Biotech Daily

Wednesday February 1, 2023

Daily news on ASX-listed biotechnology companies

*** JANUARY BDI-40 UP 13%, ASX200 6%, BIG CAPS 4%, NBI 3.5%**

*** TODAY: ASX UP, BIOTECH EVEN: NOVA EYE UP 21%**
- NEXT SCIENCE DOWN 11%

*** MESOBLAST H1 RECEIPTS DOWN 34% TO $5m**

*** ANTERIS RECEIPTS DOWN 49.4% TO $4m**

*** EPSILON RECEIPTS DOWN 24% TO $3.8m**

*** ANALYTICA HAS 1 QUARTER CASH; PRODUCT SALES TALKS**

*** TOTAL BRAIN 95% VOTE TO DELIST, CAPITAL RETURN**

*** MESOBLAST RESUBMITS REMESTEMCEL-L GVHD FDA APPLICATION**

*** AMPLIA STARTS AMP945 PANCREATIC CANCER TRIAL COHORT 2**

*** ISLAND: 'FDA REQUIRES SMALL ASCENDING DOSE TRIAL, DATA'**

*** ANTISENSE COMBINATION MOUSE STUDY BACKS NEW PATENT**

*** RACE ZANTRENE CARDIO-PROTECTION TRIAL ETHICS APPROVAL**

*** MICROBA: 'LEAD MICROBIOME SPECIES REDUCE TUMORS, IN MICE'**

*** ENA, COPD FOUNDATION SURVEY BACKS ANTI-VIRAL NASAL SPRAY**

*** GENETIC TECHNOLOGIES, QIAGEN DIAGNOSTICS ALLIANCE**

*** CHERYL MALEY REPLACES CLARITY DIRECTOR DR O'BRYAN-TEAR**

*** ACTINOGEN APPOINTS DR DANA HILT CMO**

*** AUSBIOTECH: ERICA KNEIPP DIRECTOR, GRAHAM MCLEAN OBSERVER**

*** TRACY WEIMAR REPLACES STARPHARMA CO SEC NIGEL BAADE**

*** MACH7 APPOINTS TONY PANTHER CO SEC**

MARKET REPORT

The Australian stock market was up 0.33 percent on Wednesday February 1, 2023, with the ASX200 up 25.0 points to 7,501.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Nova Eye was the best, up five cents or 20.8 percent to 29 cents, with 6,990 shares traded. Mesoblast climbed 9.5 percent; Antisense was up 7.3 percent; Uscom improved 6.7 percent; Paradigm was up four percent; Alcidion, Dimerix, Imugene and Pharmaxis were up more than three percent; Actinogen rose 2.2 percent; Amplia, CSL, Cynata, Orthocell and Universal Biosensors were up more than one percent; with Cochlear, Proteomics and Resmed up by less than one percent.

Next Science led the falls, down seven cents or 11.4 percent to 54.5 cents, with 335,370 shares traded. Kazia lost 7.4 percent; Immutep was down 5.1 percent; Clinuvel fell 4.1 percent; Medical Developments, Patrys and Telix were down more than three percent; Emvision, Genetic Signatures, Oncosil and Pro Medicus shed more than two percent; Atomo and Neuren were down more than one percent; with Avita, Nanosonics and Polynovo down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) was up 12.8 percent in January to $20,059 million, its highest point since December 31, 2021, but 13.2 percent below the all-time high of $23,103 million at August 31, 2021.

The ASX200 was up 6.2 percent in January to 7,477 points and just 0.8 percent below its all-time high of 7,535 points, also at August 31, 2021.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed up 4.2 percent in January to $204,869 million, up 11.3 percent for the year to January 31, 2023.

The three Big Caps were 5.1 percent below their collective all-time high of $215,852 million at August 31, 2021.

In January, Cochlear climbed 4.4 percent to $13,975 million, CSL was up 4.3 percent to $143,739 million, with Resmed up 3.7 percent to $47,155 million.

The Nasdaq Biotechnology Index (NBI) was up 3.5 percent to 4,361 points in January and up 4.6 percent for the 12 months to January 31, 2023.

The year began with a tale of two tables. The BDI-20 was overwhelmingly up, with 15 companies improving and just four falling, while the Second 20 was overwhelmingly down, with 11 down and just five up. Five of the BDI-40 were unchanged.

Overall, 20 companies were up, 12 by more than 10 percent and seven by more than 20 percent; while 15 fell, with just five down by more than five percent.

Pro Medicus again added the most to the BDI-40 - $1,333 million – but it was Kazia climbing $10 million or 66.7 percent from a very low base to $25 million that was the best by percentage, followed by Volpara (53.8%), Avita (31.6%), Universal Biosensors (31.25%), Polynovo (28.1%), Pro Medicus (23.6%), Cyclopharm (20.2%), Proteomics (17.3%), Clinuvel (16.7%), Patrys (14.3%), Cynata (14.0%) and Nanosonics (13.4%).

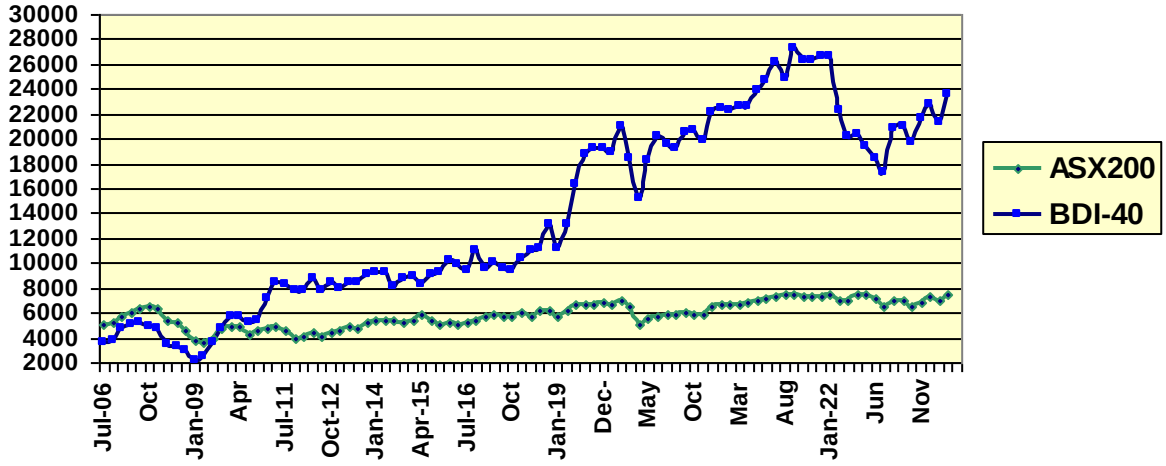
Impedimed led the falls, down $32 million or 22.7 percent to $109 million, followed by Antisense (15.4%), Nova Eye (14.6%), Prescient (10.3%) and Next Science (10.2%).

Cannabis Corner was the only index to fall, shedding 1.8 percent in January to $887 million, but down 24.0 percent for the year to January 31, 2023. Four of the 11 companies were up, five fell and two were unchanged. Cronos lost $24 million or 12.9 percent to $284 million, while Incannex added $24 million or 8.9 percent to $294 million.

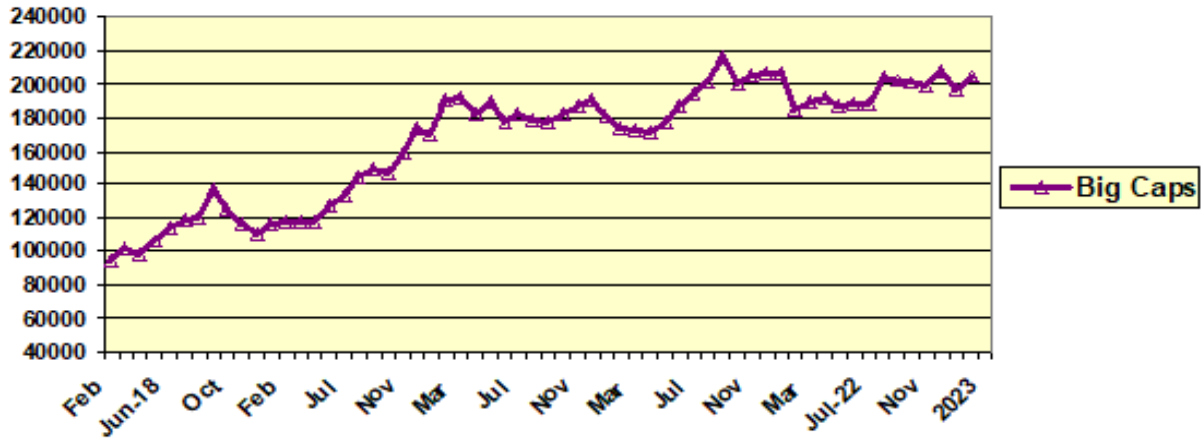
Outside the BDI-40, Aroa, Medadvisor and Microba were at 12-month highs.

On the Nasdaq, Redhill, with Australian assets, recovered 47.4 percent from a low base to $28 million, Eyepoint (formerly Psivida) was up 28.6 percent to $225 million and Queensland's Protagonist improved 17.9 percent to $927 million.

BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2023- Adjusted



Big Caps $m (Cochlear, CSL, Resmed) Jan 31, 2018 – Jan 31, 2023



MESOBLAST

Mesoblast says customer receipts for the six months to December 31, 2022 fell 33.7 percent to $US3,667,000 ($A5,199,000) compared to the prior corresponding period.
Mesoblast said receipts for its Temcell royalties for graft-versus-host-disease in Japan, for the three months to December 31, 2022 fell 59.0 percent to $US1,448,000.
The company said it had a cash burn for the three months to December 31, 2022 of $US16,506,000, with cash and cash equivalents of $US67,619,000 at December 31, 2022 compared to $US94,849,000 at December 31, 2021.
Mesoblast was up nine cents or 9.5 percent to $1.04 with 4.6 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says receipts from customers for the 12 months to December 31, 2022 fell 49.4 percent to $4,196,000 compared to the previous corresponding period.
Anteris said receipts for its Duravr aortic valve replacement technologies for the three months to December 31 fell 72.8 percent to $823,000 compared to the prior period.
The company said it had a cash burn of $8,645,000 for the three months to December 31, 2022, with cash and cash equivalents of $13,805,000, compared to $21,300,000 at December 31, 2021, with $13,126,000 in unused finance facilities available.
Anteris was up 62 cents or 2.4 percent to $26.12.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS CO)

Epsilon says receipts from customers for the 12 months to December 31, 2022 fell 23.6 percent to $3,805,000 compared to the prior corresponding period.
Epsilon said its receipts from customers for its marijuana products for the three months to December 31, 2022 were up 202.4 percent to $1,385,000 compared to the previous corresponding period.
The company said that it had a cash burn of $868,000 for the three months to December 31, 2022, with cash and equivalents of $811,000 compared to $2,335,000 at December 31, 2021, with $950,000 in unused finance facilities available providing 2.03 quarters of cash.
Epsilon was untraded at 2.3 cents.

ANALYTICA

Analytica says it has one quarter of cash and is “in discussions for potential sales of its developed products”.
Analytica said the sales of products was “the main focus of the company to realize significant revenue” and was also in advanced discussions with directors to provide additional non diluting unsecured loans to the company.
The company said it was reviewing all funding options to address its long-term and ongoing funding needs.
Analytica said that receipts from customers for its Pericoach intra-vaginal pelvic floor strengthening devices for the six months to December 31, 2022 was up 385.0 percent to $34,000 compared to the prior corresponding period.
The company said that it had a cash burn of $586,000 for the three months to December 31, 2022, with cash and equivalents of $21,000 compared to $572,000 at December 31, 2021, with $612,000 in financing facilities available providing 1.08 quarters of cash.
Analytica was untraded at 0.1 cents.

TOTAL BRAIN

Total Brain says that its extraordinary general meeting has overwhelmingly voted delist for the ASX and approve a capital return to shareholders.
Total Brain was up 0.2 cents or 4.3 percent to 4.9 cents with 4.6 million shares traded.

MESOBLAST

Mesoblast says it has resubmitted its remestemcel-L biological licence application to the US Food and Drug Administration for acute graft versus host disease in children.
In 2020, Mesoblast said the FDA required a further trial of remestemcel-L for steroid refractory acute graft versus host disease (BD: Oct 2, 2020).
Earlier that year, the FDA Oncologic Drugs Advisory Committee voted nine to one in favor that the available data supported the efficacy of remestemcel-L, or Ryoncil for paediatric steroid-refractory acute graft-versus-host disease (BD: Aug 14, 2020).
The company said the resubmission contained information required by the FDA in the complete response letter it received in September 2020.
Mesoblast said the resubmission of the application contained long-term survival data, data showing treatment benefits, analyses showing validated potency assay, and manufacturing changes related to increased potency, data demonstrating manufacturing consistency and reproducibility and specifications for commercial release.
Mesoblast chief executive Prof Silviu Itescu said there was “an urgent need for a therapy that improves the dismal survival outcome in children with [steroid resistant, acute graft versus host disease]”.
“Our team has worked tirelessly over the past two years to provide a comprehensive response to the FDA,” Prof Itescu said.
“We are grateful for the agency’s active dialogue and constructive feedback that will ensure a high bar is met in terms of product consistency and predictability of clinical outcomes,” Prof Itescu said.

AMPLIA THERAPEUTICS

Amplia says that the first of three cohort 2 pancreatic cancer patients has begun dosing at the AMP945 increased dose in its phase Ib/IIa ‘Accent’ trial.
Amplia managing-director Dr Chris Burns said that “identifying a safe and well-tolerated dose of AMP945 that effectively shuts down [focal adhesion kinase] activity is a critical part of the phase Ib arm of the Accent trial”.
“Based on our extensive pre-clinical studies, we are hopeful that AMP945 used in conjunction with standard-of-care drugs gemcitabine/nab-paclitaxel, will improve patient outcomes,” Dr Burns said.
Amplia said the phase Ib stage was a single-arm, open-label study to select an optimal dose of AMP945 by assessing the safety, tolerability, pharmaco-kinetics, pharmaco-dynamics and preliminary efficacy of AMP945 in combination with gemcitabine and nab-paclitaxel (Abraxane) in first-line patients with advanced pancreatic cancer.
The company said that the phase IIa stage was a single-arm, open-label study designed assess the optimal dose of AMP945 in combination with gemcitabine and nab-paclitaxel.
Amplia said that the primary endpoint of the phase IIa trial was the objective response rate of patients to treatment, with further endpoints to assess efficacy by other means as well as safety and tolerability.
Amplia was up 0.1 cents or 1.1 percent to nine cents.

ISLAND PHARMACEUTICALS

Island says the US Food and Drug Administration requires a further “small” trial as well as protocol amendments for its application for a trial of ISLA-101 for dengue fever.
Island said that following the FDA clinical hold on its investigational new drug application for a phase IIa trial, the FDA “further clarified that amendments to the protocol and [application] will be necessary to advance the program”.
The company said that additional data would be “obtained in a small single ascending dose clinical trial that measures blood concentration of ISLA-101”.
Island said the aim of the study was to ensure that administered doses could achieve blood concentrations of ISLA-101 safely, that were predicted to be effective against the dengue virus.
The company said it was working with vendors and consultants to formulate the most efficient clinical plan and to understand related timing.
Island said the trial was expected to be conducted in Australia.
Island managing-director Dr David Foster said that the FDA had provided “very clear feedback on next steps, and we are in the process of working through the plan and associated timelines”.
“In view of the vast body of data associated with ISLA-101 we anticipate that the results of the ascending dose trial will be positive, and that we will be able to advance the Peach phase IIa clinical trial once this preliminary study has been completed and data analyzed,” Dr Foster said.
Island was unchanged at 15 cents.

ANTISENSE THERAPEUTICS

Antisense says a mouse study combining an antisense oligonucleotide targeting CD49d with a dystrophin exon-skipping restoration drug improves muscle function.
Antisense said the use of the combination improved the specific maximum force of the lower leg extensor digitorum longus muscle and the eccentric muscle force remaining following induced damage to the extensor digitorum longus muscle.
The company said that the study supported the potential for ATL1102 use in combination with dystrophin restoration drugs to show benefit over the use of a dystrophin restoration agent alone for Duchenne muscular dystrophy.
Antisense said it had filed a patent application to IP (intellectual property) Australia, titled ‘Combination Compositions and Methods for Treatment of Muscular Dystrophy protecting the combination of ATL1102 with the dystrophin restoration exon-skipping drugs.
The company said that if granted the patent would protect its intellectual property to 2044, “well beyond the patent life of the registered dystrophin restoration drugs”.
Antisense said that “notably the dystrophin restoration drugs have yet to demonstrate in controlled clinical studies a slowing of the loss of ambulation beyond use of corticosteroids, highlighting the clinical need for a more efficacious therapeutic approach”.
Antisense head of drug discovery and patents Dr George Tachas said that the “encouraging effects observed in our study of the combination treatment on … muscle function suggest the potential for the combination treatment to show benefit beyond monotherapy is on the right track”.
“The study design and functional endpoints assessed have featured in many … mouse studies published in the scientific literature and as such supports the validity of our study and its outcomes,” Dr Tachas said.
Antisense was up 0.6 cents or 7.3 percent to 8.8 cents with 1.6 million shares traded.

RACE ONCOLOGY

Race says it has ethics approval for the observational stage of a trial of Zantrene with doxorubicin and cyclophosphamide for cardiovascular risk in breast cancer.
Race said that the New South Wales-based Hunter New England ethics committee approved the 50-patient observational stage of the planned phase I/IIb clinical trial in breast cancer patients to be treated with doxorubicin and cyclophosphamide and who have two or more cardiovascular risk factors.
The company said it required research institutional governance including site budget and contracting approval.
Race said the study's aim was to identify the rate and level of heart damage caused by chemotherapy, using cardiac imaging and biochemical methods, and the data would inform the design of a subsequent phase I/II interventional trial, to avoid the permanent heart damage that can be caused by chemotherapy as well as potentially improving anti-cancer outcomes.
Race managing-director Damian Clarke-Bruce said that cardio-protection for breast cancer was "a significant unmet need and our pre-clinical data suggests that Zantrene may help to address the therapeutic gap for patients whilst still delivering clinical efficacy".
Race was up 3.5 cents or 1.9 percent to $1.915.

MICROBA LIFE SCIENCES

Microba says it has had "positive results" in its microbiome-based immuno-oncology program for melanoma, in mice.
Microba said the study showed a significant reduction in tumor volume for mice treated with an immune checkpoint inhibitor together with Microba's therapeutic leads, when compared to control mice that received the inhibitor alone.
Microba head of therapeutics Prof Trent Munro said the results "provide the foundations for our immune-oncology program and a roadmap to clinical translation".
"We believe these initial animal model results are compelling and show the impact the microbiome can have in improving the response to [immune checkpoint inhibitor] therapy, which is a backbone in modern cancer treatment".
"A novel microbiome-based therapeutic that can positively influence response rates for patients receiving immune checkpoint inhibitor therapy would represent a substantial commercial opportunity for Microba," Prof Munro said.
Microba said that immune checkpoint inhibitors had become the standard-of-care for a range of tumor types and despite their impact on patients, about 70 percent of patients did "not respond to the drugs leaving a large underserved patient population".
The company said that differences in the microbiomes of responders and non-responders had been observed in international studies and treatment of the microbiome using fecal microbiome transplant has shown the ability to turn non-responders into responders.
Microba said it had identified a number of lead microbial species that may underpin clinical immune checkpoint inhibitors response and selected strains were assessed in an immune checkpoint inhibitors-refractive mouse melanoma model, for their ability to reduce tumor burden.
The company said that the data showed "a significant reduction in tumor size in mice treated with Microba's therapeutic leads together with [immune checkpoint inhibitor] ICI treatment.
Microba was up half a cent or 1.5 percent to 34.5 cents.

ENA RESPIRATORY

Ena says a 376-patient survey shows patients support taking an antiviral nasal spray when at risk for exposure to a respiratory virus to prevent exacerbations.

Ena said the survey was conducted with the Florida, Miami-based COPD (chronic obstructive pulmonary disease) Foundation and found more than 80 percent of patients "expressed interest in a potential new seasonal anti-viral nasal spray taken either twice weekly during the winter months or for two weeks after exposure to someone with a respiratory illness" with up to 58 percent of patients with frequent COPD exacerbations "very interested".

The company said that 92 percent of patients said they were vaccinated for influenza, pneumonia and Covid-19, with 35 percent reporting hospitalizations after contracting viral illnesses in the past.

Ena said the study, titled 'The COPD Foundation's COPD360Net Initiative Approach to Patient-Centric Drug Development: A Case Study in Using Patient Surveys to Inform New Treatments for Viral Respiratory Infections' was co-authored by Ena's Dr Christophe Demaison, published in the Journal of Patient Experience and available at: https://journals.sagepub.com/doi/10.1177/23743735231151554.

Last year, Ena said it would partner with the Miami-based COPD Foundation to develop its INNA-051 nasal spray for people with chronic lung diseases (BD: Feb 24, 2022).

Ena chief executive officer Dr Demaison said the survey results validated "the need for seasonal prophylaxis against respiratory viral infections and the value of INNA-051 for patients at high risk of complications from the flu, colds, Covid-19 and other common respiratory illnesses".

Ena is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies says it will form "a strategic alliance" with the Hilden, Germany-based molecular testing company Qiagen NV.

Genetic Technologies said the alliance would "develop a 'centre of excellence' facility in Australia initially servicing Australia and New Zealand with potential for expansion, showcasing the life science and diagnostics expertise of both organizations".

The company said the relationship was "expected to open a wide range of new commercial opportunities … with enhanced automation capability and increased capacity supporting long-term revenue growth".

Genetic Technologies said it would "unlock the Australian reimbursable market for all testing categories, including the Genetype hereditary cancer test … [and] make the Genetype breast, ovarian and colorectal cancer tests the most comprehensive offering in the market later in 2023".

The company said Qiagen would provide software, hardware, consumable and technical products, including reagents and software to complete validation.

Genetic Technologies said that its accredited and certified laboratory would "play an important role providing analytical services and insights".

Qiagen Australia head of commercial operations Rod Gleeson said his company was "excited to take our existing partnership with [Genetic Technologies] to the next level".

"This strategic alliance will leverage Qiagen testing technologies from sample to insight for multiple applications," Mr Gleeson said. "Further we believe this will facilitate growth and expansion in the region and potentially even beyond."

Genetic Technologies was up 0.05 cents or 20 percent to 0.3 cents with 6.4 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Cheryl Maley as a non-executive director, replacing Dr Gillies O'Bryan-Tear, who will resign effective from May 15, 2023.
Clarity said Ms Maley had more than 25 years of experience in the pharmaceutical industry, working in the US, Philippines and Australia.
The company said most recently, Ms Maley was Novartis Oncology Australia and New Zealand general manager, and was a director for Medlab Clinical.
Clarity said Ms Maley held a Bachelor of Science, Diploma of Education and Masters of Business Administration from the Armidale, New South Wales-based University of New England.
Clarity fell three cents or 3.5 percent to 83 cents.

ACTINOGEN MEDICAL

Actinogen says it has appointed Dr Dana Hilt as chief medical officer with former chief medical officer Prof Paul Rolan continuing as head of clinical pharmacology.
Actinogen said Dr Hilt had more than 25 years of experience in central nervous system drug development.
The company said that most recently, Dr Hilt was Frequency Therapeutics chief medical officer and previously worked for Lysosomal Therapeutics, Guilford Pharmaceuticals, Ascend Pharmaceuticals, Critical Therapeutics and Amgen.
Actinogen said Dr Hilt had a Doctor of Medicine from Boston's Tufts University and held academic positions at the University of Maryland and University of South California.
Actinogen was up 0.2 cents or 2.2 percent to 9.2 cents.

AUSBIOTECH

Ausbiotech says it has appointed Erica Kneipp as a directors and Graham McLean as a board observer.
Ausbiotech said Ms Kneipp was involved in the establishment of the $20 billion Medical Research Future Fund and the Biomedical Translation Fund, and was currently CSIRO's human health program research director.
The industry organization said Mr McLean had worked for Stryker as an executive for 16 years and was currently chair of Universal Biosensors and a director of Cleanspace.

STARPHARMA

Starpharma says it has appointed Tracy Weimar from Vistra Australia as interim company secretary, replacing chief financial officer Nigel Baade effective from today.
Starpharma said Ms Weimar had more than 20 years of experience in commercial, company secretarial and non-executive director roles in the pharmaceutical industry.
The company said Mr Baade would continue as chief financial officer until March 2023.
Starpharma was unchanged at 56.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it has appointed Tony Panther as company secretary, replacing Veronique Morgan-Smith effective from February 1, 2023.
Mach7 said that the change followed Vistra Australia team reassignments
Mach7 was up one cent or 1.4 percent to 72 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JAN 31, 2023

Company $Am	**Feb-22**	**Jan-22**	**Feb-22**
Cochlear	12,665	13,388	13,975
CSL	124,642	137,769	143,739
Resmed	46,715	45,479	47,155
BDI-20			
Avita	334	247	325
Clinuvel	1,137	1,066	1,244
Compumedics	67	35	32
Cyclopharm	165	109	131
Cynata	67	43	49
Genetic Signatures	196	126	126
Immutep	325	242	259
Kazia	127	15	25
Medical Developments	335	128	133
Mesoblast	732	638	700
Nanosonics	1,533	1,287	1,459
Neuren	433	1,012	975
Nova Eye	44	41	35
Opthea	401	427	444
Pharmaxis	55	44	42
Polynovo	867	1,348	1,727
Pro Medicus	4,708	5,648	6,981
Starpharma	441	225	231
Telix	2,089	2,217	2,243
Volpara	235	132	203
Second 20			
Actinogen	213	181	163
Alcidion	304	184	184
Amplia	31	16	17
Antisense	114	65	55
Atomo	119	31	31
Dimerix	75	47	45
Emvision	162	144	132
Impedimed	311	141	109
Imugene	1,800	867	867
Micro-X	108	67	72
Next Science	240	147	132
Oncosil	29	47	43
Orthocell	85	81	77
Paradigm	332	393	389
Patrys	51	56	64
Prescient	130	97	87
Proteomics	106	110	129
Resonance	71	28	27
Universal Biosensors	152	48	63
Uscom	19	9	9

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, Pharmaxis, Polynovo, Telix, Volpara and non-biotech stocks. Through Australian Ethical Superannuation he has an indirect interest in other companies: **https://www.australianethical.com.au/personal/ethical-investing/companies-we-invest-in/.** These holdings are liable to change.

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