Biotech Daily

Monday October 2, 2023

Daily news on ASX-listed biotechnology companies

*** SEPTEMBER INDICES: BDI-40 UP 0.7%; ASX200, BIG CAPS, NBI, CC DOWN**

*** TODAY: ASX DOWN, BIOTECH UP: NOVA EYE UP 18%; PRESCIENT DOWN 5%**

*** US FDA APPROVES CYCLOPHARM TECHNEGAS - $280m A YEAR MARKET**

*** VICTORIA: BEN CARROLL RESEARCH; NATALIE HUTCHINS JOBS, INDUSTRY**

*** AMPLIA: 'NARMAFOTINIB (AMP945) IMPROVES CHEMO, IN MICE'**

*** AVITA: FDA DATA QUERY DELAYS RECELL GO 6 MONTHS**

*** POLYNOVO RECEIVES BARDA $15.5m FOR NOVOSORB TRIAL**

*** IMAGION WILL 'REDUCE HEADCOUNT' TO CUT COSTS**

*** PACIFIC EDGE: FDA PROPOSES LAB TEST REGULATORY CHANGES**

*** PHARMAXIS REQUESTS 'COMPANY RESTRUCTURE' TRADING HALT**

*** FIL (FIDELITY) BELOW 5% IN STARPHARMA**

*** ACADIA PARK BELOW 5% IN IMPEDIMED**

*** MESOBLAST LOSES 19-YEAR DIRECTOR MICHAEL SPOONER**

*** CLEO CSO, DIRECTOR DR ANDREW STEPHENS FULL-TIME**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday October 2, 2023, with the ASX200 down 15.4 points to 7,033.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Nova Eye was the best, up 3.5 cents or 17.95 percent to 23 cents, with 705,422 shares traded. 4D Medical climbed 16.7 percent; Imugene improved 8.7 percent; Cynata climbed 7.7 percent; Actinogen and Compumedics were up five percent or more; Alcidion and Micro-X gained four percent or more; Genetic Signatures and Proteomics were up more than three percent; Cyclopharm, Dimerix, Immutep, Neuren, Orthocell and Polynovo rose more than one percent; with Clinuvel and Pro Medicus up by less than one percent.

Prescient led the falls, down 0.3 cents or 5.3 percent to 5.4 cents, with 497,354 shares traded. Emvision and Opthea fell more than four percent; Atomo, Next Science, Paradigm and Starpharma were down more than three percent; Avita, Impedimed and Resmed shed two percent or more; CSL, Mesoblast, Nanosonics, Universal Biosensors and Volpara were down more than one percent; with Cochlear down by 0.2 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Southern Spring arrived for the Biotech Daily Top 40 Index (BDI-40) which was up 0.7 percent to a collective market capitalization of $20,842 million, with all other indices down.

The benchmark ASX200 fell 3.5 percent in September, but was up 8.9 percent for the year to September 30, while the BDI-40 was up 28.9 percent for the 12 months.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell a further 7.5 percent in September and were down a significant 14.05 percent for the year, primarily from losses by CSL and Resmed, despite the latter's continuous record revenue and profit results.

Cochlear fell the least, down 6.05 percent to $16,747 million, from last month's largest market capitalization in its history – while Resmed was down 7.4 percent to $34,711 million, on concerns over the impact of the recently-approved weight loss drugs, and the CSL Magic Pudding was off the boil, down 7.7 percent to $121,752 million.

The Nasdaq Biotechnology Index (NBI) fell 3.9 percent in September, but was up 4.9 percent for the year. The 11 companies in Cannabis Corner lost 16.9 percent in September and 44.3 percent for the year to September 30, 2023 (see below).

Fifteen of the Biotech Daily Top 40 Index (BDI-40) companies were up, nine by more than 10 percent; but 24 fell, with 12 down by more than 10 percent.

Pro Medicus was the numerical best, adding $820 million to the index, compensating for the plethora of generally small falls.

From a much lower base, Resonance was the percentage best, up 33.3 percent to $36 million, followed by Proteomics (28.3%), Cyclopharm (18.2%), Genetic Signatures (17.7%), Micro-X (13.8%), Starpharma (13.3%), Antisense (13.0%), Universal Biosensors (11.8%), Pro Medicus (10.7%), Opthea (9.0%) and Telix (4.8%).

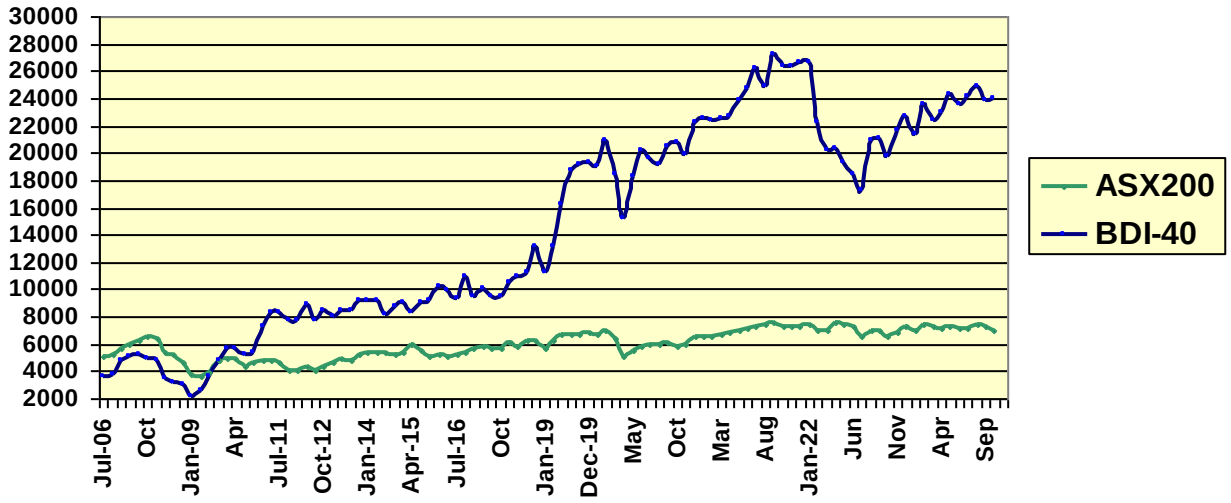
Patrys led the falls, down $7 million or 33.3 percent to $14 million, followed by 4D Medical (32.5%), Imugene and Prescient (29.2%), Mesoblast (25.5%), Clinuvel (22.4%), Pharmaxis (17.2%), Alcidion (11.95%), Polynovo (11.4%), Dimerix and Neuren (11.1%), and SDI (10.4%).

Outside the BDI-40, Clarity was at its highest market capitalization at $306 million, along with Arovella, Painchek, Mach7 Technologies and Microba.

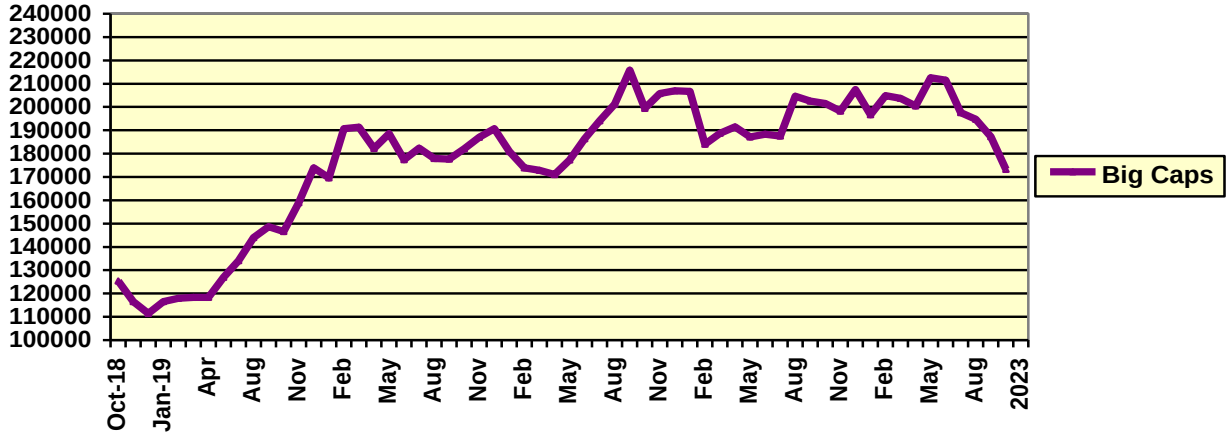
Seven of the 11 marijuana companies fell, three improved and one was unchanged. Next month Melodiol (Creso) will be replaced by Little Green Pharma, with Algorae (formerly Living Cell) climbing on the bandwagon, having moved from cell therapies to marijuana.

On the Nasdaq, Adelaide's Bionomics jumped $US2.3899 or 243.84 percent to $US3.370 ($A5.218) on Thursday, but closed the month at $US2.70, with a market capitalization of $34 million, 61.9 percent above the previous month. Redhill with Australian assets fell a further 37.55 percent to $5 million, Eyepoint (formerly Psivida) was down 18.7 percent to $435 million and Queensland's Protagonist shed 15.1 percent to $1,493 million.

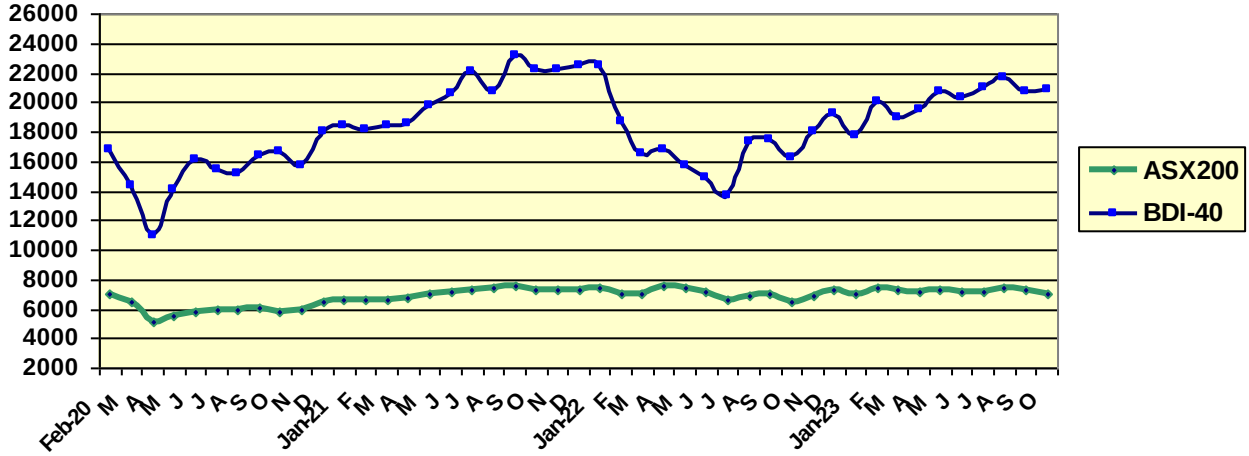
BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2023- Adjusted



Big Caps $m (Cochlear, CSL, Resmed) Sep 30, 2018 – Sep 30, 2023



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



CYCLOPHARM

Cyclopharm says the US Food and Drug Administration has approved Technegas for pulmonary embolism imaging - opening a $US180 million ($A279.5 million) a year market.

Cyclopharm managing-director James McBrayer told Biotech Daily that Technegas had been approved as a point-of-care combination product meaning that the FDA considers the Technegas generators as both a device and a drug.

Mr McBrayer said the company's founders contacted the FDA to discuss approval 32 years ago, in 1991, he joined the company in 2008 and his first contact with the US regulator was the following year in 2009.

Mr McBrayer said the US was the 65th jurisdiction to approve Technegas.

In its announcement to the ASX, Cyclopharm said the US was the largest market for Technegas and "strong pre-existing demand [was] expected to drive sales momentum for an immediate US wide rollout".

The company said that the FDA approval allowed broad use of Technegas, supporting wider future indications across other respiratory disease states including chronic obstructive pulmonary disease (COPD), asthma, long Covid and lung cancer

Cyclopharm said it would complete final assembly of its first wave of 200 generators, with plans for the first air shipments to arrive in the US by early November.

The company said it would provide and install Technegas generators to nuclear medicine departments to increase adoption and use of the single patient consumables which generated recurring annuity style revenue.

Cyclopharm said that agreements were in place for third-party distribution, generator service, installation and administrative support for Technegas in the US, with 420 formal expressions of interest in the product.

The company said that over the past three decades Technegas had been successfully used in 64 countries worldwide, amassing 4.7 million patient studies, with Technegas the preferred nuclear medicine lung ventilation imaging agent, referenced, in the Canadian and European nuclear medicine guidelines.

Cyclopharm said that the FDA approval covered the complete Technegas product, including its manufacture in and distribution from Australia.

The company said the US had about four million procedures a year to rule out pulmonary embolism, with 15 percent, or 600,000 procedures, using nuclear medicine for patients contra-indicated for computed tomography contrast media, including pregnant patients, those with renal impairment or allergies to the contrast or had radiation concerns.

Cyclopharm said the initial target of 600,000 nuclear medicine imaging procedures was estimated to be about $US90 million a year, and it expected a 50 percent share over the next two to three years, rising to more than 80 percent over three to five years; and it hoped to double the US nuclear medicine pulmonary embolism imaging market.

Cyclopharm said that US reimbursement codes were based on established procedures and Technegas could be used immediately under existing bundled procedural codes.

"While FDA approval for Technegas is a major milestone for Cyclopharm, our ability to now make this technology available to US clinicians and to the patients they serve, is where the key significance lies," Mr McBrayer said.

In 2020, Cyclopharm said its 240-patient, phase III Technegas lung imaging trial was halted after data from 200 patients met the primary efficacy endpoint and in January the Society of Nuclear Medicine and Molecular Imaging called on the FDA to expedite the approval of Technegas (BD: Sep 15, 2020; Jan 22, 2021).

In 2021, Cyclopharm received an FDA complete response letter and in March 2023 filed its response (BD: Jun 28, 2021; Mar 30, 2023).

Cyclopharm was up four cents or 1.4 percent to $2.87 with 482,472 shares traded.

VICTORIA GOVERNMENT

Victoria Premier Jacinta Allan says that Deputy Premier Ben Carroll has been appointed as the Minister for Medical Research.
In a media release on her website Ms Allan said that Tim Pallas would continue as Treasurer and Mary-Anne Thomas would continue as the Minister for Health.
Ms Allan said that Natalie Hutchins had been appointed the Minister for Jobs and Industry to lead the Department of Jobs, Skills, Industry and Regions.
The media release said that the Ministry would be sworn-in by the State Governor today.

AMPLIA THERAPEUTICS

Amplia says that narmafotinib, formerly AMP945, "significantly reduces pancreatic cancer-associated fibrosis through inhibition of [focal adhesion kinase] activity" in mice.
Amplia said that in a number of in-vivo pancreatic cancer models, narmafotinib could be used to improve the chemotherapy response.
Amplia chief executive officer and co-author of the study, Dr Chris Burns, told Biotech Daily that the data reported at the conference used mouse models of pancreatic cancer and the results further underpinned the rationale of combining a focal adhesion kinase (FAK) inhibitor with chemotherapy.
Dr Burns said that the Accent trial was a combination of narmafotinib with the Australian standard-of-care, namely Gemcitabine and nab-paclitaxel and was well underway with a phase IIa trial to begin shortly.
In August, Amplia said it began dosing the last of the third cohort in its phase Ib/IIa trial of AMP945 for pancreatic cancer, identifying a dose for phase IIa (BD: Aug 2, 2023).
In 2022, Amplia said it had dosed the first of 12 patients in the open-label trial, studying the pharmaco-kinetics, safety and efficacy of AMP945 in combination with nab-paclitaxel (Abraxane) and gemcitabine for pancreatic cancer (BD: Aug 2, 2022)
Today, Dr Burns told Biotech Daily that "importantly, the poster also shows benefits of the combination of narmafotinib with Folfirinox [folinic acid, 5-fluorouracil, irinotecan and oxaliplatin] the latter being the preferred treatment option in the US and Europe".
In the ASX media release Dr Burns said that the new pre-clinical data "provides additional support for the activity of narmafotinib in combination with the two major chemotherapy regimens for pancreatic cancer".
Amplia said that plans were underway to begin clinical trials using narmafotinib in combination with Folfirinox in a similar design to the Accent trial.
The poster, titled 'Pulsed priming with narmafotinib reduces fibrosis and enhances both gemcitabine/Abraxane & FOLFIRINOX response in pancreatic cancer' was presented at the American Association for Cancer Research Pancreatic Cancer Conference in Boston.
Amplia said that the data from the studies further supported the combination of narmafotinib (AMP945) with chemotherapy in pancreatic cancer.
The company said that the poster described work conducted by its collaborators at the Sydney's Garvan Institute of Medical Research and was presented by postdoctoral researcher Dr Kendelle Murphy.
Dr Burns said that the company was "delighted that this extensive body of research from the Garvan Institute on our best-in-class FAK inhibitor narmafotinib is being presented at such a prestigious conference".
"The Garvan team have done an outstanding job and this poster represents the first public disclosure of the breadth of that work demonstrating the impressive activity of the drug in these preclinical studies," Dr Burns said.
Amplia was unchanged at 8.1 cents.

AVITA MEDICAL

Shortly before the market closed on Monday, Avita said the US Food and Drug Administration requires more data for its Recell Go application, delaying its launch.

In an announcement to the ASX, titled 'Form 8-K', Avita said that at the halfway point of the 180-day pre-market approval (PMA) process, it received a notice from the FDA that additional information regarding the PMA was "required for the continuation of a substantive review".

The company said that the request was "not unique to the breakthrough device program [and] places the application file on hold for approximately four to six months while the company addresses the FDA's questions", but did not disclose the FDA questions.

The company said that when it had filed its response to the FDA's request, the application would re-enter the 180-day cycle, with 90 days remaining in the review period.

Avita said that the "timing would imply a product launch between May 1 and July 1, 2024".

In June, the company said it had submitted a pre-market approval supplement application for Recell Go, starting "a prioritized, interactive review of the PMA under the FDA's breakthrough device program, which follows a 180-day review cycle" (BD: Jun 30, 2023).

Avita said at that time that Recell Go eliminated the need to manually manage skin samples, with single-use processing cartridges on an electronic device.

The company said that Recell Go maintained FDA breakthrough device designation from previous devices, granting it prioritized review with approval expected in January 2024.

Avita fell nine cents or two percent to $4.47.

POLYNOVO

Polynovo says it has received a further $US10 million ($A15.5 million) from the US Biomedical Advanced Research and Development Authority for its pivotal Novosorb trial.

In 2021, Polynovo said it had enrolled the first of 150 patients in the Biomedical Advanced Research Development Authority (BARDA)-funded, pivotal trial of its Novosorb biodegradable temporizing matrix (BTM) for full-thickness burns, with BARDA providing $US15 million for the trial (BD: Sep 21, 2021).

At that time, the company said the trial would be conducted over three years in 20 US and five Canadian burns centres and would compare Novosorb BTM against the existing standard-of-care for full thickness burn patients.

Today, Polynovo said the further $US10 million in BARDA funding took the total for the trial to $US25 million.

Polynovo said the trial had enrolled 71 patients of a target 120, with recruitment expected to be completed by June 30, 2024.

The company said it was recruiting at 22 US burn centres and one Canadian site, with five more US sites, four Canadian sites and three Indian sites in the process of joining the trial.

Polynovo said the trial was gathering data on the effectiveness of Novosorb as a burns treatment and would allow it to file a pre-market approval (PMA) application with the US Food and Drug Administration; and, if approved, Novosorb would be used to treat full thickness burns and might lead to BARDA buying Novosorb for disaster management.

The company said Novosorb was already indicated for full thickness burns outside the US and had Commission Européenne mark.

Polynovo chair David Williams said "BARDA and Polynovo have a clear end-game to bring our technology to as many patients as possible".

"It is an honor for us to know that our technology will play an important part in the US preparedness for mass disasters," Mr Williams said.

Polynovo was up 2.5 cents or 1.9 percent to $1.33 with 768,957 shares traded.

IMAGION BIOSYSTEMS

Imagion says it will undergo “expense reduction initiatives” to reduce its cash burn, including reducing staff.
Imagion said the staff restructuring “will allow the company to better align its resources with the upcoming expenditures as the company advances its Magsense Her2 program”.
The company did not specify how many staff would be lost or the details of the further expense reduction initiatives.
Imagion chief executive officer Dr Isaac Bright said “the decision to reduce headcount is difficult for any business to make”.
“However, it is the right thing for the company as we increase focus on business partnering opportunities while navigating current market conditions,” Dr Bright said.
“We remain confident that we can continue to build value for our shareholders and improve outcomes for patients, as we remain on schedule to submit an [investigational new drug application to the US Food and Drug Administration] in the first quarter of 2024,” Dr Bright said.
Imagion was up 0.05 cents or 3.7 percent to 1.4 cents with 1.9 million shares traded.

PACIFIC EDGE

Pacific Edge says the US Food and Drug Administration has proposed rule changes to have laboratory developed tests (LDTs) like its Cxbladder regulated as medical devices.
Pacific Edge said the proposed changes would require it to present evidence to the FDA that its Cxbladder genomic biomarker urine test for the detection of bladder cancer was safe and effective in addition to the Clinical Laboratory Improvement Amendment (CLIA) regulatory pathway.
The company said it was “working through the implications of this proposed rule change” but noted the FDA announcement reflected an ongoing process that had significant implications for the multi-billion-dollar US clinical testing industry.
Pacific Edge said the proposed rule change would be phased in during a four-year period, after the changes were finalized, and that a 60-day comment period was expected to open on the rule changes on October 3, 2023.
Pacific Edge said the FDA had not provided a timeline on when it would make a final decision on the proposed US Federal Food, Drug and Cosmetic Act.
The company said the American Clinical Laboratory Association had opposed unilateral FDA action to regulate laboratory developed tests under medical device authority, and that it shared many of the views the Association had published.
Pacific Edge chief executive officer Dr Peter Meintjes said the current regulatory system worked “well for patients and therefore any changes to the regulatory system must maintain that standard outcome”.
“We will continue to work with our partners regarding regulation of our industry that is in the best interests of all stakeholders,” Dr Meintjes said.
“Notwithstanding this position, we have long recognized [the] FDA’s intention to extend its oversight to include [laboratory developed tests],” Dr Meintjes said.
“Consequently, Pacific Edge has been working to prepare the company for this potential regulatory change to minimize any disruption to our US operations, including adopting good clinical practice guidelines, and digitalizing our clinical development program,” Dr Meintjes said.
“We will continue to inform shareholders of our ability to comply with all evolving regulatory requirements,” Dr Meintjes said.
Pacific Edge fell 1.5 cents or 12 percent to 11 cents.

PHARMAXIS

Pharmaxis says it has requested a trading halt “pending an announcement by the company to the market in relation to a company restructure”.
Trading will resume on October 4, 2023, or on an earlier announcement.
Pharmaxis last traded at 3.3 cents.

STARPHARMA HOLDINGS

FIL Limited (Fidelity Investment) says it has ceased its substantial shareholding in Starpharma with the sale of 1,130,580 shares.
The Hong Kong-based FIL said it sold the shares in 17 transactions between September 19 and September 27, 2023 at prices ranging from 15.00 cents to 16.58 cents a share.
Last month, FIL said that it held 21,422,025 Starpharma shares, or 5.22 percent.
Biotech Daily calculates FIL retains 20,291,445 Starpharma shares, or 4.94 percent.
Starpharma fell half a cent or three percent to 16 cents.

IMPEDIMED

Acadia Park Pty Ltd and associates say they have ceased their substantial shareholding in Impedimed.
In July, Impedimed said it had received a Corporations Act 2001 203D notice from Acadia Park Pty Ltd calling for the replacement of directors (BD: Jul 31, 2023).
Last week, the company said an extraordinary general meeting voted to replace directors with about 58 percent of votes in favor (BD: Sep 28, 2023).
Today, Acadia said the association arose “for the purposes of controlling or influencing the composition of Impedimed’s board of directors” and had ceased.
Impedimed fell half a cent or 2.9 percent to 17 cents.

MESOBLAST

After the market closed on Friday, Mesoblast director Michael Spooner said in an Appendix 3Z final director’s interest notice that he had resigned on September 26, 2023.
According to the Commsec website, Mr Spooner was a former Mesoblast executive chair and had been with the company for 19 years, since his appointment on October 1, 2004.
Last week, in an announcement about Jane Bell being appointed chair of the audit and risk committee, the company “thanked retiring director the chair of the audit and risk committee Mr Michael Spooner for his many years of dedicated service and contributions and wished him well in his future endeavors”.
Mesoblast fell half a cent or 1.3 percent to 38.5 cents.

CLEO DIAGNOSTICS

Cleo says chief scientific officer and executive director Dr Andrew Stephens has moved from part-time to full-time, effective from October 1, 2023.
Cleo said Dr Stephens had agreed to expand his commitment to the company with the remaining terms and conditions of his employment agreement unchanged.
The company said the move was “designed to direct clear executive focus on the company’s phased development strategy to deliver a simple and accurate blood test capable of detecting ovarian cancer at every stage”.
Cleo was untraded at 18 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEPTEMBER 30, 2023

Company $Am	**Oct-22**	**Sep-23**	**Oct-23**
Cochlear	13,706	17,826	16,747
CSL	138,271	131,942	121,752
Resmed	49,538	37,488	34,711
BDI-20			
Avita	208	636	582
Clinuvel	901	949	736
Compumedics	43	35	33
Cyclopharm	133	225	266
Cynata	45	23	23
Genetic Signatures	126	62	73
Immutep	212	338	332
Kazia	27	38	39
Medical Developments	145	76	74
Mesoblast	582	415	309
Nanosonics	1,057	1,268	1,258
Neuren	853	1,592	1,415
Nova Eye	31	39	37
Opthea	475	201	219
Pharmaxis	43	29	24
Polynovo	923	1,028	911
Pro Medicus	5,552	7,659	8,479
Starpharma	255	60	68
Telix	1,462	3,527	3,696
Volpara	140	193	184
Second 20			
4D Medical	171	231	156
Actinogen	160	45	44
Alcidion	162	159	140
Amplia	20	17	16
Antisense	57	54	61
Atomo	34	18	17
Dimerix	51	27	24
Emvision	108	131	133
Impedimed	112	363	353
Imugene	1,160	465	329
Micro-X	80	57	65
Next Science	163	112	116
Orthocell	82	79	74
Paradigm	352	171	172
Patrys	41	21	14
Prescient	118	65	46
Proteomics	116	106	136
Resonance	26	27	36
SDI	97	106	95
Universal Biosensors	55	51	57

* 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.

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