

Biotech Daily

Wednesday May 15, 2024

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: PRESCIENT UP 10%; ACTINOGEN DOWN 7%
- * FEDERAL BUDGET DETAILS, COMMENT & RESPONSE
 - ATSE, STA, AUSBIOTECH
- * AMPLIA RIGHTS RAISE \$4.3m FOR AMP945 PANCREATIC CANCER TRIAL
- * ANTEOTECH SHARE PLAN RAISES \$1.4m; TOTAL \$6.8m
- * CONTROL BIONICS PLACEMENT RAISES \$1m
- * BTC TO SELL WEXLER CARDIO-THORACIC SURGICAL PRODUCTS
- * ANTERIS 1st 'VALVE-IN-VALVE-IN-VALVE' PROCEDURE
- * RECCE DOSES 4,000mg R327 IN 20-MINUTES
- * ARGENICA: 'ARG-007 REDUCES BRAIN CELL DAMAGE, IN FERRETS'
- * ALLAN MOSS, BLUEFLAG INCREASE, DILUTED TO 6.95% IN AMPLIA
- * MA (MOELIS) TAKES 5.5% OF TRAJAN
- * ZHENG YANG, CAMBIUM DIRECTOR DR SEBASTIAN TSENG TAKE 13%
- * CYNTEC TAKES 8.2% OF CAMBIUM
- * HARRY PERKINS APPOINTS LORRAINE DRISCOLL DIRECTOR

MARKET REPORT

The Australian stock market was up 0.35 percent on Wednesday May 15, 2024, with the ASX200 up 26.9 points to 7,753.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded.

Prescient was the best, up 0.4 cents or 10.0 percent to 4.4 cents, with 1.3 million shares traded. Alcidion climbed 8.5 percent; Amplia was up seven percent; Impedimed and Neuren improved five percent or more; Cynata climbed 4.1 percent; Atomo, Medadvisor, Opthea and Universal Biosensors were up three percent or more; Nova Eye and Pro Medicus rose two percent or more; Cochlear, CSL and Paradigm were up more than one percent; with Telix up by 0.2 percent.

Actinogen led the falls, down 0.2 cents or 6.9 percent to 2.7 cents, with 3.1 million shares traded. Avita, Compumedics and Percheron lost six percent or more; Emvision fell 5.15 percent; Clinuvel, Orthocell and Polynovo were down more than three percent; Clarity, Curvebeam, Nanosonics and Resonance shed more than two percent; Dimerix, Immutep, Imugene, Mesoblast and Next Science were down more than one percent; with Cyclopharm, Proteomics and Resmed down by less than one percent.

FEDERAL BUDGET, COMMENT & RESPONSE

Federal Treasurer Dr Jim Chalmers' third Budget did not name biotechnology but the Budget Papers say there will be increased spending on research and tax incentives.

Dr Chalmers told the Parliament that all taxpayers would receive a tax reduction and that households and small businesses would receive energy bill relief.

"From July 1, Australians will receive an energy rebate of \$300 - and one million small businesses will get a bit more," Dr Chalmers said.

While the 'Future Made in Australia' program focused on energy and renewables, Dr Chalmers said the Government was "changing the way we attract and deploy investment".

Dr Chalmers said that a new Act and new framework would impose rigour and focus investment on "transformational opportunities ... setting conditions to ensure investors benefiting from our incentives are supporting their people and communities to lift private investment in skills, workforces and local supply chains".

"We will create a front door for investors to accelerate and coordinate transformational projects, establish a domestic National Interest Account, that adds discipline to investments in the national interest, and strengthen and streamline approvals – across environmental, planning, cultural heritage and foreign investment," Dr Chalmers said

Dr Chalmers told Parliament the Government would extend the \$20,000 instant asset write-off until June 30, 2025, providing \$290 million for up to four million small businesses.

The Budget Papers said the Government would "undertake a strategic examination of Australia's research and development system to strengthen its alignment with Australia's priorities and improve innovation and research and development outcomes".

Under the heading 'Improving cancer outcomes' the Budget Papers said \$71.0 million would be provided over four years from 2024-'25 "to continue support services, programs and research to improve cancer outcomes for Australians, in line with the Australian Cancer Plan".

The Budget Papers said an additional \$1.4 billion would be committed over 13 years to the Medical Research Future Fund, to translate research into medical practice, continue existing research missions and introduce two new missions for low-survival cancers and reducing health inequities, as well as patient-centred research, and supporting innovative treatments, clinical trials, more advanced healthcare, and for breakthrough discoveries.

The Federal Government said it would provide \$18.8 million over two years from 2024-'25 to continue the development of the National One Stop Shop for Clinical Trials and Human Research and support current systems.

The Papers said Research and Development Tax Incentive payments were expected to increase by \$499.0 million in 2024-'25 and \$2.6 billion over five years "due to increases in the overall number and value of expected claims, with higher-than-expected growth in claims by companies in the 'Professional, Scientific and Technical Services' sector".

AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING

The Australian Academy of Technological Sciences and Engineering welcomed the Budget commitment to reviewing "languishing investment" in science and innovation.

ATSE said science and innovation needed "immediate and sustained investment to power a future made in Australia" and warned against investment being "kicked further down the road".

The Academy said Australia lagged behind the US, Japan, and Germany which spent "more than 3.0 percent of their GDP on the research and development, which powers their economies".

ATSE chief executive officer Kylie Walker welcomed the Government's commitment to developing clean energy but said it was critical "to recognize that developing these industries requires innovations that will only come from a strong and well-funded science and technology sector".

"ATSE also welcomes the announced review of Australia's research and development system," Ms Walker said. "It is critical that this work gets underway to make up for lost time and to bring Australia closer to nations at the forefront of technological innovation."

SCIENCE AND TECHNOLOGY AUSTRALIA

Science and Technology Australia welcomed the research and development system review as a way to reach a 3.0 percent GDP investment in research and development.

Science and Technology Australia welcomed "the Future Made in Australia Budget commitments ... to turbo-charge the transition to net-zero and a future of green energy".

The industry organization said "a strategic investment in powerfully increasing diversity in science, technology, engineering and mathematics" was another welcome initiative.

Science and Technology Australia president Prof Sharath Sriram said it was "a strong Budget for a future based on science and innovation".

"The review of the [research and development] system is timely and welcome, it has the potential to better connect the innovation ecosystem to support business, build a thriving economy, and accelerate the development of products and solutions," Prof Sriram said. "This can reverse the decline in national investment in [research and development]."

AUSBIOTECH

Ausbiotech says it "looks forward to engaging with Government further to understand what areas are included as 'key industries'" in its Future Made in Australia proposal.

A media release from Ausbiotech summarized the Budget announcements and said the organization would work with the Government to understand the details.

AMPLIA THERAPEUTICS

Amplia says it has raised \$4.27 million at 5.5 cents a share in its two-for-five entitlement offer to fund its phase IIa trial of narmafotinib (AMP945) for pancreatic cancer trial. Last month, Amplia said that it expected to raise \$4.27 million at 5.5 cents a share in a two-for-five, fully-underwritten, non-accelerated, non-renounceable retail entitlement offer to take the trial to interim analysis (BD: Apr 16, 2024).

Today, the company said the rights offer raised \$1,983,000 from eligible shareholders and \$2,285,000 from the shortfall underwriters.

Amplia said director Dr Robert Peach took-up \$150,000 of the shortfall, with managingdirector Dr Chris Burns and director Jane Bell subscribing for a cumulative \$78,000.

The company said it had enrolled 19 of the 26 patients in the phase IIa trial of narmafotinib with chemotherapy and would conduct an interim analysis to determine whether six or more patients had a partial response.

Amplia said that if six or more patients had at least a partial response, it would enroll a further 24 patients, bringing the total trial cohort to 50 patients.

Dr Burns said the rights offer allowed Amplia "to continue to actively progress development of our best-in-class [focal adhesion kinase] inhibitor narmafotinib, with specific focus on delivering critical interim data in our ongoing phase II ... trial".

"The excellent recruitment progress and support from clinicians seen to date in the Accent trial is extremely encouraging and we expect it to allow us to report interim data [by October] this year," Dr Burns said.

The company said Taylor Collison was lead manager and underwriter to the raise. Amplia was up 0.4 cents or seven percent to 6.1 cents.

<u>ANTEOTECH</u>

Anteotech says it has raised \$1,396,123 in its share purchase plan at 2.5 cents a share, taking the total raised with the placement to about \$6,800,000.

Last month, Anteotech said it had "commitments" for a \$5.4 million placement at 2.5 cents a share, with a share plan for \$1.0 million to follow (BD: Apr 8, 2024).

Today, the company said investors would receive one option for every two shares bought, exercisable at 3.5 cents each within two years, with further options to be issued for every option exercised within 12 months, exercisable at five cents by April 30, 2027.

Anteotech said it had accepted oversubscriptions of about \$400,000.

Anteotech fell 0.1 cents or 4.35 percent to 2.2 cents.

CONTROL BIONICS

Control Bionics says it has "firm commitments" to raise \$1.04 million at 4.3 cents a share in a placement to professional and sophisticated investors.

Control Bionics said the issue price was a 2.6 percent discount to the 15-day volume weighted average price to May 10, 2024.

The company said the funds would be used to make its three operating businesses earnings before interest, taxation, depreciation and amortization (Ebitda) positive Ebitda, build its Neuronode Only business, deliver first commercial sales of its Drove autonomous wheelchair controller, identify opportunities to scale and commercialize Neurostrip. Control Bionics said Lynx Advisors Pty Ltd was lead manager and would receive six percent of the amount raised in fees as well as 500,000 options exercisable at 10 cents each within three years.

Control Bionics was untraded at five cents.

BTC HEALTH

BTC says it will exclusively distribute and sell the Houston, Texas-based Wexler Surgical Inc's cardio-thoracic surgical instruments in Australia and New Zealand.

BTC said Wexler Surgical's cardio-thoracic, vascular, minimally invasive and paediatric instruments had Australian Therapeutic Goods Administration approval.

The company said the products had formerly been distributed by Melbourne's Advanced Biomedical, with the rights to be transferred to subsidiary BTC Cardio from May 18, 2024. BTC did not state the commercial terms of the agreement.

BTC chair Dr Richard Treagus said the company was "delighted to be partnering with Wexler and to be representing their products in this region".

BTC was up 0.1 cents or 2.3 percent to 4.5 cents with two shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has performed a valve-in-valve procedure with its Duravr transcatheter heart valve in a patient who already had two valve replacements.

Anteris said the patient received their third valve-in-valve replacement, or a 'valve-in-valve' procedure, at Stockholm's Karolinska University Hospital.

The company said the patient had previously received a surgical valve, which failed after seven years and was replaced six years ago by inserting a second transcatheter aortic valve replacement (TAVR) inside the existing surgical valve.

Anteris said the second valve replacement had failed, and surgeons deemed the patient was "unsuitable for a surgical intervention and that commercially available TAVR devices would not provide meaningful benefit to the patient".

The company said the surgical team determined Duravr would "offer the only alternative in this case" and, following compassionate use approval, the patient underwent the 'valve-in-valve-in-valve' procedure and was successfully treated.

Anteris chief medical officer Dr Chris Meduri said that "in native aortic stenosis patients we are achieving normalized pre-disease haemodynamics as well as normal flow beyond what has been achieved in the past".

"In the near future 30 percent of the TAVR market will be patients needing a second replacement," Dr Meduri said.

Anteris fell 28 cents or 1.4 percent to \$20.22.

RECCE PHARMACEUTICALS

Recce says it has dosed the first volunteers at the highest rate of 4,000mg intra-venous dose over 20-minutes in its phase I/II trial of R327 for urinary tract infection.

In April, Recce said it had approval to dose six-participants in its phase I/II urinary tract infection and urosepsis trial at an intra-venous 4,000mg of R327 over 30-minutes and identified 30-minutes as "the potential optimum infusion time and increased to a higher concentration ... to investigate R327's high concentration potential" (BD: Apr 26, 2024). Today, the company said that 4,000mg was the "highest dose tested in participants in this trial with minimum inhibitory concentration activity against bacteria already identified among existing clinical samples, with this increase in dose optimization an important exercise for regulatory purposes".

Recce said the remaining participants in the cohort would be dosed "over the coming days", with full efficacy data for intra-venous R327 to be made available at the completion of the trial in line with study protocol.

Recce fell one cent or 1.6 percent to 61 cents.

ARGENICA THERAPEUTICS

Argenica says a study of ARG-007 for moderate traumatic brain injury shows it "significantly reduced damage to brain cells" in ferrets.

Argenica said it had partially-funded the study, conducted by the University of Adelaide, which was designed to assess the therapeutic potential of ARG-007 in protecting brain cell, or neuron, integrity using ferret models of traumatic brain injury.

The company said ferret brains "more closely resemble the gross anatomy of the human brain with respect to features such as sulci and gyri, the raised and folded structures, in the cerebral cortex and white matter content compared with the rodent brain" and was more likely to replicate the outcomes of traumatic brain injury in humans.

Argenica said the study showed ARG-007 could "significantly reduce damage to the axons of brain cells as measured by amyloid precursor protein and neuro-filament M-14.9 accumulation, both validated biomarkers of axonal injury".

The company said the treatment was able to "significantly reduce the expression of key inflammatory markers in microglia [and, or] macrophages and astrocytes post-injury in areas of the brain responsible for memory and mental functioning" as well as improved motor function in a balance and coordination test post-injury.

Argenica said the study expanded on previous published and announced data in rodent models and provided it "with further robust evidence regarding the potential of ARG-007 as a treatment following [traumatic brain injury]".

The company said it would "continue to advance the pre-clinical efficacy studies in [traumatic brain injury] including validating this study in a larger ferret study". Argenica managing-director Dr Liz Dallimore said the data showed "ARG-007 had significant potential as a therapeutic drug following [traumatic brain injury]". Argenica was up six cents or 9.2 percent to 71 cents.

AMPLIA THERAPEUTICS

Allan Moss and Blueflag Holding say they have bought 5,389,000 shares in Amplia, taking their substantial holding to 18,861,500 shares, but been diluted to 6.94 percent. The Sydney-based former Macquarie Bank managing-director, Mr Moss, and Blueflag said they bought the shares in a rights issue for \$296,395, or 5.5 cents a share, and were diluted by the company's issue of shares (see above).

TRAJAN GROUP

MA (Moelis Australia) Financial Group says it has become substantial in Trajan with 8,332,632 shares or 5.47 percent.

The New York-based MA said it bought shares between June 20, 2023 and May 13, 2024, with the most recent purchase 693,440 shares for \$554,817 or 80 cents a share. Trajan was up 5.5 cents or six percent to 96.5 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Zheng Yang Biomedical Technology and Cambium director Dr Sebastian (Yu-Hung) Tseng say they have become substantial with 99,677,861 shares (13.02%). The Taipei, Taiwan-based Zheng Yang and Dr Tseng said that on April 5, 2024 they received 30,414,723 shares for no consideration in the then Regeneus' merger and on April 10, 2024 bought 69,263,138 shares for \$415,579, or 0.6 cents a share. Cambium was up 0.1 cents or 16.7 percent to 0.7 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

The Taipei, Taiwan-based Cyntec Co Ltd says it has become substantial in Cambium with the 62,966,489 shares, or 8.2 percent.

Cyntec said with parent-company Orient Europharma Co Ltd it bought 62,966,489 shares on April 10, 2024 for \$377,799, or 0.6 cents a share.

HARRY PERKINS INSTITUTE OF MEDICAL RESEARCH

The Harry Perkins Institute says it has appointed the City of Canning corporate and commercial director Lorraine Driscoll to its board.

The Perth-based Harry Perkins Institute said Ms Driscoll was a director of Basketball Western Australia and had served on the board of Visibility Association for the Blind Inc and been company secretary for the Asia Pacific Lottery Association.