worldwide, with the publication made after “extensive consultations” with healthcare practitioners and decision makers.
The company said the guideline was a “leading clinical standard” for doctors and other healthcare clinicians and government agencies.
Truescreen was unchanged at 2.6 cents.

PYC THERAPEUTICS

PYC says the US Food and Drug Administration has provided fast track status for VP-001 for retinitis pigmentosa type-11, facilitating its development and review.
PYC said the fast-track designation increased frequency of meetings with the FDA to discuss drug development, made it eligible for “accelerated approval” and “priority review” and allowed it the potential for a “rolling review” in support of a new drug application.
PYC was up 0.2 cents or 3.45 percent to six cents with 2.8 million shares traded.

RESONANCE HEALTH

Resonance says its “at-the-market” standby equity capital facility with Acuity Capital expired on July 31, 2023.
In 2021, Resonance said its controlled placement agreement with Acuity had increased from $5 million to $7.75 million and extended to July 31, 2023 (BD: Jul 1, 2021).
Today, the company said it had issued Acuity 20,000,000 shares as collateral, which it had agreed to return and cancel for no consideration given the facility had expired.
Resonance fell 0.1 cents or 1.9 percent to 5.2 cents.

MESOBLAST

Mesoblast has requested a trading halt, pending an announcement “in relation to the US Food and Drug Administration’s review of its biologics licence application resubmission”.
Mesoblast said the review was for remestemcel-l for paediatric graft versus host disease.
Trading will resume on August 4, 2023 or on an earlier announcement.
Mesoblast last traded at $1.09.

OPTISCAN IMAGING

Peters Investments says it has increased its shareholding in Optiscan from 143,166,667 shares (19.449%) to 206,296,445 shares (24.0705%).
The Perth-based Peters Investments said it bought 63,129,778 shares on July 31, 2023 for $5,050,382 or eight cents a share.
Last month, Optiscan said that its one-for-three, pro-rata, entitlement offer at eight cents a share raised $8,784,701 and it had placed the $7,914,115 shortfall to its underwriters, for a total of $16,698,816 (BD: Jul 13, 2023).
Optiscan fell 0.1 cents or 1.3 percent to 7.8 cents.

OPTISCAN IMAGING

Orchid Capital Investments says it has increased its substantial shareholding in Optiscan from 119,313,333 shares (16.21%) to 155,109,996 shares (18.58%).
The Singapore-based Orchid said that on July 31, 2023 it acquired 35,796,663 shares for $2,863,733 or 8.0 cents a share, through its role as underwriter of a rights issue.
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IMPEDIMED

Acadia Park Pty Ltd and its associates say they have become a substantial shareholder in Impedimed, with 161,653,990 shares or 8.008% of the company.
On Monday, Impedimed said Acadia Park had called for the removal of chair Donald Williams and directors Amit Patel, David Anderson and Daniel Sharp. (BD: Jul 31, 2023).
Today, the Sydney-based Acadia Park said the associated parties included Matra Capital, Jonnola Pty Ltd, Nola Hodgson, Jonathan Scales, Pakasoluto Pty Ltd, the Barkl family, the Henderson family, the Mahnken family, MBA Investments, Sunlora Pty Ltd, the Moore family, the Warne family, the Standard Company Pt Ltd, Siew Luan and Stephen Atkinson, the Low family and John Nolan.
Impedimed was unchanged at 19.5 cents with 1.9 million shares traded.

STARPHARMA HOLDINGS

The Hong Kong-based Allianz says it has increased its shareholding in Starpharma from 41,249,500 shares (10.10%) to 48,480,000 shares (11.81%).
Allianz said that between July 5, 2022 and July 31, 2023 it bought and sold shares, at prices ranging from 22 cents to 71.28 cents a share.
Starpharma was unchanged at 19.5 cents with two million shares traded.

HEXIMA

Sydney's Dr John Tarrant says he has increased his substantial shareholding in Hexima from 25,791,526 shares (15.44%) to 28,114,619 shares (16.83%).
Dr Tarrant said that through Balmain Resources Pty Ltd, Cadex Petroleum Pty Ltd and Plough Lane Superannuation, between July 10 and August 1, 2023, he bought shares, with the single largest purchase on July 12 of 598,093 shares for $14,374, or an average of 2.4 cents a share.
Hexima was unchanged at 1.9 cents.

THE GENERAL SIR JOHN MONASH FOUNDATION

The General John Monash Foundation says it has appointed Paul Ramadge as its chief executive officer.
The Foundation said that Mr Ramadge had experience in higher education, cross-cultural engagement, funding, not for profits and media organizations.
The Foundation said that previously Mr Ramadge was the managing-director of The Plus Alliance, a collaboration of the University of New South Wales, King's College London and the Arizona State University.
The organization said that Mr Ramadge was the inaugural director of Monash University's Australia-Indonesia Centre and was a senior editor at Melbourne's The Age newspaper.
Mr Ramadge holds a Diploma in Arts from the Armadale, New South Wales University of new England.
Mr Ramadge told Biotech Daily that his aim was to make the Monash Foundation scholarships as well-regarded as the United Kingdom's Rhodes scholarship and the US Fullbright scholarships.
The John Monash Foundation said that its scholarship program was in its twentieth year and had 248 scholarships awarded to Australians to study in the fields of health and medicine, engineering, science, fine arts, education, law, political theory, business and entrepreneurship.
The Foundation said the scholarships recognized excellence and leadership, and honored the legacy General John Monash.
The organization said that the scholarships provided $75,000 a year for up to three years at the candidates chosen university, as well as travel support and advice for relocating overseas, with additional benefits from partner universities Kings College London, Madrid's Instituto de Empresa (IE University), England's Cranfield University and the Netherlands University of Groningen.