



Biotech Daily

Tuesday March 1, 2022

Daily news on ASX-listed biotechnology companies

- * FEBRUARY BDI-40 DOWN 12%, ASX200 UP 1%, BIG CAPS UP 3%, NBI DOWN 4%
- * TODAY: ASX, BIOTECH UP: AVITA UP 26%; RESONANCE DOWN 7%
- * FIREBRICK TO APPEAL TGA NASODINE KNOCK-BACK
- * AVITA H2 REVENUE UP 37% TO \$19m, LOSS DOWN 9% TO \$20m
- * IMEX REVENUE UP 22.5% TO \$13.3m, LOSS UP 30% \$4.7m
- * HYDRIX H1 REVENUE UP 1.5% TO \$5.2m, LOSS DOWN 50.1% \$2.4m
- * CRESO REVENUE UP 154% TO \$6.2m, LOSS DOWN 6.3% TO \$30m
- * EPSILON REVENUE DOWN 21% TO \$5.5m, LOSS DOWN 15.4% TO \$9m
- * CARDIEX H1 REVENUE DOWN 12.6% TO \$2.3m, LOSS UP 147% TO \$5.1m
- * OSTEOPORE REVENUE DOWN 26% TO \$1.1m, LOSS UP 86% TO \$3.6m
- * AVECHO BEGINS TPM-CBD OSTEOARTHRITIS TRIAL
- * STARPHARMA: 'SPL7013 REDUCES OMICRON 95% IN 1min, IN-VITRO'
- * CARDIEX COMPLETES 10-FOR-1 CONSOLIDATION
- * ASX SUSPENDS IQ3 ON ACCOUNTS
- * MEDICAL DEVELOPMENTS REQUESTS 'FDA HOLD FEEDBACK' HALT
- * ANTERIS REQUESTS CAPITAL RAISING TRADING HALT
- * EPSILON REQUESTS 'VALENS PARTNERSHIP' TRADING HALT
- * ALTERITY BELOW NASDAQ \$US1 BID RULE, AGAIN
- * FIRST SENTIER TAKES 6.7% of NANOSONICS
- * CRYOSITE DIRECTOR ANDREW KROGER TAKES 43%

MARKET REPORT

The Australian stock market was up 0.67 percent on Tuesday March 1, 2022, with the ASX200 up 47.4 points to 7,096.5 points. Twenty-five of the Biotech Daily Top 40 stocks were up, nine fell, four traded unchanged and two were untraded. All three Big Caps were up.

Avita was the best, up 66 cents or 25.7 percent to \$3.23, with 964,008 shares traded. Prescient climbed 19.35 percent; Imugene and Paradigm improved 12 percent or more; Polynovo was up 10 percent; Neuren and Opthea were up more than eight percent; Alcidion, Clinuvel, Pharmaxis and Starpharma were up five percent or more; Actinogen, Emvision, Mesoblast and Telix climbed more than four percent; Antisense, Cyclopharm, Impedimed, Nanosonics and Patrys were up more than three percent; Oncosil and Orthocell rose more than two percent; Cochlear, Cynata, Immutep, Pro Medicus and Resmed were up more than one percent; with CSL up 0.4 percent.

Resonance led the falls, down one cent or 7.1 percent to 13 cents, with 170,000 shares traded. Kazia lost 5.45 percent; Uscom fell 4.2 percent; Micro-X was down three percent; Nova Eye and Proteomics shed two percent or more; with Genetic Signatures down 1.2 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Last month we said there was no gilding the lily. But how about “it’s a buying opportunity” or “a much-needed market correction” or “Ukraine” or “Covid” or possibly even “China”?

The Biotech Daily Top-40 Index (BDI-40) fell a further 11.6 percent in February from a collective market capitalization of \$18,743 million to \$16,568 million, its lowest point since September 30, 2020.

The double digit falls for two consecutive months amounted to a 26.4 percent downturn, compared with the 34.4 percent fall in the first two months of the Covid-19 pandemic.

By comparison, between October 31, 2007 and February 28, 2009 – the Global Financial Crisis – the BDI-40 fell 50.5 percent to \$3,345 million, when the ASX200 fell 55.8 percent.

For the year to February 28, 2022, the BDI-40 fell 10.3 percent, the Nasdaq Biotechnology Index was down 19.1 percent, the benchmark ASX200 was up 5.6 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) recovered 9.2 percent.

In the month of February, the NBI lost 4.1 percent, the ASX200 gained 1.1 percent and the cumulative market capitalization of the three Big Caps was up 2.6 percent – led by Cochlear up 15.8 percent to \$14,661 million, Resmed up 4.6 percent to \$48,842 million and CSL up 0.5 percent to \$125,234 million.

Thirty-two of the BDI-40 companies fell in February, with 25 down more than 10 percent and 11 down more than 20 percent. Seven companies were up, with Uscom unchanged.

Despite a 17 percent increase in revenue and reduced losses, Atomo led the falls, down \$42 million or 35.3 percent to \$97 million, followed by Micro-X (29.6%), Medical Developments (27.5%), Telix (26.8%), Next Science (25.8%), Imugene (23.7%), Polynovo (23.5%), Paradigm (22.9%), Dimerix (22.7%), Prescient (22.3%), Volpara (21.7%) and Actinogen (21.6%).

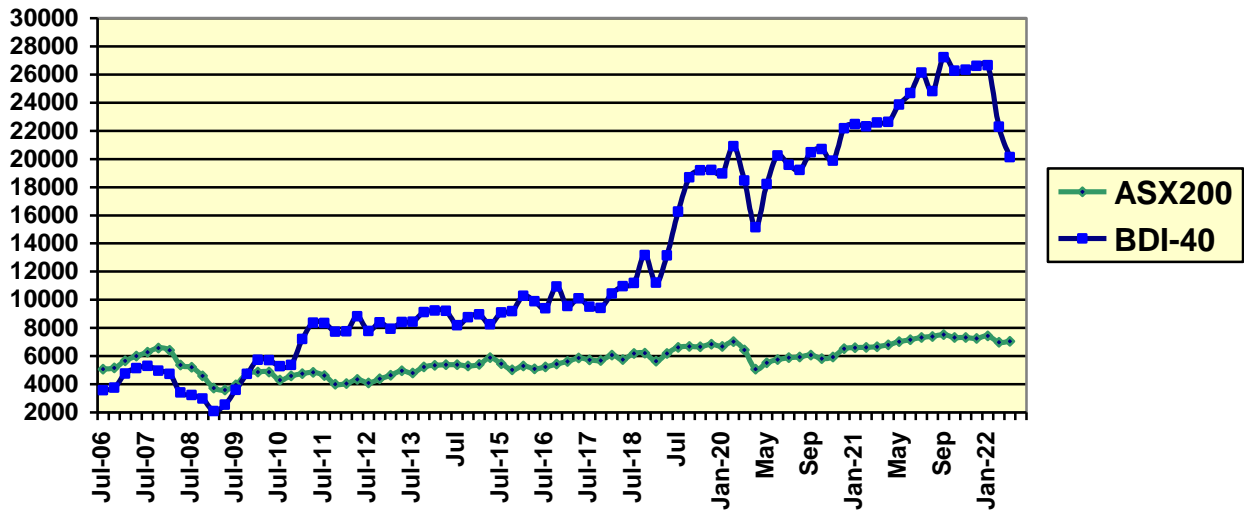
Proteomics recovered 25.5 percent to \$133 million to lead the seven up, but below its \$140 million market capitalization a year ago, followed by Neuren (9.5%), Universal Biosensors (6.6%), Kazia (4.7%), Patrys (3.85%), Pro Medicus (3.6%) and Oncosil (3.4%).

Outside the Top 40, the only significant gains were Cogstate up 11.1 percent, Cronos up 27.8 percent as it incorporates CDA (formerly Cannabis Doctors Australia) and Incannex bouncing back from last month’s fall to just below the December 31, 2021 high tide mark of \$755 million. With Emyria up 18.5 percent, the three companies dragged the Cannabis Corner First 11 up 16.8 percent, despite six companies falling and two unchanged.

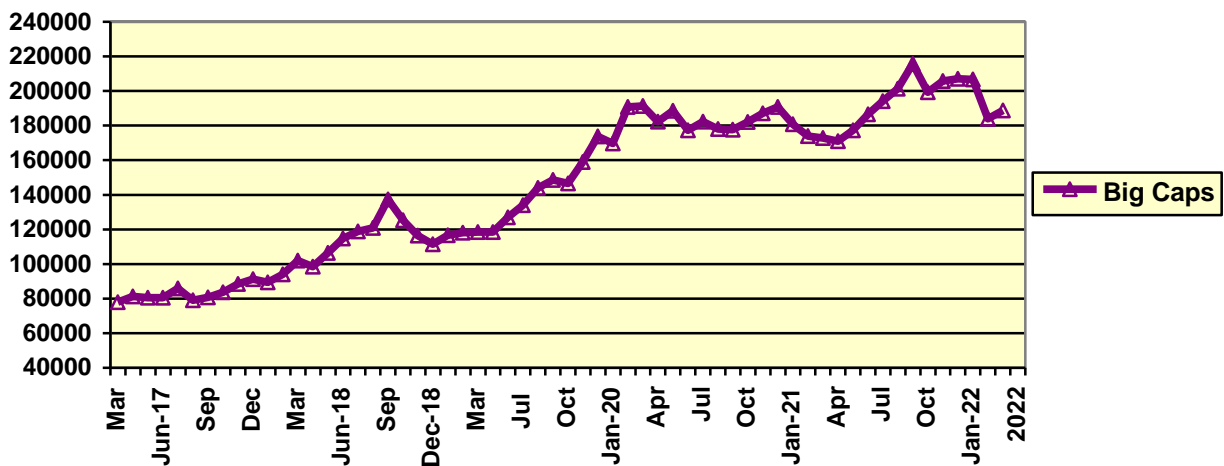
On the Nasdaq, Eyepoint (formerly Psivida) was up 3.3 percent to \$464 million, Queensland’s Protagonist fell 19.4 percent to \$1,596 million, and Redhill, with Australian assets, fell 19.0 percent to \$158 million.

Biotech clearly is not for the faint-hearted.

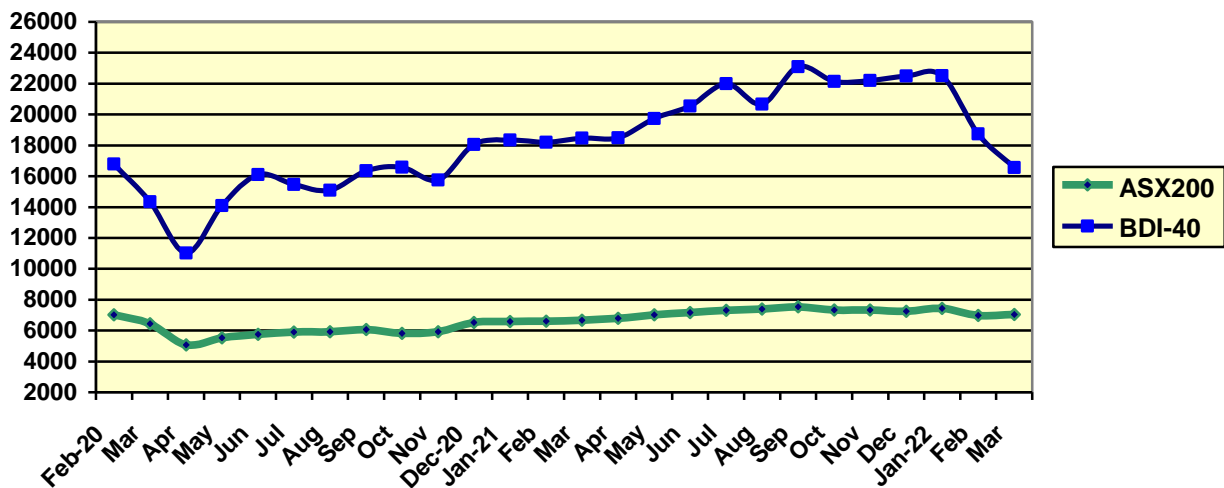
BDI-40 v ASX200 Jun 30, 2006 to Feb 28, 2022- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Feb 28, 2017 – Feb 28, 2022



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Feb 28, 2022 (current, raw data)



FIREBRICK PHARMA

Firebrick says it will appeal against the Australian Therapeutic Goods Administration initial decision not to approve Nasodine nasal spray, based on the existing clinical data.

Firebrick said that if the appeal was successful, it could lead to approval of Nasodine “sometime in 2022” and if unsuccessful, the company would re-submit the application to the TGA at the end of the year, after completing the planned second phase III trial.

Firebrick executive chair Dr Peter Molloy said that “the potential for an appeal was telegraphed in our prospectus”.

On January 28, Firebrick listed on the ASX to commercialize its Betadine-based anti-viral Nasodine nasal spray (BD: Feb 1, 2022).

Today, the company said its prospectus disclosed it was waiting for a formal TGA letter confirming its decision and the reasons not to approve Nasodine, and that it would decide whether to file an appeal.

Firebrick said it “recently received that letter” and had decided to proceed with the appeal. “Nasodine is clearly safe and has met all of the TGA’s stringent quality and manufacturing requirements, with the TGA delegate’s residual concern being whether there is sufficient proof of clinical efficacy as a treatment for the common cold,” Dr Molloy said.

“We believe that the first phase III trial in 2019 sufficiently supports the clinical efficacy of Nasodine to allow approval in Australia, without additional studies,” Dr Molloy said. “This appeal allows us to present our case to a new delegate and potentially achieve approval this year, while we also complete a second phase III trial this coming winter.”

Firebrick said it had until May 20, 2022 to file its appeal submission to the Minister of Health and thereafter, the Minister or a delegate had two months to reach a decision and advise the company.

According to the Firebrick prospectus, the chosen endpoint for the 260-patient, phase III trial was the impact on nasal symptoms compared to a saline nasal spray placebo.

The prospectus said that Nasodine “achieved a positive benefit of eight percent on that endpoint, but it was not statistically significant and as a result, the phase III trial did not meet its primary endpoint”.

The prospectus said that the phase III trial “did show that Nasodine significantly reduced overall cold severity and impact of the cold on daily activities in subsets of people with stronger cold symptoms at enrolment, those with confirmed viral infections, and those who commenced treatment within 24 hours of symptom onset”.

Firebrick fell 4.5 cents or 10 percent to 40.5 cents.

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2021 was up 37.3 percent to \$US13,956,000 (\$A19,256,483) with net loss after tax down 9.1 percent to \$US14,427,000 (\$A19,906,369).

Avita said that this financial report was for the six months to December 31, 2021 but it was in transition to a calendar year reporting period, for the year to December 31.

The company said revenue from sales of its Recell system for the treatment of burns was up 64.0 percent to \$US13.8 million and other revenue included funding from the US Biomedical Research and Development Authority (BARDA) which was down 80.9 percent to \$US200,000 compared to the previous corresponding period.

Avita said diluted loss per share fell 21.6 percent to 58 US cents, net tangible asset backing per share was up 55.5 percent to \$US4.12, and it had cash of \$US55,511,000 at December 31, 2021 compared to \$US59,765,000 at December 31, 2020.

Avita was up 66 cents or 25.7 percent to \$3.23 with 964,008 shares traded.

IMEX HEALTH SERVICES

Imex says revenue for the year to December 31, 2021 was up 22.5 percent to \$13,372,709 with net loss after tax up 30.0 percent to \$4,699,772.

Imex said revenue came from sales, licensing and leasing of its internet cloud-based Aquila radiology data platform and its Hiruko medical imaging software platform.

The company said diluted loss per share was up 4.1 percent to 15.22 cents with net tangible assets per share down 47.8 percent to 25.33 cents.

Imex said it had cash and cash equivalents of \$4,186,428 at December 31, 2021 compared to \$10,796,484 at December 31, 2020.

Imex fell seven cents or 7.2 percent to 90 cents.

HYDRIX

Hydrix says revenue for the six months to December 31, 2021 was up 1.5 percent to \$5,169,769 with net loss after tax down 50.1 percent to \$2,406,651.

Hydrix said revenue came from sales of its cardiac monitoring and diagnostic technologies, including the Angel Medical Guardian System implantable heart-attack warning device.

The company said diluted loss per share was down 62.4 percent to 1.47 cents with net tangible assets per share down from 2.47 cents to negative 0.81 cents.

Hydrix said it had cash and cash equivalents of \$2,733,919 at December 31, 2021 compared to \$9,215,639 at December 31, 2020.

Hydrix was up one cent or 9.1 percent to 12 cents.

CRESO PHARMA

Creso says revenue for the year to December 31, 2021 was up 154.0 percent to \$6,218,337, with net loss after tax down 6.3 percent to \$30,030,967.

Creso said its revenue mainly came from the sales of its marijuana products, including \$3,634,530 in sales from Mernova Medicinal marijuana products

The company said sales from North America were up 199.5 percent to \$3,638,235 and sales from Europe and the Middle East were up 109.3 percent to \$2,580,102.

Creso said diluted loss per share was down 67.3 percent from 8.30 cents in the previous year to 2.71 cents in the year to December 31, 2021, with net tangible asset backing per share was up 10.2 percent to 1.51 cents, and cash and cash equivalents of \$7,184,746 at December 31, 2021, compared to \$6,047,091 at December 31, 2020.

Creso fell half a cent or nine percent to 6.1 cents with 15.1 million shares traded.

EPSILON HEALTHCARE (FORMERLY THC GLOBAL GROUP)

Epsilon says revenue for the year to December 31, 2021 was down 20.9 percent to \$5,498,149 with net loss after tax down 15.4 percent to \$8,908,397.

Epsilon said that revenue was primarily from the sales of its medical marijuana products.

The company said that it had experienced "negative trading conditions" in Canada, as well as lower margins, product outages and supply chain issues.

Epsilon said basic loss per share was down 30.5 percent to 4.61 cents, net tangible assets per share fell 32.0 percent to 6.96 cents.

The company said it had cash and cash equivalents of \$2,335,569 at December 31, 2021 compared to \$6,967,941 at December 31, 2020.

Epsilon was in a trading halt (see below) and last traded at 5.3 cents.

CARDIEX

Cardiex says revenue for the six months to December 31, 2021 was down 12.6 percent to \$2,335,236, with net loss after tax up 147.35 percent to \$5,131,803.

Cardiex said its revenue mainly came from sales of its Sphygmocor blood pressure monitor and wearables, with US sales down 27.4 percent to \$1,576,670, sales in Europe up 104.6 percent to \$342,206, and sales in the Asia Pacific down 14.85 percent to \$173,457.

The company said diluted loss per share was up 112.0 percent from 0.25 cents in the previous year to 0.53 cents in the six months to December 31, 2021, with net tangible asset backing per share was up 36.0 percent to 1.02 cents

Cardiex said it had cash and cash equivalents of \$5,465,471 at December 31, 2021, compared to \$3,322,319 at December 31, 2020.

Cardiex was up five cents or 10.75 percent to 51.5 cents.

OSTEOPORE

Osteopore says revenue for the year to December 31, 2021 was down 26.0 percent to \$1,113,009 with net loss after tax up 86.1 percent to \$3,620,898.

Osteopore said that revenue came primarily from sales of its 3D-printed, bio-resorbable bone regeneration technology.

The company said its diluted loss per share was up 69.8 percent to 3.09 cents, with net tangible asset backing per share down 41.5 percent to 4.49 cents.

Osteopore said it had cash and cash equivalents of \$4,530,175 at December 31, 2021 compared to \$9,027,016 at December 31, 2020.

Osteopore was unchanged at 20 cents.

AVECHO BIOTECHNOLOGY

Avecho says it has begun dosing 15 patients in a phase IIa study of a topical, tocopheryl phosphate mixture-enhanced marijuana-derived cannabidiol (CBD) for osteoarthritis.

Avecho chief executive officer Dr Paul Gavin said that osteoarthritis was “a chronic and poorly managed pain condition, with limited treatment options available”.

“Increasingly, CBD is being prescribed for a range of pain conditions, despite a relative absence of formal human clinical trials demonstrating its effectiveness,” Dr Gavin said.

“Commencement of patient dosing is an important milestone in our ongoing efforts to understand and quantify how it could help,” Dr Gavin said.

Avecho said that the tocopheryl phosphate mixture (TPM) formulation had been shown “to increase the dermal absorption of CBD in laboratory experiments by five times”.

The company said that 15 with painful arthritis of the fingers or thumb had completed baseline assessments and begun their treatment regimen, with the formulation to be applied to painful joints of the fingers and/or thumb each day over four weeks.

Avecho said that assessment would include pain scores, functional scores, and assessments of grip strength using a dynamometer, with results expected by July 2022.

Avecho said the proof-of-concept study was being run by principal investigator Dr Daniel Lewis with co-investigator The Lambeth Initiative’s Prof Iain McGregor.

Avecho was up 0.2 cents or 16.7 percent to 1.4 cents with 1.7 million shares traded.

[STARPHARMA](#)

Starpharma says SPL7013, reduces the Sars-Cov-2 Omicron variant virus infectivity by 95 percent in one minute and 99.5 percent in five minutes, in-vitro.

Starpharma said SPL7013 was the anti-viral agent in its Viraleze nasal spray, as well as Vivagel BV for bacterial vaginosis and condom coatings and reduced the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in laboratory-based anti-viral and virucidal assays.

The company said that testing at the San Diego, California-based Scripps Research Institute showed that SPL7013 outperformed other agents used in anti-viral nasal sprays, including iota-carrageenan and heparin, with the anti-viral and virucidal activity consistent with activity against the other variants, including Delta, Alpha, Beta and Gamma.

The Scripps Institute's Prof Philippe Gallay said the studies "found that SPL7013 can abolish infection with all nine Sars-Cov-2 variants tested".

"In fact, it appears that SPL7013 is even better able to block the more highly infectious variants than the early variants of Sars-Cov-2," Prof Gallay said.

Starpharma chief executive officer Dr Jackie Fairley said the company was "pleased to see that SPL7013 is virucidal and achieved more than 99.5 percent reduction of infectious virus in the Omicron variant".

"The high level of activity against Omicron is entirely consistent with previous data for SPL7013, which has shown antiviral and virucidal activity in multiple viruses," Dr Fairley said. "This new data further illustrates SPL7013's breadth of activity and the potential real-world benefits of Viraleze."

Starpharma was up 4.5 cents or 5.1 percent to 92.5 cents with 1.9 million shares traded.

[CARDIEX](#)

Cardiex says that following an extraordinary general meeting approval, its 10-for-one consolidation has been completed and it has 109,953,700 shares on issue.

[IQ3 CORP](#)

The ASX says that it has suspended IQ3 Corp under Listing Rule 17.5 following its failure to lodge the relevant periodic report by the due date.

IQ3 said the audit review of its report for the six months to December 31, 2021 "has not yet been completed" and it expects to release the audited report on March 7, 2022.

IQ3 last traded at 12 cents.

[MEDICAL DEVELOPMENTS](#)

Medical Developments has requested a halt pending "feedback received from the [US Food and Drug Administration] on its US clinical hold response".

Trading will resume on March 3, 2022 or on an earlier announcement.

Medical Developments last traded at \$3.41.

[ANTERIS TECHNOLOGIES](#)

Anteris has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on March 3, 2022 or on an earlier announcement.

Anteris last traded at \$18.67.

EPSILON HEALTHCARE

Epsilon has requested a trading halt “pending an announcement relating to an update on the company’s partnership with the Valens Company”.

Trading will resume on March 3, 2022 or on an earlier announcement.

Last year, Epsilon said the Kelowna, British Columbia-based Valens Canada agreed to extend their binding heads of agreement to January 31, 2022 (BD: Dec 1, 2021).

In September, Epsilon said it had a partnership with Valens Canada and received its first order worth \$540,000 for the use of its Southport Queensland marijuana manufacturing facility (BD: Sep 9, 20, 2021).

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says it has received a non-compliance letter from the Nasdaq requiring it to ensure its share price is above \$US1.00 within 180 days

In 2015 and 2020, the then Prana and Alterity, respectively, received similar Nasdaq compliance letters (BD: Nov 9, 2015; Feb 7, 2020).

In 2016, Prana undertook an effective six-to-one ADS consolidation through a ratio change with its Australian shares to comply with the Nasdaq rule, with one ADS representing 60 Australian shares compared with the previous 10 Australian shares (BD: Mar 10, 2016).

In 2020, Alterity said it had “temporary relief” from the compliance requirement due to the Covid outbreak and later raised \$35 million at 3.7 cents a share, implying a Nasdaq ADR price of \$US1.57 (BD: Apr 22, Oct 16, 2020).

Today, Alterity said that the Nasdaq had informed the company that its American depository share price had been below the \$US1.00 minimum for the mandated minimum number of business days and it had 180 days to August 22, 2022 to regain compliance, with the minimum bid price at or above \$US1.00 for 10 consecutive business days.

The company said that the deficiency notice only applied to the Nasdaq and not the shares trading on the ASX.

Alterity fell 0.2 cents or 9.5 percent to 1.9 cents with 3.4 million shares traded.

NANOSONICS

First Sentier Investors Holdings, a Mitsubishi UFJ Financial Group subsidiary, says it has become a substantial shareholder in Nanosonics with 20,270,513 shares (6.72%).

The Sydney based First Sentier and Tokyo, Japan-based Mitsubishi UFJ, said that it bought shares between November 4, 2021 and February 11, 2022, with the single largest acquisition 438,303 shares for \$2,047,138 or \$4.67 a share on February 8, 2022.

Nanosonics was up 16 cents or 3.8 percent to \$4.35 with 2.1 million shares traded.

CRYOSITE

Cryosite director Andrew John Kroger says he has increased his substantial shareholding from 20,266,964 shares (41.52%) to 20,983,203 shares (42.99%).

The London-based Mr Kroger said that on February 25 and 28, 2022, he bought 716,239 shares on-market for \$322,308 or 45 cents a share.

Cryosite was unchanged at 45 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT FEB 28, 2022

Company \$Am	Mar-21	Feb-22	Mar-22
Cochlear	14,114	12,665	14,661
CSL	122,963	124,642	125,234
Resmed	35,722	46,715	48,842
BDI-20			
Avita	641	334	319
Clinuvel	1,069	1,137	997
Compumedics	75	67	60
Cyclopharm	246	165	136
Cynata	91	67	60
Genetic Signatures	247	196	172
Immutep	221	325	295
Kazia	167	127	133
Medical Developments	406	335	243
Mesoblast	1,445	732	719
Nanosonics	1,833	1,533	1,265
Neuren	157	433	474
Nova Eye	48	44	37
Opthea	535	401	343
Pharmaxis	32	55	48
Polynovo	1,666	867	662
Pro Medicus	4,719	4,708	4,878
Starpharma	873	441	359
Telix	1,074	2,089	1,529
Volpara	353	235	184
Second 20			
Actinogen	34	213	167
Alcidion	253	304	254
Amplia	30	31	29
Antisense	103	114	97
Atomo	133	119	77
Dimerix	48	75	58
Emvision	171	162	141
Impedimed	157	311	284
Imugene	476	1,800	1,374
Micro-X	172	108	76
Next Science	243	240	178
Oncosil	81	29	30
Orthocell	99	85	81
Paradigm	549	332	256
Patrys	47	51	53
Prescient	67	130	101
Proteomics	140	106	133
Resonance	94	71	65
Universal Biosensors	72	152	162
Uscom	25	19	19

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, 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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