

Biotech Daily

Tuesday February 1, 2022

Daily news on ASX-listed biotechnology companies

- * JANUARY BDI-40 DOWN 17%, ASX200 6%, BIG CAPS 11%, NBI 12%
- * TODAY: ASX, BIOTECH UP: PATRYS UP 16%; STARPHARMA DOWN 3%
- * FIREBRICK UP 225% ON \$7m IPO FOR NASODINE ANTI-VIRAL SPRAY
- * EPSILON RECEIPTS DOWN 28% TO \$5m
- * NOVA EYE H1 GLAUCOMA SALES UP 1.6% TO \$6.5m
- * NUHEARA: 'TRIAL VALIDATES SELF-FITTED HEARING AIDS'
- * DIMERIX: DENMARK OKAYS PHASE III DMX-200 FSGS TRIAL
- * CLARITY TO DOSE NEUROBLASTOMA 2nd COHORT
- * RADIOPHARM: TERRAPOWER TO PROVIDE ACTINIUM-225
- * CHIMERIC, PENNSYLVANIA CHM2101 RESEARCH DEAL
- * RESAPP: CHINA COUGH ANALYSIS PATENT
- * CARRINGTON TRUST TAKES 5.2% OF BCAL
- * IMUGENE APPOINTS DR STEPHEN CHA CMO
- * NEUREN APPOINTS GERRY ZHAO FOR CORPORATE DEVELOPMENT
- * CO SEC TIM SLATE REPLACES ZELIRA DIRECTOR JASON PETERSON
- * MEDADVISOR APPOINTS RAEANN GROSSMAN COTIVITI DIRECTOR
- * LAZARD BELOW 5% IN MAYNE
- * CORRECTION: MTP CONNECT

MARKET REPORT

The Australian stock market rebounded 0.49 percent on Tuesday February 1, 2022, with the ASX200 up 34.4 points to 7,006.0 points. Thirty-two of the Biotech Daily Top 40 stocks were up, four fell, three traded unchanged and one was untraded. All three Big Caps rose.

Patrys was the best, up 0.4 cents or 16 percent to 2.9 cents, with 9.6 million shares traded. Neuren climbed 14.5 percent; Dimerix was up 10.6 percent; Actinogen, Impedimed and Proteomics improved eight percent or more; Atomo and Uscom were up 7.1 percent; Alcidion, Amplia, Immutep and Imugene climbed more than six percent; Next Science, Oncosil and Prescient were up five percent or more; Emvision, Mesoblast and Telix rose more than four percent; Orthocell, Polynovo, Pro Medicus and Resonance were up more than three percent; Antisense, Clinuvel, Nanosonics, Paradigm, Resmed and Volpara rose more than two percent; Cochlear and Cynata were up more than one percent; with Avita, CSL, Genetic Signatures, Opthea and Universal Biosensors up by less than one percent.

Starpharma led the falls, down 3.5 cents or 3.2 percent to \$1.05 cents, with 207,405 shares traded. Compumedics lost 2.6 percent; with Nova Eye and Medical Developments down by more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

There's no gilding the lily. The January global downturn didn't miss the Australian biotechnology sector - the Biotech Daily Top-40 Index (BDI-40) fell 16.8 percent.

The collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) lost 11.0 percent; the benchmark ASX200 was down a modest 6.4 percent; and the Nasdaq Biotechnology Index (NBI) fell 11.9 percent.

For the year to January 31, 2022, the Big Caps gained 5.8 percent, the ASX200 was up 5.5 percent, the BDI-40 rose 3.0 percent, with the NBI down 17.6 percent.

But it is instructive the difference time points make: today, the ASX200 is up and the biotech screens are predominantly green.

The big falls are either "a buying opportunity" as many chief executive officers and directors are want to say, or "a cold shower of reality", as the bears prefer. It depends on one's appetite for gambling, investing or speculating.

Cochlear led the Big Caps fall, down 12.1 percent to \$12,665 million, with CSL down 11.0 percent to \$124,642 million and Resmed down 10.7 percent to \$46,715 million.

While the unadjusted BDI-40 is at its lowest point since March 31, 2021 at \$18,743 million, it is 11.6 percent above the pre-pandemic high of \$16,788 million and 70.2 percent better than the pandemic low of \$11,103 million (see charts below).

Thirty-six of the BDI-40 companies fell in January, with 10 down by more than 20 percent, three were up and Impedimed looked good by not moving.

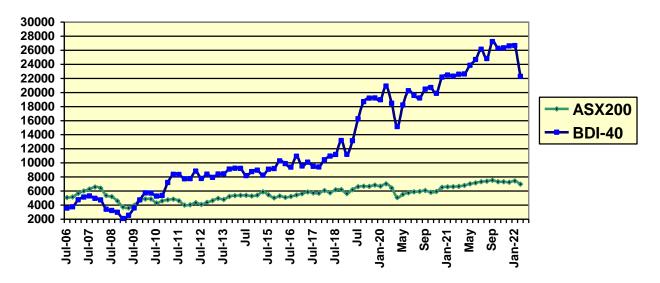
Patrys had the extremely bad luck of announcing a drug manufacturing delay last week, to lead the falls down \$25 million or 32.9 percent to \$51 million, followed by Pro Medicus (28.3%), Actinogen (25.0%), Kazia (23.5%), Genetic Signatures (23.4%), Paradigm (23.0%), Immutep (22.4%), Imugene (21.9%), Avita (21.6%) and Nanosonics (20.7%).

Resonance was the best, up \$6 million or 9.2 percent to \$71 million, with Cyclopharm up 7.8 percent to \$165 million and Compumedics up 1.5 percent to \$67 million.

Outside the Top 40, Cronos was the best – and the only member of the Cannabis Corner First 11 to improve – up 37.3 percent on its merger with CDA (formerly Cannabis Doctors Australia) and posting the first combined half year receipts of \$28.6 million. The 11 companies in the revised Cannabis Corner fell 13.95 percent in January, but were 15.4 percent above January 31, 2021.

From a low base, Immuron was up 30.4 percent to \$30 million, followed by Anteris (27.1%), Adherium (16.7%), Recce (14.5%), Resapp (14.3%), Noxopharm (8.8%), Trajan (7.6%), Botanix (7.4%) and Nyrada (6.9%).

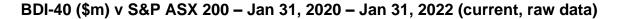
On the Nasdaq, Eyepoint (formerly Psivida) lost 21.4 percent to \$449 million, Queensland's Protagonist fell 11.8 percent to \$1,981 million, but Redhill, with Australian assets, climbed 6.6 percent to \$195 million.

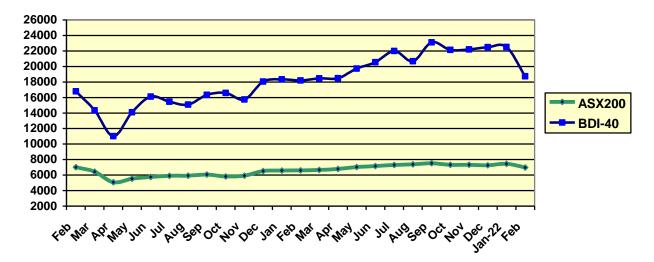


BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2022- Adjusted

Big Caps \$m (Cochlear, CSL, Resmed) Jan 31, 2017 – Jan 31, 2022







FIREBRICK PHARMA

Firebrick opened on the ASX last Friday, January 28, 2021 up 125 percent having raised \$7 million at 20 cents a share to commercialize its anti-viral Nasodine.

Firebrick climbed 45 cents or 225 percent to a high of 65 cents, before closing up 33 cents or 165 percent at 53 cents.

In the prospectus, Firebrick executive chair Dr Peter Molloy said he started the company in 2012 with executive director and chief operating officer Dr Stephen Goodall "with the mission to develop a broad-spectrum antiviral nasal spray as a treatment for the common cold".

Dr Molloy said that previously he was responsible for the Betadine range in Australia and launched Betadine Sore Throat Gargle.

"I believed that a nasal spray based on the same active ingredient (povidoneiodine) could kill the viruses responsible for the common cold and lead to an important new approach to treating an ailment that afflicts virtually everyone," Dr Molloy said.

"If approved by [the Australian Therapeutic Goods Administration], Nasodine will be the first approved nasal spray medicine that targets the cause of the common cold - viruses - and treat colds where they start, in the nose," Dr Molloy said.

Dr Molloy said that Nasodine had been in three human clinical trials and was "only one successful phase III clinical trial away from approval as a treatment for the common cold in adults", with that trial scheduled for this year, along with a phase II trial for Covid-19 in South Africa.

Today, Firebrick said that the South African Health Products Regulatory Authority had approved the trial, titled 'Reduction of nasal shedding of Sars-Cov-2 in Covid-19 positive patients by the use of Nasodine (povidone-iodine 0.5%) Nasal Spray'.

Dr Molloy told Biotech Daily that he expected the trial to enrol about 200 severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) positive patients.

Firebrick said the trial "intended to demonstrate that frequent, repeated application of Nasodine nasal spray in Covid-19 subjects who are [rapid antigen test]-positive, leads to reduction or elimination of nasal shedding of the Sars-Cov-2 virus".

The company said it was awaiting ethics approval for the trial.

The prospectus said that former Biota executive Dr Simon Tucker was the chief scientific officer, the University of Western Australia's Prof Peter Friedland the chief medical officer, with Stanford University medicine professor Prof Phyllis Gardner and Peter Kash non-executive directors.

Firebrick said that Dr Monique Baldwin was the company's head of regulatory affairs with Robyn Branigan the head of marketing.

The prospectus said Euroz Hartleys was the sole lead manager to the initial public offer. Firebrick fell eight cents or 12.3 percent to 57 cents with 9.6 million shares traded.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS CO)

Epsilon says receipts from customers for the 12 months to December 31, 2021 was up 28.0 percent to \$4,981,000 compared to the prior corresponding period.

Epsilon said its receipts from customers for its marijuana products for the three months to December 31, 2021 was down 71.9 percent to \$458,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$1,711,000 for the three months to December 31, 2021, with cash and equivalents of \$2,335,000 compared to \$6,968,000 at December 31, 2020.

Epsilon fell 0.1 cents or 1.5 percent to 6.6 cents.

NOVA EYE MEDICAL

Nova Eye says it expects to report sales of its glaucoma surgical devices for the six months to December 31, 2021 up 1.6 percent to \$6.5 million.

Nova Eye managing-director Tom Spurling said the results followed the "execution of several initiatives to drive market awareness of our proprietary canaloplasty technology for the treatment of glaucoma, currently marketed as the Itrack device".

"There were two major components to this outcome," Mr Spurling said.

"First, solid growth in revenue in Germany due to investments in our commercial infrastructure, including a direct sales team," MR Spurling said.

"Second, continued growth in China as a result of the sustained marketing and sales effort of our local distribution partner," Mr Spurling said.

Nova Eye fell half a cent or 1.7 percent to 29.5 cents.

NUHEARA

Nuheara says a clinical trial by the National Acoustics Laboratory of its self-fitted hearing aids has validated their benefits compared to unaided listening.

Last year, Nuheara said it had concluded recruitment in a 50-candidate trial of its hearing aids (BD: Nov 25, 2021).

Today, Nuheara said that following the National Acoustics Laboratories report it intended to file a US Food and Drug Administration 510(k) submission.

Nuheara managing-director Justin Miller said "this is a pivotal development for Nuheara as we position ourselves to complete a US FDA 510(k) submission by the end of March 2022 and, pending FDA clearance, entering the US regulated hearing aid market with world leading hearing aid products".

Nuheara was unchanged at 1.6 cents with 3.7 million shares traded.

DIMERIX

Dimerix says the Danish Medicines Agency has approved its up-to 250-patient phase III trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS) kidney disease. Dimerix said the Danish approval was the first time that DMX-200 had been approved for use in patients outside Australia or New Zealand, and constituted a "major milestone". Dimerix said recruitment in Denmark would begin when ethics approval was received. Dimerix was up 2.5 cents or 10.6 percent to 26 cents with 2.6 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it will advance to a second, higher-dose cohort in its up-to 34-paediatric patient, dose-escalation trial of copper-67 for the treatment of high-risk neuroblastoma Clarity said the first cohort of three patients had no dose-limiting toxicities while receiving 75 mega becquerel (MBq) per kilogram of copper-67, and that the three patients had also received multiple doses of copper-64 for the imaging of tumors, without any adverse events.

The company said that following safety review committee approval, the trial would advance to a dose of 175MBq/kg of copper-67.

Clarity fell two cents or 2.7 percent to 73 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has a supply agreement with the Bellevue, Washington-based Terrapower for the provision of actinium-225 isotopes for its cancer drug pipeline. Radiopharm said the agreement would last an initial three years, with the option to extend for two successive one-year periods, and that all data, discoveries, and inventions to come from the agreement would be "the property of Radiopharm as client of Terrapower." The company did not disclose the commercial terms of the agreement. Radiopharm was up 3.25 cents or 10.2 percent to 35 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has signed a research agreement with the University of Pennsylvania to develop CHM2101 for gastrointestinal cancers.

Chimeric said it would sponsor the research but did not disclose the commercial terms. The company said that the University of Pennsylvania would conduct pre-clinical studies and it would have the right of first negotiation with the University to licence intellectual property arising from the research.

The company said that the research would be led by one of the inventors of CHM2101, Prof Xianxin Hua, a professor of cancer biology at the University's School of Medicine. Chimeric was up two cents or 9.5 percent to 23 cents.

RESAPP HEALTH

Resapp says the China Patent Office has granted a patent for its cough sound-based audio processing pipeline for the diagnosis of respiratory disease.

Resapp said that the patent, titled 'A method and apparatus for processing patient sounds' would protect its intellectual property until March 29, 2032.

The company said the patent was owned by the University of Queensland and was licenced exclusively to Resapp for the lifetime of the patent.

Resapp fell 0.1 cents or 1.3 percent to 7.4 cents with 5.7 million shares traded.

BCAL DIAGNOSTICS

Capital Property Corporation as trustee for the Carrington Trust says it has become a substantial share-holder in Bcal with 10,750,302 shares (5.2%).

The Canberra-based Capital Property said that the shares were acquired between July 23, 2021 and January 19, 2022 with the most recent acquisition 439,349 shares for \$49,527 or 11.3 cents a share.

Bcal was up one cent or 9.5 percent to 11.5 cents.

IMUGENE

Imugene says it has appointed Dr Stephen Cha as its chief medical officer. Imugene said that Dr Cha had more than 16 years' experience in oncology drug development, most recently at the Santa Ana, California-based NKGen Biotech. The company said that Dr Cha was formerly the head of oncology at Samumed LLC and an executive at Pfizer, Puma Biotechnology. MEI Pharma, Allergan and Amgen. Imugene said that Dr Cha held a Bachelor of Science from the University of California San Diego and a Doctor of Medicine from Boston's Tufts University.

Imugene was up two cents or 6.45 percent to 33 cents with 39.7 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Gerry Zhao as the head of corporate development. Neuren said Mr Zhao had more than 16 years' experience in investment banking and financial services, with 12 years at Merrill Lynch responsible for healthcare investment banking coverage.

The company said Mr Zhao had more recently facilitated "the \$400m strategic licence and commercial partnership between China Grand Pharmaceutical and Healthcare Holdings and Telix Pharmaceuticals in November 2020".

Neuren was up 50 cents or 14.5 percent to \$3.94 with 570,330 shares traded.

ZELIRA THERAPEUTICS

Zelira says it has appointed company secretary Tim Slate a director following the resignation of Jason Peterson.

Zelira said Mr Peterson's resignation was in "accordance with CPS Capital Group's revised 'Board Representation Policy' and 'Conflict Management' procedures.

The company said Mr Peterson would continue as corporate advisor to the company through CPS Capital.

Zelira was up 0.1 cents or 3.6 percent to 2.9 cents.

MEDADVISOR

Medadvisor says Raeann Grossman has been appointed a director and representative of major shareholder, the South Jordan, Utah-based Cotiviti.

Last year, Cotiviti said it acquired 43,999,999 Medadvisor shares for \$US11,305,140 (\$A15,793,252) in an off-market transfer from the Irving, Texas-based Health Management Services (BD: Aug 24, 2020).

Today, Medadvisor said that Ms Grossman had experience in US healthcare, and previously worked for United Healthcare's Optum, Gorman Group and Censeo. Medadvisor was unchanged at 37.5 cents.

MAYNE PHARMA

Lazard Asset Management Pacific says it has ceased its substantial holding in Mayne Pharma, falling below five percent.

The Sydney-based Lazard said that between March 9, 2021 and January 28, 2022, it bought and sold shares with the largest single sale of 6,848,970 shares for \$1,885,159 or 27.5 cents a share on November 30, 2021.

Mayne was up 1.5 cents or six percent to 26.5 cents with 3.5 million shares traded.

CORRECTION: MTP CONNECT

Last night's edition incorrectly spelt the name of MTP Connect's interim chief executive officer Stuart Dignam.

Biotech Daily apologizes profusely to a former ABC Radio colleague and knows that the check sub-editor needs to sharpen up, even on big days when too many companies are filing their Appendix 4C quarterly reports.

It explains, but does not excuse.

Sorry Stuart.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JAN 31, 2022

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Company \$Am	Feb-21	Jan-22	Feb-22
Cochlear	12,859	14,405	12,665
CSL	121,433	140,034	124,642
Resmed	39,607	52,309	46,715
BDI-20	740	400	224
Avita	712	426	334
	1,091	1,412	1,137
Compumedics	81	66	67
Cyclopharm	239	153	165
Cynata	96	78	67
Genetic Signatures	271	256	196
Immutep	259	419	325
Kazia Madiaal Davalan manta	152	166	127
Medical Developments	472	356	335
Mesoblast Nanosonics	1,363	882	732
	2,062	1,934	1,533
Neuren	148 48	475 47	433 44
Nova Eye	40 660	47 479	44 401
Opthea Pharmaxis	35	479 66	401 55
Polynovo	35 1,719	1,002	867
Pro Medicus	4,294	6,569	4,708
	4,294 611	0,509 525	4,708
Starpharma Telix	1,102	2,164	2,089
	373	2,164	2,089
Volpara Second 20	575	202	235
Actinogen	29	284	213
Alcidion	213	336	304
Amplia	213	32	31
Antisense	103	130	114
Atomo	161	123	119
Dimerix	57	79	75
Emvision	203	207	162
Impedimed	144	311	311
Imugene	498	2,306	1,800
Micro-X	133	117	108
Next Science	239	246	240
Oncosil	106	36	29
Orthocell	92	101	85
Paradigm	519	431	332
Patrys	54	76	51
Prescient	70	150	130
Proteomics	70	128	106
Resonance	87	65	71
Universal Biosensors	81	176	152
Uscom	24	23	19
	<i>L</i> 1	20	10

* 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: <u>https://www.australianethical.com.au/personal/ethicalinvesting/companies-we-invest-in/</u>. These holdings are liable to change.

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