Biotech Daily

Wednesday July 10, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 10%; PRESCIENT DOWN 9%**

*** VICTORIA $5m FOR RESEARCH; MONASH UNI MANUFACTURING CENTRE**

*** IDT RIGHTS RAISE $7m**

*** PACIFIC EDGE Q1 CXBLADDER TEST VOLUMES DOWN**

*** BLUECHIIP: MORE ORDERS FROM UNNAMED CLIENT**

*** NEUROTECH 'NTI164 FURTHER BENEFITS FOR AUTISM AT 12-WEEKS'**

*** TRYPTAMINE COMPLETES PHASE IIa PSILOCYBIN FIBRO-MYALGIA TRIAL**

*** RADIOPHARM DOSES 1st RAD204 LUNG CANCER PATIENT**

*** IMUGENE DOSES 1st BILE TRACT CANCER EXPANDED COHORT PATIENT**

*** PYC STARTS VP-001 RP11 MULTIPLE DOSE TRIAL**

*** TRIVARX COMPLETES PHASE II MEB-001 DEPRESSION SLEEP STUDY**

*** OPTHEA REVIEW SUPPORTS OPT-302 FOR AMD**

*** FISHER & PAYKEL $1.1m M-D LEWIS GRADON RIGHTS, OPTIONS AGM**

*** ORTHOCELL REQUESTS 'STRIATE APPROVAL' TRADING HALT**

*** SANDON CAPITAL TAKES 18% OF IDT**

*** BIO-MELBOURNE EXTENDS LEADERSHIP WORKSHOP ENTRY DEADLINE**

MARKET REPORT

The Australian stock market was down 0.16 percent on Wednesday July 10, 2024, with the ASX200 down 12.9 points to 7,816.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 were down, eight traded unchanged and two were untraded.

Dimerix was the best, up 4.5 cents or 10.2 percent to 48.5 cents, with 5.9 million shares traded. Curvebeam and Proteomics climbed more than nine percent; Imugene rose 5.9 percent; Cynata was up four percent; Micro-X increased 3.9 percent; 4D Medical, Alcidion and Emvision rose two percent or more; with Clinuvel, Cochlear, Genetic Signatures, Impedimed, Medical Developments and Starpharma up by one percent or more.

Prescient led the falls, down 0.4 cents or 9.1 percent to four cents, with 377,807 shares traded. Resonance lost 5.3 percent; Actinogen fell 4.1 percent; Nova Eye, Immutep, Percheron and SDI were down more than three percent; Avita and Telix shed more than two percent; Clarity, Neuren and Paradigm were down more than one percent; with CSL, Cyclopharm, Nanosonics, Polynovo, Pro Medicus and Resmed down by less than one percent.

VICTORIA GOVERNMENT, MONASH UNIVERSITY

The Victoria Government says it has expanded the Medicines Manufacturing Innovation Centre at Monash University and granted $5 million to 10 research projects.

A media release from the Deputy Premier and Minister for Medical Research Ben Carroll said the expanded centre was opened today following an investment more than $16 million from the Government into the Monash Technology Precinct.

The Government said the Centre helped Victorian medicines manufacturers invest in research and development, develop new products and skills.

The Victoria Government said the Centre's added facility would help industry solve technical challenges, develop product formulations "and encourage investment in life-saving therapies".

The media release said the Centre was one of 10 recipients in the latest round of the Cumming Global Centre for Pandemic Therapeutics Foundation grants, which had awarded $5 million to 10 local research projects.

In 2022, the Victoria Government said that with Karori Capital chair Geoffrey Cumming it would provide $325 million for a pandemic preparedness and therapeutics centre based at the Peter Doherty Institute (BD: Aug 31, 2022).

Last year, the Doherty Institute said the second round of Cumming Global Centre Foundation Grants had opened, offering about $5 million for pandemic therapeutic projects (BD: Oct 25, 2023).

Today, the Government said grants were awarded to the Walter and Eliza Hall Institute in Parkville and the Commonwealth Scientific and Industrial Research Organisation's Australian Centre for Disease Preparedness in Geelong.

The Victoria Government said Monash University's Medicines Manufacturing Innovation Centre would use the funds to develop a therapeutic agent to treat respiratory viruses and prevent lung infections.

The Government said the grants would support researchers world-wide to uncover technologies and fast-track the development of treatments for viruses and infectious diseases that could cause future pandemics, with a full list of recipients available at: https://www.doherty.edu.au/cumming-global-centre-for-pandemic-therapeutics.

Mr Carroll said Victoria's medical researchers were "leading the way to fast-track new treatments and drive innovation, resulting in the well-deserved recognition by the Cumming Centre for Global Pandemic Therapeutics".

IDT AUSTRALIA

IDT says it has raised about $7 million at nine cents a share in its fully-underwritten, one-for-4.5 entitlement offer.

Last month, IDT said it hoped to raise about $7 million at 9.0 cents a share, or a 7.8 percent discount to the 30-day volume weighted average price, in a one-for-4.5, fully-underwritten rights offer (BD: Jun 4, 2024).

Today, the company said that it had received applications from investors to raise about $4,845,822, with the remaining $2,183,921 shortfall to be allocated to the underwriters.

IDT chair Mark Simari said the company was "pleased with the strong support shown by shareholders for the equity raising which helps strengthen our balance sheet".

"As previously announced, the proceeds will be deployed to fund capital expenditure relating to current and expected future works in mRNA therapeutics, enhancing IDT's capabilities in antibody drug conjugate ahead of an expected increase in work orders and general working capital," Mr Simari said.

IDT was unchanged at 11 cents.

PACIFIC EDGE

Pacific Edge says processed Cxbladder urine tests fell 25.9 percent in the three months to June 30, 2024 to 7,188 tests compared to the record prior corresponding period.

Last year, Pacific Edge said that sales of its 31,565 Cxbladder non-invasive urine tests for bladder cancer for the year to March 31, 2023 totalled $NZ19,616,000 ($A18,540,000) (BD: May 25, 2023).

Later, the company said it had conducted a record 9,706 tests for bladder cancer in the three months to June 30, 2023; and this year, said it had processed 32,633 Cxbladder tests for the year to March 31, 2024 (BD: Jul 18, 2023; Apr 9, 2024).

Today, Pacific Edge said volumes of its tests were down 0.3 percent compared to 7,210 tests in the prior three months to March 31, 2024, with US volumes down 3.2 percent to 5,905 tests.

The company said the result followed from a “further reduction in our direct sales team and previously reported improvements in sales force efficiency alongside a growing contribution from Kaiser Permanente following the incorporation of Cxbladder into its electronic medical records system”.

Pacific Edge said it had limited “back-filling of commercial staff while [US] Medicare reimbursement uncertainty continues”.

The company said processed Cxbladder tests in Asia Pacific were up 15.5 percent in the three months to 1,283 tests, compared to the three months to March 31, 2024.

Pacific Edge said the region benefitted from increased demand in New Zealand and record volumes in Australia and Asia.

Pacific Edge fell 0.3 cents or 3.6 percent to eight cents.

BLUECHIIP

Bluechiip says it has received a further purchase order from an unnamed US company and has appointed Cogent Venture Partners to assist its strategic review.

Bluechiip said “the client which cannot be named is was one of the world’s largest global pharmaceutical companies, based in one of the world’s largest biotechnology hubs in California” and had purchased additional sample management devices to increase use of the products at its facilities.

The company said the additional sale provided “accelerated adoption for Bluechiip to continue to expand across the client’s multiple facilities in North America especially as our key customer case studies are becoming available”.

Bluechiip said it had engaged Cogent Venture Partners to assist in its strategic review and had begun cash management actions in North America and Australia.

Last month, the company said it raised $367,600 at 0.44 cents a share in a placement for working capital while it undertook a strategic review (BD: Jun 12, 2024).

Today, Bluechiip said it had agreed with the Department of Industry, Science and Resources to end its supply chain resilience initiative grant and was no longer engaged with Fujifilm Irvine Scientific Inc under its licence and development agreement.

In 2022, the company said it had received a $787,810 grant from the Federal Government’s Supply Chain Resilience Initiative program for its chip ‘enabled consumables’ (BD: Dec 2, 2022).

In 2021, Bluechiip said it had a two-year contract with the Santa Ana, California-based Fujifilm Irvine Scientific for its in-vitro fertilization, or assisted reproductive, technologies (BD: Oct 26, 2021).

Bluechiip was up 0.1 cents or 25 percent to 0.5 cents with 2.2 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says 12-week analysis of its 54-patient, phase II/III trial of the marijuana-based NTI164 shows “further beneficial improvements” in autism spectrum disorder.

In April, Neurotech said the trial led to “a statistically significant improvement in severity of illness at eight weeks ($p < 0.001$)” (BD: Apr 17, 2024).

Today, the company said the 26 patients receiving NTI164 had a 36 percent improvement in clinical global impression-severity of illness scale (CGI-S) scores from week-eight to week-12 and a 56 percent improvement from baseline.

Neurotech said a further analysis had been conducted in the 28-patient placebo cohort who had crossed-over to NTI164 treatment from the end of week eight to week 12.

The company said the 28 patients had a baseline score of 5.21, or markedly ill, which rose to 5.25 at week eight and then fell 21 percent to 4.11, or moderately ill, after receiving NTI164 treatment for the four weeks to the 12-week mark.

Neurotech said the placebo group began on a low dose of 5mg/kg of NTI164 a day in week nine and received the maximum tolerated dose of up-to 20mg/kg a day in week 12.

The company said the results were “very encouraging” and that there were no serious adverse events or adverse events related to NTI164 reported in all 54 children at 12 weeks of treatment.

Neurotech said there were five adverse events reported relating to headache, viral infections and a single urinary tract infection, but that they were not deemed to be treatment related.

Neurotech executive director Dr Thomas Duthy said patients who had “received NTI164 for 12 weeks in total continued to improve following the primary analysis at eight weeks, so much so their symptoms are barely noticeable”.

“In general, this means substantial lifestyle improvements for the patient and their caregivers, which makes us very proud to be supporting these clinical trials in autism,” Dr Duthy said.

Neurotech was up 0.1 cents or 1.35 percent to 7.5 cents with 3.0 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has dosed all five patients in its phase IIa trial of TRP-8802 oral psilocybin in combination with psycho-therapy for fibro-myalgia associated with pain.

Tryptamine said the trial was conducted at the University of Michigan and began in January 2024.

The company said researchers from the University of Michigan hoped to present the study results at the International Association of Pain Conference in the Netherlands from August 5-9, 2024.

Tryptamine said the presentation was “expected to provide the company with exceptional exposure to industry experts, as well as potential collaborators and partners”.

The company said the results would be used to inform additional clinical studies using TRP-8803 intra-venous-infused psilocin, which had “the potential to further improve efficacy, and safety, along with enhancing both the patient and therapist experience”.

Tryptamine chief executive officer Jason Carroll said “up-to 30 percent of US fibromyalgia patients may resort to the use of opioids to alleviate their pain and traditional treatment approaches only address the symptom, not its cause”.

“Our firm belief is that the use of psychedelic-assisted therapy can provide a significant benefit to these patients, which would focus on addressing the cause of their pain and not merely masking the symptom,” Mr Carroll said.

Tryptamine was up 0.15 cents or 8.1 percent to two cents with 3.0 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has dosed the first of up-to 21 patients in its phase I, dose-escalation, study of RAD204 for non-small cell lung cancer (NSCLC).
Radiopharm said the patient was dosed at the Wollongong Hospital in New South Wales and that the study was open at Brisbane's Princess Alexandria Hospital and Perth's Hollywood Private Hospital.
Radiopharm managing-director Riccardo Canevari said the company was "delighted to announce this important milestone in our evolution to a clinical-stage company."
"Despite progressive improvements in the first-line setting for metastatic NSCLC, the majority of patients will progress and require further therapeutic options in the second-line setting," Mr Canevari said. "Current options following progression offer modest activity, making this setting an area of unmet need.".
"With RAD204, we hope to provide an alternative strategy that can improve clinical outcomes for NSCLC patients, while preserving quality of life," Mr Canevari said.
Radiopharm was up 0.1 cents or 2.9 percent to 3.6 cents with 2.45 million shares traded.

IMUGENE

Imugene says it has dosed the first of 10 bile tract cancer patients in the expanded cohort of its phase I trial of Vaxinia, or CF33, for advanced solid tumors.
Last year, Imugene said it had 'early positive signals' from 34 patients treated in the phase I monotherapy or combination trial and had US Food and Drug Administration fast-track status for bile duct cancer, or cholangio-carcinoma (BD: Mar 3, Nov 6, Nov 28, 2023).
In April, the company said it had expanded its phase I trial of Vaxinia for metastatic advanced solid tumors to include 10 bile tract cancer patients (BD: Apr 15, 2024).
Today, Imugene said the first bile tract cancer expansion cohort patient was treated at Melbourne's St Vincent's Hospital.
Imugene managing-director Leslie Chong said given the results seen to date the company was "eager to see the potential of Vaxinia in bile tract cancer".
"We look forward to now advancing to the higher doses in the trial to gather further key data and make a genuine difference to patients in need of innovative treatment options," Ms Chong said.
Imugene was up 0.3 cents or 5.9 percent to 5.4 cents with 46.1 million shares traded.

PYC THERAPEUTICS

PYC says it has begun a six-patient, multiple-ascending dose study to assess the safety, tolerability and efficacy of VP-001 for retinitis pigmentosa type 11 (RP11).
Last week, PYC said its nine-patient, single-ascending dose study of VP-001 for retinitis pigmentosa type-11 showed the drug was safe and well-tolerated at the highest intra-vitreal dose of 75 micrograms (µg) (BD: Jul 1, 2024).
Today, the company said the multiple ascending dose study would be held at five sites in the US with two cohorts of three patients receiving either 30µg or 75µg of VP-001.
PYC said patients would receive three doses, each administered eight weeks apart, with a safety review four weeks after each dose.
The company said the primary endpoint of the study was treatment emergent ocular adverse events and treatment emergent serious adverse events in a 52-week period.
PYC said the data would be collected for secondary and exploratory endpoints, including efficacy, to support a proposed registrational study expected to begin in 2025.
PYC was up half a cent or 4.2 percent to 12.5 cents with 2.8 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has completed its 400-patient, phase II, sleep signal study of current major depressive episode using its MEB-001 artificial intelligence algorithm.
Last year, the then Medibio said it began a 400-participant, phase II trial of its MEB-001 "sleep signal analysis" algorithm for current major depressive episodes at 14 US sleep centres (BD: Sep 4, 2024).
Today, the company said the study aimed "to continue to validate its innovative algorithm to assist in the screening and diagnosis of major depressive episode in test subjects".
Trivarx said it would "provide preliminary results imminently", prior to further engagement with the US Food and Drug Administration, which was scheduled for "the coming months".
Trivarx chair David Trimboli said following the company's phase I initiative and ongoing algorithm training it was "confident of positive results for MEB-001".\
Last year, Medibio said its 313-subject, phase I trial of MEB-001 showed its heart rate depression test had 71.65 percent sensitivity and, 71.43 percent specificity, but provided no statistical significance (BD: Jul 24, 2023)
Today, Mr Trimboli said the results would "help inform our ongoing dialogue with the US [Food and Drug Administration] and commercial pathway".
Trivarx was up 0.7 cents or 28.0 percent to 3.2 cents with 8.0 million shares traded.

OPTHEA

Opthea says a scientific review supports the use of sozinibercept, or OPT-302, as a treatment for wet age-related macular degeneration (AMD).
Opthea said the article, co-authored by chief innovation officer and former managing-director Dr Megan Baldwin, chief research director Dr Ian Leitch and the head of formulation development Dr Michael Gerometta, was titled 'Vascular Endothelial Growth Factor (VEGF) C and D Signaling Pathways as Potential Targets for the Treatment of Neovascular Age-Related Macular Degeneration: A Narrative Review' and published in Ophthalmology and Therapy, with the article available at: https://bit.ly/4cwk4Dh.
Opthea said the article reviewed the "evidence that in retinal diseases, such as wet AMD, the patho-physiology is broader than dysregulation or overproduction of VEGF-A".
Opthea chief executive officer Dr Frederic Guerard said the review showed OPT-302 had "potential as a novel, first-in-class VEGF-C/D 'trap' to prevent blood vessel growth and vascular leakage in the retina and deliver superior visual outcomes in wet AMD patients when combined with standard-of-care anti-VEGF-A therapies".
Opthea was unchanged at 36.5 cents with 2.7 million shares traded.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says its annual general meeting will vote to issue managing-director Lewis Gradon 100,000 performance rights and 190,000 options.
Fisher & Paykel said Mr Gradon's rights and options were part of his long-term variable remuneration and were worth a total of about $NZ1,212,120 ($A1,095,000), with the options exercisable at the five-day volume weighted average price prior to their grant date.
According to Fisher & Paykel's preliminary final report, Mr Gradon's total cash-based remuneration for the year to March 31, 2024 was $NZ2,872,284.
The company said the meeting would vote to elect Michael Daniell and Graham McLean as directors and approve the auditor's remuneration and be held online and in person at 15 Maurice Paykel Place, Auckland, New Zealand on August 28, 2024 at 2pm (NZST).
Fisher & Paykel was up 58 cents or 2.1 percent to $28.02 with 438,165 shares traded.

ORTHOCELL

Orthocell has requested a trading halt “pending an announcement by the company in relation to receipt of regulatory approval for Striate in Canada”.
Trading will resume on July 12, 2024, or on an earlier announcement.
Orthocell last traded at 37 cents.

IDT AUSTRALIA

Sydney’s Capital Pty Ltd says it has increased its substantial shareholding in IDT from 50,418,489 shares (16.6%) to 77,326,834 shares (18.0%).
Sandon said that between July 21, 2023 and July 9, 2024 it bought 16,336,300 shares on market and in an entitlement offer for $1,411,079, or 8.6 cents a share and 10,572,045 shares through One Fund Services for $935,731, or 8.85 cents (see above).

BIO-MELBOURNE NETWORK

Bio-Melbourne Network says it has extended expressions of interest for its second workshop on leading and managing scientific staff until July 15, 2024.
Earlier this year, Bio-Melbourne Network said it would hold a workshop with Sydney’s Marlow Hampshire Pty Ltd on leading and managing technical and scientific staff on February 21-to-22 and August 5-to-6, 2024 (BD: Jan 23, 2024).
Today, the Network said Marlow Hampshire was a professional services organization and that the workshop was called ‘Industry Program – Leading and Managing: The People Side of Technology and Manufacturing Teams in Bioscience’.
Bio-Melbourne Network said workshop participants would “gain a solid experience-based foundation in leading and managing technical and scientific staff, as well as highly practical tools, techniques and tips that can be applied in the workplace”.
The Network said the two-day event was valued at $1,500 and would be held at Cliftons Training Centre, 440 Collins Street, Melbourne on August 5 and 6, 2024.
For expressions of interest go to: https://www.marlowhampshire.com.au/contact.