



Biotech Daily

Monday July 29, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: OPTHEA UP 7%; MESOBLAST DOWN 6%**
- * **IMPEDIMED RECEIPTS EVEN AT \$11.5m**
- * **MICRO-X RECORD RECEIPTS UP 80% TO \$7m**
- * **MEMPHASYS \$500k ANDREW GOODALL PLACEMENT, \$590k RDTI LOAN**
- * **DORSAVI WINS \$110k WORKPLACE MOTION CONTRACTS**
- * **PACIFIC EDGE: NOVITAS DELAYS CXBLADDER REIMBURSEMENT CHANGES**
- * **ORTHOCELL STRIATE+ SINGAPORE SUBMISSION**
- * **OPTISCAN COMPLETES TELE-PATHOLOGY BETA-TESTING**
- * **PATRY'S: 'INCONSISTENCIES DELAY PAT-DX1 TRIALS'**
- * **SYNTARA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **IMPEDIMED 15m M-D, DIRECTOR RIGHTS, OPTIONS EGM**
- * **REGAL FUNDS TAKES 9.6% OF IMMUTEP**
- * **EDGE CAPITAL BELOW 5% OF OSTEOPORE**
- * **TRYPTAMINE APPOINTS PROF DAVID CASTLE ADVISOR**
- * **DR TONY KEATING REPLACES TRIVARX DIRECTOR DR TOM YOUNG; HALT**

MARKET REPORT

The Australian stock market was up 0.86 percent on Monday July 29, 2024, with the ASX200 up 68.3 points to 7,989.6 points. Thirteen of the Biotech Daily Top 40 companies were up, 12 were down, 11 traded unchanged and four were untraded.

Opthea was the best, up three cents or 7.3 percent to 44 cents, with 2.4 million shares traded. Alcidion and Clarity climbed more than five percent; Amplia was up 3.4 percent; Nova Eye and Telix rose more than two percent; CSL, Nanosonics, Polynovo, Pro Medicus and Starpharma were up one percent or more; with Cochlear, Emvision, Genetic Signatures and Medadvisor up by less than one percent.

Mesoblast led the falls, down 6.5 cents or 5.8 percent to \$1.06, with 9.5 million shares traded. Actinogen fell 4.7 percent; Cyclopharm, Cynata and Impedimed lost more than three percent; Avita and Resmed shed more than two percent; with Clinuvel, Dimerix, Micro-X, Neuren, Next Science and Universal Biosensors down by more than one percent.

IMPEDIMED

Impedimed says receipts from customers for the year to June 30, 2024 were up \$6,000 from \$11,487,000 in the prior corresponding period to \$11,493,000.

Impedimed said receipts from customers for the three months to June 30, 2024 were up 10 percent to \$2,970,000, due primarily to contracts and sales of its Sozo bio-impedance spectroscopy system for lymphoedema, heart failure and malnutrition.

The company said it sold 38 Sozo units in the three-month period to June 30, 2024, with 23 units sold in the US, compared to 18 total units sold in the prior quarter, of which 13 were sold in the US.

Impedimed said it had a cash burn of \$4,737,000 for the three months, with cash and cash equivalents of \$24,632,000 at June 30, 2024 compared to \$45,710,000 at June 30, 2023. Impedimed fell 0.2 cents or three percent to 6.4 cents with 6.3 million shares traded.

MICRO-X

Micro-X says customers receipts for the year to June 30, 2024 were up 79.5 percent to a record \$6,989,000, compared to the previous corresponding period.

Micro-X said sales receipts from its Rover mobile digital x-ray machines and Argus bomb detection systems for the three months to June 30 were down 25.4 percent to \$1,279,000. The company said the increased annual receipts were due to its "strategy to convert existing inventory into cash, with an approximate \$2.4 million reduction in Mobile digital radiology inventory during the year".

Micro-X said it had a cash burn of \$4,322,000 for the three months, with cash and cash equivalents of \$3,228,000 at June 30, 2024 compared to \$5,223,000 at June 30, 2023, leaving it with 0.75 quarters of available funding.

The company said it expected \$5 million of cash inflows in the three months to September 30, 2024 from contracts, including \$2.65 million initially expected before June 30, 2024.

Micro-X said it had reduced operating costs by about \$700,000 a year, was continuing to sell excess inventory and expected about \$5.5 million from a Federal Research and Development Tax Incentive.

The company said it would receive an estimated \$12.7 million in contracted project payments before June 2025, subject to milestones.

Micro-X fell 0.1 cents or 1.3 percent to 7.5 cents.

MEMPHASYS

Memphasys says it has raised \$500,000 at 0.8 cents a share from former director and substantial shareholder Andrew Goodall and has taken a \$586,000 loan.

Memphasys said the placement price was a 2.29 percent premium to the 30-day volume weighted average price and the funds would be for its Felix sperm separation system, including its clinical trial of the device for Australian Therapeutics Goods Administration submission, as well as the development of its oxidative stress measurement system.

Memphasys said Mr Goodall would receive one option for every share acquired, exercisable at 1.1 cents each within two years from their issue date.

The company said following the issue of shares, Mr Goodall would hold 288,714,397 shares in the company, or about 19.98 percent.

Memphasys said it had \$586,000 loan against its expected \$1.1 million Federal Research and Development Tax Incentive for the year to June 30, 2024, from an undisclosed lender, at 15 percent interest a year, payable by November 30, 2024.

Memphasys was up 0.1 cents or 12.5 percent to 0.9 cents with 4.6 million shares traded.

DORSAVI

Dorsavi says it has signed about \$110,000 in contracts for its workplace motion analysis devices through its agreement with insurance company QBE Australia.

In 2022, Dorsavi said it would provide its motion analysis technology to insurer QBE for a further three years following a 2020 agreement (BD: Jun 24, 2022).

Today, the company said the contracts were with “major Australian enterprises in the mining, healthcare and shipping sectors”.

Dorsavi said the mining contracts included using wearable sensors and video analysis to identify areas of injury risk and that it would provide mitigation strategies to reduce workplace risks prevalent in specific mining roles.

The company said a healthcare provider had commissioned it to “assess non-clinical roles within the hospital and identify high-risk manual handling tasks and develop actionable strategies aimed at reducing workplace injuries”.

Dorsavi said its shipping industry contracts were for the use of its video artificial intelligence algorithm to categorize different movement risks involved in lashing shipping containers onto shipping vessels.

Dorsavi chief executive officer Dr Andrew Ronchi said the additional customers were an “expansion of our work on preventing musculo-skeletal injuries using wearable sensors and video algorithms and validates our technology and commercialization strategy”.

Dorsavi was unchanged at 1.2 cents.

PACIFIC EDGE

Pacific Edge says Novitas has been granted an extension to finalize or withdraw changes that would limit reimbursement for its Cxbladder cancer tests in the US.

Last year, Pacific Edge said its Medicare administrative contractor Novitas had warned its Cxbladder tests would cease to be covered by Medicare in the US because it did not consider the tests “medically reasonable and necessary”; and later, said Novitas had delayed implementing the changes with submissions on the draft local coverage determination (LCD) for non-coverage of Cxbladder, with Novitas and First Coast Service Options to take up-to a year from July 27, 2023 (BD: Jul 6, 28; Sep 11, 2023).

On Friday, Pacific Edge said it received no updates from Novitas regarding the expected finalization of the reimbursement changes (BD: Jul 26, 2024).

Today, the company said Novitas announced on Saturday morning it was “considering all the feedback from interested parties” and the time to finalize the LCD was “unknown”.

Pacific Edge was untraded at 7.8 cents.

ORTHOCELL

Orthocell says its application to market and sell Striate+ for guided bone and tissue repair has been accepted for review by the Health Services Authority of Singapore.

Last week, Orthocell said it would expand regulatory approvals to additional territories for its Striate+ collagen barrier membrane for dental implants and Remplir collagen wrap for nerve repair damage (BD: Jul 24, 2024).

Today, the company said the evaluation of its application was “now in progress”.

Orthocell managing-director Paul Anderson said Singapore was “a key strategic stepping stone into the wider [Association of Southeast Asian Nations] market”.

“Once Singapore and Brazil applications are approved, Striate+ will be available for sale for use in guided bone and tissue repair in seven large and attractive markets,” he said.

Orthocell was unchanged at 38.5 cents.

OPTISCAN IMAGING

Optiscan says it has completed the beta-testing phase of its cloud-based, artificial intelligence, tele-pathology platform with Prolucid Technologies.

Last year, Optiscan said it would work with Prolucid Technologies to develop artificial intelligence (AI) algorithms and tele-pathology work-flows for its confocal laser endo-microscopes (BD: Jan 30, 2023).

At that time, the company said that the up-to 24-month project, with the Mississauga, Ontario-based Prolucid, would take images from its platform technology to display results of an artificial intelligence algorithm to clinicians for immediate decision-making during clinical workflows.

Today, Optiscan said the beta phase of testing included the ability to register, authenticate, and securely connect devices to the cloud platform.

The company said the testing showed its devices could “stream images to the cloud platform as they are acquired, enabling real-time visualization by remote users”.

Optiscan said the session data could also be pushed to cloud storage for post-session review, with proof-of-concept for post-session review, image annotation, and session data comparison workflows successfully implemented and the development of a commercial version of the technology currently underway.

The company said that “user authentication, data transmission latency, patient privacy protection, data encryption, synchronization, and management have been implemented, ensuring compliance with stringent cybersecurity requirements”.

Optiscan said the development was “a further evolution in Optiscan's imaging technology, allowing real-time collaboration and quick decision-making between clinicians and pathologists all over the world”.

Optiscan was up half a cent or 2.3 percent to 22 cents.

PATRY'S

Patry's says the manufacture of PAT-DX1 for use in clinical trials has been delayed following “an inconsistency with one of the processes used in specification testing”.

In 2021, Patry's said that Covid-19 delayed PAT-DX1 manufacturing by six months, and in 2022, said purification of the fermentation process resulted in less drug product than expected, delaying the first clinical study to mid-2023 (BD: Aug 3, 2021; Jan 24, 2022).

Last year, the company said the trial had been delayed to 2024 due to sporadic issues relating to the cell line used to produce the drug and in December said it would have PAT-DX1 in time for its first-in-human trial by 2025 (BD: Mar 31; Dec 13, 2023)

Earlier this month, Patry's said that specification testing for the manufacturing run of PAT-DX1 would be completed “by the end of July 2024 ... one month later than was anticipated” (BD: Jul 1, 2024).

Today, the company said it expected to complete the manufacture of PAT-DX1 “in the second half of August 2024” and that specification testing must be successfully completed for the drug material to be released for use in clinical trials.

Patry's was unchanged at 0.7 cents with 3.4 million shares traded.

SYNTARA

Syntara has requested a trading halt “in relation to the outcome of a capital raising by way of a placement ... to institutional and sophisticated investors”.

Trading will resume on July 31, 2024, or on an earlier announcement.

Syntara last traded at four cents.

IMPEDIMED

Impedimed says investors will vote to issue 15,000,000 rights and 15,000,000 options to managing-director Dr Parmjot Bains and executive director McGregor Grant.

Impedimed said its extraordinary general meeting would vote to issue Dr Bains 8,500,000 performance rights and 8,500,000 options, exercisable at seven cents each within seven years.

The company said the meeting would vote to issue chief financial officer Mr Grant 6,500,000 performance rights and 6,500,000 options, exercisable at the same terms as Dr Bains' options.

Impedimed said the securities were part of its employee incentive plan and were in addition to Dr Bains' yearly pay of \$490,000 and Mr Grant's annual salary of \$430,000.

The company said investors would vote to approve Dr Bains and Mr Grant's termination benefits.

Last week, Impedimed said interim managing-director Dr Bains had been promoted to the role permanently, with executive director McGregor Grant appointed as chief financial and operating officer (BD: Jul 23, 2024).

The meeting will be held online on August 28, 2024 at 10am (AEST).

IMMUTEP

Regal Funds Management Pty Ltd says it has increased its substantial shareholding in Immutep from 121,230,690 shares (8.51%) to 138,951,484 shares (9.57%).

The Sydney-based Regal Funds said that it bought the shares between June 24 and July 24, 2024, with the single largest purchase 4,164,625 shares for \$1,582,558, or 38 cents a share.

Immutep was unchanged at 34 cents with 2.8 million shares traded.

OSTEOPORE

Edge Capital Fund says it has ceased its substantial shareholding in Osteopore.

The Singapore-based Edge Capital said it exercised 1,492,000 options for \$57,740, or 3.8 cents a share and sold shares between May 10 and July 17, 2024, with the single largest sale 1,507,598 shares on July 16 for \$105,984, or 7.0 cents a share.

Osteopore was unchanged at 5.1 cents.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has appointed Prof David Castle to its scientific advisory board on a three-year term.

Tryptamine said Prof Castle had been a professor at the University of Melbourne, scientific director at the Centre for Complex Interventions and Centre for Addictions and Mental Health at the University of Toronto, Ontario, and was currently a professor at the University of Tasmania's Centre for Mental Health Service Innovation.

The company said as a member of its scientific advisory board Prof Castle would provide consulting services on regulatory engagement and grant funding initiatives, in connection with its clinical trial of oral psilocybin with psychotherapy for mental health disorders.

Tryptamine fell 0.1 cents or five percent to 1.9 cents with 2.1 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says Dr Tony Keating has been appointed a part-time, executive director from today, replacing Dr Thomas Young; and has requested a trading halt.

Trivarx said Dr Keating had been co-founder and chief executive officer of Resapp up-to its sale to Pfizer for \$180 million, and prior to Resapp was director of commercial engagement at the University of Queensland's Uniquest.

Last year, Neuroscientific said chair Paul Rennie and director Stephen Quantrill were replaced by directors Chris Ntoumenopoulos and Dr Keating; and later, said Dr Keating had been appointed an executive director (BD: Dec 5, 2023, Apr 2, 2024).

According to his LinkedIn profile, Dr Keating held a Bachelor of Engineering, Master of Engineering and Doctor of Philosophy from the University of Queensland.

Trivarx said it would pay Dr Keating \$96,000 a year including superannuation, with \$60,000 in shares as director fees and \$36,000 in cash paid monthly.

The company thanked Dr Young for his service and wished him well for his future endeavors.

Separately, Trivarx requested a trading halt "pending an announcement regarding the performance results of its phase II ... study".

Earlier this month, Trivarx said it had completed its 400-patient, phase II, sleep signal study of current major depressive episode using its MEB-001 artificial intelligence algorithm (BD: Jul 10, 2024).

Trading will resume on July 31, 2024, or on an earlier announcement".

Trivarx last traded at 3.6 cents.