Biotech Daily

Thursday March 14, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: CYNATA UP 13%; MICRO-X DOWN 11%**

*** WEHI, PETER MACCALLUM KILL LEUKAEMIA CELLS, IN-VITRO, MICE**

*** FLINDERS UNI DEVELOPS PORTABLE KIDNEY DISEASE TEST**

*** MESOBLAST $37m RIGHTS TAKES TOTAL TO $97m**

*** PYC RIGHTS TO RAISE $74.6m**

*** PAINCHEK PLACEMENT RAISES $2.5m; TOTAL $5m**

*** PAINCHEK, NOURISH CARE UK PAIN APPLICATION RESELLER**

*** CHIMERIC EXPECTS 3 CANCER TRIALS RESULTS THIS YEAR**

*** AVECHO: TGA OKAYS PHASE III TPM-MARIJUANA INSOMNIA TRIAL**

*** PHARMAUST ADDS DATA TO MONEPANTEL FDA ORPHAN DRUG APPLICATION**

*** CLINUVEL 1.5m SHARE BUY-BACK**

*** PETER MEURS, SKIPTAN INCREASE, DILUTED TO 15% OF DIMERIX**

*** AUSBIOTECH APPOINTS DELL KINGSFORD SMITH BOARD OBSERVER**

*** PACIFIC EDGE TO LOSE CHAIR CHRIS GALLAHER, DIRECTOR MARK GREEN**

*** MEMPHASYS APPOINTS MICHAEL ATKINS DIRECTOR**

*** RACE APPOINTS PROF ERIN HOWDEN TO SCIENTIFIC ADVISORY BOARD**

*** CORRECTION: BIO-MELBOURNE NETWORK**

MARKET REPORT

The Australian stock market fell 0.2 percent on Thursday March 14, 2024, with the ASX200 down 15.8 points to 7,713.6 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and two were untraded.

Cynata was the best, up two cents or 12.9 percent to 17.5 cents, with 181,295 shares traded. Clinuvel climbed 10.7 percent; Universal Biosensors was up 6.9 percent; Amplia, Curvebeam, Impedimed and Nova Eye were up five percent or more; Imugene improved 4.35 percent; Telix was up three percent; Cochlear, Compumedics, CSL, Immutep, Next Science, Opthea and Prescient rose one percent or more; with Avita, Emvision, Genetic Signatures and Volpara were up by less than one percent.

Micro-X led the falls, down 1.5 cents or 11.1 percent to 12 cents, with 611,751 shares traded. Paradigm lost 9.9 percent; Polynovo was down 6.8 percent; Dimerix shed 5.8 percent; 4D Medical, Neuren and Resonance fell more than four percent; Actinogen, Atomo and Starpharma were down more than three percent; Clarity and Pharmaxis shed more than two percent; Mesoblast and Nanosonics were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH
PETER MACCALLUM CANCER CENTRE

The Walter and Eliza Hall Institute says it has identified two proteins critical for B-cell acute lymphoblastic leukaemia development.

The Institute said researchers were able to "kill leukaemia cells … and stop cancer cells from growing" by studying the regulatory protein erythroblast transformation-specific related gene (ERG) and the cellular myelocytomatosis gene (c-MYC), in mice and in-vitro.

WEHI said researchers then focused on the creation of ribosomes which were essential for making proteins, and targeted the enzyme DNA polymerase I.

The Institute said "one of the drugs used in the study to target [polymerase I] was an agent developed by the Peter MacCallum Cancer Centre" which killed cancerous cells and halted their development in laboratory models of B-cell acute lymphoblastic leukaemia.

WEHI said the research titled 'ERG and c-MYC regulate a critical gene network in BCR::ABL1-driven B-cell acute lymphoblastic leukaemia' was published in Science Advances and available at: https://www.science.org/doi/10.1126/sciadv.adj8803.

WEHI researcher Dr Kira Behrens said the study "looked at the proteins that control how specific genes switch 'on' or 'off' to analyze how normal B-cells [and B-cell acute lymphoblastic leukaemia] can develop".

"We discovered that these proteins were actually the master regulators of several important pathways and processes within the leukaemia cell," Dr Behrens said.

"By targeting [polymerase I] with inhibitors, we were able to kill leukaemia cells and stop their growth in our pre-clinical and human tissue models," Dr Behrens said. "This was a surprising, yet remarkable discovery, as we were able to unravel a new pathway and potential drug target that can hopefully be used in the fight against leukemia in the future."

FLINDERS UNIVERSITY

Flinders University says a study of 57 human urine samples for kidney disease shows that its portable colorimetric paper test can provide "quantitative urinalysis".

Flinders University said the device could be used for "more regular monitoring of … disease progression and for screening high-risk populations for early interventions".

The University said the device readings were comparable to values provided by South Australia Pathology and it had filed for an Australian patent.

The University said the study, titled 'Point-of-care image-based quantitative urinalysis with commercial reagent strips: Design and clinical evaluation' was available at https://www.sciencedirect.com/science/article/pii/S1046202324000483?via%3Dihub.

Flinders University researcher Prof Youhong Tang said the device had been "designed as an open platform so it has the capability to be used not just for urinalysis, but for different types of tests using colorimetric test strips and for test strips from any manufacturer".

The study's co-author Dr Damian Tohl said "the readings from the new device showed a strong correlation with the clinical values and an improvement on the traditional method of reading the commercially available paper test strips".

"We have developed a portable colorimetric paper test strip reader that uses a camera and image processing software to automatically obtain a reading," Dr Tohl said.

"Paper-based colorimetric tests are popular because they are inexpensive and quick and easy to perform, however, reading the result requires comparison of the test strip with reference color blocks and may be affected by variations in ambient light and color perception between users," Dr Tohl said. "Our device includes a calibration process so that results are invariant to variations in ambient light to produce quantitative measurements with improved accuracy."

MESOBLAST

Mesoblast says it has “firm commitments” for $36.7 million to complete its non-renounceable rights offer at 30 cents a share, taking the total raised to $97 million.
Last year, Mesoblast said it hoped to raise up-to $36 million in an institutional placement and $61 million in a one-for-four retail and institutional entitlement offer, at 30 cents a share (BD: Dec 4, 2023).
Later, the company said it raised $36 million in an “over-subscribed” placement, $19 million in the institutional rights offer and $5.3 million in its retail rights offer, taking the total to $60.3 million of a hoped-for $90 million (BD: Dec 5, 2023; Jan 21, 2024).
Today, Mesoblast said the $36.7 million commitments were “primarily from Mesoblast’s existing major shareholders” and that its chief medical officer Dr Eric Rose had subscribed for an additional $1.5 million, subject to shareholder approval.
Mesoblast fell half a cent or 1.3 percent to 37 cents with 9.1 million shares traded.

PYC THERAPEUTICS

PYC says it hopes to raise $74.6 million in a one-for-four, non-underwritten, pro-rata, accelerated, non-renounceable entitlement offer at eight cents a share.
PYC said the offer price was a 5.9 percent discount to the last traded price, or a 1.1 percent discount to the five-day volume weighted average price of shares up-to and including March 13, 2024.
The company said the entitlement offer would comprise an institutional and retail component, and that if it did not raise the intended amount, it would “need to re-evaluate its fundraising options and, or its projected budget and timeline”.
PYC said the funds would be used to support human trials of its two blinding eye disease drug candidates as well as its polycystic kidney disease drug candidate, its Phelan-McDermid Syndrome drug program and general working capital.
The company said existing major shareholder Australian Land Pty Ltd, which held 32.95 percent of its shares, intended to take its full entitlement of about $24.6 million.
PYC said the institutional offer opened today and would close tomorrow, with the retail offer for shareholders on the record date of March 18, to open on March 20 and close on April 8, 2024.
Separately, PYC requested a trading halt regarding the proposed capital raising.
Trading will resume March 18, 2024, or on an earlier announcement.
PYC last traded at 8.5 cents.

PAINCHEK

Painchek says it has raised $2.5 million through a placement 2.51 cents a share, taking the total raised with its recent $2.5 million share plan to $5.0 million.
In February, Painchek said it would raise $2.5 million in a fully-underwritten share purchase plan and intended to raise a further $2.5 million in a placement following the share plan (BD: Feb 14, 2024).
Today, the company said it would use the funds for US Food and Drug Administration regulatory clearance, market entry and commercialization for its pain-assessment facial recognition application for adults and commercializing its application for infants.
Painchek said Canaccord Genuity was the lead manager to the placement.
Painchek was unchanged at 2.9 cents with 6.2 million shares traded.

PAINCHEK

Painchek says the Bournemouth, England-based Nourish Care will sell its pain assessment software in the UK for an initial term of one-year.

Painchek said the pain assessment software would be available on Nourish Care's platform which currently supported more than 320,000 people, including in residential, disability and home care.

The company said pain score assessments made by its software were sent to Nourish Care "instantly upon completion at the point of care".

Painchek said it was "unable to provide an estimate for the revenue to be derived from this agreement" but that sales would be included in its future financial reports.

Painchek chief executive officer Phillip Daffas said that "since 2022, the best-in-class integration between Painchek and Nourish Care has facilitated best-practice pain management and quality, technology-driven care".

"This latest agreement strengthens our existing partnership and is set to rapidly accelerate Painchek's sales in the UK by leveraging [Nourish Care's] current client base across home care, disability and the 500,000 aged care bed market," Mr Daffas said.

CHIMERIC THERAPEUTICS

Chimeric says it expects to have preliminary data from three trials of its chimeric antigen receptor T-cell (CAR-T) and natural killer cell therapies for cancers this year.

Chimeric said it hoped to receive US Food and Drug Administration Approval for a dose expansion cohort of its 11-patient, phase Ib trial of CHM1101 for recurrent or progressive glioblastoma, with preliminary data expected by the end of the year.

Last year, the company said it had 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 (BD: Nov 2, 2023).

Today, Chimeric said it would begin its phase Ia dose escalation trial of CHM2101 for colorectal and gastric cancer and neuro-endocrine tumors and provide clinical updates on patients treated at the initial dose level.

Last year, the company said the US Food and Drug Administration approved its investigational new drug application for a phase Ia trial of CHM2101 for gastro-intestinal cancers (BD: Oct 31, 2023).

Today, Chimeric said it expected its 12-patient, phase Ib trial of CHM0201 in combination with interleukin-2 and Vactosertib for acute myeloid leukemia to "be resumed shortly and anticipates completion of the clinical trial in 2024".

Last month, the company said it had paused the phase Ib trial due to "a lack of staff" and expected to complete it this year (BD: Feb 8, 2024).

Chimeric chief executive officer Jennifer Chow said that "in 2023, Chimeric made incredible progress advancing our mission to bring the promise of cell therapy to more patients, setting up the foundation for us to achieve multiple key clinical catalysts in 2024".

"With positive phase Ia data for CHM1101, FDA clearance for CHM2101 and the initiation of the … phase 1b clinical trial, we are truly excited about delivering on key clinical catalysts in 2024," Ms Chow said.

"We are proud to have now treated over 30 patients across all of our clinical programs and remain focused on further advancing our clinical programs to create value realization for patients and shareholders in 2024," Ms Chow said.

Chimeric fell 0.1 cents or 3.45 percent to 2.8 cents.

AVECHO BIOTECHNOLOGY

Avecho says the Australian Therapeutic Goods Administration has approved its 519-patient, phase III TPM-marijuana-for-insomnia trial, with no changes to the study design.
Avecho said it met the TGA to present its final phase III tocopheryl phosphate mixture (TPM)-cannabidiol (CBD) soft-gel capsule for insomnia trial design and submission strategy and received a “non-binding … positive response”
The company said the response gave it confidence the trial, “if successful, may support an Australian regulatory approval” and it expected recruitment to begin this month.
In 2022, the company said the randomized, placebo-controlled, phase III trial would study 75mg and 150mg daily doses of its cannabidiol-tocopheryl phosphate mixture (TPM) versus placebo, in three treatment groups (BD: Dec 22, 2022).
Avecho was up 0.1 cents or 25 percent to 0.5 cents with 46.4 million shares traded.

PHARMAUST

Pharmaust says it has filed further data on monepantel for motor neuron disease to the US Food and Drug Administration for its orphan drug application.
Last year, Pharmaust said it had completed its 12-patient, phase I trial of monepantel for motor neuron disease and had applied for FDA orphan drug status (BD: Dec 1, 2023).
In January, the company said the FDA requested further data for its application “due to the absence of pre-clinical or clinical data to establish the potential for the drug to be effective” (BD: Jan 29, 2024).
Today, the company said the data was in a formal amendment to the original application, with the timeline for the FDA granting the designation of up-to 90 days.
Pharmaust fell 1.5 cents or four percent to 36 cents with 3.8 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will begin a 12-month, on-market buy-back of up-to 1,500,000 shares.
Clinuvel said the “the recent decline of market valuation is no longer commensurate with the performance and expected outlook for the company”.
The company said the repurchase would “be executed conditional on the prevailing share price, market performance, and the company’s capital position”.
Clinuvel said it had seven consecutive years of profitability, a compound annual increase in revenues of 26 percent and net profit after tax of 18 percent for the five years to June 30, 2023, as well as a market path for Scenesse for vitiligo, and a “diversified pipeline”.
According to its most recent filing Clinuvel had 49,410,338 shares on issue, making the buyback equivalent to 3.0 percent of its share capital (BD: Feb 29, 2024).
Clinuvel was up $1.41 or 10.7 percent to $14.61 with 450,905 shares traded.

DIMERIX

Peter Meurs and Skiptan Pty Ltd say they have increased their holding in Dimerix and been diluted from 64,929,440 shares (16.74%) to 69,375,992 shares (15.09%).
The Melbourne-based Mr Meurs and Skiptan said that on March 12, 2024 they exercised 4,446,552 unlisted options for $560,266, or 12.6 cents each.
On Tuesday, Dimerix said it had “commitments” for a $20 million placement at 30 cents a share to complete its phase III trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS) (BD: Mar 12, 2024).
Dimerix fell two cents or 5.8 percent to 32.5 cents with 8.75 million shares traded.

AUSBIOTECH

Ausbiotech says it has appointed Cochlear's Dell Kingsford Smith as a board observer.
Ausbiotech said Ms Smith was Cochlear's head of Asia Pacific medical affairs market access and government affairs and had worked for Johnson & Johnson and Janssen.
According to her Linkedin profile, Ms Kingsford Smith held a Master of Commerce and a Master of Dental Surgery from the University of Sydney.

PACIFIC EDGE

Pacific Edge says chair Chris Gallaher will retire at the end of the year, with director Mark Green to not seek re-election at its September annual general meeting.
Pacific Edge said Mr Gallaher had worked for Pacific Edge since July 2016 and had "resolved to reduce his governance commitments" and retire following the appointment of a successor and a structured handover at the end of 2024.
The company said Mr Green had been a director since May 2021 and intended not to seek re-election following his family "having made new commitments offshore".
Pacific Edge was unchanged at 8.7 cents.

MEMPHASYS

Memphasys says it has appointed Michael Atkins as a non-executive director, effective immediately.
Memphasys said Mr Atkins was chair of Castle Minerals and a director of SRG Global and had been an advisor to Canaccord Genuity and a director at Paterson Securities, and held a Bachelor of Commerce from the University of Western Australia.
Memphasys was unchanged at 1.1 cents with 1.2 million shares traded.

RACE ONCOLOGY

Race says it has appointed the Melbourne-based Baker Heart and Diabetes Institute's Prof Erin Howden to its scientific advisory board.
Race said it Prof Howden had published more than 100 scientific papers, including on the adverse effects of chemotherapy on cardio-vascular fitness of cancer patients, and was an honorary research fellow at the University of Melbourne and Monash University.
According to her Linkedin profile, Prof Howden holds a Bachelor of Health Science from the University of Tasmania and a Doctor of Philosophy from the University of Queensland.
Race was up 2.5 cents or 1.9 percent to $1.325.

CORRECTION: BIO-MELBOURNE NETWORK

Tuesday's edition gave the old details for the rescheduled Bio-Melbourne Network seminar on innovations in cardiovascular health.
Bio-Melbourne Network said it had postponed said the medical technology seminar from February 13 to April 16, 2024.
The date was correct but the time has been changed to 7.45am to 10.30am (AEST), and the venue will be the Science Gallery Melbourne Theatre, 114 Grattan Street, Carlton.
For details and registration go to: https://bit.ly/3NA1I9S.