

Biotech Daily

Wednesday October 26, 2022

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: VOLPARA UP 10%; USCOM DOWN 7%
- * FEDERAL BUDGET DETAILS; COMMENT & RESPONSE
- * AUSBIOTECH PERTH CONFERENCE OPENS: AUSBIOINVEST
- * POLYNOVO TAKES NOVOSORB BTM TO HONG KONG FOR ASIA
- * NEUROTECH CLAIMS MARIJUANA NTI164 EFFICACY FOR AUTISM
- * ARGENICA DOSES 1st ARG-007 PHASE I COHORT
- * IMMUTEP IMP321 HNSCC TRIAL CONTINUES UNCHANGED
- * PARADIGM DOSES 1st UK PPS OSTEOARTHRITIS PATIENT
- * INVION PHOTOSOFT ACTIVE 'AGAINST BACTERIA, FUNGUS' IN-VITRO
- * AROVELLA TO CLOSE PERTH OROMIST R&D FACILITY
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- * BOTANIX RECEIVES \$3.7m FEDERAL R&D TAX INCENTIVE
- * LBT RECEIVES \$1.2m FEDERAL R&D TAX INCENTIVE
- * ONE FUNDS TAKES 13% OF IDT
- * HARBOUR TAKES 5% OF AROA
- * MEDIBIO APPOINTS DAVID TRIMBOLI CHAIR

MARKET REPORT

The Australian stock market was up 0.18 percent on Wednesday October 26, 2022, with the ASX200 up 12.3 points to 6,810.9 points.

Fourteen of the Biotech Daily Top 40 were up, 13 fell, nine traded unchanged and four were untraded.

Volpara was the best, up six cents or 9.8 percent to 67.5 cents, with 316,200 shares traded. Resonance rose 8.3 percent; Cynata was up 4.7 percent; Clinuvel and Emvision climbed more than three percent; Imugene and Pro Medicus improved more than two percent; Antisense, Impedimed, Nanosonics, Orthocell and Telix were up more than one percent; with Avita, Cochlear, Paradigm and Resmed up by less than one percent.

Uscom led the falls, down 0.4 cents or 7.3 percent to 5.1 cents, with 291,878 shares traded. Starpharma lost 5.3 percent; Next Science fell 4.6 percent; Kazia, Neuren and Polynovo were down three percent or more; Dimerix, Oncosil and Opthea shed two percent or more; Mesoblast and Pharmaxis were down more than one percent; with CSL, Medical Developments and Proteomics down by less than one percent.

FEDERAL BUDGET: COMMENT & RESPONSE

Federal Treasurer Jim Chalmers' first Budget focussed on the cost of living, housing, child care and Budget repair, but with some spending on medical research and manufacturing. Dr Chalmers said that the \$15.0 billion National Reconstruction Fund would "help lift the speed limit of our economy, boosting supply chains and Australia's industries, creating jobs and growing rural and regional Australia".

A media release from the Federal Minister for Industry and Science Ed Husic said that the Fund would "deliver targeted co-investments in independently assessed projects across seven priority areas: resources; agriculture, forestry and fisheries; transport; medical science; renewables and low emission technologies; defence capability; and enabling capabilities".

Mr Husic said the Government would consult with industry, unions and stakeholders to ensure the Fund was appropriately designed and targeted to maximise the benefits of the \$15 billion investment.

Treasury Budget papers said that expenses for the Research and Development Tax Incentive administered by the Australian Taxation Office were "expected to remain constant in real terms from 2022-'23 to 2025-'26, reflecting the number and size of expected claims from eligible companies with an annual turnover of less than \$20 million". The Budget papers said that the Government would provide \$452.0 million over six years from 2022-'23 for cancer centres in Brisbane and Adelaide, with \$4.0 million to develop a medical research centre within the Launceston General Hospital in Tasmania. In the Budget speech, Dr Chalmers said the Government would provide 480,000 fee-free places at Technical and Further Education (TAFE) centres and a \$50 million TAFE Technology Fund for modernization, along with 20,000 additional university places for disadvantaged Australians.

Federal Health Minister Mark Butler said the Government was "making medicines cheaper for Australian households" with the maximum cost of general prescriptions under the Pharmaceutical Benefits Scheme to fall from a maximum co-payment of \$42.50 to \$30.00 from January 1, 2023.

BIOTECH DAILY EDITORIAL OPINION

There is not much to say about Federal Treasurer Dr Jim Chalmers first Budget, because very little directly impacts the biotechnology sector.

The forward estimates appear to maintain both the Ausbiotech-Labor Government Research and Development Tax Incentive and the Abbott-Hockey Liberal-National Party Government \$20 million Medical Research Future Fund.

Similarly, it appears that the budgets for the Commonwealth Scientific and Industrial Research Organisation, the National Health and Medical Research Council and the Australian Research Council are being maintained.

There is \$456 million for medical research in Adelaide, Brisbane and Launceston.

Medical manufacturing is one part of the \$15 billion infrastructure fund, yet to be developed, and the life sciences sector should benefit from the 'Made in Australia' program, if companies are able to capitalize on it.

But the major benefits of the Budget for biotechnology are downstream. A number of programs, including cheaper childcare, paid parental leave, better aged care and more university and Technical and Further Education (TAFE) places will improve the lives of staff, including board and management, as it will for all companies.

The bigger economic picture, including small wage rises and some element of inflation are nothing new to business in general, or to our sector. Increased costs will be passed-on.

In terms of reimbursement for drugs, diagnostics and devices, the Federal Labor Government will have to turn its attention to repairing and improving Medicare and hospitals to ensure that patients see their doctors and are treated to the highest possible standards. Thankfully, this is core Labor policy.

David Langsam Editor

AUSBIOTECH

Ausbiotech says that the Budget "delivered on the Government's election promises, confirming a range of commitments with a notable cut to the Entrepreneurs' program".

Ausbiotech said the sector was not mentioned in top-line announcements but "programs around resilience still place medical science as a key priority area".

The industry organization said it welcomed support for the Australian Therapeutic Goods Administration modernization, despite minor changes to cost recovery.

Ausbiotech said there was "a concerning cut to the Entrepreneurs' Programme" and while the cuts were aimed at the delivery process, it would cut 75 percent of the program's funds and it was "unclear at this stage if it leaves a workable program".

AUSBIOTECH

Ausbiotech says its 2022 Conference and Ausbioinvest began in Perth today with "record numbers of life science delegates" including more than 1,000 registered attendees.

Ausbiotech said that the one-day Ausbioinvest investment conference on Thursday October 27, had more than 300 companies registered.

The industry organization said that the three-day event included more than 160 speakers at more than 40 sessions.

Ausbiotech said that Ausbioinvest had 29 companies, from early to late-stage, actively seeking investors or partners to support their funding and co-development, and would hear from Vida Ventures co-founder Dr Arjun Goyal and Arch Venture Partners principal Dr Nilay Thakar.

The industry organization said that ASX listing general-manager James Posnett would discuss "opportunities and headwinds for Australian life sciences".

Ausbiotech said that the Western Australia State Government had three ministers in attendance, including Deputy Premier Roger Cook, the Minister for Innovation and ICT, Medical Research; Emergency Services and Volunteering Stephen Dawson and the Minister for Health Amber-Jade Sanderson.

The Ausbiotech Conference program is available at:

https://www.ausbiotechnc.org/conference-programme-2022; and the Ausbioinvest program is at: https://www.ausbiotechinvestment.com.au/2022-programme.

POLYNOVO

Polynovo says that two wound treatments completed in Hong Kong, signal its intention to "lift the priority of pursuing India, China, Japan, and other jurisdictions".

Polynovo said one patient was a reconstruction case and the other a 33 percent partial/full thickness burn, treated with Novosorb biodegradable temporizing matrix (BTM).

The company said it intended to send staff to Hong Kong to determine the ongoing resources needed to increase sales.

Polynovo chair David Williams said "Hong Kong is an exciting market for Polynovo, and also provides access to patients from the Greater Bay Area" which included Guangdong, Hong Kong and Macau.

"We also see this as a window for patients from the mainland while awaiting regulatory approval in China," Mr Williams said. "We are following the lead of companies like China Grand who purchased Sirtex and are treating mainland patients in Hong Kong."

Polynovo fell seven cents or 3.6 percent to \$1.875 with 2.5 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says 20-week data from its 14-patient phase I/II trial of its medical marijuana NTI164 shows "statistically significant efficacy" in children with autism.

Neurotech said that over the 20-week treatment period, severity of illness as measured by the clinical global impressions scale decreased by 26 percent from baseline (p = 0.005), with similarly significant outcomes in children's anxiety (p = 0.001), social responsiveness (p = 0.012) and adaptive behavior (p = 0.0005).

The company said that the low tetrahydrocannabinol (THC) and combined cannabinoids NTI164 was safe and well-tolerated at the maximum dose for each patient.

Neurotech said it had filed a clinical trial protocol with Monash University to begin a phase II/III trial of NTI164 in about 55 children with autism spectrum disorder.

Neurotech was untraded at 13 cents.

ARGENICA THERAPEUTICS

Argenica says the first cohort of eight healthy subjects of its phase I trial of ARG-007 has been successfully dosed, indicating "good safety and tolerability".

Last week, Argenica said it had dosed the first of 32 subjects in the dose-escalation trial, assessing the safety and tolerability of intra-venous ARG-007 (BD: Oct 17, 2022).

Today, the company said that subject to review from its safety committee, it intended to begin dosing its second cohort immediately, commencing with a sentinel subject.

Argenica was up one cent or two percent to 51 cents.

IMMUTEP

Immutep says its 154-patient, phase IIb trial of IMP321, or eftilagimod alpha, with pembrolizumab in squamous cell carcinoma will continue unchanged. Immutep said the data monitoring committee reviewed safety data from 47 patients. Immutep was unchanged at 28 cents.

PARADIGM PHARMACEUTICALS

Paradigm says it has dosed the first subject in its phase III trial of injectable pentosan polysulfate sodium, or Zilosul, for knee osteoarthritis pain.

In January, Paradigm said it had dosed the first two of 930 patients in the randomized, double-blind, placebo-controlled trial (BD: Jan 16, 2022).

Today, the company said it intended to dose subjects at seven sites in the UK, with a further eight in Australia, and 58 in the US.

Paradigm chief medical officer Dr Donna Skerrett said that the first patient dosed outside the US and Australia was "another important milestone in our global phase III program." Paradigm was up one cent or 0.8 percent to \$1.29.

INVION

Invion says its Photosoft light therapy compounds show activity against antibiotic-resistant Staphylococcus aureus, Escherichia coli and Candida albicans fungus, in vitro. On Monday, Invion said in-vitro studies showed eight out of 10 Photosoft photo-dynamic

compounds displayed anti-viral activity against the Dengue virus after exposure to light (BD: Oct 25, 2022).

Today, the company said five of the seven Photosoft compounds tested against two strains of methicillin-resistant Staphylococcus aureus bacteria showed anti-microbial activity and the same five compounds "were very active against two Candida albicans strains" and showed "potential" against Escherichia coli.

Invion was unchanged at 1.05 cents with four million shares traded.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says it will close its Perth-based Oromist research and development facility by April 2023 and focus on its invariant natural killer T-cell program.

In 2012, the then Suda acquired the Novamist sublingual technology platform to develop spray formulations of existing drugs (BD: Dec 21, 2012).

Arovella said a review determined that closing the Oromist program would save about \$1.5 million a year, with the facility closure incurring one-off costs of up to \$300,000. Arovella was up 0.1 cents or 3.3 percent to 3.1 cents with 1.8 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says the Beloit, Wisconsin-based Northstar Medical Radioisotopes will supply it with actinium-225 over a term of 10 years.

In February, Radiopharm said it had a supply agreement with the Bellevue, Washington-based Terrapower for actinium-225 isotopes for its drug pipeline (BD: Feb 1, 2022). Today, the company said actinium-225 was integral to the development of "several radiopharmaceutical products within Radiopharm's broad portfolio of activities" and would be used in drug trials involving targeted alpha therapy in multiple disease areas. Radiopharm fell one cent or 8.3 percent to 11 cents with 3.1 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the re-election of Brenda Shanahan at its annual general meeting was opposed by 5,235,136 votes (23.23%) with 17,299,815 votes (76.77%) in favor. Clinuvel said the remuneration report was opposed by 18.54 percent of the meeting with Prof Andrew Likierman elected overwhelmingly.

According to its most recent filing, Clinuvel had 49,410,338 shares on issue, meaning that the opposition to Ms Shanahan's re-election amounted to 10.6 percent of the company, sufficient to requisition extraordinary general meetings.

Clinuvel was up 73 cents or 3.9 percent to \$19.40 with 80,444 shares traded.

ONCOSIL MEDICAL

Oncosil says the adoption of its remuneration report faced 46,481,822 opposition votes (20.0%) at its annual general meeting, with 185,978,070 votes (80.0%) in favor.

The company said all other nine resolutions passed more easily.

On Monday, Oncosil said that director Dr Martin Cross had resigned, with two resolutions to be withdrawn from the annual general meeting (BD: Oct 24, 2022).

According to its most recent filing, Oncosil had 991,242,262 shares on issue, meaning that the 46,481,822 votes against the remuneration report amounted to 4.7 percent of the company, not sufficient to requisition an extraordinary general meeting.

Oncosil fell 0.1 cents or two percent to 4.9 cents.

CRONOS AUSTRALIA

Cronos says Elizabeth Jansen has withdrawn her proposed resolution to appoint Dr Benjamin Jansen a director of the company

Last month, Cronos said it received a notice from Matua Hasyo Charlie Jansen as trustee for the Whanau Family Trust calling for the removal of directors chief executive officer Rodney Cocks and director and chief commercial officer Guy Headley (BD: Sep 20, 2022). The company told Biotech Daily that Dr Jansen was a founder of Cannabis Doctors Australia, which it acquired in 2021, and a former doctor with Cannabis Doctors Australia. Also in September, Cronos said that chief medical officer and director Dr Benjamin Jansen, a founding director of Cannabis Doctors Australia "ceased his position" and later that month, the company said it had received a Section 249N notice to appoint Dr Benjamin Jansen as a director (BD: Sep 23, 28, 2022).

Today, Cronos said that as a result of the withdrawal of Ms Jansen's notice, investors would not be asked to consider the proposal at its annual general meeting. The company told Biotech Daily that the earlier requisition currently stands.

Cronos fell six cents or 6.25 percent to 90 cents.

BLUECHIIP

Bluechiip says its annual general meeting will vote to issue 4,900,000 performance rights to managing-director Andrew McLellan.

Bluechiip said the rights would vest in three equal tranches, contingent on the company's share price increasing at or above the ASX small ordinaries accumulation index.

The company said investors would vote on the remuneration report, the election of director Michael Ohanessian, the performance rights plan and a new constitution.

Bluechiip fell 0.1 cents or three percent to 3.2 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has received \$3,669,439 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Botanix said the rebate related to expenditure for the year to June 30, 2022.

Botanix was unchanged at 6.3 cents.

LBT INNOVATIONS

LBT says it has received \$1,206,058 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

LBT said the rebate related to expenditure for the year to June 30, 2022.

LBT was up 0.1 cents or 1.6 percent to 6.2 cents.

IDT AUSTRALIA

One Funds Management says it has increased its substantial shareholding in IDT from 27,998,434 shares (11.67%) to 31,777,934 shares (13.19%).

The Sydney-based One Funds said that on October 21, 2022 it bought 3,779,500 shares for \$781,535 or 20.7 cents a share.

IDT was up 0.1 cents or one percent to 10 cents.

AROA BIOSURGERY

The Wellington, New Zealand-based Harbour Asset Management says it has become substantial in Aroa with 18,000,512 shares, or 5.252 percent of the company. Harbour said that between July 28 and October 25, 2022, it bought 2,095,042 shares for \$1,777,532, or 84.85 cents a share.

Aroa fell four cents or 4.5 percent to 85 cents.

MEDIBIO

Medibio says it has appointed two-month director David Trimboli as its chair.

In June, Medibio managing-director Claude Solitario resigned and was replaced as chief executive officer by Dr Thomas Young last month (BD: Jun 22, Sep 19, 2022).

In 2014, Medibio backdoor-listed into the former Bioprospect to commercialize its claimed heart rhythm diagnostic for depression (BD: Oct 27, 2014).

Medibio fell 0.05 cents or 33.3 percent to 0.1 cents.

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