



Biotech Daily

Monday November 4, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: CURVEBEAM UP 20%; AMPLIA DOWN 9%**
- * **OPTISCAN FEDERAL \$3m FOR MONASH UNI G-I ENDO-MICROSCOPE**
- * **OSTEOPORE UP-TO \$11m FOR REGEN STEM CELLS**
- * **TELEX: CMS TO REIMBURSE RADIO-PHARMACEUTICALS SEPARATELY**
- * **ENLITIC UP-TO \$454k DARWINIST ENSIGHT DISTRIBUTION DEAL**
- * **BOTANIX AGM 35% OPPOSE DIRECTOR RIGHTS**
- * **L1 CAPITAL TAKES 18.6% OF ANTERIS**
- * **DORSAVI APPOINTS 62 CAPITAL ADVISORS, FOR 40m RIGHTS**

MARKET REPORT

The Australian stock market was up 0.56 percent on Monday November 4, 2024, with the ASX200 up 45.8 points to 8,164.6 points.

Fourteen of the Biotech Daily Top 40 companies were up, 19 fell, six traded unchanged and one was untraded.

Curvebeam was the best, up 1.8 cents or 19.6 percent to 11 cents, with two million shares traded.

Paradigm and Syntara climbed more than seven percent; Atomo and Universal Biosensors were up four percent or more; Clarity and Telex rose more than three percent; Avita, Cochlear, CSL, Immutep and Starpharma were up one percent or more; with 4D Medical, Neuren, Opthea, Orthocell and Resmed up by less than one percent.

Amplia led the falls, down one cent or 8.7 percent to 10.5 cents, with 3.4 million shares traded.

Nova Eye shed 6.1 percent; Aroa lost five percent; Cyclopharm fell 4.1 percent; Emvision was down 3.6 percent; Cynata, EBR, Imugene, Mesoblast and Proteomics shed two percent or more; Dimerix, Impedimed, Medical Developments, Micro-X, Nanosonics and Percheron were down more than one percent; with Clinuvel, Genetic Signatures, Polynovo and Pro Medicus down by less than one percent.

OPTISCAN IMAGING

Optiscan says it has \$3 million from the Federal Government to develop a gastro-intestinal (GI) endo-microscope with Melbourne's Monash University.

Optiscan said the agreement for the "development of a scope agnostic gastro-intestinal flexible endo-microscope" was an extension of its longstanding relationship with Monash University which developed the original technology.

The company said it would use about \$1 million of the \$3 million Cooperative Research Centres Projects grant to develop a miniaturized, flexible, digital endo-microscopic probe designed to integrate with biopsy channels of commercially available endoscopes.

Optiscan said it had made "significant progress towards ... a platform which combines advanced miniaturized endo-microscopy with [artificial intelligence], to deliver real-time, slide-free imaging with sub-cellular resolution in a flexible format suitable for [gastro-intestinal] endoscopy procedures".

The company said Monash University would assist the project by incorporating computing algorithms allowing for real-time assessment of cancerous and pre-cancerous gastro-intestinal lesions.

Optiscan managing-director Prof Camile Farah said the agreement was "a significant step towards better diagnosis and treatment of gastro-intestinal diseases".

"The targeted advantages of our next-[generation] flexible endo-microscope are not just related to delivery of better medical outcomes," Prof Farah said. "This endo-microscope is also being specifically designed as a stand-alone medical imaging system agnostic to the commercial endoscope manufacturers."

"This will make adoption of our imaging platform easier for clinicians and hospitals already invested in their preferred endoscope system, while also providing flexibility to strike commercial arrangements with a wider range of endoscope manufacturers such as Olympus, Fuji, Pentax, Karl Storz and Ambu," Prof Farah said.

"Optiscan's imaging system has the potential to revolutionize [gastro-intestinal] diagnostics, not only for [gastro-intestinal] cancers, but also for improving accuracy and speed in detecting conditions such as Crohn's disease, ulcerative colitis, and irritable bowel syndrome," Dr Farah said.

Optiscan was up one cent or 6.25 percent to 17 cents.

OSTEOPORE

Osteopore says it will invest up-to \$US7 million (\$A10.6 million) in a special purpose vehicle (SPV) called Regen for the development of regenerative medicines.

Osteopore said Regen was founded by Dr Xianmin Zeng and Prof Brian Kennedy, with each party to invest \$US5 million to \$US7 million, in cash or in kind, with the investment in tranches, pending due diligence, funding and approvals.

Osteopore said Dr Zeng was the founder of Rxcell Inc which was developing induced pluripotent stem cells for degenerative diseases including age-related macular degeneration; and Prof Kennedy was the director of the Healthy Longevity Translational Research Program at the National University of Singapore and chief executive officer of San Francisco's Buck Institute for Research on Aging.

Osteopore said the Regen would have "access to the company's clinical and technical advisory panel, leveraging [its] ... extensive expertise in research and development, clinical trials, regulatory processes, and commercialization".

Osteopore chair Mark Leong said the company's "investment with Dr Zeng and Dr Kennedy places us at the forefront of regenerative medicine".

Osteopore was unchanged at four cents with 1.15 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Centers for Medicare and Medicaid Services will reimburse radio-pharmaceuticals and nuclear imaging tests separately, beyond pass-through status. In 2022, Telix said the CMS had granted transitional pass-through payment status for its Illucix prostate cancer imaging agent, allowing it to be reimbursed when used in the performance of positron emission tomography and computed tomography in the hospital outpatient setting (BD: May 30, 2022).

A US Centers for Medicare and Medicaid Services (CMS) 2025 November 1, 2024 fact sheet said the payment for diagnostic radio-pharmaceuticals was previously “packaged into the payment for the nuclear medicine tests [with which] they are used”.

The CMS said that it had decided to reimburse radio-pharmaceuticals separately because “the payment amount for the nuclear medicine tests may not adequately account for the cost of certain high-cost diagnostic radio-pharmaceuticals”.

Telix said that the separate payments would be based on “‘mean unit cost’ derived from hospital claims data and apply to any specialized diagnostic radio-pharmaceutical without pass-through status and with a threshold per day cost greater than US\$630 (\$A954)”.

A Telix spokesperson said that the pricing of Illucix would “similar to what it is now”.

“The new rule maintains reimbursement for [US] Medicare fee-for-service patients,” the spokesperson said.

The company said the revision was “a significant decision for patients and hospitals, with the change facilitating equitable access to advanced imaging agents for all patients into the future”.

Telix said the changes ensured “consistent reimbursement for Medicare fee-for-service patients, following expiry of pass-through status” and provided “greater certainty and consistency in pricing policy across all customer segments”.

The company said the changes would apply to Illucix after its pass-through status expired, effective from July 1, 2025.

Telix said the revised reimbursement rates would apply to its pipeline of investigational diagnostic imaging agents including TLX007-CDx for prostate specific membrane antigen (PSMA) imaging of prostate cancer, TLX250-CDx for kidney cancer imaging, and TLX101-CDx, or Pixclara, for brain cancer imaging, subject to approvals and reimbursement after pass-through expired.

The company said that if TLX007-CDx was approved in the US it would be “the only company with two PSMA-PET imaging agents on the market, enabling broader patient reach, including into currently under-served populations, and with greater flexibility to offer the product most suitable for a patient based on their clinical profile, indication and eligibility for reimbursement”.

Telix said the changes could “be particularly beneficial for any [US] Medicare patients currently subject to a co-payment in hospital out-patient settings”.

Telix Precision chief executive officer Kevin Richardson said the company welcomed “the decision by CMS to unbundle payments for diagnostic radio-pharmaceuticals, as it will provide certainty for patients and physicians seeking access to safe and effective diagnostic radio-pharmaceuticals”.

“Moreover, it will promote continued investment in bringing new imaging agents to market across a range of disease states, as there is a clear commercial pathway to recouping the investment in innovation and the significant infrastructure and operational costs of delivering high quality service to patients,” Mr Richardson said.

“We are pleased to see the reimbursement landscape change in favour of patients,” Mr Richardson said.

Telix was up 75 cents or 3.5 percent to \$22.20 with 2.5 million shares traded.

ENLITIC

Enlitic says it has an up-to \$US300,000 (\$A454,000) deal for its Ensign 2.0 medical imaging management software to be included and distributed by Darwinist.

Enlitic said the Sheffield, England-based Darwinist's Beagle middle-ware platform simplified the deployment and management of artificial intelligence tools from third party vendors for use in hospitals, with partners including Red Hat and IBM (International Business Machines).

The company said that the initial contract expected to generate shared revenue for Enlitic of up-to \$US100,000 a year for three years.

Enlitic said once it completed an integration process its Ensign 2.0 artificial intelligence-based software for the management of radiology imaging data, including the Encog and Endex modules, would be distributed to Darwinist's clinical trial hospital customers on Darwinist's Beagle platform, presenting Enlitic as a 'supported vendor'.

The company said the agreement provided "scope for Enlitic to be promoted to 'suggested vendor' and 'recommended vendor' status contingent on certain milestones", which would be expected to bring increased revenues to Enlitic,

Enlitic said its Ensign 2.0 Endex and Encog modules would "initially be rolled out to an agreed number of clinical trial sites with scope for expansion".

Enlitic managing-director Michael Sistenich said the company's "new distribution arrangement with Darwinist provides us with an opportunity to be deployed in advance of [artificial intelligence] analysis, standardizing data prior to it being routed to the [artificial intelligence] models that Darwinist supports".

Enlitic fell 0.3 cents or 4.7 percent to 6.1 cents with 1.15 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says investors passed all resolutions but with up-to 34.94 percent against the issue of performance rights to directors Danny Sharp and Dr Stewart Washer.

Last month, Botanix said that its annual general meeting would vote to increase the director fee pool 50 percent to \$450,000 and grant chair Vince Ippolito 24,000,000 performance rights (BD: Oct 3, 2024).

The company said in the notice of meeting that it proposed that directors Matthew Callahan, Dr Washer, Mr Sharp and Dr William Bosch be issued 3,000,000 performance rights, each.

Today, the company said Mr Sharp's and Dr Washer's performance rights were opposed by 177,719,013 votes (34.94%), each, with 65.06 percent in favor.

Botanix said the issue of performance rights to Dr Bosch was opposed by 32.07 percent of the vote, with resolutions to issue Mr Ippolito and Mr Callahan's performance rights opposed by 7.45 percent and 7.42 percent, respectively.

The company said the three resolutions to approve Dr Washer, Dr Bosch and Mr Sharp's termination benefits were opposed by 30.94 percent to 33.84 percent of the meeting, with Mr Ippolito and Mr Callahan's termination benefits opposed by 5.55 percent of the meeting.

Botanix said the approval of the amended plan was opposed by 19.23 percent, with the remaining resolutions including the director fee pool increase passed more easily with more than 93.24 percent support.

According to its most recent notice, Botanix had 1,814,037,788 shares on issue, meaning that the 177,719,013 votes against Mr Sharp's and Dr Washer's rights amounted to about 9.8 percent of the company, sufficient to requisition extraordinary general meetings.

Botanix fell 2.5 cents or 7.25 percent to 32 cents with 8.35 million shares traded.

ANTERIS TECHNOLOGIES

L1 Capital Pty Ltd says it has increased its substantial shareholding in Anteris from 3,693,941 shares (17.48%) to 3,929,401 shares (18.59%).

The Melbourne-based L1 Capital said that in 10 transactions between September 9 and October 31, 2024 it bought 235,460 shares on-market for \$2,676,672, or \$11.37 cents a share.

Anteris was up one cent or 0.1 percent to \$10.21.

DORSAVI

Dorsavi says it has appointed Perth's 62 Capital Pty Ltd as its corporate advisor, and will pay 62 Capital 40,000,000 performance rights.

Dorsavi said 62 Capital would help it to identify and evaluate "potential growth strategies for the company including but not limited to corporate advisory, mergers and acquisitions, equity and debt raisings and value creating opportunities".

The company said it would issue 62 Capital 10,000,000 performance rights if its 15-day volume weighted average price reached two cents within two years and a further 10,000,000 performance rights on its 15-day volume weighted average price reaching 2.5 cents within two years.

Dorsavi said it would issue a further 20,000,000 rights to 62 Capital if its 15-day volume weighted average price reached four cents within two years, with all the performance rights subject to shareholder approval.

Dorsavi chair Gernot Abl said 62 Capital had "been strong supporters of our company for a number of years and have a strong foundational understanding of the Dorsavi business and a long-term focus with its portfolio companies".

"We have confidence this partnership will provide value for the business and support in increasing Dorsavi's reach to access new investor and partner communities," Mr Abl said. Dorsavi was unchanged at one cent.