Biotech Daily

Monday September 1, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: 4D MEDICAL UP 36%; CURVEBEAM DOWN 8%**

*** AUGUST BDI-40 DOWN 10%, BIG CAPS DOWN 13%, ASX200 UP 2.6%**

*** AUSBIOTECH WELCOMES FEDERAL NHMRC DRAFT STRATEGY**

*** 4D MEDICAL WINS FDA CT VQ CLEARANCE**

*** SYNTARA: 'FDA WANTS PHASE IIb SNT-5505 MYELOFIBROSIS TRIAL'**

*** NEURA, UNI-NSW BRAIN RESEARCH PARTNERSHIP**

*** INTEREST TAKES OPTHEA REVENUE UP 58% TO $8.5m; LOSS DOWN 26% TO $249m**

*** HYDRIX REVENUE DOWN 5% TO $10m; LOSS DOWN 69.5% TO $3m**

*** BOTANIX REVENUE UP 857% TO $5.8m; LOSS UP 526% TO $85m**

*** CHIMERIC $4m REVENUE; LOSS DOWN 17% TO $10m**

*** CARDIEX REVENUE DOWN 67% TO $3.5m; LOSS UP 95.5% TO $13m**

*** ISLAND REQUESTS GALIDESIVIR FOR MARBURG DISEASE FDA MEETING**

*** OSTEOPORE INVESTS $500k IN OSTEORX FOR 'LONGEVITY'**

*** ARGENICA REQUESTS 'RESULTS' TRADING HALT**

*** FIREBRICK CHAIR DR PETER MOLLOY DILUTED TO 12.7%**

*** FIREBRICK DIRECTOR STEPHEN GOODALL DILUTED TO 12.4%**

*** ONCOSIL APPOINTS TIM LUSCOMBE, DAVID WOOD CO-CO-SECS**

MARKET REPORT

The Australian stock market fell 0.51 percent on Monday September 1, 2025, with the ASX200 down 45.4 points to 8,927.7 points. Nine of the Biotech Daily Top 40 companies were up, 20 fell, 10 traded unchanged and one was untraded.

4D Medical was the best for the second trading day in a row, up 20.5 cents or 36.0 percent to 77.5 cents, with 23.0 million shares traded. Optiscan climbed 20.1 percent; Genetic Signatures improved 7.4 percent; Compumedics was up 3.6 percent; Cynata and Telix rose more than two percent; Neuren was up one percent; with Clinuvel, Imricor and Pro Medicus by up less than one percent.

Curvebeam led the falls, down one cent or 8.3 percent to 11 cents, with 129,000 shares traded. Mesoblast and Resonance lost more than seven percent; Medadvisor and Paradigm were down more than five percent; Nanosonics and Starpharma fell four percent or more; Actinogen, EBR, Nova Eye and Syntara were down more than three percent; Aroa, Emvision, Immutep, Medical Developments and Orthocell shed more than two percent; Alcidion, Clarity and CSL were down more than one percent; with Avita, Cochlear, Cyclopharm and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

There's no gilding the sow's ear. August was a bad month for Australian biotechnology. That said, it will make the Spring bounce-back look terrific or we really are in trouble.

Apart from CSL's 21.5 percent divestment write down, Telix announced a second FDA complete response letter wiping $2,028 million from its market capitalization and Mesoblast posted its first Ryoncil profits that didn't meet "market expectations". Luckily for the Biotech Daily Top 40 Index (BDI-40), on the monthly basis, Mesoblast was up $52 million to $3,098 million, despite Friday's sell-down, which curiously started on Thursday.

Biotech Daily believes the markets are skittish due to "global concerns", also known as the unpredictable nature of the Donald J Trump presidency of the United States and the bizarre behavior of the Secretary of Health and Human Services, Robert F Kennedy.

While the US does not have much impact on Australian biotechnology, the so-called "masters of the universe" are in full panic mode. The Telix complete response letter does not affect forecast revenue. Mesoblast has just begun selling Ryoncil. The CSL divestment of Seqirus is expected to add value.

In the last month of Southern Winter, the Biotech Daily Top 40 Index (BDI-40) fell 10.1 percent to a collective market capitalization of $18,900 million – its lowest point since May 31, 2024, while the benchmark ASX200 improved 2.6 percent to 8,973 points. The Nasdaq Biotechnology Index (NBI) rose 4.9 percent in August.

All four Big Caps, Cochlear, CSL, Pro Medicus and Resmed (which are not included in the BDI-40), fell in August, down 13.0 percent to $215,588 million. CSL lost $28,181 million or 21.5 percent to $102,992 million, followed by Pro Medicus 6.8 percent to $31,353 million, Cochlear 5.7 percent to $19,633 million and Resmed 0.9 percent to $61,610 million.

In August, 15 BDI-40 companies were up, with nine up by more than 10 percent, while 23 fell, with 14 down by more than 10 percent. Two were unchanged.

4D Medical was the best, climbing $153 million or 136.6 percent to $265 million, followed by Curvebeam (51.6%), Cynata (42.9%), Actinogen (34.2%), Starpharma (23.8%), Emvision (14.8%), Prescient (13.2%), Neuren (13.0%) and Nanosonics (11.3%).

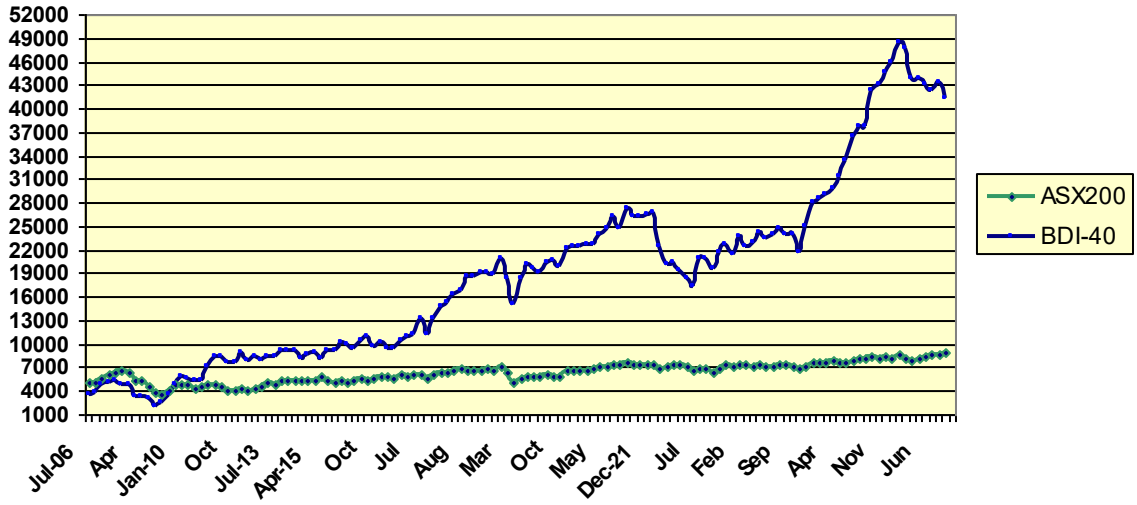
Syntara lost $54 million in August, down 55.1 percent to $44 million; followed by Universal Biosensors (42.9%), Amplia (31.6%), Medadvisor (29.8%), Telix (28.5%), Clarity (27.2%), Avita (19.4%), Genetic Signatures (18.7%), Alcidion (16.9%), Impedimed (16.8%), Optiscan (15.9%), Paradigm (15.6%), Compumedics (13.1%) and Resonance (11.9%).

Cannabis Corner climbed a collective 2.75 percent in August to $299 million. Avecho climbed $6 million or 37.5 percent to $22 million, while Neurotech led the falls, down $6 million or 28.6 percent to $15 million.

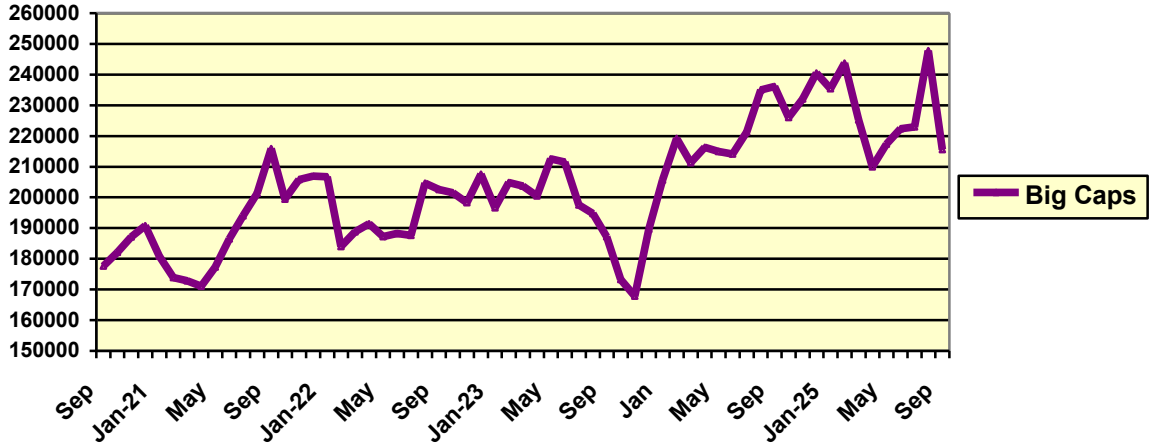
On the Nasdaq, Neuphoria (Bionomics) jumped 45.8 percent to $35 million followed by Eyepoint (16.3%), Incannex (10.6%) and Protagonist (8.1%).

Imricor replaces Universal Biosensors in the BDI-40.

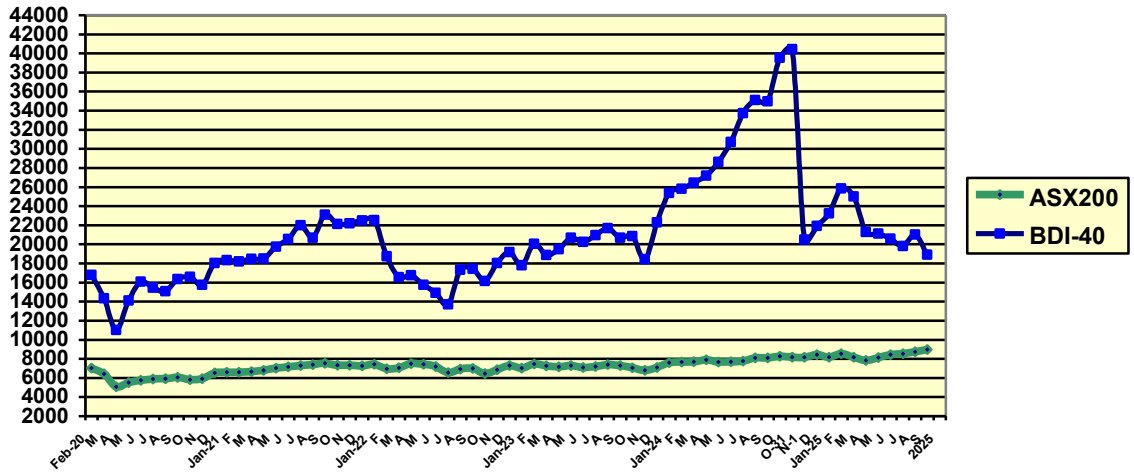
BDI-40 v ASX200 Jun 30, 2006 to Aug 31, 2025- Adjusted



Big Caps $m (COH, CSL, PME, RMD) Aug 31, 2020 – Aug 31, 2025



BDI-40 ($m) v S&P ASX 200 – Jan 31, 2020 – Aug 31, 2025 (Pre-Covid to date)



FEDERAL GOVERNMENT, NHMRC STRATEGY, AUSBIOTECH

National Health and Medical Research Strategy chair Rosemary Huxtable says the draft strategy sets out a 10-year plan Australia's health and medical research system.

The draft strategy said it expected the final strategy by the end of this year.

Ms Huxtable said that "supporting a thriving health and medical research ecosystem and skilled Australian researchers is essential for advancing knowledge and strengthening both the research and health sectors, ultimately leading to meaningful improvements in the well-being and prosperity of the Australian community".

Ms Huxtable said the strategy followed consultation in 2024 and 2025 with researchers, clinicians, policymakers, industry leaders, community leaders and consumers.

Ms Huxtable said "stakeholders can provide formal feedback through submissions and by participating in webinars, workshops and roundtables".

"All feedback will be analysed and synthesised to identify common themes, gaps and opportunities, to inform the development of actionable solutions that address the sector's needs and ambitions and place Australia at the forefront of global health and medical innovation," Ms Huxtable said.

The draft National Health and Medical Research Strategy said that health and medical research underpin "a modern, outcomes focused health system that can deliver equitably for the community … [and] is the foundation upon which health treatments, technologies and models of care are discovered, trialed, translated and commercialized, helping to improve health outcomes and, as a result, enabling a strong economy and fair society".

The draft National Strategy said its purpose was to: "deliver a plan to strengthen and leverage Australia's … research capability, leading to better health outcomes from a productive and efficient research ecosystem; provide strategic direction across the entire research continuum from initial discovery through to translation and scalable manufacturing of transformative research outcomes; ensure equity, access and workforce development through inclusive policies, broad participation and sustained investment in a diverse, skilled research community; [and] align and integrate with other [Federal Government] strategic initiatives

Last week, the Federal Minister for Health and Aged Care Mark Butler said the 10-year plan was "a step closer with the release … of a draft strategy for consultation".

"We have world-class medical researchers right here in Australia whose ideas can bring better health outcomes for Australians and people around the world," Mr Butler said.

"This landmark strategy will accelerate health and medical research in Australia to deliver innovative, equitable health outcomes," Mr Butler said.

"I encourage members of the Australian health and medical research community to review and provide feedback to Ms Huxtable on the draft strategy to ensure it reflects their vision and priorities," Mr Butler said,

Ausbiotech said it welcomed the draft National Health and Medical Research Strategy saying it "marks a significant step towards a national approach to health and medical research" and had engaged with Ms Huxtable and her departmental colleagues as they developed the draft Strategy and was continuing to engage its membership.

Ausbiotech chief executive officer Rebekah Cassidy said the sector "needs a coordinated and well-invested research sector".

"Without research, there is no pipeline of health innovation, no pipeline of companies, and no ecosystem to sustain them," Ms Cassidy said. Ms Cassidy said the draft strategy recognized "the need to strengthen sovereign manufacturing capability, streamline regulatory pathways, and incentivize local procurement of medical products to build sovereign capability and supply chain resilience".

The draft strategy is available at: https://bit.ly/47lVISv.

4D MEDICAL

4D Medical says the US Food and Drug Administration has granted its computed tomography ventricular-perfusion (CT VQ) 510(k) clearance.

4D Medical said its CT VQ scan was the “first non-contrast imaging modality capable of delivering quantitative ventilation and perfusion analysis directly from standard chest CT scans”, with VQ scans primarily used to diagnose pulmonary embolism, or lung blood clots, as well as used to evaluate chronic thrombo-embolic pulmonary hypertension (CTEPH), other airway diseases, and pre-operative planning for lung surgeries.

The company said more than one million nuclear VQ scans were performed in the US, each year, with an average reimbursement of $US1,150 a scan, or $US1.1 billion a year.

4D Medical managing-director Prof Andreas Fouras said “FDA clearance of CT VQ is a defining milestone for 4D Medical and for lung health”.

“For the first time in history, doctors can order a lung perfusion scan without requiring their patients to be injected with any radioactive tracer or contrast media,” Prof Fouras said.

“And unlike historical advancements in medical imaging, such as the introduction of [magnetic resonance imaging], this technology is instantly compatible with an install base of 14,500 CT scanners already deployed across the US,” Prof Fouras said.

“With FDA clearance now secured, 4D Medical is positioned to accelerate the commercial rollout of CT VQ across the United States,” Prof Fouras said.

“The company will engage with leading healthcare providers, academic centres, and strategic partners, to integrate this groundbreaking technology into clinical practice, supporting a shift toward safer, more efficient, and more accessible respiratory care,” Prof Fouras said.

4D Medical climbed 20.5 cents or 36 percent to 77.5 cents with 23 million shares traded.

SYNTARA

Syntara says the US Food and Drug Administration has recommended it conduct a phase IIb trial of amsulostat for myelofibrosis prior to a phase III trial.

Last month, Syntara fell 52.6 percent following news it had FDA guidance to conduct a phase II trial of amsulostat, or SNT-5505, for myelofibrosis with a control arm prior to a phase III trial (BD: Aug 11, 2025).

At the time, the company said the FDA had reviewed a data package that included interim data from its ongoing open-label trial of amsulostat with ruxolitinib, as well as a proposal for a registrational study, and said the FDA “provided guidance that a phase II trial with a control arm be undertaken to acquire additional safety and efficacy data, focusing on improvements in symptoms and spleen volume reductions in order to optimize the design and efficiency of a subsequent pivotal phase III trial”.

Today, Syntara said the phase IIb study would compare amsulostat to placebo in patients on a Janus kinase (JAK) inhibitor that were “not well controlled”, with the FDA recommending the study to “pinpoint the safety and efficacy profile” of amsulostat.

The company said the phase IIb study would reduce the clinical risk in the subsequent phase III trial, with the selection of patients and study endpoints based on data more accurately related to the effect of amsulostat in comparison to the data from its current open-label phase IIa study; and it expected its two blood cancer studies in myelodysplastic syndrome to report interim data by July 1, 2026.

Syntara said that it recognized the “volatility” in its share price, but said amsulostat hadn’t lost “any of its potential long-term value”, with positive interim data recently presented at the European Haematology Association meeting.

Syntara fell 0.1 cents or 3.7 percent to 2.6 cents with 1.7 million shares traded.

NEUROSCIENCE RESEARCH AUSTRALIA

Neuroscience Research Australia says it has a 10-year agreement with Sydney's University of New South Wales for brain health research.

The Sydney-based non-profit research institute, Neura, formerly the Prince of Wales Medical Research Foundation, said it would establish a "council to forge deeper collaborations … and unlock significant co-investment in new research programs, better facilities and the strategic recruitment of academic and research staff".

Neura said the research would include protecting brain health, maximizing brain function with the development of strategies that prevent loss of function and protect quality of life, and advancing diagnostics using neuroscience, genomics and artificial intelligence (A.I.).

The Institute said that, with the University of New South Wales it would develop the infrastructure for at-scale implementation of emerging therapies for Alzheimer's disease with the South-Eastern Sydney Local Health District.

Neura said more than 20 senior researchers and academics held conjoint positions at the Institute and the University of New South Wales, developing research, teaching and clinical practice across both institutions.

Neura chief executive officer Prof Matthew Kiernan said the agreement would lead to "opportunities to collaborate on increasingly profound breakthroughs in diagnosis and treatment of society's most pressing concerns".

"It formally aligns the curiosity and agility of a globally recognized medical research institute with the academic power of one of Australia's highest-ranked universities but also opens up opportunities to align with industry and expedite those outcomes," Prof Kiernan said.

The University of New South Wales vice chancellor Prof Attila Brungs said the "renewed partnership builds on our deep links and great successes while opening the door to a new chapter".

"Together, we're taking a significant leap forward, deepening our shared commitment to creating positive societal change and advancing research that makes a real difference, now and for generations to come," Prof Brungs said.

OPTHEA

Opthea says revenue for the year to June 30, 2025 was up 57.9 percent to $US5,557,000 ($A8,490,447), with net loss after tax down 26.1 percent to $US162,791,000 ($A248,700,000).

Opthea said that "interest income" was up 62.95 percent to $US5,532,000 and that "almost all of its finance income" was earned on short-term bank deposits.

In March, the company said its 993-patient, phase III 'Coast' trial of OPT-302 with aflibercept for wet AMD "failed to meet [its] primary endpoint"; and it would discontinue its wet age-related macular degeneration (AMD) trials after its 'Shore' phase III trial of OPT-302 with ranibizumab missed its primary endpoint of mean change in best corrected visual acuity (BD: Mar 24, 31, 2025).

In April, Opthea said that "in light of the negative trial results" it would decrease costs, including reducing its workforce by about 65 percent and in July said it had cut its staff by 85 percent and 50 percent of its board of directors (BD: Apr 10, Jul 30, 2025).

Today, Opthea said diluted loss per share fell 61.5 percent to 13.29 US cents, with negative net tangible assets per share up 128.6 percent to negative 16 US cents, with cash and equivalents of $US48,443,000 at June 30, 2025, compared to $US172,471,000 the prior year.

Opthea was in a suspension and last traded at 60 cents.

HYDRIX

Hydrix says revenue for the year to June 30, 2025 was down 4.9 percent to $10,092,472 with net loss after tax down 69.5 percent to $2,919,257.
Hydrix said the revenue came from its medical technology consulting services, including from its Guardian heart device business.
The company said that diluted loss per share was down 69.4 percent to 1.15 cents, with negative net tangible assets per share was up 57.5 percent from negative 1.53 cents to negative 2.41 cents, and cash and equivalents of $914,274 at June 30, 2025, compared to $1,153,080 at June 30, 2024.
Hydrix was untraded at 1.6 cents.

BOTANIX PHARMACEUTICALS

Botanix says revenue for the year to June 30, 2025 was up 856.6 percent to $5,757,266, with net loss after tax up 526.4 percent to $85,873,894.
Botanix said revenue was from sales of its Sofdra topical gel for excessive underarm sweating, with the loss attributed to expenditure from commercial production of Sofdra.
The company said diluted loss per share was up 408.7 percent to 4.68 cents, with net tangible assets per share down 38.1 percent from 4.38 cents to 2.71 cents, and cash and equivalents of $64,966,581 at June 30, 2025, compared to $79,308,130 the prior year.
Botanix was unchanged at 14.5 cents with 6.2 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has $3,968,525 revenue for the year to June 30, 2025, primarily from a funding payment, with net loss after tax down 16.75 percent to $10,430,424.
Earlier this year, Chimeric said it had $4.0 million in non-dilutionary funding “from an undisclosed US-based philanthropic family office” to develop its CHM CDH17 for cancers (BD: Feb 27, 2025).
Today, the company said it had received $US2.5 million ($3.82 million) in non-dilutive funding from the “undisclosed US-based philanthropic family office”.
Chimeric said diluted loss per share fell 57.2 percent to 0.77 cents, net tangible assets per share was down 58.7 percent from negative 1.09 cents to negative 0.45 cents, with cash and equivalents of $5,757,474 at June 30, 2025, compared to $3,053,001 the prior year.
Chimeric was unchanged at 0.3 cents with 2.6 million shares traded.

CARDIEX

Cardiex says revenue for the year to June 30, 2025 was down 67.4 percent to $3,551,284, with net loss after tax up 95.5 percent to $6,765,365.
Cardiex said revenue was from sales of its hypertension and vascular disease devices and Sphygmocor central blood pressure technology, with the increase in loss largely due to the fall in revenue.
The company said $7,669,307 of revenue from the prior year was recorded “upon the early conclusion and subsequent payment in full of the multi-year Clinichain clinical trial” and that excluding Clinichain, revenue increase by 10 percent of $314,955.
Cardiex said diluted loss per share rose 8.8 percent to 3.7 cents, with net tangible asset per share down 22 percent from 1.18 cents to 0.92 cents, and had cash and equivalents of $2,433,097 at June 30, 2025, compared to $481,429 the prior year.
Cardiex fell 0.1 cents or 3.2 percent to three cents with 1.9 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has requested a meeting with the US Food and Drug Administration on Galidesivir for Marburg virus disease, as part of its investigational new drug application.
Island said the type C meeting would “seek alignment with the regulator regarding the use of the animal rule for Galidesivir’s” as well as to provide feedback on any other required documentation, study design, quality control and priority review voucher potential.
The company said the FDA’s animal rule allowed for a drug approval based on animal data when human trials were unethical or not feasible, provided safety was shown in humans and the disease was well-modelled in animals.
Island said that “based on previous clinical development work, which was underpinned by over $US70 million in funding support from the US government” it might have to undertake one additional animal efficacy study prior to the submission of a new drug application.
The company said it had requested an in-person meeting by January 2026.
Island fell half a cent or 2.3 percent to 21.5 cents.

OSTEOPORE

Osteopore says it will invest $500,000 into special purpose vehicle Osteorx, which will focus on “cellular regeneration, gero-science and longevity science”.
Osteopore said the Bay Area, California-based stem cell company Rxcell Inc would have a controlling stake in Osteorx, with Rxcell’s Dr Xianmin Zeng and Dr Brian Kennedy to provide an in-kind contribution, with Osteopore contributing “clinical, regulatory, and commercialization experience”.
Osteopore fell 0.2 cents or 16.7 percent to one cent with 2.1 million shares traded.

ARGENICA THERAPEUTICS

Argenica has requested a trading halt pending an announcement “regarding top line results of its phase II ARG-007 acute ischaemic stroke clinical trial”.
Trading will resume on September 3, 2025 or on an earlier announcement.
Argenica last traded at 65 cents.

FIREBRICK PHARMA

Firebrick executive chair Dr Peter Molloy says his 31,811,017 share-holding has been diluted from 14.35 percent to 12.74 percent, by a private placement on August 29, 2025.
Last week, Firebrick said it had commitments to raise $1.4 million at 6.3 cents a share in a placement of its shortfall, taking the total raised to $1.595 million (BD: Aug 26, 2025).
Firebrick fell 0.1 cents or 1.3 percent to 7.4 cents.

FIREBRICK PHARMA

Firebrick executive director Stephen Goodall says his 31,038,290 share-holding has been diluted from 14.00 percent to 12.43 percent (see above).

ONCOSIL MEDICAL

Oncosil says it has appointed Tim Luscombe and David Wood joint company secretaries, replacing Acclime’s Olga Smejkalova, effective from September 1, 2025.
Oncosil was unchanged at a post 400-to-one consolidation $1.145 with two shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT AUGUST 31, 2025

Company $Am	Aug 31, 2024	Jul 31, 2025	Aug 31, 2025
Cochlear	19,419	20,830	19,633
CSL	148,808	131,173	102,992
Pro Medicus	15,376	33,626	31,353
Resmed	52,484	62,141	61,610
BDI-20			
Avita	343	222	179
Clarity	2,280	1,625	1,183
Clinuvel	772	650	628
Compumedics	57	61	53
Cyclopharm	153	116	109
Cynata	35	35	50
EBR Systems	345	634	573
Genetic Signatures	170	75	61
Immutep	588	396	360
Impedimed	97	95	79
Medical Developments	46	69	66
Mesoblast	1,085	3,046	3,098
Nanosonics	945	1,230	1,369
Neuren	1,944	2,178	2,462
Nova Eye	48	41	43
Orthocell	80	312	293
Polynovo	1,637	891	936
SDI	111	105	105
Syntara	44	98	44
Telix	6,184	7,123	5,095
Second 20			
4D Medical	181	112	265
Actinogen	122	76	92
Alcidion	97	154	128
Amplia	33	117	80
Aroa	188	217	224
Atomo	13	14	15
Botanix	724	294	294
Curvebeam	67	31	47
Dimerix	248	282	270
Emvision	185	149	171
Imricor	129	393	450
Imugene	434	78	82
Medadvisor	245	47	33
Micro-X	35	55	51
Optiscan	163	88	74
Paradigm	86	141	119
Prescient	35	38	43
Proteomics	108	59	52
Resonance	29	17	18
Starpharma	41	42	52

* Biotech Daily editor, David Langsam, owns shares in 4D Medical, Acrux, Actinogen, Alcidion, Amplia, Clarity, Cochlear, Control Bionics, EBR, Nanosonics, Neuren, Patrys, Percheron, Polynovo and Telix as well as 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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