



# Biotech Daily

Monday July 3, 2023

*Daily news on ASX-listed biotechnology companies*

- \* 17-YEAR BDI-40 UP 488%, ASX200 UP 42%
- \* FY 2023 ALL UP: BDI-40 53%, ASX200 10%, BIG CAPS 5%; NBI 9%, CC 9.5%
- \* TODAY: ASX, BIOTECH UP: ATOMO UP 64%; CYNATA DOWN 8%
- \* LUMOS UP 564% ON FDA FEBRIDX APPROVAL AS 'AID TO DIAGNOSIS'
- \* PACIFIC EDGE PREPARES TO LOSE US CXBLADDER COVER
- \* DIMERIX TO START CHINA PHASE III DMX-200 KIDNEY DISEASE TRIAL
- \* UNIVERSAL BIOSENSORS: FDA WANTS MORE XPRECIA INFORMATION
- \* MACH 7 POTENTIAL \$60m US VETERANS CONTRACT
- \* MICRO-X EXHIBITS ARGUS BOMB X-RAY DETECTOR
- \* EMYRIA TO ACQUIRE PAX CENTRE FOR \$1.7m
- \* IMRICOR APPOINTS AL FAISALIAH MEDICAL SAUDI ARABIA DISTRIBUTOR
- \* RHYTHM ESTABLISHES UK SUBSIDIARY FOR COLOSTAT
- \* RESPIRI EXTENDS ACCESS ACQUISITION CLOSING DATE
- \* DVT: IQ GROUP DOCA FAILS, CREDITOR MEETING
- \* PHARMAUST EGM 18% DISSENT
- \* GZ FAMILY TAKES 14% OF ATOMO
- \* REBECCA WILSON REPLACES LBT CHAIR JOANNE MOSS
- \* HERAMED APPOINTS CHAIR RON WEINBERGER EXECUTIVE
- \* LIVING CELL APPOINTS BRAD LATHAM DIRECTOR, PROF CAROLINE SUE CMO
- \* INVEX LOSES CHAIR DR JASON LOVERIDGE, CSO PROF ALEXANDRA SINCLAIR
- \* BIONOMICS APPOINTS ALAN FISHER CHAIR, TIM CUNNINGHAM CFO

## MARKET REPORT

The Australian stock market was up 0.59 percent on Monday July 3, 2023, with the ASX200 up 42.8 points to 7,246.1 points. Twenty-three of the Biotech Daily Top 40 stocks were up, nine fell and eight traded unchanged.

Atomo was the best, up 1.4 cents or 63.6 percent to 3.6 cents, with 4.6 million shares traded. Pharmaxis climbed 12.2 percent; Dimerix was up 11.3 percent; 4D Medical rose nine percent; Paradigm was up 6.1 percent; Amplia, Medical Developments and Nova were up more than five percent; Cyclopharm improved 4.5 percent; Clinuvel and Kazia were up more than three percent; Actinogen, Compumedics, Genetic Signatures, Impedimed, Imugene, Proteomics, Resonance and Volpara rose two percent or more; Mesoblast was up 1.8 percent; with Next Science, Opthea, Pro Medicus and Resmed up by less than one percent.

Cynata led the falls, down one cent or eight percent to 11.5 cents, with 560,261 shares traded. Universal Biosensors lost 7.7 percent; Neuren fell 3.1 percent; Avita, Emvision and Polynovo shed more than one percent; with CSL, Nanosonics, SDI and Telix down by less than one percent.

## BIOTECH DAILY TOP 40 INDEX (BDI-40)

For the financial year to June 30, 2023, the Biotech Daily Top 40 Index (BDI-40) climbed 52.6 percent to a cumulative market capitalization of \$20,944 million, compared to the benchmark ASX200 up 9.7 percent to 7,203 points (see charts below).

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) was up 5.3 percent to \$197,578 million – heavily influenced by CSL – with the Nasdaq Biotechnology Index (NBI) up 8.75 percent to 4,077 points.

For the 17 years since the inception of the BDI-40 Index, on June 30, 2006, the ASX 200 has climbed 41.96 percent from 5,074 points to 7,203 points.

The BDI-40 has climbed 11.6 times that, up 487.8 percent, from \$3,563 million to \$20,944 million in raw, unadjusted capitalization, and slightly better when adjusted for departures.

Eight of the original BDI-40 remain in the index: Immutep (Prima), Imugene, Mesoblast, Neuren, Opthea (Circadian), Pharmaxis, Polynovo (Metabolic) and Starpharma. Uscom has been in the BDI-40 for most of the 17 years but has been replaced from today by SDI.

In the month of June, the BDI-40 saw a plethora of small falls, a couple of large tumbles, and several major gains; with 12 up, seven by more than 10 percent and 24 down, with 12 down by 10 percent or more – mainly in the smaller Second 20.

Avita was the best for the month and year, up \$224 million or 51.49 percent in June to \$660 million (up 281.5% for the year), followed by Immutep (41.7%), Impedimed (33.5%), Next Science (15.7%), Paradigm (15.4%), Pro Medicus (12.0%) and Mesoblast (12.3%).

Atomo led the June and year to June 30 falls, down \$4 million or 23.5 percent to \$13 million for the month, followed by Starpharma (21.6%), Imugene (19.1%), Emvision (15.7%), Actinogen (13.1%), 4D Medical (12.2%) and Amplia (11.8%).

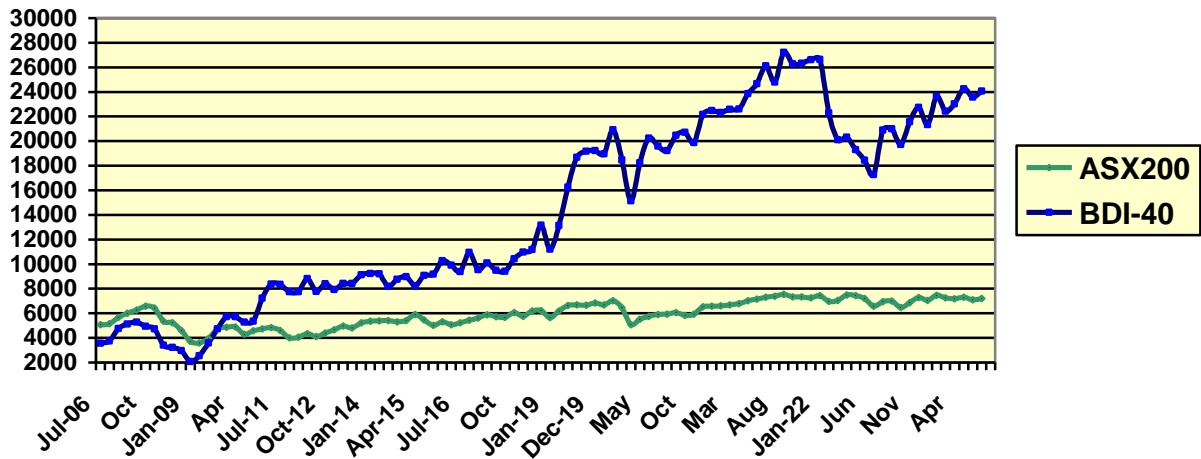
For the 12 months, Avita climbed 281.5 percent from \$173 million to \$660 million followed by Impedimed (236.1%), Neuren (229.9%), Telix (157.2%), Mesoblast (133.8%), Cyclopharm (97.9%), Nova Eye (85.2%) and Volpara (80.2%).

Atomo led the 12-month falls, down \$19 million or 59.4 percent to \$13 million, followed by Starpharma (57.9%), Cynata (57.7%), Kazia (57.6%), Genetic Signatures (54.8%), Patrys (48.8%) and Imugene (45.8%).

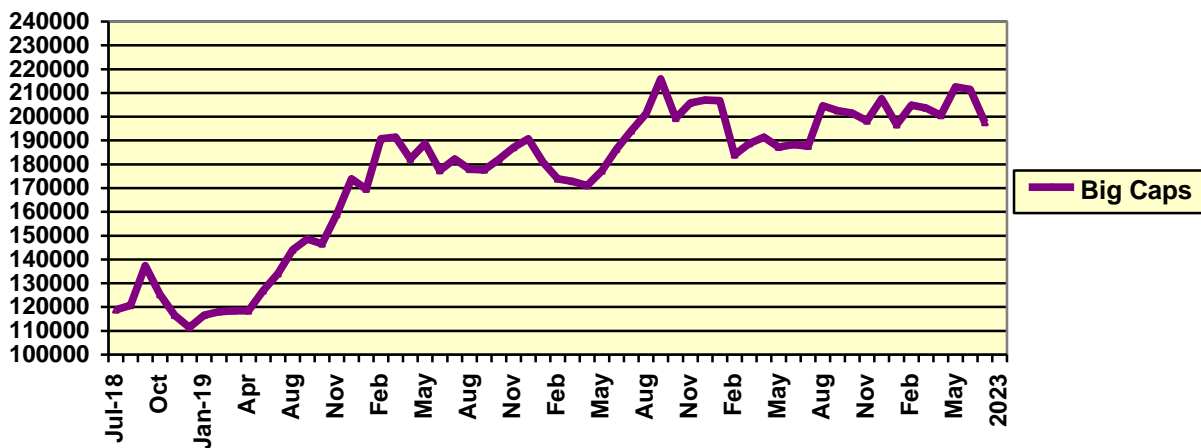
Outside the BDI-40, Bioxyne rose 375 percent in 12 months, from \$8 million to \$38 million, followed by Nuheara (191.7%), Arovella (180.0%), EBR (167.7%), Inoviq (116.7%), Medadvisor (109.2%) and Microba (97.8%). Regeneus fell 89.5 percent in the financial year from \$19 million to \$2 million followed by Pacific Edge down 87.6 percent from \$502 million to \$62 million, Exopharm (80%), Rhythm Bio (63.4%) and Bionomics (61.8%).

The 11 Cannabis Corner companies rose 9.5 percent to \$795 million for the year, with Botanix up 210.9 percent to \$171 million; Vitura up 108.0 percent to \$287 million; and from a low base, Zelira up 88.8 percent to \$17 million. The other eight either fell or barely moved for the 12 months. The 11-company high of \$1,405 million was at the end of 2021.

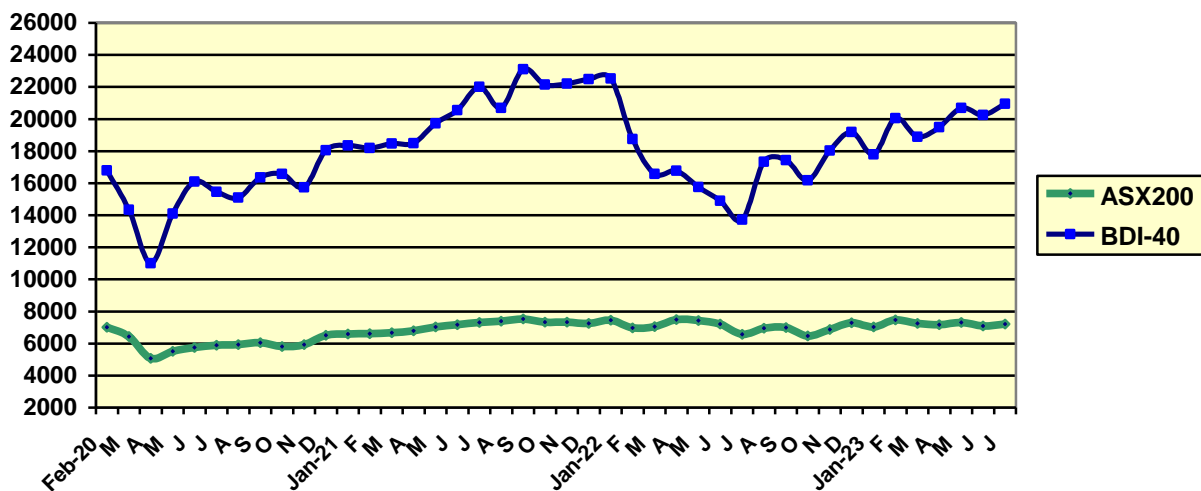
**BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2023- Adjusted**



**Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2018 – Jun 30, 2023**



**BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Jun 30, 2023 (pre-Covid to date)**



## LUMOS DIAGNOSTICS

Lumos says it has US Food and Drug Administration clearance to market its Febridx rapid, point-of-care, finger-prick, blood test to differentiate bacterial from viral infections.

Last year, Lumos said the FDA refused 510(k) clearance to market Febridx as it “did not demonstrate substantial equivalence to the predicate device”, citing concerns with risks associated with false negative viral infection results (BD: Jul 11, 2022).

Later that year, the company said it had filed an appeal to the FDA’s decision, which was rejected a month later when the FDA upheld its decision (BD: Aug 8, Oct 3, 2022).

At that time, Lumos said it was still able to file a new Febridx application to the FDA but “based on the feedback received from the FDA, [it was...] likely to require further investment and time to generate additional data before a new application could be submitted”.

Not long after, Lumos said it had results from a 496-person trial of Febridx that showed the device had a negative predictive value of 98.7 percent for bacterial infections and a 66.7 percent negative predictive value for viral infections (BD: Oct 19, 2022).

Today, the company said that following a pre-submission meeting in January 2023, it submitted a new 510(k) application for Febridx, which had been reviewed by the FDA and demonstrated “substantial equivalence to the predicate device”.

Lumos said the FDA clearance allowed Febridx to be marketed in the US for use “as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology in patients presenting in urgent care or emergency care settings”.

Lumos said Febridx had already received registration in the UK, Europe, Canada, UAE, Brazil, Turkey, Pakistan, Singapore, Malaysia and Australia.

Lumos chief executive officer Doug Ward said the company was “delighted to finally secure clearance to market our Febridx ... in the US as we continue to believe it has an important role to play in antibiotic stewardship”.

“With this clearance in hand, we anticipate securing our first commercial orders in the US before the end of ... 2023,” Mr Ward said.

Lumos was up 6.2 cents or 563.6 percent to 7.3 cents with 248.3 million shares traded.

## PACIFIC EDGE

Pacific Edge says its Cxbladder urine test for bladder cancer may lose US insurance cover from July 17, 2023, with some patients having to pay directly for the test.

Last month, Pacific Edge said its Cxbladder test for bladder cancer would cease to be covered by Medicare in the US from July 17, 2023 (BD: Jun 7, 2023).

Today, the company said all patients would be required to sign an ‘Advance beneficiary notice of non-coverage’ before taking the test and they would be encouraged to complete a patient assist form as part of the test ordering process.

Pacific Edge said Medicare and Medicare Advantage tests were about 60 percent of commercial Cxbladder tests performed in the year to March 31, 2023, which accounted for 77.7 percent of its operating revenue.

Pacific Edge chief executive officer Dr Peter Meintjes said the company expected many patients to accept some responsibility for payment if their insurer declined to cover the test once their physician explained how a Cxbladder test safely avoided a cystoscopy.

“While the impact on demand for our tests in the US is uncertain, we expect the new approach to improve collections in the event of denial from any non-contracted insurer, including Medicare, and make some contribution to revenues after July 17,” Dr Meintjes said.

Pacific Edge was untraded at 7.7 cents.

## DIMERIX

Dimerix says the Chinese National Medical Products Administration has acknowledged its phase III trial of DMX-200 for focal segmental glomerulosclerosis is “acceptable”.

Dimerix said the China regulator added that it “may not be required to conduct any further clinical studies before proceeding with the Action3 study in the Chinese population”.

The company said it intended to open clinical sites in China and that the trial was currently recruiting in Hong Kong and Taiwan.

Dimerix said it would also submit an investigational new drug application for its DMX-200 on mainland China.

Dimerix was up 0.7 cents or 11.3 percent to 6.9 cents with 1.2 million shares traded.

## UNIVERSAL BIOSENSORS

Universal Biosensors says the US Food and Drug Administration has requested “additional information” in response to its 510k application for its Xprecia Prime device.

In March, Universal Biosensors said it had submitted a 510(k) application to the FDA for its Xprecia Prime blood coagulation diagnostics (BD: Mar 24, 2023).

Today, the company said it had until December 13, 2023 to respond but expected a response to be submitted “well before the deadline”.

Universal Biosensors said it had signed a new distribution deal with Ebos Group Ltd for the exclusive sale of Xprecia Stride in Australia and New Zealand, with expected annual sales of about \$300,000.

Universal Biosensors said it had an amended agreement with Siemens Healthcare Diagnostics Inc whose distribution rights to sell Xprecia Stride, scrapping the \$2.2 million license fee it would have had to pay for the sale of Xprecia in the US.

Universal Biosensors fell two cents or 7.7 percent to 24 cents.

## MACH 7 TECHNOLOGIES

Mach 7 says it will provide its medical imaging systems to the US Veterans Health Administration (VHA) with a potential phase I total contract value of \$11.7 million.

Mach 7 said the contract included providing its vendor neutral archive and Eunity enterprise diagnostic viewer to the VHA’s National Teleradiology Program (NTP) to help form its picture archiving communication system (PACS) system.

The company said the NTP had been the VHA’s in-house teleradiology service for more than a decade, which supported 125 sites across the Veterans Integrated Services Networks (VISN) and was projected to interpret between 1.0 million and 1.5 million studies a year.

Mach 7 said it was one of several sub-contractors participating in the project under prime vendor Frontier Acquisitions LLC.

Mach 7 said the phase I program had a 12-month implementation and professional service fee period, then a fee per study subscription licence over a three-year term.

The company said phase II of the project was contingent on a number of factors in phase I, but involved an expansion into the Veterans Affairs’ hospital network, with a potential total contract value of \$47.9 million over a five-year term.

Mach 7 chief executive officer Mike Lampron said that “as a veteran myself, I’m proud that Mach7 has been given the honor to do its part in supporting our veterans”.

“This opportunity will allow us to expand our footprint into the US public health sector,” Mr Lampron said.

Mach 7 was up 11.5 cents or 18.55 percent to 73.5 cents.

## [MICRO-X](#)

Micro-X says it has demonstrated its Argus x-ray camera for the first time in the US at the International Association of Bomb Technicians and Investigators in Florida.

Micro-X said it exhibited its portable, backscatter, remote operation stand-off imaging device having recently complete its first field tests in Australia where images “were transmitted more than 1,500 metres line of sight from the target”.

The company said the showcase was attended by leading bomb disposal experts from military, law enforcement and first responder organizations.

Micro-X chief executive officer Kingsley Hall said the company was “delighted to have our first opportunity to demonstrate Argus’ unique capability to customers in the US”.

Micro-X has previously said it was developing its portable x-ray technology for general medical purposes as well as specifically for air ambulances for stroke patients.

Micro-X was unchanged at 12 cents.

## [EMYRIA](#)

Emyria says it will acquire Perth’s Pax Centre for \$1.7 million, with \$400,000 in cash and through the issue of 10,236,220 shares.

In March, Emyria said Pax Centre would develop a program for 3,4-methylene-dioxy-meth-amphetamine (MDMA)-assisted therapy for patients with post-traumatic stress disorder, which would provide clinical delivery and data monitoring for Pax Centre’s psychiatrists (BD: Mar 7, 2023).

Today, the company said the Pax Centre currently generated more than \$2.6 million a year and had “strong relationships with referrers and major health payers”.

Emyria managing director Dr Michael Winlo said the acquisition would strengthen the company’s clinical service foundations and build “a unique model for the delivery of emerging mental health treatments, such as psychedelic assisted therapies”.

Emyria was up 1.5 cents or 12 percent to 14 cents with 1.3 million shares traded.

## [IMRICOR MEDICAL SYSTEMS](#)

Imricor says it has a five-year, distribution agreement with Riyadh-based Al Faisaliah Medical Systems to distribute its cardiac ablation products in Saudi Arabia.

Imricor said Al Faisaliah was a subsidiary of Tibbiyah Holding Company and would obtain and maintain all required regulatory approvals to import and sell its products in Saudi Arabia, which was expected to be completed by October 2023.

The company said it anticipated product to launch in Saudi Arabia by October 1, 2023, with procedures to be completed in the first 12-months of the partnership.

Imricor was up 4.5 cents or 13.6 percent to 37.5 cents.

## [RHYTHM BIOSCIENCES](#)

Rhythm says it has established a fully-owned subsidiary to assist with the importation and distribution of its Colostat bowel cancer test in the UK and other parts of Europe.

Rhythm said Rhythm Biosciences UK Ltd would provide “the opportunity to engage directly with local customers and direct involvement with the supply chain requirements of Colostat.

The company said chair Otto Buttula and chief financial officer Paul Smith would be directors of the UK subsidiary.

Rhythm was up eight cents or 19.5 percent to 49 cents.

## RESPIRI

Respiri says it has extended the closing date for completing its acquisition of Access Managed Services LLC to August 10, 2023 to complete its “capital raise activities”. In May, Respiri said it would raise \$4.5 million in convertible notes to buy distributor Access Managed Services LLC (BD: May 24, 2023). Respiri fell 0.4 cents or 10.5 percent to 3.4 cents.

## IQ GROUP (IN ADMINISTRATION)

IQ Group administrators, Sydney’s DVT (de Vries Tayeh) says that deed of company arrangement has failed and a creditors meeting has been called for July 21, 2023. Last year, IQ3 said it had entered voluntary administration, with the Sydney’s DVT Group “to maximise the outcome for all stakeholders” (BD: Mar 11, 2022). In May, the DVT Group said that proponents of the deeds of company arrangement for the IQ Group of companies had requested a series of extensions due to delays in raising sufficient funds and were granted a final extension to June 30, 2023 (BD: May 31, 2023). Today, DVT said the deed proponents were “unable to satisfy the conditions precedent of each of the [deeds] as they have been unable to raise sufficient funds”. The administrator said that a virtual concurrent meeting of creditors would be held on July 21, 2023 at 11am, to vote on whether the deeds should be terminated and the companies placed into liquidation and, if applicable, administrator’s remuneration as the liquidator.

## PHARMAUST

Pharmaust says all eight resolutions at its extraordinary general meeting passed, but with up to 18.12 percent opposition to the special resolution amending its constitution. Pharmaust said 114,248,998 votes (81.88%) were in favor of amending its constitution, with 25,278,841 votes (18.12%) against. The company said all other resolutions passed with 9.01 percent to 15.57 percent dissent. According to its most recent filing, Pharmaust had 317,474,940 shares on offer, meaning that the 25,278,841 votes against the amendment of its constitution amounted to 7.96 percent, sufficient to requisition extraordinary general meetings. Pharmaust was in a trading halt at 7.3 cents.

## ATOMO DIAGNOSTICS

GZ Family Holdings Pty Ltd says it has increased its substantial holding in Atomo from 45,987,536 shares (8.06%) to 79,787,536 shares (13.98%). The Sydney-based GZ said it bought shares between May 17 and June 22, 2023, with the single largest purchase 28,800,000 shares for \$777,600 or 2.7 cents a share. Atomo was up 1.4 cents or 63.6 percent to 3.6 cents with 4.6 million shares traded.

## LBT INNOVATIONS

LBT says it has appointed director Rebecca Wilson as its chair replaced Joanne Moss, effective from today. LBT said Ms Wilson was currently the chair of Alcidion and non-executive director of London’s Ateria Health. LBT was unchanged at three cents.

## HERAMED

Heramed says it has appointed non-executive chair Dr Ron Weinberger as its executive chair on a base salary of \$250,000 and entitled to bonuses, effective from today.

Heramed said Dr Weinberger had been non-executive chairman since August 2018 and was previously Nanosonics and Emvision chief executive officer.

The company said David Groberman remained as chief executive officer.

Heramed was up 0.1 cents or 1.5 percent to 6.6 cents.

## LIVING CELL TECHNOLOGIES

Living Cell says it has appointed Bradley Latham as a non-executive director and Prof Carolyn Sue as chief medical officer of Ntcell effective from July 1, 2023.

Living Cell said Mr Latham had been chief executive officer of Sydney Markets since 2006 and held a Master of Management from the University of New South Wales.

The company said Prof Sue had been a director of the company but resigned to focus on the role of chief medical officer for Ntcell.

Living Cell was up 0.1 cents or 6.7 percent to 1.6 cents with 1.3 million shares traded.

## INVEX THERAPEUTICS

Invex says chair Dr Jason Loveridge and executive director and chief scientific officer Prof Alexandra Sinclair will resign, effective from July 10, 2023.

Invex said the resignations were a response to major shareholders who no longer supported Dr Loveridge and Prof Sinclair, following the ASX release of June 28, 2023.

Last week, the company fell 52.2 percent following the six-page 'Update' that said enrolment had slowed for its phase III clinical trial of Presendin for idiopathic intracranial hypertension, suggested protocol changes including a reduction from 240-patients to 130-patients and canvassed the use of Presendin for weight loss (BD: Jun 28, 2023).

Today, Invex said Dr Loveridge had been its chair since March 2019 and Prof Sinclair an executive director since June 2019 and had made "considerable contributions".

Invex said David McAuliffe would be interim chair from July 10, on \$60,000 a year.

Invex fell 2.5 cents or 12.5 percent to 17.5 cents with 2.5 million shares traded.

## BIONOMICS

Bionomics says it has appointed director Alan Fisher as its chair replacing Dr Errol De Souza and Tim Cunningham as its chief financial officer, replacing Adrian Hinton.

Bionomics said that Dr De Souza would continue as a director and Mr Hinton, who had been acting chief financial officer for four years would continue as a financial controller.

The company said it had appointed Dr Julie Kerner as head of business operations, Dr Atul Mahableshwarkar as acting chief medical officer and Francisco Bejar as a US business development adviser, with the head of strategy and development Connor Bernstein departing, effective from June 30, 2023.

Bionomics said that Mr Fisher was a director of Centrepont Alliance and Thorney Technologies Limited.

The company said that Mr Cunningham was a chief financial officer consultant at Danforth and previously was Organogenesis chief financial officer, had worked for KPMG and Price Waterhouse Coopers; and held a Bachelor of Science in accounting from Boston College and a Master of Business Administration from Boston University.

Bionomics was up 0.1 cents or 5.6 percent to 1.9 cents with 2.75 million shares traded.



## BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JULY 2, 2023

<b>Company \$Am</b>	<b>Jul-22</b>	<b>Jun-23</b>	<b>Jul-23</b>
Cochlear	13,070	15,998	15,084
CSL	129,608	147,793	134,243
Resmed	44,932	47,679	48,251
<b>BDI-20</b>			
Avita	173	436	660
Clinuvel	734	924	888
Compumedics	27	30	32
Cyclopharm	95	188	188
Cynata	52	24	22
Genetic Signatures	166	84	75
Immutep	251	264	374
Kazia	85	40	36
Medical Developments	104	74	67
Mesoblast	397	826	928
Nanosonics	1,014	1,518	1,430
Neuren	479	1,752	1,580
Nova Eye	27	50	50
Opthea	387	276	257
Pharmaxis	36	39	35
Polynovo	897	1,025	1,070
Pro Medicus	4,408	6,198	6,943
Starpharma	302	162	127
Telix	1,417	3,725	3,644
Volpara	106	193	191
<b>Second 20</b>			
4D Medical	173	263	231
Actinogen	90	84	73
Alcidion	139	120	120
Amplia	19	17	15
Antisense	50	42	39
Atomo	32	17	13
Dimerix	39	23	24
Emvision	116	108	91
Impedimed	108	272	363
Imugene	1,056	707	572
Micro-X	65	64	62
Next Science	155	108	125
Orthocell	80	72	69
Paradigm	220	240	277
Patrys	41	23	21
Prescient	101	65	65
Proteomics	98	117	104
Resonance	26	18	19
SDI	95	96	98
Universal Biosensors	78	54	55

\* Biotech Daily editor, David Langsam, owns shares in 4D Medical, 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.

**Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053**  
**email: [editor@biotechdaily.com.au](mailto:editor@biotechdaily.com.au); [www.biotechdaily.com.au](http://www.biotechdaily.com.au); twitter: @biotech\_daily**