

Biotech Daily

Wednesday May 10, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: PROTEOMICS UP 11%; AMPLIA DOWN 10%
- * FEDERAL BUDGET DETAILS, COMMENT & RESPONSE
 - BIOTECH DAILY, MTP CONNECT, ATSE, AAMRI, AUSBIOTECH
- * NEW SOUTH WALES UNIVERSITY PARKINSON'S PREDICTION SOFTWARE
- * ONCOSIL RIGHTS RAISE \$9.9m
- * CYNATA 'OVERSUBSCRIBED' SHARE PLAN RAISES \$2.05m; TOTAL \$7.05m
- * COGSTATE PROFIT WARNING, TO CUT STAFF 13%, COSTS
- * PROTEOMICS: SONIC HEALTHCARE US PROMARKERD DISTRIBUTOR
- * PHARMAUST: STABLE MONEPANTEL EARNS MND \$119k
- * ALTERITY TREATS 1st AUSTRALIAN ATH434 MSA PATIENT
- * AUDEARA TO RELEASE 41m ASX ESCROW SHARES
- * MAYNE PHARMA TO BUY-BACK UP-TO 10% OF SHARES
- * RESPIRI TELLS ASX 4C QUERY: 'PLANNING AN EQUITY RAISE'
- * CRESO TELLS ASX: 'PSILOCYBIN, HEALTH HOUSE PUSHED PRICE 50%'
- * YARRA CAPITAL TAKES 6.3% OF NANOSONICS
- * JENCAY INCREASES, DILUTED TO 7% OF NOVA EYE
- * PLANET INNOVATION DILUTED TO 23% OF LUMOS

MARKET REPORT

The Australian stock market fell 0.12 percent on Wednesday May 10, 2023, with the ASX200 down 8.4 points to 7,255.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and one was untraded. All three Big Caps rose.

Proteomics was best, up 10 cents or 11.1 percent to \$1.00, with 849,681 shares traded. Mesoblast climbed 4.8 percent; Alcidion, Cynata and Telix were up more than three percent; Clinuvel, Dimerix and Starpharma rose more than two percent; CSL was up 1.1 percent; with Cochlear, Neuren, Opthea, Paradigm and Resmed up less than one percent.

Amplia led the falls, down 1.1 cents or 10 percent to 9.9 cents, with 175,819 shares traded. Kazia lost 5.3 percent; Universal Biosensors fell 4.3 percent; Micro-X, Pharmaxis and Uscom were down more than three percent; Antisense, Genetic Signatures, Immutep, Impedimed, Prescient and Volpara shed two percent or more; Medical Developments and Polynovo were down more than one percent; with Avita, Cyclopharm, Nanosonics, Next Science and Pro Medicus down less than one percent.

FEDERAL BUDGET 2023

Federal Treasurer Dr Jim Chalmers' second Budget did not mention biotechnology but the Budget Papers say there will be increased spending on related measures.

Dr Chalmers' Budget speech included incentives for small business and lowering the cost of living for working Australians, as well as balancing the budget and bringing it back to "a small surplus" in 2022-'23 to be followed by small deficits in following years.

Dr Chalmers spoke of cost-of-living relief including improvements to the Medicare national health service, funding for Technical and Further Education places as well as child care and paid parental leave. He mentioned the \$15 billion National Reconstruction Fund, to support "green industries, manufacturing and more" but focussed on renewable energy.

The Papers said that the cost of the Research and Development Tax Incentive were "expected to increase over the period 2023-'24 to 2026-'27 due to the increases in [the] number and value of expected claims following the reopening of international markets post Covid-19" by \$176 million in 2023-'24 and \$942 million over four years to 2026-'27.

The Budget Papers said the Medical Research Future Fund (MRFF) managed by the Future Fund Board had an investment mandate of the Reserve Bank of Australia's Cash Rate target plus 1.5 to 2.0 percent per annum, net of costs, over a rolling 10-year term.

The Budget Papers said that since inception to March 31, 2023, MRFF investments returned 4.0 percent per annum against a benchmark return of 2.6 percent, but for the 12-month period ending March 31, 2023, the MRFF's return was 1.3 percent against the benchmark return of 3.5 percent.

The Budget Papers said the MRFF was valued at \$21.7 billion as at March 31, 2023.

The Budget Papers said that "directing savings from the closure of the Entrepreneurs' Programme into the new Industry Growth Program ... [would] focus on operating in the priority areas of the National Reconstruction Fund".

The Papers said that the National Reconstruction Fund had seven priority areas including medical science and the new \$392.4 million Industry Growth Program would "support Australian small to medium-sized enterprises and start-ups to commercialize their ideas and grow their operations" in the priority areas of the National Reconstruction Fund.

The Government said it would "support the resilience of nuclear medicine supply chains through the design and construction of a new, safe and reliable nuclear medicine manufacturing facility and sustainment of existing capabilities".

"Nuclear medicine is critical to Australia's health system, touching the lives of thousands of Australians each year," the Budget Papers said. "Maintaining a nuclear medicine sovereign capability will reduce the risk of unplanned supply disruptions and promote positive health outcomes for Australians, especially in regional areas."

The Budget Papers said \$91.1 million would be provided over two years to establish the Australian Centre for Disease Control, within the Department of Health and Aged Care.

BIOTECH DAILY EDITORIAL

The Federal Budget had very little directly for the biotechnology sector.

There is a share of the \$392.4 million Industry Growth program and some incentives for small to medium sized businesses, with a bit for climate change and information technology.

We might be pleased that there were no cuts to any programs, other than Entrepreneurs Programme funds being transferred to the Industry Growth Program.

The Budget appeared to have two aims: redirecting funds to reducing the cost of living through funding Medicare, cheaper prescriptions, greater access to child care, increased benefits and others which are good for all businesses; and making the Labor Government look like it can manage the economy.

The \$400 billion commitment for already obsolete submarines could be re-directed to useful innovation – including in biotechnology.

But we guess that Industry Minister Ed Husic didn't get much of a look-in, when it came to framing this Budget.

David Langsam, Editor

MTP CONNECT

MTP Connect says the 2023 Federal Budget "includes a welcome commitment to the establishment of a new \$392.4 million Industry Growth Program".

The Budget Papers said that the Program was for the seven priority sectors, which were medical science; renewables and low emissions technologies; transport; value-add in the agriculture, forestry, and fisheries sectors; value-add in resources; defence capability; and enabling capabilities.

MTP Connect chair and former Victoria Labor Health Minister Jaala Pulford said the program, "supported by substantial ongoing funding, will help turbocharge the commercialization journey of medical science start-ups and [small and medium sixed enterprises]".

"We welcome the Australian Government's commitment to establishing the Industry Growth Program," Ms Pulford said.

"In a tough budget environment, it's a welcome commitment to the potential of the [medical technologies and pharmaceuticals] sector to deliver new, high paying jobs and economic growth, through the development and commercialization of new medicines and medical devices," Ms Pulford said.

"The Industry Growth Program has the potential to work hand-in-glove with the National Reconstruction Fund, providing integrated support throughout a company's commercial lifecycle," Ms Pulford said.

AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING

The Australian Academy of Technological Sciences and Engineering welcomed measures for science and technology but called for further strategy and investment.

ATSE chief executive officer Kylie Walker said that "time is of the essence for Australia to grow as a leading innovation nation, rapidly decarbonize our economy and become a global renewable energy powerhouse".

Ms Walker said that innovation was "the life-blood of economic, social, health and environmental progress".

"We have a time-bound opportunity to bring together Australia's ingenuity and abundant natural assets to truly leverage our renewable energy advantage," Ms Walker said.

"The figures released in April have shown a continued decline in research and development spending with total government spending on [research and development] reaching a low of 0.49 percent of GDP" Ms Walker said.

"The Australian Research Council and the Universities Accord Reviews have shown that Australian research is in crisis and our potential to lead the world in renewable energy is being left largely untapped," Ms Walker said.

"In next year's budget, we hope to see a commitment to lifting research funding to international competitive levels," Ms Walker said.

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

The Association of Australian Medical Research Institutes welcomed "ongoing support for medical research in the latest Federal Budget".

AAMRI president Prof Kathryn North and chief executive officer Dr Saraid Billiards welcomed "the new and ongoing investments announced in ... [the] Budget".

"Our mid-career researchers are tomorrow's scientific leaders," Prof North said. "Australia has invested so much in this talented group, and without action to support them, we will lose them and the value they bring to our nation's future scientific breakthroughs."

The Association said that "every time a highly skilled researcher is unable to secure funding to continue their research, more than 15 years of past training and expertize is lost from medical research".

AAMRI said it was looking forward to the consultation process for a national health and medical research strategy on how to govern the two major government funding sources: the Medical Research Endowment Account and the Medical Research Future Fund.

Dr Billiards said the consultation was critical to ensure a clear plan for Federal medical research funding that's prioritized and allocated in a way that benefits all Australians and "supports and develops a thriving health and medical research workforce".

AUSBIOTECH

Ausbiotech says it welcomes enhanced support for small and medium sized enterprises and start-ups, with the establishment of an Industry Growth Program.

Ausbiotech said that the program would provide advice and matched grant funding from \$50,000 to \$5 million to develop a pipeline of investment-ready projects for the National Reconstruction Fund to consider.

The organization said it was "pleased to see \$18.1 million over four years ... for the Buy Australia plan to provide tools, increase engagement and encourage greater access and transparency to tender processes ... [which] might provide greater access to procurement, which would offer the biotech sector much needed demand security for those in the process of technology development"

Ausbiotech said it was "interested to see the provision of \$116 million over five years to support artificial intelligence and quantum growth" along with \$3.2 million for the National Gene Technology Scheme.

The industry organization said that "notably missing from the Budget was mention of funding for Australia's One Stop Shop for clinical trials, a proposal that has been in development for many years ... to improve co-ordination and harmonization across jurisdictions, and offer a single point of access for clinical trials".

Ausbiotech said it would continue to advocate for the initiative.

The organization said it was "disappointing to see that a sustainable funding model hasn't yet been offered to our world-class regulator" and hoped that funds for the Australian Therapeutic Goods Administration would be in future Budgets.

Ausbiotech said that "many in the industry will be discouraged to note that \$61 million has been slashed from the Export Market Development Grants as part of the Government's efficiency gains, and to also hear that the Government has formally indicated that the patent box measure will no longer proceed".

Ausbiotech chief executive officer Lorraine Chiroiu said the organization was "pleased to see enhanced support for [small and medium sized enterprises] and start-ups and the establishment of the Industry Growth Program to replace and expand on the Entrepreneur's Program.

Ms Chiroiu said there "a few notable disappointments" including that the previous Government's "patent box" regime to provide a 17 percent concessional tax rate for income derived from medical and biotechnology patents would no longer proceed.

"There was no mention of funding for Australia's One Stop Shop for clinical trials, a proposal aiming to improve coordination and harmonisation across jurisdictions and offer a single point of access for clinical trials, in spite of years of development and two years of consultation," Ms Chiroiu said.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says that with Boston University it has developed software that shows "promise" in detecting Parkinson's disease.

The University said researchers used a machine learning program to compare the metabolites in 39 blood samples from patients with Parkinson's diagnosis collected up to 15 years earlier and compared them with 39 control patients.

The University of New South Wales said the researchers found "unique combinations of metabolites that could prevent or potentially be early warning signs for Parkinsons".

The University said the software was called Crank-MS, an acronym for the classification and ranking analysis using neural network generates knowledge from mass spectrometry. A media release from the University said the system used neural networks to analyze biomarkers in bodily fluids which showed "early promise in detecting Parkinson's disease years before the first symptoms start appearing".

The University said the research, titled 'Interpretable Machine Learning on Metabolomics Data Reveals Biomarkers for Parkinson's Disease' was published in ACS Central Science and the full article was at: https://pubs.acs.org/doi/10.1021/acscentsci.2c01468.

Co-developer Prof Alexander Donald said that "Crank-MS can be readily applied to other diseases to identify new biomarkers of interest".

Prof Donald said validation studies were needed using larger cohorts before the software could be used reliably, but Crank-MS tool had been 96 percent accurate.

The University said the research showed the neuro-protectant metabolite triterpenoid was "found in lower concentrations in the blood of those who later developed Parkinson's disease compared to those who did not".

The University said triterpenoids regulated oxidative stress and were commonly found in foods such as apples, olives, and tomatoes, suggesting future studies examining whether eating these foods could protect against developing Parkinson's disease.

The University said the tool was publicly available to any researchers using machine learning for disease diagnosis using metabolomics data, with results generated in less than 10 minutes on a conventional laptop computer.

ONCOSIL MEDICAL

Oncosil says it has raised \$6,370,810 of a hoped-for \$9,892,423 placement at 1.0 cent a share, and has placed the \$3,521,612 shortfall with investors.

Earlier this year, Oncosil said it had a "binding commitment" for up-to \$2 million in a \$9.9 million rights offer and last month said Defender Asset Management had committed to subscribing up-to \$3 million of any shortfall (BD: Mar 17, Apr 21, 2023).

Today, the company said there would be on attaching option for every share bought, exercisable at 3.0 cents by April 30, 2027.

Oncosil was unchanged at one cent with 4.4 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has raised about \$2.05 million of a hoped-for \$2 million in an oversubscribed share plan following a \$5 million placement at 21.5 cents a share. Cynata said it scaled-back applications by 2.37 percent, and investors would receive one option for every two shares bought, exercisable at 30 cents each by April 1, 2025. Cynata said the \$7.05 million would be used for a planned phase II trial of CYP-001 in for acute graft-versus-host disease and working capital (BD: Apr 6, 2023). Cynata was up half a cent or 3.1 percent to 16.5 cents.

COGSTATE

Cogstate says about 13 percent of its fulltime workforce will "exit the company" to reduce annual costs by about \$2.6 million once the restructure is complete.

Cogstate said the restructure would incur a one-off cost of \$600,000 with most of the headcount reductions from its clinical trials and healthcare units and the remainder of the costs would be cut from operating expenses.

The company said it expected revenue for the year to June 30, 2023 between \$39 million to \$41 million, a nine to 11 percent reduction from the previous period, with net profit before tax expected between \$600,000 and \$1.6 million.

Last year, Cogstate said revenue for the year to June 30, 2022 was up 37.6 percent to \$US44,980,356 (\$A65,385,038) with net profit after tax up 83.7 percent to \$US10,692,600 (\$A15,543,142) (BD: Aug 30, 2022).

Cogstate chief executive officer Brad O'Connor said due to continued revenue delays in the clinical trials segment, the company was taking proactive steps to reduce its cost structure with the goal of improved earnings in 2024.

"As a result of technology investments in process automation that we have implemented over the last two years, and associated efficiency gains, the management team has confidence that our clinical trials business will be appropriately resourced post restructure, even allowing for anticipated revenue growth next year," Mr O'Connor said. Cogstate fell eight cents or 4.85 percent to \$1.57.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has an exclusive licence agreement with Sonic Healthcare USA for the use and distribution of its Promarkerd test for diabetic kidney disease in the US. Last year, Proteomics said it had a letter of intent with the Austin, Texas-based Sonic Healthcare USA for a US licence for its Promarkerd test, and in January extended that letter of intent to February 28, 2023 (BD: Aug 9, 2022 and Jan 31, 2023).

Today, the company did not disclose the commercial terms of the five-year agreement but said it was extendable, included royalties at a price set by Proteomics and provided terms for payment for Promarkerd reagents.

Proteomics managing director Dr Richard Lipscombe said the agreement with Sonic Healthcare USA was ideal to bring "Promarkerd technology to the world's premier healthcare market, potentially benefiting millions of patients with diabetes".

"The US is one of our key addressable markets and we expect this partnership to significantly increase the reach and adoption of Promarkerd through Sonic Healthcare USA's physician and patient focused channels," Dr Lipscombe said.

Proteomics was up 10 cents or 11.1 percent to \$1.00.

PHARMAUST

Pharmaust says an independent study of its monepantel tablets showing it could be stored for 12 months, earning a Fight Motor Neuron Disease milestone of \$118,927.

Pharmaust said the study by Catalent Pharma Solutions found that at a temperature of 25°C with 60 percent humidity, monepantel tablets could be kept for 12 months and remain within the specifications for human clinical trials.

The company said it would receive a further \$138,135 milestone payment for completing cohort three in its trial of monepantel for motor neuron disease and amyotrophic lateral sclerosis, and another \$150,143 for completing cohort four.

Pharmaust was up 0.2 cents or 2.5 percent to 8.3 cents with 1.7 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has treated the first patient in Australia in its 60-patient, randomized, double-blind, controlled, phase II trial of ATH434 for multiple system atrophy.

Previously, Alterity said it had enrolled patients in the trial in the UK, US, Italy and New Zealand (BD: Jun2, 2022; Mar 8, 16, Apr 4, 2023)

Today, Alterity chief executive officer David Stamler said the dosing of the first Australian patient was "an important milestone as [the trial is] now enrolling in five countries". Alterity was unchanged at 0.7 cents with 1.2 million shares traded.

AUDEARA

Audeara says it will release 40,800,678 shares from ASX escrow on May 18, 2023. According to its most recent filing, following the release from escrow Audeara would have 143,300,000 shares available for trading.

Audeara was unchanged at 4.8 cents.

MAYNE PHARMA

Mayne Pharma says it will conduct an on-market buy-back of up to 10 percent of the 85,074,288 shares on issue, funded by its current cash reserves.

Mayne said the timing and actual number of shares purchased under the buy-back would depend on the share price, market conditions and forecast future capital requirements. The company said the buy-back would start on May 25, 2023 and end on May 24, 2024. Mayne Pharma fell 37 cents or nine percent to \$3.74 with 500,848 shares traded.

RESPIRI

Respiri has told an ASX Appendix 4C Quarterly Report query that it is planning an equity raise to fund the next 12 months, as it increases its US revenue base.

The ASX asked Respiri if it expected to continue to have net operating cash outflows of about \$1,170,000 and if it would not have two quarters of cash, how it would improve and/or address its net operating cashflows during the June and September quarters? Last month, Respiri said it had customers receipts for the three months to March 31, 2023 of \$101,000, taking receipts for the six months to March 31 to \$111,000, with a cash burn of \$1,170,000 for the three months and cash and equivalents at March 31 of \$938,000. Today, Respiri said 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 ... RPM". Respiri was unchanged at 4.3 cents.

CRESO PHARMA

Creso has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said that Creso shares rose 50.0 percent from a low of 1.2 cents on May 8 to an intraday high of 1.8 cents on May 9, 2023 and noted a "significant increase" in the volume of shares traded.

Creso said it had announced results from a phase II trial of psilocybin for post-traumatic stress disorder by subsidiary Halucenex Life Sciences and that it had completed the acquisition of Health House International.

Creso was up 0.4 cents or 25 percent to two cents with 98.3 million shares traded.

NANOSONICS

Yarra Capital Management Ltd and related parties say they have increased their holding in Nanosonics from 15,142, 937 shares (5.02%) to 19,055,009 shares (6.30%). The Melbourne-based Yarra Capital said between May 24, 2022 and May 5, 2023 it bought 7,497,051 shares for \$32,297,222, or an average of \$4.31 a share and sold 3,584,979 shares for \$15,496,401, or an average of \$4.32 a share. Nanosonics fell one cent or 0.2 percent to \$5.38 with 424,206 shares traded.

NOVA EYE MEDICAL

Jencay Capital Pty Ltd says it has increased and been diluted in Nova Eye from 11,465,423 shares (7.98%) to 13,287,956 shares (6.98%).

In March, Nova Eye said it had commitments for an \$8 million placement at 18 cents a share (BD: Mar 2, 2023).

Today, the Sydney-based Jencay Capital said that between April 9, 2020 and May 5, 2023 it bought 1,822,533 shares for \$432,044, or an average of 23.7 cents a share and was diluted in a placement.

Nova Eye was unchanged at 25 cents.

LUMOS DIAGNOSTICS HOLDINGS

Planet Innovation Holdings Ltd says its 68,021,060 substantial share-holding in Lumos has been diluted from 28.42 percent to 23.34 percent.

Melbourne's Planet Innovation said that between March 14, 2023 and May 4, 2023 its holding in Lumos was diluted by 5.08 percent due to a convertible notes conversion. Last year, Lumos said it had an \$8 million, two-year, convertible note facility with Lind Partners and SBC Global Investment Fund (BD: Nov 21, 2022). Lumos was unchanged at 1.9 cents.