



Biotech Daily

Monday April 3, 2023

Daily news on ASX-listed biotechnology companies

- * MARCH BDI-40 UP 3%, ASX200 DOWN 1%, BIG CAPS DOWN 1.5%; NBI UP 1%
- * TODAY: ASX UP, BIOTECH DOWN: KAZIA UP 7%; DIMERIX DOWN 13%
- * AVECHO RIGHTS FOR \$11m
- * MEMPHASYS 1st JAPAN FELIX SALE, 1st INDIA FELIX LIVE BIRTH
- * IMMUTEP: 'EFTI EXTENDS NON-SMALL CELL LUNG CANCER SURVIVAL'
- * TELIX FILES UK ILLUCCIX APPLICATION
- * FIREBRICK CLOSES NASODINE COVID-19 RECRUITMENT EARLY
- * BOTANIX: FDA MID-CYCLE REVIEW SOFPIRONIUM BROMIDE OK; HALT
- * PYC TO TRIAL PYC-001 FOR AUTOSOMAL DOMINANT OPTIC ATROPHY
- * OPTISCAN ESTABLISHES US COMMERCIAL OPERATIONS
- * PRO MEDICUS UP-TO 10.4m SHARE BUY-BACK
- * ISLAND TO RELEASE 38m SHARES FROM ESCROW

MARKET REPORT

The Australian stock market was up 0.63 percent on Monday April 3, 2023, with the ASX200 up 45.2 points to 7,223.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and three were untraded. All three Big Caps were up.

Kazia was the best, up one cent or 7.1 percent to 15 cents, with 852,593 shares traded. Avita and Mesoblast climbed more than three percent; Micro-X and Orthocell rose more than two percent; Antisense, Cyclopharm, Nova Eye, Pro Medicus, Resmed, Telix and Universal Biosensors were up more than one percent; with Cochlear, CSL, Next Science and Opthea up by less than one percent.

Dimerix led the falls, down 1.5 cents or 13.0 percent to 10 cents, with 1.7 million shares traded. Oncosil lost 8.3 percent; Immutep fell 7.7 percent; Patrys was down 6.25 percent; Cynata was down 5.4 percent; Actinogen, Alcidion, Impedimed, Pharmaxis and Proteomics fell four percent or more; Medical Developments, Neuren and Resonance were down more than three percent; Emvision, Prescient and Volpara shed two percent or more; Clinuvel was down 1.7 percent; with Nanosonics and Polynovo down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) climbed 3.2 percent in March to \$19,482 million, despite most companies posting share price and market capitalization falls.

Twenty-five of the BDI-40 fell, with 11 down by 10 percent or more; while 13 were up, with seven up by more than 10 percent.

But the \$778 million increase in Neuren's market capitalization, following US Food and Drug Administration approval of trofinetide for Rett syndrome, more than compensated the mainly small falls - many as little as \$1 million.

Neuren was the best, up \$778 million or 84.0 percent to \$1,704 million, followed by Impedimed (74.8%), Nova Eye (44.1%), Kazia (28.0%), Cyclopharm (22.1%), Prescient (19.4%), Resonance (12.5%) and Nanosonics (9.8%).

Oncosil led the falls, down \$23 million or 65.7 percent to \$12 million, followed by Patrys (40.0%), Polynovo (29.7%), Medical Developments (23.2%), Compumedics (21.9%), Micro-X (19.4%), Dimerix (18.5%), Actinogen (17.3%), Starpharma (16.4%), Opthea (12.6%) and Genetic Signatures (10.7%).

The ASX200 fell 1.1 percent to close March at 7,178 points, while the Nasdaq Biotechnology Index (NBI) rose 1.25 percent in March to 4,126 points.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 1.5 percent in March to \$200,502 million.

CSL dragged the three Big Caps down, falling \$5,165 million or 3.6 percent to \$137,716 million, while Cochlear climbed 4.0 percent to \$15,199 million and Resmed rose 3.3 percent to \$47,587 million.

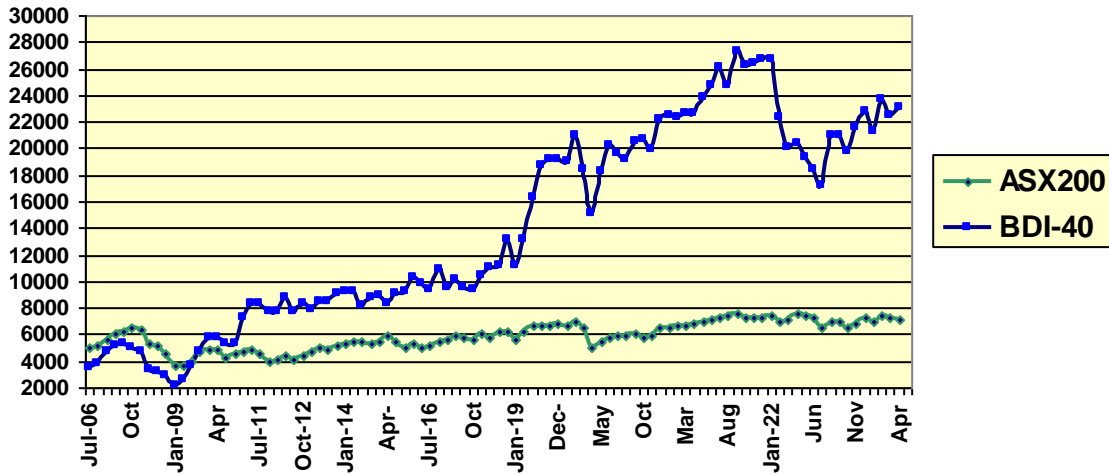
Outside the BDI-40, the rest of the biotechnology sector was a mix of small falls, large falls and small gains. Notably, Third 20 contenders for promotion including 4D Medical, Pacific Edge and Trajan were about 50 percent of their value a year ago, with Vitura (Cronos) up for the year, but down in March. Clarity was up for the month and year, but 23 percent below its \$259 million November 30, 2022 high.

Cannabis Corner continued its downward slide, falling a further 9.96 percent in March and down 43.3 percent for the year to March 31, 2023. Six companies fell, three were up and two were unchanged. Botanix added \$30 million or 33.7 percent to \$119 million while Vitura (Cronos) lost \$80 million to \$209 million.

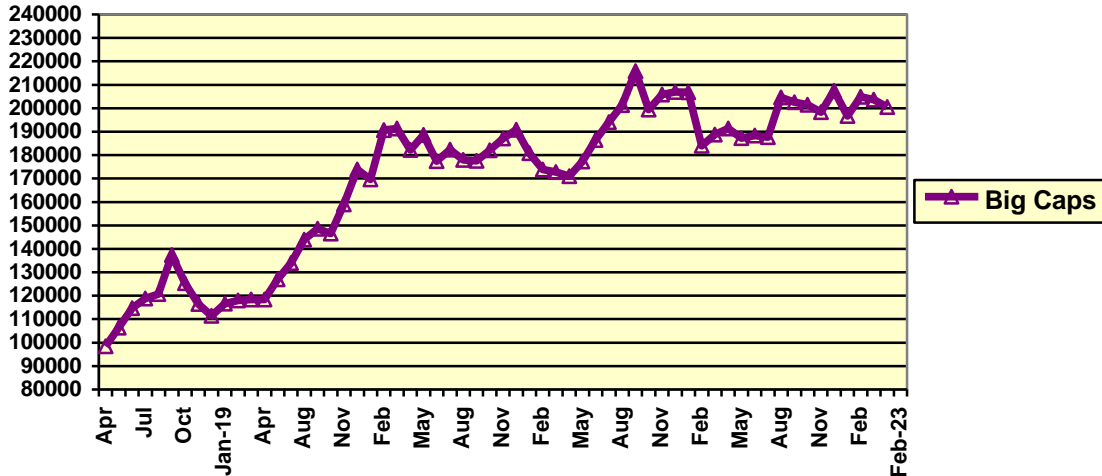
In the US, Queensland's Protagonist climbed 48.7 percent to \$1,763 million, Eyepoint (formerly Psivida) was up 6.5 percent to \$180 million, but Israel's Redhill - with Australian assets - fell 54.8 percent to \$14 million.

Benitec, developing ddRNAi treatments for HIV and hepatitis C, among other indications, was worth \$8.8 million at March 31, 2023, compared to the \$8 million when it left the ASX in April 2020 for what some call "the better valuations of the US market", having been worth as much as \$162 million on the ASX at March 31, 2014 (BD: Mar 31, 2020).

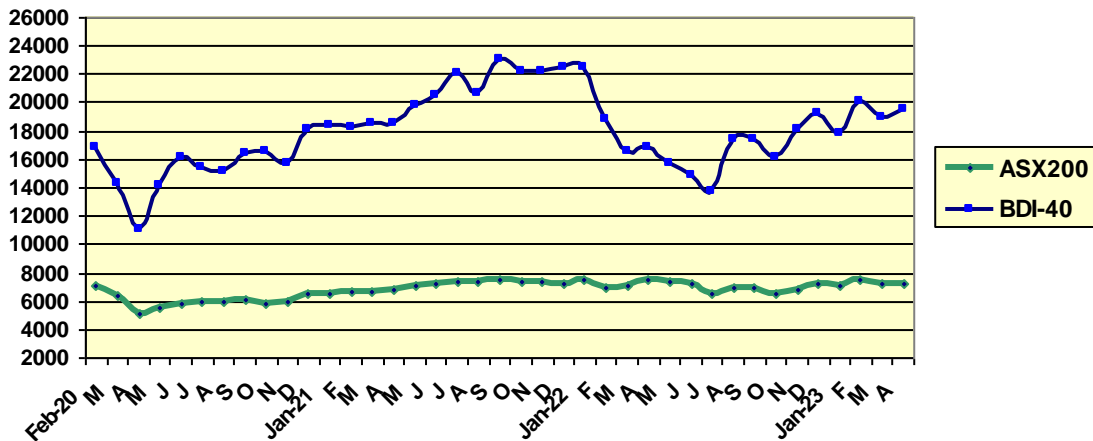
BDI-40 v ASX200 Jun 30, 2006 to Mar 31, 2023- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Mar 31, 2018 – Mar 31, 2023



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Mar 31, 2023 (current, raw data)



AVECHO BIOTECHNOLOGY

Avecho says it hopes to raise about \$11 million in a non-renounceable, one-for-one rights offer at 0.6 cents a share, a 33.33 percent discount to the last closing price.

Avecho said it would issue three options for every two shares purchased, exercisable at 1.2 cents each within three years of issue.

The company said the funds would be used to progress its phase III trial of its tocopheryl phosphate mixture (TPM) oral marijuana-based cannabidiol (CBD) product for insomnia, including manufacturing costs, patient recruitment, investigator and site costs and contract research organization management.

Avecho said Peak Asset Management and CPS Capital were joint lead managers of the offer, which was not underwritten.

The company said the entitlement offer had a record date of April 6, it would open on April 13 and close on May 3, 2023.

Avecho fell 0.3 cents or 33.3 percent to 0.6 cents with 29.8 million shares traded.

MEMPHASYS

Memphasys says it has its first commercial sale of 30 sterile single-use Felix cartridges in Japan and reported the first birth using the Felix sperm separator in India.

Memphasys said it sold 30 units of its Felix in-vitro fertilization cartridges and console to Kobe assisted reproductive technology clinic in Japan but did not disclose the terms of the sale.

The company said that Coimbatore Women's Hospital Centre in Tamil Nadu, India had reported the first birth of a healthy boy using the Felix system.

Memphasys said it has had to suspend sales of Felix in India following Central Drugs Standard Control Organisation changes on August 9, 2022, but had submitted a voluntary product registration and had plans to manufacture Felix in India to expedite the review process and reduce manufacturing costs.

Memphasys was up 0.3 cents or 18.75 percent to 1.9 cents with 4.1 million shares traded.

IMMUTEP

Immutep says its 36-patient, phase II trial of efitlagimod alpha for second line non-small cell lung cancer showed survival benefit compared to standard-of-care.

Immutep said the trial of efitlagimod alpha, or efiti, in combination with pembrolizumab showed a median overall survival of 9.9 months and a 39 percent overall survival rate at 21 months compared to a median overall survival rate of six-to-nine months and a 10-15 percent survival rate for standard-of-care chemotherapy.

The company said all 36 patients had confirmed progression after standard-of-care first line treatment with anti-programmed death-X (PD-X) therapy.

Immutep said the results were presented at the 2023 European Lung Cancer Congress by the Barcelona, Spain-based Hospital de la Santa Creu I Sant Pau's Prof Margarita Majem.

"In this difficult-to-treat patient population, these clinical results beneficially show that subcutaneous administration of efitlagimod alpha in combination with pembrolizumab is safely stimulating a broad immune response that may revert resistance to anti-PD-X therapy," Prof Majem said.

"The data supports further clinical investigation of efitlagimod alpha in combination with pembrolizumab for patients with anti-PD-(L)1 refractory non-small cell lung cancer that have limited treatment options," Prof Majem said.

Immutep fell two cents or 7.7 percent to 24 cents with 1.7 million shares traded.

TELEX PHARMACEUTICALS

Telix says it has filed a marketing authorization application with the UK Medicines and Healthcare products Regulatory Agency for its Illuccix prostate cancer imaging device. Telix said the application for its Illuccix 25 microgram kit for radio-pharmaceutical preparation for positron emission tomography imaging of prostate cancer had a review period of 150-days.

The company said it would file a separate application for the European Union.

Telix said that Illucix had US Food and Drug Administration, Canada Health and Australian Therapeutic Goods Administration approval.

Telix Europe, Middle East and Africa chief executive officer Raphaël Ortiz said the company was “committed to ensuring widespread access to commercially available gallium-based [prostate specific membrane antigen-positron emission tomography] imaging across the EU and UK”.

Telix was up 11 cents or 1.6 percent to \$7.01 with 1.1 million shares traded.

FIREBRICK PHARMA

Firebrick says it has closed recruitment in its phase II trial of its Nasodine nasal spray for Covid-19, with 39-patients enrolled instead of the planned 210 patients.

Firebrick said the randomized, controlled, phase II trial started in April 2022 in South Africa at five clinical sites but it had halted enrolment over the summer.

The company said the reduced number of patients was due to “ongoing very low numbers of new cases of Covid-19 in South Africa”.

Firebrick executive chair Dr Peter Molloy said he was confident the number of patients would not impact the company’s “ability to detect statistically robust outcomes on the primary and secondary endpoints”.

Firebrick said the nasal swabs had been collected and were being analyzed by a specialist virology laboratory in the Netherlands, with results expected by June, 2023.

Firebrick fell half a cent or 2.4 percent to 20 cents.

BOTANIX PHARMACEUTICALS

Botanix says its sofipronium bromide for primary axillary hyperhidrosis, or excessive sweating, has passed a US Food and Drug Administration mid-cycle review.

Last year, Botanix said it had filed a new drug application for sofipronium bromide topical gel and the application was under review (BD: Sep 26, Dec 8, 2022).

Botanix said the FDA mid-cycle review identified no clinical safety issues, risk management issues or advisory board requirements.

The company said the review process was ongoing and continued discussions with the FDA would focus on labelling, clinical outcome assessments, patient instructions and brand name.

Botanix said it remained on-track to reach its planned approval date for sofipronium bromide in September, 2023.

Separately, Botanix said it had requested a trading halt pending the release of “an announcement in relation to a proposed capital raising”, with trading to resume on April 5, 2023, or on an earlier announcement.

Botanix last traded at 10 cents.

PYC THERAPEUTICS

PYC says in-vitro and in-vivo data supports conducting human trials of PYC-001 for autosomal dominant optic atrophy in 2024.

PYC said autosomal dominant optic atrophy was a progressive blinding eye disease in childhood with no available treatment options.

The company said it would take its PYC-001 drug to human trials in 2024 pending the completion of formal toxicological studies.

PYC chief executive officer Dr Rohan Hockings said the retinitis pigmentosa program gave the company “a very clear template and substantial read-through insight” for fast-tracking PYC-001 to human studies.

“We are very much looking forward to seeing what addressing the underlying cause of [autosomal dominant optic atrophy] can do for patients in the context of this stellar non-clinical data,” Dr Hockings said.

PYC was up half a cent or 7.7 percent to seven cents.

OPTISCAN IMAGING

Optiscan says it has established commercial operations in the US, with offices in the medical technologies’ innovation precinct in Minneapolis, Minnesota.

Optiscan said it had established Optiscan Imaging, Inc. as a standalone company with its own premises, regional leadership, operational, constitutional and taxation obligations.

Optiscan managing-director Dr Camile Farah said the decision followed “a period of considered review and analysis of various business models, commercial structures, and healthcare ecosystems”.

“The pursuit of a direct market model reflects our future growth aspirations, which includes development of new devices for large addressable markets, and the anticipated adoption of our unique slide-free, biopsy-free technology,” Dr Farah said.

“Our partnership with, and membership of, the Medical Alley and new commercial hub in Minnesota, puts Optiscan at the epicentre of health innovation and care, aligning well with our objective of establishing a new standard of digital pathology and precision surgery across the North America region”.

Optiscan was up half a cent or five percent to 10.5 cents.

PRO MEDICUS

Pro Medicus says it intends to buy-back up to 10,443,225 shares in an on-market buy-back, starting on April 3, 2023.

Last week in a final buy-back notice, the company said it bought-back 86,379 shares for \$3,521,244.

Today, the company said it would buy-back up-to 10 percent of its total 104,432,253 shares on offer, with Goldman Sachs as its broker.

Pro Medicus was up 75 cents or 1.2 percent to \$64.62 with 163,749 shares traded.

ISLAND PHARMACEUTICALS

Island says it will release 38,022,140 shares from ASX escrow on April 13, 2023.

According to its most recent announcement, the company had 43,246,328 shares on offer, meaning that following the release of shares in escrow it will have a total of 81,268,468 shares on offer.

Island was untraded at seven cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT MAR 31, 2023

Company \$Am	Apr-22	Mar-23	Apr-23
Cochlear	14,821	14,618	15,199
CSL	129,170	142,881	137,716
Resmed	47,414	46,174	47,587
BDI-20			
Avita	287	511	497
Clinuvel	912	943	939
Compumedics	53	32	25
Cyclopharm	153	140	171
Cynata	59	43	40
Genetic Signatures	173	122	109
Immutep	334	211	229
Kazia	135	25	32
Medical Developments	275	125	96
Mesoblast	745	719	704
Nanosonics	1,201	1,371	1,505
Neuren	501	926	1,704
Nova Eye	36	34	49
Opthea	403	390	341
Pharmaxis	47	32	33
Polynovo	725	1,696	1,193
Pro Medicus	5,113	6,371	6,747
Starpharma	369	225	188
Telix	1,305	2,213	2,170
Volpara	222	199	193
Second 20			
Actinogen	187	150	124
Alcidion	247	171	159
Amplia	28	16	16
Antisense	84	66	60
Atomo	71	27	22
Dimerix	58	36	37
Emvision	163	106	105
Impedimed	258	107	187
Imugene	1,462	835	803
Micro-X	99	67	54
Next Science	187	157	146
Oncosil	32	35	12
Orthocell	84	76	74
Paradigm	256	378	401
Patrys	53	55	33
Prescient	94	62	74
Proteomics	127	114	116
Resonance	60	24	27
Universal Biosensors	151	64	58
Uscom	19	9	9

* Biotech Daily editor, David Langsam, owns shares in 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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