Biotech Daily

Thursday October 24, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYNATA, MEDICAL DEVELOPMENTS UP 4%;**
- NOVA EYE DOWN 8%

*** TELIX WINS FDA TLX101-CDx BRAIN CANCER PRIORITY REVIEW**

*** VAXXAS RAISING $100m FOR NEEDLE-FREE VACCINES**

*** CHIMERIC DOSES FIRST 8 PHASE Ib CHM0201 AML PATIENTS**

*** GERMANY OKAYS ONCOSIL PANCREATIC CANCER TRIAL; HALT**

*** LBT INSTALLS 1st ASTRAZENECA APAS CONTACT PLATE**

*** OSTEOPORE, MEDSITE 5-YEAR BRAZIL DISTRIBUTION DEAL**

*** ARGENT 'COMMITMENTS' FOR $200k PLACEMENT**

*** MEMPHASYS EXPEDITES FELIX CE MARK**

*** ALCIDION AGM 37.5% OPPOSE EQUITY INCENTIVE PLAN**

*** MEDICAL DEVELOPMENTS 23% OPPOSE PLACEMENT CAPACITY**

*** ANTEOTECH M-D DAVID RADFORD 5m RIGHTS, 11m OPTIONS AGM**

*** AUDEARA 4.25m M-D, CHAIR, DIRECTOR OPTIONS AGM**

*** ORTHOCELL REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NYRADA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** GENETIC TECHNOLOGIES EXTENDS 'FUND RAISING' SUSPENSION**

*** KARST PEAK DILUTED TO 6% OF CURVEBEAM**

*** QBIOTICS: STEPHEN DOYLE M-D, DR SUE FODEN CHAIR, DR GORDON**

*** DORSAVI LOSES INTERIM CHAIR DR MICHAEL PANACCIO**

*** ARGENICA LOSES DIRECTOR LIDDY MCCALL**

*** ALCIDION LOSES DIRECTOR SIMON CHAMBERLAIN**

MARKET REPORT

The Australian stock market fell 0.12 percent on Thursday October 24, 2024, with the ASX200 down 9.7 points to 8,206.3 points.

Seven of the Biotech Daily Top 40 companies were up, 23 fell, eight traded unchanged and two were untraded.

Medical Developments was the best, up two cents or 4.4 percent to 47 cents, with 294,215 shares traded, followed by Cynata, up one cent or 4.35 percent to 24 cents with 114,397 shares traded.

Syntara rose 2.2 percent; Clinuvel, Prescient and Telix improved more than one percent; with Clarity and CSL up by less than one percent.

Nova Eye led the falls, down 1.5 cents or 7.9 percent to 17.5 cents, with 845,273 shares traded.

Mesoblast lost 5.5 percent; Curvebeam, Cyclopharm, Dimerix, Resonance and Universal Biosensors were down more than three percent; Emvision, Genetic Signatures, Imugene, Micro-X, Neuren, Percheron, Polynovo and SDI shed two percent or more; 4D Medical, Avita, Cochlear, Immutep, Medadvisor and Nanosonics were down more than one percent; with Aroa, Pro Medicus, Proteomics and Resmed down by less than one percent.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has accepted its new drug application for TLX101-CDx, or Pixclara, for imaging brain cancer and granted it priority review.

In April, Telix said the FDA had granted fast-track designation for Pixclara, or TLX101-CDx, positron emission tomography (PET) for glioma imaging; and later, filed a new drug application for the imaging agent with the FDA (BD: Apr 16, Aug 28, 2024).

Today, the company said the FDA had designated a Prescription User Drug Fee Act (PDUFA) goal date of April 26, 2025, with US commercial launch expected in 2025.

Telix said TLX101-CDx was “already included in international clinical practice guidelines for the imaging of gliomas” but there was currently no FDA-approved targeted amino acid PET agent for adult and paediatric brain cancer imaging commercially available in the US.

The company said it was reviewing the potential use of Pixclara as a “companion diagnostic agent” for its TLX101-Tx investigational neuro-oncology drug that targeted the same amino acid transporter mechanism with therapeutic radiation.

Telix Precision business chief executive officer Kevin Richardson said “that the FDA approval of Pixclara will drive a step-change for brain cancer imaging in the US and bring it into line with a more advanced standard-of-care currently used in other markets”.

“There is currently a critical need for better imaging in brain cancer, and Telix is dedicated to delivering precision medicine solutions that address patient needs and enhance both cancer imaging and treatment outcomes,” Mr Richardson said.

Telix was up 35 cents or 1.7 percent to $21.46 with 1.2 million shares traded.

VAXXAS PTY LTD

Vaxxas says that it hopes to raise up to $100 million for its needle-free vaccines.
Vaxxas chair and One Ventures principal Dr Paul Kelly told Biotech Daily that Vaxxas hoped to raise the funds specifically for needle-free vaccines.
In September, Endpoints Capital said that it lent Vaxxas $9.7 million against its expected Federal Research and Development Tax Incentive for its “needle-free” vaccine and drug delivery technology to “enable Vaxxas to advance ongoing [research and development] work to develop the company’s world-leading vaccination technology” (BD: Sep 25, 2024).
Today, Dr Kelly said that he expected the $100 million capital raising to close “early in the new year”.
Dr Kelly said that the capital raising was being conducted by Wilson’s Advisory and JP Morgan.
Vaxxas is a private company.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first eight patients with relapsed or refractory acute myeloid leukaemia in its phase Ib trial of CHM0201, with no dose-limiting toxicities.
Earlier this year, Chimeric said it had dosed the first patient in its up-to 20-patient, phase Ib trial of its CHM0201 natural killer (NK)-cells therapy in combination with standard-of-care azacitidine and venetoclax for acute myeloid leukaemia; and in June, said it had dosed the first cohort of three patients (BD: Feb 8, Jun 5, 2024).
Today, Chimeric chief operating officer Dr Rebecca McQualter told Biotech Daily that the trial had dosed eight patients with relapsed or refractory disease, in the dose finding part of the trial, with the remaining 12 patients with newly diagnosed acute myeloid leukemia yet to be enrolled, bringing the total number of patients in the phase Ib study to 20 total patients.
Chimeric was unchanged at 0.9 cents with 20.15 million shares traded.

ONCOSIL MEDICAL

Oncosil says the German Federal Joint Committee has approved a trial of its pancreatic cancer device compared to standard first-line chemotherapy.
Oncosil said the German regulatory body would allow the randomized controlled trial to be “conditionally reimbursed while additional evidence is gathered to support its effectiveness”.
The company said it had received “draft notification of medical device regulation approval for the … device”, lifting post-market restrictions on the device, relieving administrative costs and allowing it to re-submit its application to the Therapeutic Goods Administration for approval in Australia.
Oncosil managing-director Nigel Lange said he was “very pleased that the G-BA [Gemeinsamer Bundesausschuss] fulfilled its mandate, setting the course for improved care in Germany for patients with pancreatic cancer”.
“The framework for the trial, legally binding after publication [in] the Federal Law Gazette, represents a critical milestone in proving the benefits of Oncosil at the highest level of evidence,” Mr Lange said.
Separately, Oncosil requested a trading halt until October 28, 2024 for “a capital raise”.
Oncosil last traded at 1.3 cents.

LBT INNOVATIONS

LBT says it has installed the first automated plate assessment system (Apas) for reading 90mm settle plates and 55m contact plates at Astrazeneca's UK facility.
Last year, LBT said it had a $1 million deal with Astrazeneca to develop an Apas 'pharma analysis module' into its plate assessment instrument (BD: Jan 22, 2023).
In August, the company said it had an up-to $4.1 million contract with Astrazeneca for five of its Apas systems for imaging microbiology culture plate (BD: Aug 7, 2024).
At that time, LBT said it was developing a module for Apas to read 55mm contact plates for pharmaceutical environmental monitoring, expected to be completed the by July 2025, with "several customers" having already expressed interest in the technology.
Today, the company said pharmaceutical businesses used 90mm settle plates for air monitoring and smaller 55mm contact culture plates for surfaces and personnel.
LBT said that it had successfully "completed the first installation of its new Apas application for automated plate handling and analysis of contact plates used in pharmaceutical environmental monitoring".
The company said the instrument at Astrazeneca's UK facility had "been upgraded to this new and advanced instrument configuration", which was the first release including upgraded hardware and software.
LBT said the software used artificial intelligence interpretative software to analyze the plates for microbial growth and was the intelligent system within the Apas Independence that enables real-time reading and sorting of plates for laboratories.
The company said Astrazeneca's use of the technology was an "early engineering release" aimed at supporting product development and gathering user feedback, with more Astrazeneca facilities expected to adopt the Apas technology once the product was "finalized and performance targets are met".
The company said the contact plate upgrade would be available as a standalone Apas analysis module and that with the existing eight instruments sold it could potentially generate up-to $2.5 million additional revenues over seven years.
LBT managing-director Brent Barnes said the installation of its Apas contact plate application was "an important milestone in the development project enabling early user feedback".
"We have showcased the Apas contact plate capability during recent global conferences and received resounding positive interest from customers," Mr Barnes said.
"Our goal is to establish Apas Independence as a platform to automate multiple environment monitoring tests which we expect will increase the overall demand and market opportunity for the product," Mr Barnes said.
LBT fell 0.1 cents or 6.7 percent to 1.4 cents with 3.6 million shares traded.

OSTEOPORE

Osteopore says it has a five-year, exclusive distribution deal with Medsite Equipamentos e Produtos Para Saude Ltda for its cranio-facial products in Brazil.
Osteopore said the Rio de Janeiro-based Medsite would manage regulatory findings in Brazil, which it expected to take about two years.
The company did not disclose commercial terms of the agreement.
Osteopore said Brazil sales "paved the way" for market entry in other countries.
Osteopore managing-director Dr Yujing Lim said the decision to enter the Brazilian cranio-facial market was "a strategic one as it leverages the strength of US Food and Drug Administration and European Union [Conformité Européenne] mark regulatory approvals".
Osteopore was up 0.2 cents or 5.4 percent to 3.9 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says it has 'firm commitments' to raise $200,000 in a placement at 30 cents a share to an unnamed "professional and sophisticated investor".

Last year, the then MGC said 96.6 percent of its extraordinary general meeting voted in favor of a 1,000-to-one consolidation (BD: Sep 26, Oct 26, 2023).

Argent said the issue price was a 28.4 percent discount to the 15-day volume weighted average price of 41.9 cents a share and a 7.7 percent discount to the closing price of 32.5 cents a share.

The company said the funds would be used to continue its "drug development pipeline, including Cannepil and Cimetra in the US and EU markets and general working capital purposes".

Argent fell two cents or 6.15 percent to 30.5 cents.

MEMPHASYS

Memphasys says it will pursue Conformité Européenne (CE) mark registration for its Felix sperm separation device "as soon as practicable, following clinical trial completion".

Memphasys said its clinical trial of the Felix electrophoresis-based sperm separation device for in-vitro fertilization (IVF) procedures had reached "90 percent completion, with fewer than 20 patients remaining to bring the trial to a close".

The company said several additional patients at one of nine Monash IVF Group sites recruiting patients in Australia had already consented and were awaiting treatment, with the trial scheduled for completion "by the end of the … year, subject to final recruitment".

In 2022, Memphasys said that with the Monash IVF Group, it had enrolled and treated the first couple in the 104-couple study of its Felix device (BD: Jun 28, 2022).

Today, the company said it had received strategic advice from regulatory consultants suggesting that the CE mark registration process "could take less than one year after submission to the regulatory body, making it a faster route than the Australian Therapeutic Goods Administration (TGA) process".

Memphasys said the CE mark offered "significant advantages, including a broader market access as well as the ability to register with the TGA shortly after obtaining the CE mark".

The company said it was preparing its technical file for submission, expected by July 2026.

Memphasys fell 0.1 cents or 12.5 percent to 0.7 cents with 2.4 million shares traded.

ALCIDION

Alcidion says its annual meeting passed all resolutions but with up-to 37.5 percent opposition to its equity incentive plan and 27 percent against director re-elections.

Alcidion said the resolution to approve its equity incentive plan was opposed by 141,000,070 votes (37.50%), with 235,010,419 votes (62.50%) in favor.

The company said the re-election of Victoria Weekes was opposed by 138,420,645 votes (26.89%) with Daniel Sharp's re-election opposed by 137,256,857 votes (26.70%).

Alcidion said the remuneration report and re-election of William Smart were passed more easily with more than 96.96 percent in favor.

According to its most recent filing, Alcidion had 1,342,952,696 shares on offer, meaning that the votes against the equity incentive plan amounted to about 10.5 percent of the company, sufficient to requisition extraordinary general meetings.

Alcidion was unchanged at 5.8 cents with 4.5 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its annual general meeting passed all resolutions but with up to 22.95 percent against its increased placement capacity.
Medical Developments said the increased placement capacity had 7,034,295 votes (22.95%) in opposition, with 23,611,255 votes (77.05%) in favor.
The company said the remaining resolutions were all passed more easily with more than 96.8 percent support.
According to its most recent notice, Medical Developments had 112,658,324 shares on issue, meaning that the 7,034,295 votes against the placement capacity amounted to about 6.24 percent of the company, sufficient to requisition extraordinary general meetings.
Medical Developments was up two cents or 4.4 percent to 47 cents.

ANTEOTECH

Anteotech says its annual general meeting will vote to issue managing-director David Radford 5,400,000 performance rights and 10,800,000 options.
Anteotech said investors would vote to issue Mr Radford's performance rights as part of his short-term incentive plan, equal to about 25 percent of his $515,320 yearly pay and vesting on achievement of financial and non-financial performance milestones.
The company said Mr Radford's options were part of his long-term incentive remuneration, vesting in two equal tranches and exercisable at the higher of 4.8 cents or a 43 percent premium to the closing price on the grant date by the earlier of November 26, 2027 or six months after he ceased his role as a director.
Anteotech said the meeting would vote to adopt the remuneration report, re-elect chair Ewan Crouch and Dr Geoffrey Cumming as directors and approve its equity incentive plan as well as its 10 percent placement facility.
The meeting will be held at Rydge's South Bank, Rooftop South, Level 12, 9 Glenelg Street, Brisbane, on November 26, 2024 at 10am (AEST).
Anteotech was up 0.1 cents or 3.85 percent to 2.7 cents with two million shares traded.

AUDEARA

Audeara says its annual general meeting will vote to issue 4,250,000 options to managing-director Dr James Fielding, chair David Trimboli and director Bill Peng.
Audeara said shareholders would vote to issue Dr Fielding and executive director Hsin-Chieh (Bill) Peng 1,500,000 options, each, exercisable at eight cents each within two years, as well as 1,250,000 options to Mr Trimboli on the same terms.
The company said the options were in addition to Dr Fielding's $267,600 yearly pay, as well as Mr Trimboli's $50,000 annual fees and Mr Peng's $223,000 total remuneration.
Audeara said investors would vote to adopt the remuneration report, re-elect Mr Trimboli as a director, approve the 10 percent placement capacity, amend the constitution, ratify the prior issue of employee shares, increase its employee incentive plan and issue Mr Trimboli 543,586 shares in lieu of director's fees.
The meeting will be held at Grant Thornton, King George Central, Level 18, 145 Ann Street, Brisbane, on November 25, 2024 at 11am (AEST).
Audeara was untraded at 4.2 cents.

ORTHOCELL

Orthocell has requested a trading halt “pending an announcement by the company in relation to a proposed capital raising”.
Trading will resume on October 28, 2024, or on an earlier announcement.
Orthocell last traded at 69 cents.

NYRADA

Nyrada has requested a trading halt “pending an announcement by the company to the market regarding a proposed capital raising”.
Trading will resume on October 28, 2024, or on an earlier announcement.
Nyrada last traded at 14 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it “requires additional time to … secure funding to finalize its entitlement offer and secure a strategic distribution partnership”.
On Monday, Genetic Technologies requested a suspension following last week’s trading halt for its “operational review and progress on its fund raising” which it initially expected to announce on October 21, 2024 (BD: Jul 26, Oct 17, 21 2024).
Today, the company said that it expected trading to resume on November 4, 2024, or on an earlier announcement.
Genetic Technologies last traded at 3.9 cents.

CURVEBEAM A.I.

Karst Peak Capital Management LLC says its 21,857,867 shares substantial -holding in Curvebeam has been diluted from 6.83 percent to 5.82 percent due to capital raisings.
The Hong Kong and Cayman Island-based Karst Peak Capital said it was diluted by an institutional placement and rights offer on August 14, a retail rights offer on August 28 and a placement on October 16, 2024.
In August, Curvebeam said it had raised $7.9 million at 18 cents a share through a $2.0 million first tranche of its placement and $5.9 million one-for-six, institutional rights offer; and later, said it had raised $3.6 million in its retail rights offer with the $2 million second tranche of its placement to follow (BD: Aug 2, 14, 28, 2024).
Curvebeam fell half a cent or 3.6 percent to 13.5 cents.

QBIOTICS

Qbiotics says chief executive officer Stephen Doyle has been appointed managing-director, with executive chair Dr Sue Foden returning to non-executive.
Qbiotics said that founder Dr Victoria Gordon would continue as a n on-executive director.
The company said that Dr Foden had been an executive overseeing the company’s operations throughout the chief executive officer recruitment process as executive chair and would return to the role of non-executive chair.
Qbiotics said Dr Gordon would “be available to support Mr Doyle and the senior management team”.
Qbiotics is a public unlisted company.

DORSAVI

Dorsavi says interim chair Dr Michael Panaccio has resigned, effective from October 23, 2024, with non-executive director Gernot Abl appointed chair.

Dorsavi said Dr Panaccio joined its board in May 2008 and "provided significant leadership and guidance to the company".

The company said Mr Abl had experience as a public company director, a background in law, corporate finance and management consulting and more than 20 years of entrepreneurial, business strategy, and investment experience.

Dorsavi said it thanked "Dr Panaccio for his tenure on the board and wishes him all the best in his future endeavors".

Dorsavi was untraded 1.1 cents.

ARGENICA THERAPEUTICS

Argenica says non-executive director Elizabeth (Liddy) McCall will retire at its annual general meeting, to be held on November 12, 2024.

Argenica said Ms McCall had been a member of the board since 2020 and had "made a significant contribution to the company during her tenure, supporting its listing on the ASX in June 2021".

Argenica was unchanged at 73 cents.

ALCIDION GROUP

In an address to the annual general meeting and an Appendix 3Z, Alcidion says non-executive director Simon Chamberlain has resigned, effective from yesterday.