Biotech Daily

Wednesday March 30, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: VOLPARA UP 9.5%; TELIX DOWN 6%**

*** BUDGET 2022: FURTHER DETAILS, COMMENT & RESPONSE**
- AUSBIOTECH, GENESISCARE, INSULET, BIOTECH DAILY

*** GENETIC SIGNATURES $5.4m WELSH EASYSCREEN DEAL**

*** CLINUVEL DOSES 2nd AFAMELANOTIDE DNA REPAIR COHORT**

*** MEMPHASYS: INDIA, CHINA REPEAT FELIX CARTRIDGE ORDERS**

*** RECCE: 1000mg R-327 'SAFE, WELL-TOLERATED'**

*** RACE: ASTEX FREE ASTX727 FOR ZANTRENE AML, MDS TRIAL**

*** ARGENICA ARG-007 'PROTECTS ISCHAEMIC BRAIN DEATH, IN RATS'**

*** LIVING CELL, UNIVERSITY OF TECHNOLOGY SYDNEY OPTIMIZE NTCELL**

*** USCOM UNMARKETABLE PARCEL FACILITY BUYS BACK 269k shares**

*** TOTAL BRAIN, VARGA CONTINUE $700k LOAN TALKS**

*** PAINCHEK APPOINTS CYNTHIA PAYNE DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.67 percent on Wednesday March 30, 2022, with the ASX200 up 50.2 points to 7,514.5 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 12 fell and seven traded unchanged. All three Big Caps were up.

Volpara was the best, up eight cents or 9.5 percent to 92 cents, with 422,020 shares traded. Avita and Uscom climbed seven percent or more; Actinogen improved five percent; Antisense, Atomo, Emvision and Kazia were up four percent or more; Impedimed, Nanosonics, Orthocell and Pro Medicus were up more than three percent; Alcidion, Dimerix, Genetic Signatures, Immutep, Nova Eye and Oncosil rose two percent or more; Clinuvel, Cochlear, CSL and Universal Biosensors were up one percent or more; with Neuren and Resmed up by less than one percent.

Yesterday's 9.9 percent best, Telix, led the falls, down 27 cents or 5.9 percent to $4.29, with 1.7 million shares traded. Amplia, Pharmaxis and Prescient lost more than three percent; Cynata, Micro-X and Paradigm shed more than two percent; Medical Developments, Next Science, Opthea and Proteomics were down more than one percent; with Cyclopharm down by 0.3 percent.

FEDERAL TREASURY

In last night's Budget, Federal Treasurer Joshua Frydenberg said there would be new funds for mRNA vaccine manufacturing in Victoria, women's health and aged care initiatives (see BD: Mar 29, 2022; Special Budget Edition).

Mr Frydenberg said there would be greater access to cheaper medicines and small business would receive a 120 percent deduction for training employees and adopting digital technologies, along with subsidies for new apprentices and the employers who hired them.

Today, a Federal Treasury spokesperson told Biotech Daily that the $27 billion 100 percent capital expenditure write-off would conclude on July 1, 2023.

A Federal Treasury document said that the Government was "building on its reforms to employee share schemes, allowing more Australians to share in the value they create through their hard work".

The document supplied by Treasury said that currently, employee share schemes generally favored employees of listed companies and, in particular, senior managers, "because the current law imposes arbitrary caps on the number and value of options and shares that can be issued to employees of unlisted companies and junior employees".

"As part of reforms to employee share schemes to be introduced on Budget night: employees at all levels will be able to directly share in the value they help create; employees at all levels may obtain an unlimited number of shares with unlimited underlying value if safeguards are met," the Treasury document said.

The document said the changes would "codify and simplify what has been a complex regime and make it easier for businesses to establish [employee share schemes]".

FEDERAL MINISTER FOR HEALTH

The 'Biotechnology in Australia - strategic plan for health and medicine' was released by the Federal Minister for Health Greg Hunt, yesterday.

"This strategic plan represents the many ways in which the Australian Government will continue to support all parts of the research and development pipeline," Mr Hunt said.

"It provides incentives to grow Australian sovereign capacity and capability to research and manufacture locally while embedding into a growing international supply-chain for advanced medical products," Mr Hunt said.

"Australians have seen the growth of successful companies like the CSL, Resmed and Cochlear [and] I am confident that within the next decade we will see more such companies grow as shining examples of our success," Mr Hunt said.

AUSBIOTECH WELCOMES THE FEDERAL BUDGET

Ausbiotech said that the Federal Budget delivered “ongoing commitment to biotech”.

Ausbiotech said the Budget announcements included the ‘Biotechnology in Australia – Strategic Plan for Health and Medicine’, reflecting pre-Budget announcements for biotechnology and medical innovations, as well as a commitment to legislating and extending the ‘patent box’ tax deductions, strengthening the employee share scheme provisions, and support for the State of Victoria to manufacture mRNA vaccines.

The industry organization said that the Government would extend the Biomedical Translation Fund’s initial investments period by a further three years to support the commercialization of biomedical discoveries.

The industry organization said the updated $6.3 billion Medical Research Future Fund 10-year plan would provide research funding from 2022-’23, including a further $604.8 million for medical translation to support medical discoveries become part of medical practice; an extra $114.9 million, for researchers through investment, leadership and collaboration; a further $117.4 million to support innovative treatments, clinical trials, and more advanced health care and medical technology; and an extra $495.4 million, for breakthrough discoveries and for researchers to develop skills and progress their careers.

Ausbiotech said the Government will provide $988.2 million over five years to “drive university-industry collaboration, workforce mobility and research translation and commercialization” and $328.3 million over five years to support the Modern Manufacturing Strategy and National Manufacturing Priorities and address supply chain vulnerabilities.

GENESISCARE WELCOMES MRI FUNDS; GENOMICS AUSTRALIA

Genesiscare said it “welcomed a raft of measures outlined in this year’s Federal Budget’s health package, as a positive step in reducing the burden of cancer on the Australian community”.

Genesiscare said it was “the largest provider of integrated cancer care in Australia” and said it that it welcomed a raft of measures for diagnostic imaging services including: $66.0 million over four years to remove the restriction on the number of magnetic resonance imaging (MRI) machines eligible for Medicare in regional, rural and remote Australia; $24.8 million over four years for new and amended items for MRI services relating to the diagnosis of liver and breast cancers; $32.6 million over four years for a new item for positron emission tomography (PET) to inform treatment pathways for rare cancers; and $40.7 million over three years to address the reduction in testing and screening services due to the Covid-19 pandemic.

The company said it also welcomed “the significant investment in genomics research, including $28.1 million over four years to establish Genomics Australia to drive the translation and integration of genomics into the Australian healthcare system”.

Genesiscare is a private company.

INSULET ‘DISAPPOINTED’ NO FUNDS FOR TYPE 1 DIABETES OMNIPOD

Insulet, the inventor and distributor of the Omnipod Dash insulin management system, said it was disappointed that despite Ministerial assurances there were no funds for the type 1 diabetes system.

The Acton Massachusetts-based Insulet said that “given the demand by the type 1 diabetes community and the recent promise of funding by the Minister for Health [Greg Hunt in December 2021], the inclusion of Omnipod Dash System on the National Diabetes Services Scheme is a highly anticipated development”.

The company said there was “no confirmation of funding in the Federal Budget”.

Insulete said the Omnipod Dash included a wearable, tubeless insulin pod operated by a smartphone-like hand held controller, removing the need for multiple daily injections, and required “no mealtime math with built-in dosage calculations” with the pod carrying up to 72 hours of insulin.

Insulet said it was “Disappointed given no confirmation of access to Omnipod despite community pleas”.

“By being reimbursed on the [National Diabetes Services Scheme], the Omnipod Dash system would become more accessible and affordable for the diabetes community,” the company said.

BIOTECH DAILY: NOTHING DIRECT, BUT TANGENTIAL BENEFITS

The Federal Budget had no direct spending on the biotechnology sector, but funding for associated industries and other measures could benefit some companies.

Funding for aged care and the National Disability Insurance Scheme will be positive for a number of biotechnology companies, such as Painchek.

Continuation and expansion of the Medical Research Future Fund will assist our universities and research institutes and the companies with which they collaborate.

Biotech Daily sees the so-called ‘patent box’ tax deduction for successful companies as welcome, but a badly missed opportunity - as discussed in the 2021-’22 Budget.

Along with much of this pre-election spending Budget there are many small hand-outs but no structural change or new architecture.

A 150 percent tax deductibility for investment in particular projects would encourage investment. Companies would welcome the Research and Development Tax Incentive returning to the full 45 percent. The Government could establish an Independent Innovation Board to vet applications, rather than tinkering with the tick-box system.

David Langsam
Editor

GENETIC SIGNATURES

Genetic Signatures says it has an up-to $5.4 million three-year deal with Cardiff's Public Health Wales for supply of its Easyscreen diagnostics for enteric pathogens.

Public Health Wales is the UK National Health Service trust responsible for provision of health services in Wales.

Genetic Signatures said the agreement covered the provision of the Easyscreen diagnostics to seven hospitals across Wales, and included an option to extend for a further two years.

The company said there were about 685 million cases of norovirus each year, the most common cause of gastroenteritis, representing 20 percent of all cases.

Genetic Signatures said that outbreaks of gastroenteritis had been suppressed in the UK during the Covid pandemic, but it was predicted to return rapidly to pre-pandemic levels as restrictions were relaxed, with increasing numbers of outbreaks reported in childcare and aged care facilities.

Genetic Signatures chief executive officer Dr John Melki said that in awarding the contract Public Health Wales noted our "demonstrated flexibility regarding increasing the workload as needed plus the range of targets as factors supporting our application".

Dr Melki said that traction was building for non-severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) related business in Europe "after considerable effort by the sales teams, despite travel and other restrictions".

"It validates our strategy of targeting high throughput hospital and pathology laboratories and government programs to drive revenue and demonstrate the cost savings, speed and accuracy of our Easyscreen testing platform," Dr Melki said.

Genetic Signatures was up three cents or 2.6 percent to $1.20.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will dose a second cohort of six xeroderma pigmentosum patients in its CUV152, open-label, phase II trial of 16mg afamelanotide (Scenesse) for DNA repair.

Last year, Clinuvel said it had dosed its first of up to six xeroderma pigmentosum patients with afamelanotide in its CUV156 DNA repair pilot study examining safety and reduction in DNA damage (BD: Oct 22, 2021).

Today, the company said it would progress to a second cohort in the CUV152 study, of both xeroderma pigmentosum V (XPV) and xeroderma pigmentosum C (XPC) patients, with each patient receiving up to six doses of the 16mg afamelanotide implant over nine months "to confirm the ability of afamelanotide to protect DNA following ultra-violet and light induced damage".

Clinuvel head of clinical operations Dr Pilar Bilbao said "deficient DNA repair mechanisms place over two billion individuals globally at increased risk of skin cancer, and XP patients are at extreme risk of solar damage and skin cancer due to their genetic defects".

"Our innovative DNA repair program is evaluating whether afamelanotide can be safely administered to these patients to both reduce and repair DNA damage, with the ultimate goal of prolonging and improving their lives," Dr Bilbao said.

"Clinuvel's drug afamelanotide is the first ever systemic therapy to be evaluated in [xeroderma pigmentosum] patients, with clinical trials CUV152 and CUV156 now focused on XPV and XPC, respectively," Dr Bilboa said.

"In parallel, the mechanistic CUV151 study in disease-free subjects is providing further insights into afamelanotide," Dr Bilboa said.

Clinuvel said the trial was being conducted at three clinics in Europe.

Clinuvel was up 18 cents or 0.95 percent to $19.07 with 98,889 shares traded.

MEMPHASYS

Memphasys says it has its first Felix sperm selection follow-up sales from the Indian Women's Centre and China's Diagens Biotechnology Co.
In January, Memphasys said it sold the first of its Felix systems for in-vitro fertilization to the Coimbatore-based Indian Women's Centre (BD: Jan 17, 2022).
Today, the company said that while the dollar value was not material, the sale was of significant strategic importance to the company.
Memphasys said that this was the first time that any clinical in-vivo performance of the Felix System had been reported.
The company said it had a second sale of the Felix system and cartridges through its Hangzhou, China-based distribution partner Diagens.
Memphasys executive chair Alison Coutts said "it is very pleasing to receive repeat orders from existing clients, as it validates our business model and confirms the Felix system is proving effective in both research and clinical settings".
"We are now ramping up sales activities in the identified early markets, including engaging in an executive search process for a sales manager, to ensure the sales momentum continues," Ms Coutts said.
Memphasys was up half a cent or 7.1 percent to 7.5 cents.

RECCE PHARMACEUTICALS

Recce says a 1000mg dose of intravenous synthetic antibiotic candidate R-327 was safe and well-tolerated in 10 healthy male subjects.
In February, Recce said its third cohort of 10 healthy males in the trial of R327 at 500mg showed safety and tolerability (BD: Feb 21, 2022).
Recce said the dose in the fourth cohort was 20 times higher than the original 50mg dose given to the first cohort of its phase I trial.
The company said that an independent safety committee would review its data for the fourth cohort, but that it expected a recommendation to proceed to the fifth of eight cohorts from 50mg to 16,000mg, and was currently recruiting.
Recce chief executive officer James Graham said "achieving a dosing level of 1000mg is another significant milestone".
"Indicating R327 to be safe and well tolerated at a twenty-fold increase of the initial dosing level of 50mg is pleasing, not only for the unmet medical need of sepsis, but so too for synergies across our wider-infectious disease portfolio," Mr Graham said.
Recce was up half a cent or 0.5 percent to 95.5 cents.

RACE ONCOLOGY

Race says the Cambridge, UK-based Astex Pharmaceuticals will supply it with ASTX727 in a trial of Zantrene for acute myeloid leukaemia and high-risk myelodysplastic syndrome.
Race said Astex would provide ASTX727, an oral form of decitabine and cedazuridine, free of charge to Race for use in Australia, Italy, Spain, Germany and the US.
The company said additional countries might be included, subject to further agreement, and that Race and Astex would also enter into a separate safety data exchange agreement.
Race said that the agreement would facilitate its RAC-006, 60-patient, open label, phase II trial, which it said would be the first in the world to investigate the targeting of "Fatso-Fat mass and obesity associated protein" as a potential cancer treatment.
Race was up 11 cents or four percent to $2.85 with 415,344 shares traded.

ARGENICA THERAPEUTICS

Argenica says ARG-007 protects brain cells following blood flow disruption to the brain caused by global cerebral ischaemia, in rats.

Last year, Argenica said it was producing trial batches of ARG-007 as a stroke therapeutic for a proposed phase I trial (BD: Sep 15, 2022)

Today, the company said that ARG-007, administered after disruption of blood flow to the brain using a four-vessel occlusion rat model to mimic the pathological conditions of blood flow disruption to the brain, reduced cell death in hippocampal neurons in the brain.

Argenica said the animal study provided additional evidence of the neuro-protective potential of ARG-007 for new indications of cerebral ischaemia following cardiac arrest and cardiac surgery.

Argenica chief executive officer Dr Liz Dallimore said the company was “very encouraged by these results on the efficacy of ARG-007 in the [four-vessel occlusion] animal model”.

“Brain injury resulting from a reduction in blood flow to the brain following cardiac arrest and cardiac surgery can result in long-term neurological deficits in these patients,” Dr Dallimore said.

Dr Dallimore said the data provided further confirmation that ARG-007 could provide neuro-protection in applications beyond focal stroke, hypoxic ischaemic encephalopathy and traumatic brain injury.

“We will now consider ways to progress the results of this study into clinical studies,” Dr Dallimore said.

Argenica was up half a cent or 0.9 percent to 56.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says the University of Technology Sydney will optimize its NTCell encapsulated pig choroid brain cells for a clinical trial in Parkinson’s disease in 2024.

Living Cell said the University would optimize the NTCells in preparation for Australia’s first xeno-transplantation clinical trial, pending Australian Therapeutic Goods Administration and ethics approvals.

The company said the encapsulated pig choroid plexus cells would be imported from the Invercargill, New Zealand-based NZeno, optimized at University of Technology Sydney, and then manufactured at a good manufacturing practice facility.

Living Cell executive chair Prof Bernie Tuch said the optimization was “another key step as we advance this potentially ground-breaking research in Australia, following in the footsteps of New Zealand researchers.”

“Optimizing the production of encapsulation pig choroid plexus in Australia is a necessary measure before it is manufactured under [good manufacturing practice] conditions for the clinical trial,” Prof Tuch said.

Living Cell was up 0.1 cents or 14.3 percent to 0.8 cents with 2.96 million shares traded.

USCOM

Uscom says it has bought back 269,199 shares at 8.9 cents a share in unmarketable parcels worth $500 or less, held by 121 investors.

Uscom said the facility allowed investors with small parcels of stock to sell them without incurring brokerage fees.

Uscom was up 0.7 cents or 7.7 percent to 9.8 cents.

TOTAL BRAIN

Total Brain says it is negotiations with Hong Kong's Varga Capital regarding the potential extension of its $US500,000 ($A664,000) loan.
Last week, Total Brain said it had paid $560,462 in principal and interest to F45 Inc to finalize the repayment of a $US380,000 ($A514,806) loan and it had secured a five-day extension for its $US500,000 ($A675,616) loan with Varga (BD: Mar 22, 2022).
Today, the company said it expected to conclude negotiations by April 4, 2022.
Total Brain was up half a cent or 4.8 percent to 11 cents.

PAINCHEK

Painchek says it has appointed Cynthia Payne a non-executive director, effective from today.
Painchek said Ms Payne was the founder and current managing-director of Anchor Excellence, an aged care consultancy firm advising on operational and compliance best practices, an adviser to Total Constructions Pty Ltd and had spent 16 years as chief executive officer of a large private aged care provider in New South Wales.
The company said Ms Payne held a Bachelor of Applied Science (Nursing) and a Master of Business Administration from the University of New England, New South Wales.
Painchek fell 0.1 cents or 2.4 percent to 4.1 cents.