Biotech Daily

Thursday November 2, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 12.5%; KAZIA DOWN 10%**

*** KAZIA: 'ADVERSE EVENTS HALVES PAXALISIB LYMPHOMA DOSE'**

*** HAVAH 3-ARM, 300-PATIENT DUCTAL BREAST CANCER STUDY**

*** CYNATA OPENS 1st US CYP-001 GvHD PHASE II TRIAL SITE**

*** CHIMERIC DOSES 1st PHASE Ib CHM1101 GLIOBLASTOMA PATIENT**

*** IMUGENE STARTS NEXT PHASE I VAXINIA COHORTS**

*** TELIX COMPLETES $20m LIGHTPOINT ACQUISITION**

*** RESPIRI TELLS 2nd ASX 4C QUERY 'BREAKEVEN IN LATE 2024'**

*** ALLEGRA ORTHOPAEDICS BECOMES 'ALLEGRA MEDICAL TECHNOLOGIES'**

*** ISLAND WINS AUSTRALIA ISLA-101 FLAVIVIRUS PATENT**

*** ATOMO AGM 67% DEFEATS REMUNERATION REPORT; M-D OPTIONS 66%**

*** LANG WALKER TAKES 37% OF NEXT SCIENCE**

*** PERENNIAL TAKES 14% OF MICROBA**

*** MACROGEN DILUTED BELOW 5% OF MICROBA**

MARKET REPORT

The Australian stock market was up 0.9 percent on Thursday November 2, 2023, with the ASX200 up 61.4 points to 6,899.7 points. Twenty of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and one was untraded. All three Big Caps were up.

Patrys was the best, up 0.1 cents or 12.5 percent to 0.9 cents, with 4.0 million shares traded. Impedimed climbed 9.5 percent; Cyclopharm and Dimerix were up more than eight percent; Avita and Compumedics rose more than six percent; Next Science and Polynovo increased by more than four percent; Antisense, Neuren, Paradigm, Prescient and Resmed were up more than three percent; Imugene, Nova Eye and Orthocell rose more than two percent; Clinuvel, CSL, Pro Medicus and Telix were up more than one percent; with Cochlear, Medical Developments and Nanosonics up by less than one percent.

Kazia led the falls, down 0.6 cents or 9.8 percent to 5.5 cents, with 1.7 million shares traded. Micro-X lost 7.1 percent; Emvision and Proteomics shed more than six percent; 4D Medical and Actinogen were down more than five percent; Atomo, Cynata and Immutep fell four percent or more; Opthea and Pharmaxis were down more than three percent; Mesoblast shed 2.7 percent; with Amplia and Volpara down by more than one percent.

KAZIA THERAPEUTICS

Kazia says that “treatment related adverse events” has led to halving the dose of paxalisib for relapsed or refractory primary central nervous system lymphoma.
Kazia said that results from the first 14 patients in its phase II lymphoma trial showed “early clinical activity” in some patients, but “several heavily pre-treated … patients experienced treatment-related adverse events consistent with those previously reported with paxalisib, that resulted in dose reductions and, in some cases, early termination”.
The company said the protocol was being “optimized by the investigator to initiate starting doses at 15 milligrams a day or 30 milligrams once a day with the goal of improving the durability of clinical benefit and overall tolerability”.
Kazia said that in the study of up-to 25 patients with relapsed or refractory primary central nervous system lymphoma were administered paxalisib as a monotherapy for up-to 24 months, at an initial dosing regimen of 60 milligrams daily.
The company said early results included clinical activity “preliminarily observed in enrolled patients, including partial responses and stable disease”.
Kazia said the study’s objectives were to assess the clinical efficacy and safety of paxalisib with primary central nervous system lymphoma based on objective response rate, duration of response, progression-free survival and overall survival.
Kazia chief executive officer Dr John Friend said the company was “encouraged by the clinical activity preliminarily observed to date and agree with the lead investigator to reduce the dose with the goal of improving tolerability and durability of response”.
Kazia fell 0.6 cents or 9.8 percent to 5.5 cents with 1.7 million shares traded.

HAVAH THERAPEUTICS

Havah says a three-arm, up-to 300 patient, phase II platform trial will use its testosterone and anastrozole (T+Ai) combination for the treatment of breast cancer.
Havah said each arm of the trial would use one of three therapies and enroll up-to 110 patients each, with the primary endpoint of stopping surgical intervention in patients with pre-malignant breast cancer.
The Adelaide-based company said the trial would test if its T+Ai hormone therapy could reduce the breast cancer lesions in the pre-malignant ductal carcinoma in-situ, and prevent the progression of the cancer.
Havah said the trial included three collaborating companies with different agents as well as a standard-of-care arm and some observational participants.
Havah said the study was led by the San Francisco, California-based Quantum Leap Healthcare Collaborative with lead investigator the Collaborative’s founder Dr Laura Esserman at the University of California, San Francisco.
The Quantum Leap Healthcare Collaborative said the study included three investigational endocrine therapy arms: the Seattle, Washington-based Atossa Therapeutics Inc’s endoxifen, New York’s Stemline Therapeutics’ Orserdu, and Havah’s T+Ai combination of testosterone and anastrozole targeting the androgen and oestrogen receptor pathways.
Dr Esserman said ductal carcinoma in-situ indicated “the very earliest, non-invasive stage of the disease, that’s why it is important for us to seek out alternative therapies for [ductal carcinoma in-situ] patients and find ways to reduce toxicity and unnecessary surgeries”.
The Collaborative said surgery was the current standard treatment for ductal carcinoma in-situ even though many patients never progress to breast cancer, meaning patients are often over-treated with invasive procedures.
Havah is a private company.

CYNATA THERAPEUTICS

Cynata says it has opened its first US trial site for its up-to 60-patient, randomized, phase II, clinical trial of CYP-001 for high-risk acute graft-versus-host disease.

In August, Cynata said it had opened recruitment for the randomized trial of CYP-001 mesenchymal stem cells at Sydney's Westmead Hospital (BD: Aug 10, 2023).

Today, the company said it had completed a site initiation visit of its first US site at New York's Weill Cornell Medical Centre.

Cynata said CYP-001 was its off-the-shelf, induced pluripotent stem cell-derived mesenchymal stem cell product for intravenous infusion, and that it had "very encouraging safety and efficacy results" from a phase I clinical trial.

Cynata chief medical officer Dr Jolanta Airey said that "in addition to the opening of the initial clinical centres announced so far, we expect to open several more centres in Australia and the US by the end of … [2023]".

"In 2024, we plan to open further centres across Europe, Australia and the US," Dr Airey said.

"Our goals are to complete patient recruitment by the end of 2024, with primary results expected in the second half of 2025," Dr Airey said.

Cynata fell 0.5 cents or four percent to 12.0 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first of up-to 32-patients in its phase Ib trial of CHM1101 chlorotoxin chimeric-antigen-receptor T-cell (CLTX-Car-T) for glioblastoma.

In August, Chimeric said it had completed its phase Ia clinical trial of CHM1101 for glioblastoma, with the final dose-escalation cohort receiving 440 million CHM1101 cells through both intra-tumoral and intra-ventricular administration (BD: Aug 29, 2023).

At that time, the company said the first part of the phase Ib trial would enroll between three-to-six participants at the highest phase Ia dose, and based on a favorable review of results in late 2023, it would begin the second part of the phase Ib trial, in which it would enroll a further 12-to-26 patients for a dose expansion cohort.

Today, Chimeric said the first patient receiving CHM1101 as a second-line therapy in the phase Ib trial was dosed at the Texas-based St David's South Austin Medical Centre.

Chimeric said the trial was conducted under a US Food and Drug Administration investigational new drug application.

The company said on successful completion of the dose expansion cohort, it would design and initiate a registration trial, in collaboration with regulatory feedback.

Chimeric chief executive officer Jennifer Chow said the company was "thrilled to have reached this key milestone for Chimeric and the advancement of the CHM 1101 clinical development program".

"We are looking forward to building off our recently released positive phase Ia clinical data and advancing the clinical development of this unique and potentially transformative cell therapy for patients with this devastating disease," Ms Chow said.

"We believe that the full potential of CHM 101 for patients with recurrent and, or progressive glioblastoma will only be unlocked through the advancement of our clinical development program and look forward to continuing to advance this trial forward," Ms Chow said.

Chimeric was unchanged at 2.9 cents, with eight million shares traded.

IMUGENE

Imugene says it has opened cohort five of the monotherapy arm and cohort three of the combination arm of its phase I trial of Vaxinia for metastatic advanced solid tumors.
Earlier this year, Imugene said it had dosed the first Vaxinia and pembrolizumab combination patients in the study of CF33-hNIS, or Vaxinia, for metastatic advanced solid tumors (Mast) (BD: Mar 3, 2023).
Today, Imugene said it had cleared cohort four of the intravenous monotherapy dose escalation study as well as cohort two of the intravenous combination study of Vaxinia with pembrolizumab, or Keytruda, and would increase the dose about three-fold.
The company said the study aimed to recruit up-to 100 patients at 10 trial sites in the US and Australia, it began in May 2022, and was expected to run for about 24 months with funding from existing budgets and resources.
Imugene chief executive officer Leslie Chong said the company was “closer to opening and completing the final cohorts that were planned at the beginning of the trial, we have an opportunity to expand the trial by enrolling patients in additional cohorts for the monotherapy dose escalation component”.
“This will provide us with a far more robust data set to analyze and speak to at the conclusion of the [metastatic advanced solid tumor] study, and provide us with a stronger platform as we further the clinical development of CF33 and VAXINIA,” Ms Chong said.
Imugene was up 0.1 cents or 2.4 percent to 4.3 cents with 22.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has completed the acquisition of Lightpoint Medical for $US19.6 million ($A30.4 million) in equity and the remaining $US400,000 ($A621,638) in cash.
In June, Telix said it would buy the Chesham, UK-based Lightpoint and its Sensei radio-guided surgery devices for the intra-operative detection of cancer for up-to $US45 million ($A51.6 million) in a combination of scrip or cash (BD: Jun 22, 2023).
Today, the company said a further $US15 million was payable through an earn-out in the form of performance rights, pending the achievement of certain milestones.
Telix said its initial commercial objective with the acquisition was to align Lightpoint Medical’s Sensei product with its Illuccix TLX599-CDx1 programs for prostate cancer.
Telix was up 12 cents or 1.3 percent to $9.10 with 582,300 shares traded.

ISLAND PHARMACEUTICALS

Island says Intellectual Property Australia has issued a patent relating to its ISLA-101 for the treatment of flavivirus infections, such as dengue fever.
Island said the patent, titled ‘Method of Viral Inhibition’ would protect the method of treating or preventing flavivirus infections by administering ISLA-101 until April 16, 2034.
The company said it had licenced the intellectual property portfolio for ISLA-101, developed by Monash University, which was protected in the US, Canada, Brazil, and Singapore.
Island chief executive officer Dr David Foster said the patent added “to the growing intellectual property thicket that is being established around ISLA-101”.
“This Australian patent, together with the equivalent patents granted in other key markets, underpin the investment we are making in bringing forward ISLA-101 as a potential new approach to combatting the world’s growing problem with dengue fever and other mosquito-borne viral diseases,” Dr Foster said.
Island was up 0.1 cents or 1.4 percent to 7.1 cents.

RESPIRI

Respiri has told a second ASX Appendix 4C Quarterly Report query that it expects to have "operating financial breakeven in late calendar year 2024".

The ASX asked Respiri whether it expected to "reach operating financial breakeven in late calendar year 2024" and if so, "to provide the basis for this view and explain why positive monthly cash flows are forecasted to be achieved approximately a year later".

Respiri told the ASX that "current US operations cashflow forecast supports operating financial breakeven in late calendar year 2024".

Last week, Respiri filed its Appendix 4C Quarterly Report saying that it had receipts from customers of $19,000 for the three months to September 30, 2023, a cash burn of $1,884,000 for the three months and cash and cash equivalents of $563,000 at September 30, with zero quarters of cash available.

The company said that it expected revenue from its US Wheezo remote patient monitoring program, along with a $545,000 Federal Research and Development Tax Incentive and would "seek to raise new capital".

In May, Respiri told an ASX Appendix 4C Quarterly Report query that it was "planning an equity raise that is expected to fund the company's operations for the next 12 months as it grows its US revenue base through … [remote patient monitoring]" (BD: May 10, 2023).

Later in May, Respiri said it would raise $4.5 million in convertible notes to buy distributor Access Managed Services LLC and raise a further $2 million in a share plan at 3.4 cents a share (BD: May 24, 2023).

In August, the company said its share plan raised $3 million (BD: Aug 8, 2023).

Today, the ASX asked when Respiri expected to generate "in excess of $US1.1 million in annualized revenues" from the new customers described in its Quarterly Cash Flow Report.

Respiri said it expected to receive the $US1.1 million in revenue by June 2024, it would need to raise $1.3 million this year and $2.5 million in the next 12 months.

"The company is presently in discussions with a number of potential investors and is confident that it will be able to meet its capital requirements," the company said.

"However as at today's date, these discussions are incomplete and the company is not in a position to provide further details," Respiri said.

Respiri said it had $160,000 cash on hand, including $100,000 from director loans.

The ASX asked the amount and due date of the second tranche payment for the Access Telehealth acquisition.

Respiri said the Access business "continues to meet or exceed commercial and business development expectations determined as part of the original due diligence process … however, certain agreed technical warranty milestones under the sale and purchase agreement have not been met at this point in time and the board does not believe that any payable in relation to the second tranche to Access Telehealth is required at this time".

Respiri fell half a cent or 16.7 percent to 2.5 cents, with 1.5 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES (FORMERLY ALLEGRA ORTHOPAEDICS)

Allegra says following shareholder approval it has changed its name from Allegra Orthopaedics to Allegra Medical Technologies, effective from yesterday.

Last month, Allegra said its annual general meeting would vote to change its name to Allegra Medical Technologies, a special resolution requiring 75 percent votes, as it "more accurately reflects [its] proposed future operations" (BD: Sep 29, 2023).

Today, the company said it would continue to trade under the ASX code 'AMT'.

Allegra was untraded at four cents.

ATOMO DIAGNOSTICS

Atomo says investors defeated the remuneration report by 67.4 percent and the issue of options to managing-director John Kelly by 66.3 percent.
In its notice of annual general meeting, Atomo said shareholders would vote to issue 366,666 options to Mr Kelly, exercisable at 46.8 cents each by August 22, 2026.
Today, the company said the resolution to adopt the remuneration report was lost, with 83,353,596 votes (67.37%) against and 40,378,138 votes (32.63%) in favor.
Atomo said the resolution to issue options to Mr Kelly was defeated with 82,041,184 votes (66.30%) in opposition and 41,704,924 votes (33.70%) in favor.
Atomo said the remaining five resolutions all passed, but that the approval of an additional 10 percent placement capacity was opposed by 44.15 percent of the meeting, the employee option plan faced 40.39 percent opposition and the re-election of director Dr Cheri Walker had 30.47 percent opposed.
The company said the resolutions to ratify the issue of placement shares and options both faced less than 0.55 percent dissent.
Atomo fell 0.1 cents or 4.55 percent to 2.1 cents with 1.1 million shares traded.

NEXT SCIENCE

Langley Alexander Walker says he has increased his substantial shareholding in Next Science from 83,622,188 shares (31.46%) to 108,296,030 shares (37.17%).
The Sydney-based Mr Walker as director of Walker Group Holdings and the Auckland Trust Company said he bought 24,673,842 shares on November 1, 2023 for $10,363,014, or 42.0 cents a share.
Next Science was up one cent or 4.3 percent to 24.5 cents.

MICROBA LIFE SCIENCES

Perennial Value Management Ltd says it has increased its substantial shareholding in Microba from 40,232,627 shares (11.73%) to 55,075,162 shares (13.73%).
The Sydney-based Perennial said it bought and sold shares between December 2, 2022 and October 31, 2023 in more than 127 transactions with the largest purchase 4,446,157 shares on February 3 for $1,525,476, or 34.3 cents a share.
Microba was up half a cent or 2.2 percent to 23 cents.

MICROBA LIFE SCIENCES

Macrogen Inc says it has been diluted below the five percent substantial threshold in Microba due to an entitlement offer and various employee option exercises.
Last week, Microba said it raised about $12.3 million in the institutional component of its $20 million fully underwritten rights offer at 23 cents (BD: Oct 23, 2023).
Last year, the Seoul, South Korea-based Macrogen said it held 17,828,431 Microba shares, or 5.20 percent (BD: Dec 5, 2022).