Biotech Daily

Wednesday July 24, 2024

Daily news on ASX-listed biotechnology companies

VALE DR ROBIN WARREN (11.6.1937 – 23.7.2024)

*** ASX FLAT, BIOTECH UP: ALCIDION UP 20%; TELIX DOWN 7%**

*** TELIX TO RAISE $650m IN CONVERTIBLE NOTES**

*** SOMNOMED RECEIPTS UP 10% TO $90m**

*** ANTERIS RAISES $30m**

*** LTR PLACEMENT RAISES $10.5m**

*** PHARMAUST 'OVERSUBSCRIBED' PLAN RAISES $7.8m; TOTAL $17.8m**

*** DORSAVI 'COMMITMENTS' FOR $1.1m PLACEMENT**

*** HEXIMA 790m SHARES FOR REAL THING; 10-TO-1 CONSOLIDATION**

*** TRYPTAMINE STARTS PSILOCYBIN TRP-8802 IBS TRIAL**

*** BLINKLAB, COLUMBIA AEROBICS FOR SCA TRIAL**

*** ALCIDION: PATIENT CARE SUPPLIER FOR UK NORTH CUMBRIA NHS**

*** TELIX: 'FDA ACCEPTS TLX007-CDx PROSTATE CANCER IMAGING NDA'**

*** ORTHOCELL PLANS STRIATE+, REMPLIR EXPANSION**

*** ARGENICA DOSES 20 ARG-007 PHASE II STROKE PATIENTS**

*** MEMPHASYS PLANS OXIDATIVE STRESS TRIAL**

*** SOMNOMED LOSES CFO DARREN COLLINS**

*** HERAMED SETS M-D ANOUSHKA GUNGADIN INCENTIVES**

*** PROTA APPOINTS PATRICK MACHADO CHAIR**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Wednesday July 24, 2024, with the ASX200 down 7.4 points to 7,963.7 points.

Sixteen of the Biotech Daily Top 40 companies were up, 14 were down, eight traded unchanged and two were untraded.

Alcidion was the best, up 1.1 cents or 20.0 percent to 6.6 cents, with 19.9 million shares traded.

Prescient climbed 7.1 percent; Next Science and Opthea were up more than five percent; Avita, Immutep and Orthocell improved four percent or more; Universal Biosensors was up 3.6 percent; Actinogen, Cynata, Polynovo and Pro Medicus rose more than two percent; with Amplia, Clarity, Cochlear, Emvision, Impedimed and Resmed up by more than one percent.

Telix led the falls, down $1.46 or 7.2 percent to $18.85, with 18.6 million shares traded.

Imugene lost 6.7 percent; Dimerix and Nova Eye fell four percent or more; Cyclopharm and Mesoblast were down more than three percent; Syntara shed 2.6 percent; Medadvisor, Medical Developments and Paradigm were down one percent or more; with 4D Medical, Clinuvel, CSL, Nanosonics and Neuren down by less than one percent.

VALE DR ROBIN WARREN (11.6.1937 – 23.7.2024)

Biotech Daily is saddened to learn of the death of Nobel laureate Dr (John) Robin Warren yesterday evening in Perth, Western Australia.

According to Dr Warren's entry in Wikipedia, he won the Nobel Prize for Medicine in 2005 alongside Prof Barry Marshall for their work to discover the bacterium, Helicobacter pylori, which caused most peptic ulcers.

According to Prof Marshall's X (Twitter) account, Dr Warren "passed away peacefully in the company of his family".

Wikipedia said that Dr Warren trained at the Royal Adelaide Hospital and became a registrar in clinical pathology at the Institute of Medical and Veterinary Science, where he worked in laboratory haematology.

In 1963, Dr Warren was appointed honorary clinical assistant in pathology and honorary registrar in haematology at Royal Adelaide Hospital and subsequently lectured in pathology at Adelaide University, prior to his appointment as clinical pathology registrar at the Royal Melbourne Hospital. Dr Warren became a senior pathologist at the Royal Perth Hospital, where he spent the majority of his career.

Wikipedia said that Dr Warren held a Bachelor of Medicine and Bachelor of Surgery from the University of Adelaide in South Australia.

TELIX PHARMACEUTICALS

Telix says it is offering $650 million in convertible notes at an interest rate of 2.375 percent a year and convertible at $24.78, 32.5 percent above the reference price.
Telix said that the interest on the convertible notes, also referred to as convertible bonds, would be paid quarterly in arrear, with the first quarterly payment to be made on October 30, followed by January 30, April 30 and July 30 each year, with the first interest payment to be made on October 30, 2024.
The company said that the notes had a maturity date of on or about July 30, 2029, unless redeemed, repurchased or converted.
Telix said the reference share price for the notes was $18.70, or a 4.5 percent discount to the 10-day volume weighted average price and that the notes were subject to anti-dilution adjustments.
The company said the funds raised from the notes would be used for its clinical development programs including label-expansion studies for its diagnostic imaging agents and funding pivotal trials for kidney and brain cancer therapy programs.
Telix said the funding would provide financial flexibility for it “to explore opportunities and potentially pursue strategically significant [merger and acquisition] transactions and continued investment in global supply chain and manufacturing capabilities”.
The company said the convertible note offer was expected to be settled on July 30, 2024, and was subject to satisfaction of customary conditions.
Telix said the convertible notes would be listed on the Singapore Exchange with JP Morgan appointed the sole manager for the offer.
Telix managing-director Dr Christian Behrenbruch said the convertible bonds provided the company “with attractive, low-cost financing at a clear inflection point in Telix’s journey”.
“The proceeds deliver financial flexibility to execute on our strategic priorities, while reducing potential dilution of existing shareholders,” Dr Behrenbruch said.
“We have been able to capitalize on strong business execution and market conditions to deliver attractive financing terms,” Dr Behrenbruch said.
“We are very pleased with the strong support that we received from global investors in relation to the offering,” Dr Behrenbruch said.
Telix fell $1.46 or 7.2 percent to $18.85 with 18.6 million shares traded.

SOMNOMED

Somnomed says receipts from customers for the year to June 30, 2024 were up 9.6 percent to $90,410,000, compared to the previous corresponding period.
Somnomed said that receipts from sales of its oral treatments for sleep-related breathing disorders and obstructive sleep apnoea were up 11.2 percent for the three months to June 30, 2024 to $24,332,000, compared to the prior corresponding period.
The company said it had completed its planned cost reductions and that it had incurred restructuring costs of about $3.0 million in the three months to June 30, 2024, with the ongoing benefit of the savings of $5 million to be reflected by October 2024.
Somnomed said revenue in the three months to June 30, 2024 remained constrained by manufacturing limits, but improvements were “now being seen in turnaround times and growth in unit output”.
The company said that it had a cash burn of $892,000 for the three months to June 30, 2024, with cash and cash equivalents of $16,179,000 at June 30, 2024 compared to $11,956,000 at June 30, 2023.
Somnomed was up two cents or 6.1 percent to 35 cents.

ANTERIS TECHNOLOGIES

Anteris says it has raised $30.0 million in a placement to institutional and sophisticated investors at $16.00 a share for its Duravr transcatheter heart valve.
Anteris said the placement price was a 6.2 percent discount to the last closing price.
The company said the funds would be used for development of its Duravr transcatheter heart valve, manufacturing, valve-to-valve research and development and working capital.
Anteris said Canaccord Genuity and Evolution Capital were joint lead managers to the placement, with Bell Potter Securities acting as co-manager.
Anteris fell $1.35 or 7.9 percent to $15.70.

LTR PHARMA

LTR says it has received “firm commitments” to raise $10.5 million at 73 cents a share in a placement to sophisticated and institutional investors.
LTR said the issue price was a 13.2 percent discount to the 30-day volume weighted average price, and it would use $2.0 million for sales and marketing of its Spontan nasal spray for erectile dysfunction, with $1 million for a website, $2 million for research and development, $1.4 million for regulatory studies and $3.5 million for working capital.
LTR said Alpine Capital Pty Ltd was sole lead manager to the placement.
LTR fell nine cents or 10.0 percent to 81 cents with 1.55 million shares traded.

PHARMAUST

Pharmaust says it has raised $7.8 million in an over-subscribed share purchase plan at 19.0 cents a share, taking the total raised with its placement to $17.8 million.
Last month, Pharmaust said it had “firm commitments to raise $10 million in a placement at 19.0 cents a share, or a 18.4 percent discount to the 10-day volume weighted average price, with a share plan for $2 million more (BD: Jun 21, 2024).
Today, the company said demand for the share plan was “significantly in excess of the initial target of $2.0 million, closing with $7.8 million in applications being accepted”.
Pharmaust said “given the strong shareholder support and to provide all shareholders with the opportunity to participate on the same terms as the placement” it had accepted all valid applications made under the share purchase plan.
The company said the funds would be used for the Healey [amyotrophic lateral sclerosis] platform trial of monepantel, manufacturing of monepantel, preclinical models for other neurodegenerative diseases, regulatory filings, working capital and offer costs.
Pharmaust was up half a cent or 2.4 percent to 21.5 cents.

DORSAVI

Dorsavi says it has “firm commitments” to raise $1.1 million in a placement at 1.1 cents a share, with one attaching option for every share purchased.
Dorsavi said the issue price was a 13.5 percent discount to the 15-day volume weighted average price of 1.27 cents a share, with the options exercisable at two cents each within 36 months from the date of issue.
The company said the funds raised would be used for US commercialization, expand [artificial intelligence] features and for general working capital”.
The company said Sixty Two Capital was lead manager to the placement, and would receive 10,000,000 options, under the same terms as the placement options.
Dorsavi fell 0.1 cents or 7.7 percent to 1.2 cents with 2.35 million shares traded.

HEXIMA

Hexima says it will acquire Real Thing Entertainment Pty Ltd for 789,743,000 shares and 87,215,040 options, raise up-to $7.5 million and hold a 10-to-one consolidation.
Hexima said it had “a binding but conditional … agreement to acquire … Real Thing Entertainment Pty Ltd which has developed an artificial intelligence platform that allows users to achieve outcomes using simple voice commands through to complex dialogue”.
In 2022, Hexima said its phase II clinical study of HXP124, or pezadeftide, for onychomycosis, or nail fungus, was “inconclusive … [and does] not support moving directly into a phase III program” and it would be wound-up (BD: Jun 24, Jul 11, 2022).
Today, Hexima said Real Thing Entertainment had developed the Realsam voice accessibility products for visually impaired people and in 2018 launched the Realsam voice-enabled book and newspaper reader in collaboration with the UK’s Royal National Institute for Blind People.
The company said that it had a contract with the US Library of Congress’ National Library Service for a portable smart book reader and had targeted the US Department of Veterans Affairs and state accessibility programs, as well as field testing with 500 users of the Library of Congress.
Hexima said it would issue Real Thing shareholders 78,974,300 post consolidation shares and 8,721,504 post-consolidation options, exercisable at 20 cents each by March 5, 2026, and change its name to Real Thing A.I. Limited.
The company said it proposed a one-for-10 consolidation basis and would undertake a capital raising for a minimum of $4 million and up-to $7.5 million.
Hexima said it would issue two Real Thing shareholders up-to 25.0 million shares equal to the capital raising price to redeem convertible notes worth $500,000.
The company said that Real Thing director Silvio Salom and Dr Michael Georgeff as directors and appoint other senior management, with Hexima chair Geoffrey Kempler continuing as managing-director and Phillip Hains continuing as a non-executive director.
Hexima said the transaction was subject to various conditions, including shareholder approvals, and re-complying with Chapters 1 and 2 of the ASX Listing Rules.
The company said it had appointed MST Financial Services Pty Ltd as lead manager for the capital raising and pay MST the greater of $100,000 or 6.0 percent of the amount raised from investors and 2.0 percent of the amount raised from the chair’s list.
Hexima said that pending the capital raise the company would have between 128,962,886 post-consolidation shares and 146,462,886 post-consolidation shares.
The shareholder meeting is expected to be held on September 23, with the last day to update its register and send holding statements October 3, but expected it to be shortly after the record date for the consolidation of September 26, 2024.
Hexima was up 0.7 cents or 58.3 percent to 1.9 cents with 27.75 million shares traded.

TRYPTAMINE THERAPEUTICS

Tryptamine says it has dosed the first of up-to 10 irritable bowel syndrome (IBS) patients in its phase IIa, open label trial of oral psilocybin TRP-8802 and psychotherapy.
Tryptamine said the trial was a collaboration with Boston’s Massachusetts General Hospital and the first time the Hospital has administered psilocybin in a clinical study.
The company said the results were expected by April 2025, with the primary efficacy endpoints including a reduction in chronic abdominal pain and visceral tenderness.
Tryptamine said the results would inform follow-up studies using its intra-venous TRP-8803 psilocin.
Tryptamine was up 0.1 cents or five percent to 2.1 cents.

BLINKLAB

Blinklab says it will conduct an up-to 62-patient trial of aerobic physical exercise for spino-cerebellar ataxias (SCA) neuro-plasticity with New York's Columbia University
Blinklab said the partnership was aligned with its "strategy to enhance its [artificial intelligence]-powered digital platform for sensory phenotyping.
The company said the 18-month trial could show that its eyeblink conditioning test could "serve as an effective biomarker for neuro-plasticity in human SCA patients".
Blinklab said the agreement meant it would have an option to licence any intellectual property developed as a direct result of the partnership.
Blinklab chief executive officer Henk-Jan Boele said that "since the very first successful test of the Blinklab platform in the lab at Princeton University, our team's vision has always been to develop a tool that will someday be considered as a standard of care in the initial diagnosis of neuro-developmental conditions where children have difficulties in processing sensory information, such as autism and [attention deficit hyperactivity disorder]".
Blinklab said that spino-cerebellar ataxias were a group of disorders in which progressive cerebellar degeneration led to severe disability and even death.
The company said that about 150,000 Americans were living with these diseases, with no effective treatments or cures for genetic causes of the diseases.
Blinklab said Columbia University had shown aerobic training was "a promising treatment for spino-cerebellar ataxias, but the mechanism of action is not fully understood".
"Training may increase leg strength and endurance which allow compensation for balance deficits, but may also cause neuroplastic changes in the brain," the company said.
Blinklab fell half a cent or 1.8 percent to 27 cents.

ALCIDION GROUP

Alcidion says it will supply its Miya patient record systems to Carlisle, England's North Cumbria Integrated Care National Health Services Foundation Trust.
Alcidion said the North Cumbria NHS provided hospital and community healthcare services for about 500,000 people in "two acute care hospitals, eight community-based hospitals, eight integrated care communities and a number of support staff locations".
The company said it would provide a full suite of its Miya Precision technology, including Silverlink patient administration system, to give "clinicians real-time access to patient records whilst streamlining patient flow and improving clinical decision-making".
Alcidion said that the contract followed "a competitive tender process" and that it would finalize the contract prior to commencing deployment of Miya by March 2025.
The company said the total contract value was "likely to be in the range of $30 million to $40 million over 10 years depending on modules included", the contract process required business case approval and was expected to be completed by March 2025.
Alcidion managing director Kate Quirke said having been the supplier of the North Cumbria NHS patient administration system for more than eight years, the company was "able to continue our relationship by bringing the full Miya Precision capabilities, alongside our partner applications, to deliver a full electronic patient record".
"Providing an integrated, modular [electronic patient record] … allows [North Cumbria] to develop their existing digital footprint, protecting their existing investments and allowing them to realize the benefits of additional clinical capabilities such as electronic noting and integrated observations through integration with a number of existing systems," Ms Quirke said. "At a time when the healthcare system is under enormous pressure, we see this increased speed to deliver value as a real opportunity for our customers."
Alcidion was up 1.1 cents or 20 percent to 6.6 cents with 19.9 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has accepted its new drug application for TLX007-CDx as a prostate cancer imaging agent.

Earlier this year, Telix said it had submitted a new drug application to the FDA for its TLX007-CDx cold kit for prostate cancer imaging (BD: May 27, 2024).

At that time, the company said the kit would allow the use of a prostate specific membrane antigen (PSMA) imaging product with an extended distribution profile compared to current approved gallium-68 positron emission tomography (PET) imaging agents.

Today, Telix said a new drug application approval would allow it "to further enhance patient access to PSMA-PET imaging and the clinical benefits of gallium-68 imaging to underserved populations across the US, using Telix's established nuclear pharmacy distribution partnerships and industry-leading on-time reliability".

The company said the Prescription Drug User Fee Act goal date was March 24, 2025.

Telix managing-director Dr Chris Behrenbruch said the company had "seen rapid adoption and geographic expansion of PSMA-PET imaging with our first commercial product Illuccix".

"This filing acceptance is an important step towards further improving equity of access and reinforcing our commitment to innovation in prostate cancer to continue to meet the needs of healthcare professionals and their patients," Dr Behrenbruch said.

ORTHOCELL

Orthocell says it will expand regulatory approvals for its Striate+ collagen barrier membrane for dental implants and Remplir collagen wrap for nerve repair surgery.

Orthocell said it was working with its Striate+ distributor Biohorizons to expand regulatory approvals "in multiple new markets", with regulatory approval for Striate+ in Brazil and Singapore expected "within six-to-12 months" and further applications under review.

The company said regulatory approval for Remplir in Singapore was expected before 2025, and that Singapore approval was considered "the gateway" to other Association of Southeast Asian Nations, including Thailand, Malaysia, Vietnam, Indonesia and the Philippines.

Orthocell said it had a further three applications planned in Canada, Thailand and Europe and the UK within the next six-to-12 months.

Orthocell was up 1.5 cents or four percent to 39 cents.

ARGENICA THERAPEUTICS

Argenica says it has opened eight of 10 trial sites and dosed 20 of up-to 92 patients in its single-dose, placebo-controlled, phase II trial of ARG-007 for acute ischaemic stroke.

Earlier this year, Argenica said it had dosed the first cohort in the study, with no adverse events reported; and later, said following five-patient safety data it had approval to continue the trial (BD: Apr 10, Apr 29, 2024).

Today, the company said having all hospitals activated from the beginning of August would allow "greater recruitment of patients presenting to hospital emergency departments with diagnosed acute ischaemic strokes, and which meet the trial's inclusion criteria".

Argenica said the independent data safety monitoring board would meet to review safety data once 23 patients had been dosed, which was expected "in the coming weeks".

The company said recruitment of patients into the trial was "on track to complete dosing of all 92 patients before the recruitment target of the end of … 2025".

Argenica fell seven cents or 8.05 percent to 80 cents.

MEMPHASYS

Memphasys says it is preparing a trial of its oxidative stress measurement technology for reproductive performance (BD: Jul 19, 2024).
Memphasys said that in addition to its sperm separation systems, it was “advancing several other projects to extend its commercial product pipeline”.
The company said it was “exploring industry partnerships and defining appropriate clinical on-farm partners for data and blood collection”.
Memphasys was up 0.1 cents or 14.3 percent to 0.8 cents with 3.1 million shares traded.

SOMNOMED

Somnomed says one-year chief financial officer Darren Collins has resigned, effective from July 31, 2024, and a search for a replacement “will commence immediately”.
Last year, Somnomed said it had appointed Mr Collins as its chief financial officer, replacing Herve Fievet, effective from August 1, 2023 (BD: Jul 6, 2023).
Today, in its quarterly report, the company said Mr Collins would “be available to support the finance team and the transition to a new chief financial officer in the short term”.
Somnomed joint chief executive officer Amrita Blickstead thanked “Mr Collins for his service, during what has been a challenging period for Somnomed”.
“We are grateful for his assistance with the transition to a new leader of the finance function and wish him all the best for his future endeavors,” Ms Blickstead said.

HERAMED

Heramed says managing-director Anoushka Gungadin’s will have short term incentives of up to 50 percent of her salary and 15,800,000 long term incentive performance rights.
Heramed said that Ms Gungadin salary would be $308,000 a year excluding superannuation compared to the previous $US204,000 ($A309,100) a year.
The company said that the short-term incentives were pending performance indicators, as were the vesting of long-term incentives, which were also subject to shareholder approval.
Heramed was unchanged at 1.8 cents with 363 shares traded.

PROTA THERAPEUTICS

Melbourne’s Prota Therapeutics says it has appointed Patrick Machado as its chair, effective immediately.
Prota said that Mr Machado had more than 30 years of experience and would support its progress to a phase III trial of oral PRT120 for peanut allergy.
The company said that Mr Machado co-founded Medivation Inc, which developed and launched the Xtandi prostate cancer treatments and had been a director of companies in the US, Canada, Europe and Australia, including Endocyte, Principia Biopharma and Turning Point Therapeutics.
The company said that Mr Machado held a Bachelor of Arts and a Bachelor of Science in Economics from California’s Santa Clara University and a Doctor of Jurisprudence from the Cambridge Massachusetts-based Harvard Law School.
Prota is a private company.