



Biotech Daily

Tuesday November 14, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: AVITA UP 13.5%; NOVA EYE DOWN 27%**
- * **TELIX TO BUY CYCLOSAM BONE CANCER DRUG FOR UP-TO \$196m**
- * **TELIX TAKES 19.3% OF MANUA KEA CANCER DEVICES FOR \$9.6m**
- * **ORTHOCELL: 'ORTHO-ATI AS GOOD AS SURGERY' FOR TENNIS ELBOW**
- * **MEDADVISOR WINS QUEENSLAND PHARMACY PILOT CONTRACT**
- * **NOVA EYE 'MEDICARE GLAUCOMA REBATE CHANGES MAY HIT SALES'**
- * **KAZIA SUSPENDED FOR REMOVAL FROM ASX**
- * **NEUROTECH RECEIVES \$3.2m FEDERAL R&D TAX INCENTIVE**
- * **BCAL RECEIVES \$3m FEDERAL R&D TAX INCENTIVE**
- * **CYNATA RECEIVES \$2.3m FEDERAL R&D TAX INCENTIVE**
- * **RHYTHM RECEIVES \$1.7m FEDERAL R&D TAX INCENTIVE**
- * **ANTEOTECH AGM: UP-TO 23% OPPOSE DIRECTOR OPTIONS AGM**
- * **OPTISCAN PLEADS SCHULTZ TO ASX 61% PRICE QUERY**
- * **HAEMALOGIX: DAMIAN CLARKE-BRUCE M-D; BRYCE CARMINE CHAIR**
- * **SUFIAN AHMAD TAKES 11.7% OF DORSAVI**
- * **RYDER TAKES 5.3% OF LUMOS**

MARKET REPORT

The Australian stock market was up 0.83 percent on Tuesday November 14, 2023, with the ASX200 up 57.9 points to 7,006.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and five were untraded. All three Big Caps rose.

Avita was the best, up 48 cents or 13.5 percent to \$4.04, with 615,614 shares traded. Patrys climbed 11.1 percent; Actinogen was up 10 percent; Genetic Signatures improved 5.15 percent; Nanosonics and Starpharma were up more than three percent; Medical Developments and Polynovo rose two percent or more; Alcidion, Clinuvel, Orthocell, Paradigm and Telix were up more than one percent; with Cochlear, CSL, Pro Medicus and Resmed up by less than one percent.

Nova Eye led the falls, down five cents or 27.0 percent to 13.5 cents, with 4.2 million shares traded. Compumedics lost 10.5 percent; 4D Medical fell 7.6 percent; Emvision and Proteomics were down five percent or more; both Atomo and Imugene fell 4.35 percent; Immutep and Micro-X were down more than three percent; with Antisense, Impedimed, Neuren, Opthea and Volpara down by more than one percent.

TELIX PHARMACEUTICALS

Telix says it will pay the Austin, Texas-based Qsam Biosciences Inc up-to \$US125.1 million (\$A196.4 million) for its Cyclosam therapy for primary metastatic bone cancer.

Telix said Qsam Biosciences' Cyclosam, or samarium-153-1,4,7,10-tetra-azacyclododecane trimethylene phosphonic acid, or DOTMP, was "highly synergistic" with its existing therapeutic development activity in both prostate cancer and sarcoma.

The company said the acquisition would allow it to provide "care to patients from diagnosis and staging, systemic treatment of metastatic disease, to palliative care".

Telix said it would pay Qsam an upfront option fee of \$US2 million for development efforts and give it 60 days exclusivity pending diligence and a definitive agreement.

The company said that if the acquisition proceeded, it expected to pay \$US33.1 million in shares and following closing of the agreement it would pay up-to \$US90 million in cash or equity, subject to the completion of clinical and commercial milestones.

Telix said the agreement was subject to "many conditions", including satisfactory due diligence by both parties and approval of Qsam Biosciences shareholders.

Telix said if the acquisition did not close, the \$US2 million collaboration and option fee would be converted into Qsam Biosciences shares at \$US6.70 a share.

Telix managing director Dr Christian Behrenbruch said the acquisition would "bring a validated therapeutic candidate with the potential to accelerate development under the orphan drug and rare pediatric disease designations".

"With Cyclosam we plan to leverage Telix's extensive experience and success in distributing short-life radiopharmaceuticals using a cold kit product from a nuclear pharmacy," Dr Behrenbruch said.

Telix was up 13 cents or 1.4 percent to \$9.28 with 479,147 shares traded.

TELIX PHARMACEUTICALS

Telix says it will invest \$9.6 million to develop hybrid pharmaceutical-device products using its cancer-targeting products with the Paris-based Mauna Kea Technologies.

In an email to investors not released to the ASX, Telix said it would acquire 19.33 percent of Mauna Kea for the expansion of its imaging and robotics in surgery (Iris) using its cancer-targeting agents with Mauna Kea's Cellvizio surgical endo-microscopy platform.

The company said its investment would support the development of advanced imaging techniques for minimally invasive, laparoscopic and robotic, surgery, with a focus on urologic oncology.

Telix said Mauna Kea was developing real-time intra-operative visualization of cancer tissue during surgery and its Cellvizio confocal, laser, endo-microscopy, in-vivo, cellular imaging platform had US Food and Drug Administration approval and Conformité Européenne mark for multiple indications.

Telix said Cellvizio was "an ideal platform to explore applications of endo-microscopy combined with radio-pharmaceutical and fluorescence imaging techniques to build a comprehensive intra-operative imaging toolbox for urology applications".

The company said its Illuccix device enabled improved surgical planning to determine the location and extent of disease, and that Cellvizio could enable highly localized tissue visualisation to potentially define and confirm surgical margins in real-time.

Telix said as part of the collaboration it would acquire 19.33 percent of Mauna Kea's ordinary shares in a reserved private placement closing on November 17, 2023.

Telix managing director Dr Christian Behrenbruch said the partnership "brings together the cutting-edge technologies in targeted radiation, radio-guided surgery and real-time in vivo cellular imaging our respective companies are developing".

ORTHOCELL

Orthocell says a 48-patient study shows Ortho-ATI is “as effective, and potentially better than surgery” for treatment-resistant lateral epicondylitis, or tennis elbow.

Orthocell said the randomized, multi-centre, open-label, non-inferiority study compared its autologous tenocyte implantation (Ortho-ATI) to standard-of-care in tennis elbow patients with the aim of determining whether it was as effective as standard treatment.

The company said patients had suffered from pain and loss of elbow function for more than six months and had previously received and failed conservative therapy, including steroid injections, prior to enrolment in the study.

Orthocell said the study showed treatment with Ortho-ATI led to a “reduction in pain and improvement in function sooner than treatment with surgery”.

Orthocell said the study met its primary endpoint by showing Ortho-ATI was “at least as effective, if not better than surgery”.

The company said that at 12 months, patients treated with Ortho-ATI had a mean quick “disabilities of the arm, shoulder and hand” (Quickdash) score 15.7 points better than the surgery group ($p = 0.0028$).

Orthocell said all patients in the treatment group returned to work at an average of 19.3 days after treatment compared to 51.1 days after treatment in the surgery group.

Orthocell chief scientific officer Prof Minghao Zheng said “returning patients to pain free function sooner than surgical repair for severe lateral epicondylitis, is a further validation and significant milestone for the commercial development of Ortho-ATI”.

“We are absolutely delighted with the study results and the potential to deliver the first injectable cell therapy in orthopaedics, that truly addresses the cause of injury and returns patients to full use of their chronically damaged tendons without the need for surgery,” Prof Zheng said.

Orthocell was up half a cent or 1.2 percent to 42 cents with 2.1 million shares traded.

MEDADVISOR

Medadvisor says it will develop and deliver “enhancements” to its Plus One software for the 2024-'25 North Queensland Community Pharmacy scope of practice pilot program.

Medadvisor said the contract followed a tender process, as well as previous contracts in Queensland, New South Wales, Western Australia and Victoria where it had enabled in-pharmacy clinical consultations for urinary tract infection and oral contraception.

The company said it expected the program to begin on February 1, 2024 and end on May 31, 2025, with about 135 community pharmacies registered to participate.

Medadvisor said the cost of delivering the program would be partially funded by the Pharmacy Guild of Australia, and that although it did not expect revenue from the program it anticipated that the clinical services would eventually be accessible to all pharmacies nationally, which it believed would generate revenue in the future.

The company said trained prescribing pharmacists would be available to offer communities up to 23 clinical services covering acute care, chronic conditions, and medication management.

Medadvisor chief executive officer Rick Ratliff said the contract was “a testament to the company’s enduring reputation amongst its 5,700 plus pharmacy customers nationwide”.

“It also speaks to the successful outcomes that Medadvisor Solutions has assisted in delivering, through timely clinical consultations for urinary tract infection and oral contraception programs, now prescribed by about 2,150 registered pharmacies through Queensland, New South Wales, Western Australia and Victoria,” Mr Ratliff said.

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

NOVA EYE MEDICAL

Nova Eye says proposed US Medicare local coverage determination changes for glaucoma surgery could “negatively impact” sales of its Itrack “in the short term”. Last month, Nova Eye said the Wisconsin Physician Service Insurance Corporation proposed to limit or deny coverage for several minimally invasive glaucoma surgery procedures, effective from December 24, 2023 (BD: Oct 31, 2023).

At that time, the company said the changes were not expected to have an impact on sales of its Itrack device for glaucoma surgery as the device had “several indications for use by doctors with or without cataract surgery” and surgeons could use the device “in a variety of surgical techniques and to seek reimbursement accordingly”.

Today, Nova Eye said the reimbursement changes had been proposed by four additional Medicare administrative contractors, and that collectively the contractors covered the 38 US states where it made 40 percent of its annual revenue.

Nova Eye said its total US sales for the four months to October 31, 2023, were up about 74 percent on the previous corresponding period to about \$US3.34 million.

In August, Nova Eye said revenue for the year to June 30, 2023 was \$17,025,000, with record sales of its glaucoma consumable surgical devices (BD: Aug 28, 2023).

Biotech Daily calculates that \$6,808,000 of the company’s revenue for the year to June 30, 2023, was generated in the states where the Medicare changes are proposed.

Nova Eye said based on a consensus reached at a meeting of practicing glaucoma surgeons and academics at the American Academy of Ophthalmology, it “strongly disagrees” with the proposed changes.

The company said it intended to “pursue all remediation possibilities to reinstate coverage for canaloplasty”, which included engaging with the Medicare administrative contractors to address what it believed were “fundamental procedural issues with the ... changes and to provide additional clinical data to support ... continued coverage”.

Nova Eye said it expected customer confusion and misinformation in the marketplace to lead to a reduction in sales to be the “biggest challenge” from the changes, and that it had a program of “near-term initiatives” designed to reduce the expected impact on sales in the medium to long term.

Nova Eye fell five cents or 27.0 percent to 13.5 cents with 4.2 million shares traded.

KAZIA THERAPEUTICS

The ASX says it has suspended Kazia from quotation at its request under Listing Rule 17.2 to facilitate its removal from the official list, effective immediately.

Last month, Kazia said it would delist from the ASX, effective on November 14, 2023, and remain on the Nasdaq, to reduce costs (BD: Oct 11, 2023).

Kazia closed on the ASX at eight cents.

NEUROTECH INTERNATIONAL

Neurotech says it has received \$3.17 million from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Neurotech said the receipt of the research and development tax incentive took its cash balance to about \$6.1 million, which was “sufficient to fund the company’s operations through 2023-’24 and complete all active clinical trials across three pediatric neurological disorders”.

The company said the rebate related to expenditure for the year to June 30, 2023.

Neurotech was up 0.2 cents or 3.8 percent to 5.5 cents.

BCAL DIAGNOSTICS

Bcal says it has received \$3,046,000 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Bcal chief executive officer Dr John Hurrell said “the support of the [research and development tax incentive] program is essential in assisting Bcal in funding the development of Breastest as it strives to bring its first product to market in late ... 2024”. The company said the rebate related to research and development expenditure for the year to June 30, 2023.

Bcal was unchanged at 10.5 cents.

CYNATA THERAPEUTICS

Cynata says it has received \$2,315,643 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Cynata said the incentive enabled further resources to be invested towards progressing its “broad and advanced cell therapy product pipeline”.

The company said the rebate related to research and development expenditure for the year to June 30, 2023.

Cynata was unchanged at 13 cents.

RHYTHM BIOSCIENCES

Rhythm says it has received about \$1.69 million from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Rhythm said it expected to receive a further research and development tax incentive for its overseas expenditure in 2024, once verified and lodged by its tax advisers.

The company said the rebate related to expenditure for the year to June 30, 2023.

Rhythm fell one cent or 4.55 percent to 21 cents.

ANTEOTECH

Anteotech says its annual general meeting voted 23.39 percent against the resolution to issue long-term incentive options to director Dr Geoff Cumming.

Last month, Anteotech said investors would vote to issue managing-director David Radford 2,850,000 performance rights and 10,000,000 options as well as 2,500,000 options to chair Ewen Crouch and 1,500,000 options each to directors Dr Cumming, Glenda McLoughlin and Dr Katherine Woodthorpe” (BD: Oct 13, 2023).

Today, the company said the resolution to grant Dr Cumming’s long-term incentive options was opposed by 178,363,105 votes (23.39%), with 584,279,104 votes (76.61%) in favor.

Anteotech said resolutions to grant incentive options to Mr Radford, Mr Crouch, Ms McLoughlin and Dr Woodthorpe were opposed by more than 21 percent of votes, while 19.3 percent opposed Mr Radford’s short-term incentive performance rights, with less opposition to share plan options for Mr Crouch, Mr Radford and Dr Cumming.

The company said the remuneration report was opposed by 10.44 percent of investors, with the placement capacity, the placement and share plan shares and options passed more easily, and directors Ms McLoughlin and Dr Woodthorpe were re-elected easily.

According to its most recent notice, Anteotech had 2,196,442,432 shares on issue, meaning that the votes against Dr Cumming’s long-term incentive options amounted to 8.1 percent of the company, sufficient to requisition extraordinary general meetings.

Anteotech was up 0.2 cents or eight percent to 2.7 cents with 3.1 million shares traded.

OPTISCAN IMAGING

Optiscan has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 60.5 percent from 8.1 cents a share on November 10, 2023 to 13 cents a share during trading today but did not specify an increase in the volume traded.

Optiscan was up 1.1 cents or 11.1 percent to 11 cents.

HAEMALOGIX LIMITED

Sydney's Haemalogix says it has appointed Damian Clarke-Bruce as its managing-director and chief executive officer, effective from November 13, 2023.

Haemalogix said that outgoing chief executive officer Bryce Carmine would continue as the chair of the company.

Last year, Race oncology appointed Mr Clarke-Bruce as its managing-director and chief executive officer on a base salary of \$475,000 a year (BD: Dec 14, 2022).

In August, Race said that director Dr Peter Smith has been appointed an executive director, on \$190,000 a year replacing Mr Clarke-Bruce (BD: Aug 22, 2023).

Today, Mr Carmine said he was "immensely proud to have served as Haemalogix's CEO for the past eight years, during which time we have focused the strategic direction of the company on development of our portfolio from a single immunotherapy asset to potentially seven products, with two now in clinical stages".

Haemalogix said that Mr Clarke-Bruce had more than 25 years' experience in drug commercialization and portfolio strategy in the pharmaceutical and biotechnology sectors and knowledge of several therapeutic areas relating to the company's clinical strategy, including oncology, immunology and neuroscience.

The company said that prior to Race, Mr Clarke-Bruce was an executive at Pharming Healthcare Inc, as well as Novartis, Celgene and Biogen.

Haemalogix said that Mr Clarke-Bruce held a Bachelor of Science from the University of New South Wales and a Master of Science from the University of Sydney.

Haemalogix is a public unlisted company.

DORSAVI

Sufian Ahmad says he has increased his substantial shareholding in Dorsavi from 31,514,922 shares (7.95%) to 69,990,997 shares (11.73%).

The Perth-based Mr Ahmad said he bought 13,476,075 shares on market between February 16 and November 9, 2023 for \$149,131, or 1.1 cents a share, and 25,000,000 shares in a placement on November 8 for \$250,000, or one cent a share.

Last month, Dorsavi said that it had "binding commitments" to raise \$500,000 in a placement at one cent a share and had appointed Sixty Two Capital as lead manager to the placement to be paid with a six percent raising fee on funds raised under the offer (BD: Oct 31, 2023).

In his substantial shareholder notice, Mr Ahmad said the shares were held directly as well as through Sixty-Two Capital, of which he is a non-executive director, and BRSB Super Fund Pty Ltd.

Dorsavi was untraded at 1.1 cents.

LUMOS DIAGNOSTICS

The Sydney-based Ryder Capital Ltd says it has become substantial in Lumos with 25,601,613 shares, or 5.32 percent.

Ryder said between July 13 and November 3, 2023 it bought 10,380,054 shares for \$726,604, or seven cents a share.

Lumos was unchanged at seven cents with 4.5 million shares traded.