



Biotech Daily

Monday July 1, 2024

Daily news on ASX-listed biotechnology companies

- * BDI-40 18-YEAR RECORD HIGH - UP 847%; BIG CAPS UP 1,100%; ASX200 UP 53%
- * TODAY: ASX, BIOTECH DOWN: CURVEBEAM UP 22%; EMVISION DOWN 11%
- * VICTORIA \$1m FOR 20 MEDTECH START-UPS
- * ARGENT 'FIRM COMMITMENTS' FOR \$750k PRIVATE PLACEMENT
- * EMYRIA WINS \$499k WA GOVERNMENT MDMA GRANT
- * CYNATA TO PAY \$230k FOR TEKCYTE WOUND DRESSING
- * CANN: BIORTICA PAYS \$1.65m FOR EQUIPMENT
- * ZELIRA TAKES \$2.1m LOAN FROM CHAIR OSAGIE IMASOGIE
- * IMRICOR: LAUSANNE UNI INSTALS ICMR SYSTEM
- * PYC: VP-001 SAFE IN 4th, HIGHEST DOSE COHORT
- * TRYPTAMINE DOSES 1st TRP-8803 IV-PSILOPIN PATIENT
- * ANTERIS, V2V MEDTECH FINISH VCLIP TEER ANIMAL STUDY
- * PATRYS: PAT-DX1 TESTING ONE MONTH LATE
- * PHARMAUST WINS EU SME STATUS
- * MESOBLAST TO FILE RYONCIL TO FDA 'NEXT WEEK'
- * ISLAND REQUESTS 'MATERIAL TERM SHEET' TRADING HALT
- * RECCE REQUESTS 'CAPITAL RAISING' TRADING HALT
- * UIL, UTILICO TAKE 7% OF STARPHARMA
- * ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 57%
- * PROF PETER VAN WIJNGAARDEN REPLACES FLOREY CEO PROF TREVOR KILPATRICK
- * GENETIC TECHNOLOGIES LOSES 3-MONTH CFO, CO-SEC KATHRYN ANDREWS

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday July 1, 2024, with the ASX200 down 16.8 points to 7,750.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 were down, four traded unchanged and one was untraded. All three Big Caps fell.

Curvebeam was the best, up 3.5 cents or 21.9 percent to 19.5 cents, with 16,293 shares traded. Paradigm climbed 13.7 percent; Alcidion was up 8.5 percent; Genetic Signatures rose 6.3 percent; Immutep and Prescient improved more than five percent; 4D Medical and Actinogen were up more than four percent; Dimerix was up 3.9 percent; Orthocell rose 2.8 percent; Compumedics and Mesoblast were up one percent or more; with Avita up by 0.8 percent.

Emvision led the falls, down 24 cents or 11.1 percent to \$1.92, with 167,093 shares traded. Cyclopharm and Next Science lost more than six percent; Clarity, Cynata, Medadvisor, Neuren, Percheron and Pro Medicus were down five percent or more; Nanosonics, Polynovo and Syntara fell four percent or more; Imugene, Micro-X, Starpharma and Telix lost three percent or more; Cochlear and Medical Developments shed more than two percent; Impedimed, Opthea, Proteomics and Resmed lost more than one percent; with Clinuvel, CSL and SDI down by less than one percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

The Biotech Daily Top 40 Index (BDI-40) continued its record-breaking run, up a further 9.9 percent in June to a collective market capitalization of \$33,727 million, up 61.0 percent for the financial year and up 846.6 percent since inception 18 years ago.

The benchmark ASX200 was up 0.9 percent to 7,768 points in June, up 7.8 percent for the year and 53.1 percent for the 18-year comparison (see charts below).

Investors might wonder whether the 'safety' of blue-chip companies, chosen solely by market capitalization, is meaningful in any way. The BDI-40 was 15.9 times better than the ASX200 over 18 years.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) improved 2.6 percent in June to a collective market capitalization of \$206,742 million; and were up 4.6 for the year and 1,100.5 percent over the 18 years.

CSL's 6.05 percent improvement to \$142,637 million and Cochlear's 1.95 percent rise to a new record of high of \$21,362 million more than compensated Resmed's further fall of 7.3 percent to \$42,743 million. At June 30, 2006, Cochlear was \$2,994 million, CSL was at \$9,777 million and Resmed was \$4,385 million. A cumulative 11-fold increase.

As august commentators and analysts say: "Don't invest in biotech, it's far too risky."

In June, 18 of the BDI-40 companies were up, 11 by more than 10 percent; 22 fell with 14 down by more than 10 percent; with the BDI-20 leading the way.

Pro Medicus added \$2,062 million to the June index, up 16.4 percent to \$14,600 million, but Actinogen was the percentage best, up 127.4 percent to \$166 million, followed by Compumedics (35.2%), Syntara (20.8%), Cyclopharm (18.1%), Telix (16.9%), Pro Medicus (16.4%), Emvision (14.3%), Medadvisor (13.6%), Opthea (13.0%), Genetic Signatures (12.5%) and Polynovo (10.9%).

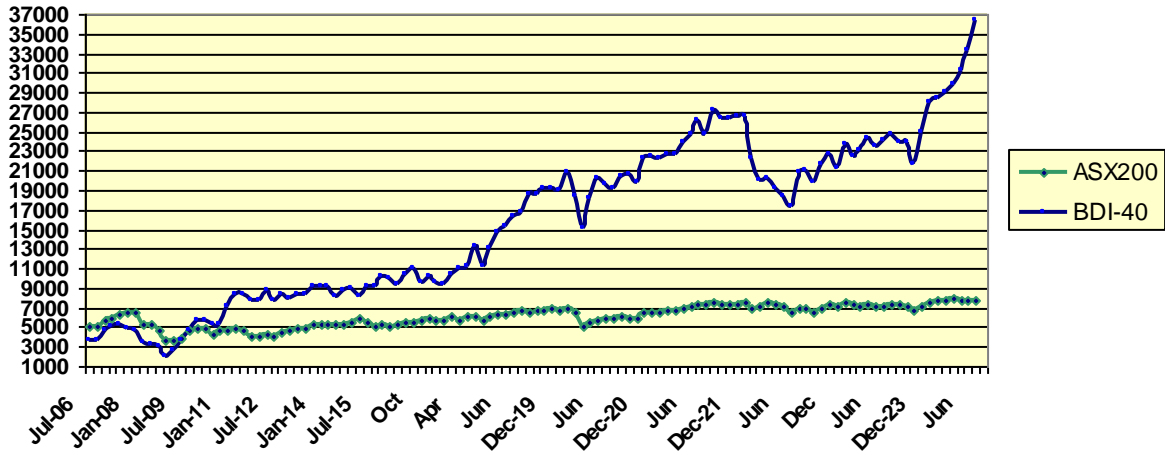
Immutep led the falls, down \$106 million or 19.8 percent to \$429 million, followed by Imugene (19.4%), Alcidion (19.2%), Avita (18.65%), Starpharma (17.0%), Atomo (15.8%), Prescient (13.9%), Curvebeam (12.1%), Nova Eye (12.0%), 4D Medical (11.7%), Cynata (11.7%), Mesoblast (11.7%), Amplia (10.5%) and Resonance (10.3%).

Cannabis Corner lost a further 22.9 percent in June, down 61.8 percent for the year, to a collective \$216 million; with eight companies down, four unchanged and none improved. Vitura was the worst for the month, down \$27 million or 57.4 percent to \$20 million - a long way (93.0%) from its \$287 million market capitalization one year ago.

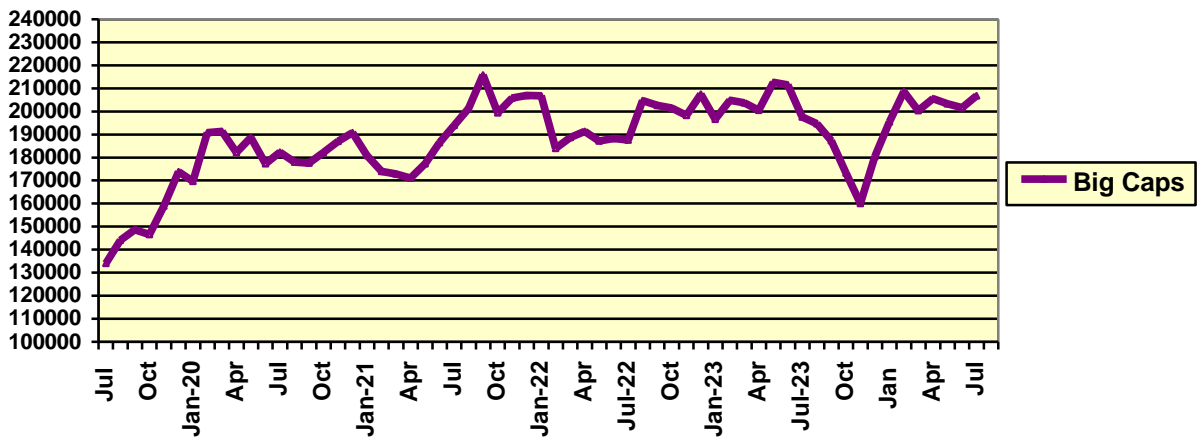
The Nasdaq Biotechnology Index (NBI) was up 3.3 percent in June, to 4,545 points, and up 11.5 percent for the year. While two of the three companies that went to the Nasdaq "for better valuations" recovered in June, for the year, Bionomics fell 42.3 percent, Incannex fell 58.1 percent and Kazia lost 72.2 percent.

Outside the BDI-40, Optiscan was the most notable - up 104.2 percent for the month to \$196 million (292.0% for the year), following its May 13 news of a collaboration with the Mayo Clinic. The share price climbed from nine cents on May 9 to 23.5 cents on June 28. Honorable mentions to Arovella, Argenica, Botanix, Mach7, Race and Recce.

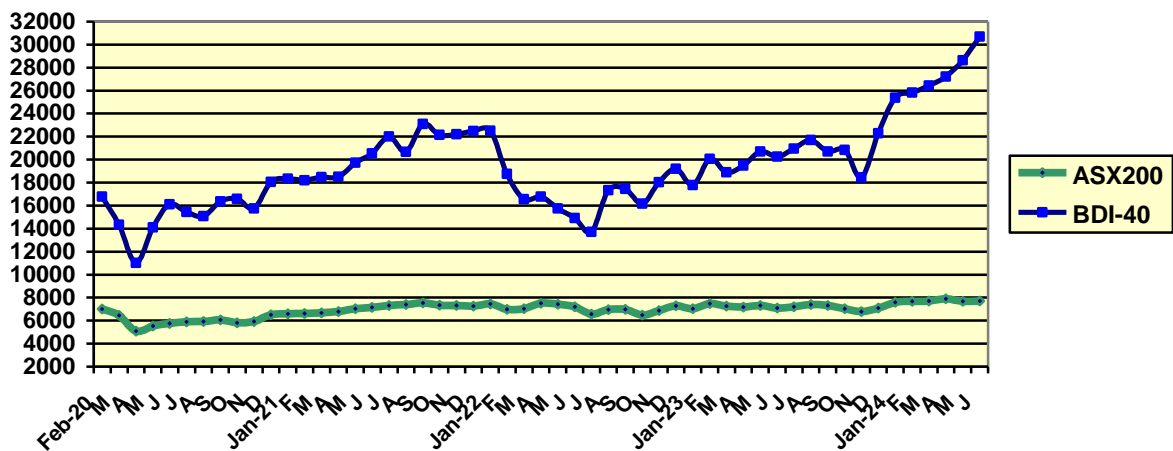
BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2024- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2019 – Jun 30, 2024



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Jun 30, 2024 (Pre-Covid to date)



VICTORIA GOVERNMENT

The Victoria Government says it has awarded 20 medical technology companies \$50,000 each to help deliver products to hospitals and healthcare providers.

A media release from Victoria Minister for Jobs and Industry Natalie Hutchins said the funding would make “it easier for [medical technology] start-ups to determine product value and bridge the gap between the development of products and getting them into hospitals and healthcare services”.

The Government said the program was a collaboration between Melbourne’s Australian Medtech Manufacturing Centre and start-up agency Launchvic to increase the number of medical technology startups in Victoria and create jobs.

The media release said the grants went to “start-ups or scale-ups”, including Melbourne’s Livac for its liver-retraction device and Tournicare for its at-home blood pressure monitor. The media release said the state budget for the year to June 30, 2025 invested \$40 million over four years to Launchvic “to continue supporting start-ups and connecting them to stakeholders and investor networks”.

Launchvic chief executive officer Dr Kate Cornick said health technologies were “Victoria’s joint-largest start-up subsector, with over 500 companies active in the state employing just over 9,000 people”.

“This program will ensure the sector’s sustainable growth by helping startups with the skills, knowledge and resources they need to fast-track market growth locally and globally,” Dr Cornick said.

The full list of recipients is available at: <https://bit.ly/3SdwGHt>.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says it has “firm commitments” from an unnamed investor to raise \$US500,000 (\$A749,946) through a placement at 80 US cents (\$A1.20) a share.

Argent said the undisclosed “professional and sophisticated investor” was an unrelated party, and that the issue price was an about 400 percent premium to the 15-day volume weighted average price of 30 cents a share.

The company said the investor would receive one attaching warrant for every two shares subscribed for, exercisable at \$1.20 each within three years from issue.

Argent said the funds would be used to continue its drug development pipeline, including the marijuana-based Cannepil and Cimetra.

Argent was up four cents or 13.3 percent to a post-1000-to-one-consolidation 34 cents.

EMYRIA

Emyria says the Western Australia Government-has granted it \$499,411 to develop its 3,4-methylene-dioxy-meth-amphetamine (MDMA) analogue.

Emyria said the Western Australia Government-backed Future Health Research and Innovation Seed Fund provided companies with funding for projects with high commercial potential.

The company said the grant would advance its collaboration with the University of Western Australia for 18 months to validate its “drug optimization pipeline and potentially identify a drug candidate for development and commercialization”.

Emyria said the funds would be used for “key screening assays and gold-standard animal models delivered by global collaborators, including the National Institutes of Health, to progress towards clinical trials”.

Emyria was up half a cent or 12.2 percent to 4.6 cents.

CYNATA THERAPEUTICS

Cynata says it will acquire the Adelaide-based Tekcyte Pty Ltd's wound dressing technology used in its CYP-006TK treatment for \$230,000 in shares.

In 2021, Cynata said that it had a licence agreement to use Tekcyte's wound dressing for a trial of its mesenchymal stem cells for diabetic foot ulcers and had an option to purchase the technology, with Tekcyte to help manufacture and supply the active dressing (BD: Jun 3, 2021).

This year, the company said a preliminary analysis of 16 patients from the randomized, 24-week, 30-patient, phase I trial of CYP-006TK mesenchymal stem cell topical wound dressing for diabetic foot ulcers (DFU) trial showed a median wound surface area reduction of 87.6 percent (BD: Feb 26, 2024).

Today, Cynata managing-director Dr Kilian Kelly said ownership of the technology strengthened the company's "intellectual property position and simplifies our commercial proposition for potential partners".

"We are very excited by the initial results in our trial of CYP-006TK in [diabetic foot ulcers], and optimistic about the potential for this product to meaningfully change outcomes for patients," Dr Kelly said.

Cynata fell 1.5 cents or 5.1 percent to 28 cents.

CANN GROUP

Cann Group says it has received \$1.65 million from the final instalment of its plant and equipment sale to Melbourne's Biortica Agrimed Ltd.

In March, Cann Group said it had a \$1.7 million purchase agreement with Biortica Agrimed, selling surplus equipment to Biortica for \$1.7 million in cash or \$1.9 million in a combination of equity and cash, subject to agreement (BD: Mar 18, 2024).

Today, the company said the sale was for "a range of plant and equipment, surplus to its needs" at a price of \$1.5 million plus GST.

Cann said "two smaller instalment payments were received during the period between the sale date and Friday's receipt".

Cann was up 0.2 cents or 7.1 percent to three cents with 1.9 million shares traded.

ZELIRA THERAPEUTICS

Zelira says chair Osagie Imasogie has loaned it \$US1,400,000 (\$A2,100,000) through a working capital loan note, convertible at 40 US cents (60 Australian cents) per note. Zelira said the conversion price was a more than 100 percent premium to the closing price on June 28, 2024, and was subject to shareholder approval.

The company said the loan had a 20 percent annual interest rate, payable monthly in cash, and would be repayable until June 28, 2026.

Zelira said the loan would be used to support advancement of its Hope marijuana for autism trial as well as general working capital.

The company said if the loan was not approved by shareholders, it would pay a 10 percent loan termination fee to Mr Imasogie.

Zelira was up five cents or 17.9 percent to 33 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has completed the sale and installation of its interventional cardiac magnetic resonance (ICMR) imaging system to Lausanne University Hospital.

Earlier this year, Imricor said it had approval for an up-to 91-patient study of its cardiac ablation catheter and irrigation pump products at the Baltimore, Maryland's Johns Hopkins Hospital; and later, said it had Swiss regulatory authority approval to open the trial at Lausanne University Hospital (BD: Jan 21, Mar 8, May 9, 2024).

Today, the company said the sale and installation was delayed by Swiss registration of the third-party HAT-500 ablation generator, manufactured by Osypka.

Imricor said physicians from other hospitals could visit and be trained with the system for cardiac ablations as it increased the number of active sites in Europe.

The company said the hospital was ready to participate in the trial to support US Food and Drug Administration approval of its products.

Imricor said the first patient was expected to be enrolled at Lausanne in August following installation of its Northstar three-dimensional mapping system and on-site training, with the trial expected to be completed by January 2025, pending a fourth site's enrolment.

Imricor managing-director Steve Wedan said the installation was a "major milestone".

Imricor fell half a cent or 0.9 percent to 52.5 cents.

PYC THERAPEUTICS

PYC says its study of VP-001 for retinitis pigmentosa type-11 (RP11) shows the drug is safe and well-tolerated at the highest intra-vitreous dose of 75 micrograms.

Last year, PYC said it had dosed the first of nine patients in the phase I study; and later, said it conducted a safety review of the first three doses of three micrograms, 10 micrograms and 30 micrograms, with a fourth cohort of three patients expected to receive the final 75 microgram dose by June trial (BD: Jun 30, 2023, Apr 29, 2024).

Today, the company said patients in cohort four received a single intravitreal dose of VP-001 in one eye, and that at four weeks it was considered safe and well tolerated in with no treatment emergent adverse events reported.

PYC said it would begin a multiple-ascending dose trial to study the two highest doses of 30 micrograms and 75 micrograms and expected to complete both studies by 2025.

PYC was unchanged at 12 cents with 2.9 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has dosed the first of up-to 12 participants in a dose-finding study of its intra-venous hallucinogenic TRP-8803 psilocin.

Earlier this year, the then Exopharm said it would raise up-to \$6.5 million at 2.0 cents a share, buy the Kelowna, British Columbia-based Tryp Therapeutics and its intra-venous psilocybin for scrip and become 'Tryptamine Therapeutics' (BD: Mar 8, 2024).

At that time, the then Exopharm said that psilocin was the active metabolite of psilocybin found in 'magic mushrooms'.

Today, the company said the study would optimize dosing and infusion rates to achieve precise blood levels of psilocin with an acceptable pharmaco-kinetics profile, with results to inform its "phase IIa patient study pipeline".

Tryptamine said the first "participant successfully underwent psilocin infusion over 140 minutes, progressed well through treatment and was discharged ... after dosing follow-up was completed".

Tryptamine fell 0.1 cents or 4.8 percent to two cents.

ANTERIS TECHNOLOGIES

Anteris says its Vclip transcatheter edge-to-edge repair system (TEER), developed with V2V Medtech, for leaky valves has passed a study in an undisclosed animal.

Last year, Anteris said it would work with the Minneapolis, Minnesota-based V2V Medtech to develop a heart valve repair device for treating mitral and tricuspid valve regurgitation, or leaky valves (BD: Apr 19, 2023).

At that time, the company said the agreement included Anteris acquiring 30 percent of V2V for up-to \$US8 million (\$A12 million) in cash and in-kind contributions, and the V2V board would have three members with two appointed by Anteris.

Today, Anteris said transcatheter edge-to-edge repair was “fast becoming the primary intervention for patients with mitral and tricuspid valve disease” but that current systems often-prevented optimal procedural outcomes or limited patient eligibility.

The company said its Vclip system was designed to address the limitations of current systems and to provide better outcomes for patients.

Anteris chief operating officer and V2V chief executive officer David St Denis said “the milestone is an important step as we advance Vclip toward a first-in-human study”.

Anteris was unchanged at \$18.31.

PATRYS

Patrys says that specification testing for the manufacturing run of PAT-DX1 will be completed “by the end of July 2024 ... one month later than was anticipated”.

In 2021, Patrys said that Covid-19 delayed PAT-DX1 manufacturing by six months, and in 2022, said purification of the fermentation process resulted in less drug product than expected, delaying first human study to mid-2023 (BD: Aug 3, 2021; Jan 24, 2022).

Last year, Patrys said the trial had been delayed to 2024 due to sporadic issues relating to the cell line used to produce the drug and in December said it would have PAT-DX1 in time for its first-in-human trial by 2025 (BD: Mar 31; Dec 13, 2023).

Today, Patrys said “specification testing must be successfully completed for the drug material to be released for use in clinical trials”.

Patrys was up 0.1 cents or 14.3 percent to 0.8 cents with 4.8 million shares traded.

PHARMAUST

Pharmaust says the European Regulatory Agency has awarded it small and medium-sized enterprise (SME) status, including regulatory fee incentives and Agency support.

Pharmaust said the status made it eligible for “a range of financial benefits, including reductions in fees for scientific advice, inspections and marketing authorization applications”.

The company said the status was available to companies with fewer than 250 employees and no more than \$EUR50 million (\$A80.6 million) in revenue.

Pharmaust managing-director Dr Michael Thurn said approval was “the beginning of a productive partnership with the key drug regulator in Europe and an important step towards accelerating start-up activities for our adaptive phase II/III ‘Strike’ study”.

“The incidence of [motor neuron disease and/or amyotrophic lateral sclerosis] in European countries are amongst the highest globally, ranging from 1.5 to 3.8 per 100,000 people,”

Dr Thurn said. “Incredibly, there is only one drug, riluzole, approved for the treatment of all types of [motor neuron disease and/or amyotrophic lateral sclerosis] in Europe which only offers patients an additional two to three months in life expectancy.”

Pharmaust was unchanged at 19.5 cents.

MESOBLAST

Mesoblast says it expects to file a biologics licence application to the US Food and Drug Administration for Ryoncil for paediatric graft versus host disease “next week”.
Mesoblast was up one cent or one percent to \$1.00 with 10.2 million shares traded.

ISLAND PHARMACEUTICALS

Island has requested a trading halt pending an announcement regarding a “proposed material non-binding term sheet”.
Trading will resume on July 3, 2024, or on an earlier announcement.
Island last traded at 7.7 cents.

RECCE PHARMACEUTICALS

Recce has requested a trading halt pending an announcement “relating to a proposed equity capital raising”.
Trading will resume on July 3, 2024, or on an earlier announcement.
Recce last traded at 60 cents.

STARPHARMA HOLDINGS

UIL and Utilico Emerging Markets Trust PLC says they increased their substantial holding in Starpharma from 19,046,000 shares (5.12%) to 27,566,682 shares (6.69%).
The Surrey, England and Bermuda-based UIL said it bought and sold shares on-market between November 25, 2019 and June 28, 2024, with the single largest purchase 2,000,000 shares on October 1, 2020 for \$3,000,000, or \$1.50 a share.
Starpharma fell 0.3 cents or 3.2 percent to 9.2 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial holding from 64,774,943 shares (54.15%) to 68,117,741 shares (56.95%).
In May, Allegra said Dr Hartnell hoped to buy the company (BD: May 27).
Allegra was in a suspension and last traded at 2.9 cents.

FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HEALTH

The Florey Institute says Prof Peter van Wijngaarden will replace Prof Trevor Kilpatrick as its director and chief executive officer.
The Institute said Prof Wijngaarden was a professor of ophthalmology at the University of Melbourne, deputy director of the Centre for Eye Research Australia, and had researched retinal imaging, artificial intelligence, multiple sclerosis and Alzheimer’s disease.
According to his LinkedIn page, Prof Wijngaarden held a Bachelor of Medicine and a Bachelor of Surgery from Melbourne’s Monash University.

GENETIC TECHNOLOGIES

Genetic Technologies says three month chief financial officer and company secretary Kathryn Andrews has resigned.
Genetic Technologies was up 0.6 cents or eight percent to 8.1 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JUN 30, 2024

Company \$Am	Jun 30, 2023	May 31, 2024	Jun 30, 2024
Cochlear	15,084	20,953	21,362
CSL	134,243	134,499	142,637
Resmed	48,251	46,129	42,743
BDI-20			
Avita	660	386	314
Clinuvel	888	759	764
Compumedics	32	43	59
Cyclopharm	188	155	183
Cynata	22	60	53
Genetic Signatures	75	136	153
Immutep	374	535	429
Impedimed	363	154	146
Medical Developments	67	37	35
Mesoblast	928	1,267	1,119
Nanosonics	1,430	824	894
Neuren	1,580	2,646	2,636
Nova Eye	50	56	50
Opthea	257	338	382
Polynovo	1,070	1,519	1,684
Pro Medicus	6,943	12,538	14,600
SDI	98	94	93
Starpharma	127	47	39
Syntara Pharmaxis	35	24	29
Telix	3,644	5,259	6,150
Second 20			
4D Medical	231	231	204
Actinogen	73	73	166
Alcidion	120	78	63
Amplia	15	19	17
Atomo	13	19	16
Clarity	128	1,580	1,689
Curvebeam	87	58	51
Dimerix	24	272	281
Emvision	91	161	184
Imugene	572	490	395
Medadvisor MDR	136	242	275
Micro-X	62	53	48
Next Science	125	76	69
Orthocell	69	76	74
Paradigm	277	87	89
Percheron ANP	39	73	77
Prescient	65	36	31
Proteomics	104	127	115
Resonance	19	29	26
Universal Biosensors	55	43	45

* 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 and Telix 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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