



Biotech Daily

Friday October 1, 2021

Daily news on ASX-listed biotechnology companies

- * **SEPTEMBER BDI-40 DOWN 4%; ASX200 DOWN 3%; BIG CAPS DOWN 8%**
- * **TODAY: ASX, BIOTECH DOWN: CYNATA UP 7%; ANTISENSE DOWN 5%**
- * **BIOTECH CALL TO ARMS: DAVID BLAKE**
- * **PRO MEDICUS, NOVANT \$40m, 7-YEAR VISAGE 7 DEAL**
- * **DIMERIX SHARE PLAN RAISES \$4m, TOTAL \$24m**
- * **PHARMAUST: OPTIONS RIGHTS OFFER FOR \$792k**
- * **REPORT TO TGA CAUTIOUS ON MDMA, PSILOCYBIN**
- * **NEUREN: FDA 'HOLD' ON NNZ-2591 FOR ANGELMAN IND**
- * **MEDIBIO LAUNCHES LUCA FOR STRESS**
- * **HAMISH GEORGE REPLACES AMPLIA CFO JEFF CARTER**
- * **DAVID FRANKS REPLACES EXOPHARM CO SEC ELIZABETH MCGREGOR**

MARKET REPORT

The Australian stock market fell 2.0 percent on Friday October 1, 2021, with the ASX200 down 146.7 points to 7,185.5 points. Nine of the Biotech Daily Top 40 stocks were up, 26 fell, four traded unchanged and one was untraded. All Big Caps fell.

Cynata was the best, up four cents or 6.9 percent to 62 cents, with 349,816 million shares traded. Osprey climbed 5.7 percent; Amplia and LBT improved more than four percent; Medical Developments and Nova Eye rose more than three percent; with Dimerix, Opthea and Resonance up by more than one percent.

Antisense led the falls, down one cent or 4.9 percent to 19.5 cents, with 1.3 million shares traded. Actinogen, Impedimed, Patrys and Telix fell four percent or more; Alterity, Compumedics, Cyclopharm, Genetic Signatures, Nanosonics, Next Science, Polynovo, Prescient and Proteomics were down three percent or more; Kazia, Mesoblast, Oncosil, Optiscan and Starpharma shed more than two percent; Clinuvel, CSL, Imugene, Paradigm, Pro Medicus, Resmed and Volpara were down by one percent or more; with Avita, Cochlear and Neuren down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

All indices retreated from last month's record highs, with the Biotech Daily Top-40 Index (BDI-40) down 4.2 percent, the ASX200 down 2.7 percent, the three Big Caps down 7.6 percent and the Nasdaq Biotechnology Index (NBI) down 4.9 percent.

The collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 7.6 percent in September to \$199,374 million, with CSL leading the pack, down 7.9 percent to \$130,713 million.

Resmed retreated 7.3 percent to \$54,257 million - its second highest end of month valuation - while Cochlear shed 6.1 percent to \$14,404 million.

For the year to September 30, the BDI-40 was up 33.5 percent, the benchmark ASX200 was up 26.1 percent, the Big Caps rose 9.5 percent and the NBI was up 19.5 percent.

The September BDI-40 saw a plethora of small falls and rises, but Imugene added a further \$410 million to its already gravity-defying \$2,212 million to close the month at \$2,622 million. Pro Medicus lost \$1,096 million to a market capitalization of \$5,488 million.

Twenty of the BDI-40 companies were up, eight by more than 10 percent, while 17 fell, with eight down by more than 10 percent.

Medical Developments was the best, recovering \$110 million or 42.5 percent to \$369 million, followed by Prescient up \$43 million in the month or 34.4 percent to a record \$168 million, Imugene (18.5%), Actinogen (14.2%), Kazia (13.1%), Orthocell (11.4%), Cynata (10.7%) and Starpharma (10.4%).

Osprey again led the falls, down a further \$8 million or 28.6 percent to \$20 million, followed by Resonance (22.6%), Proteomics (19.0%), Pro Medicus (16.6%), Telix (15.9%), Polynovo (15.1%), Dimerix (13.8%) and Universal Biosensors (11.6%).

Outside the BDI-40, Atomo, Emvision, Cogstate and Anteo were resilient in September. The collective market capitalization of the 22 companies in Cannabis Corner was up 0.75 percent to \$1,737 million.

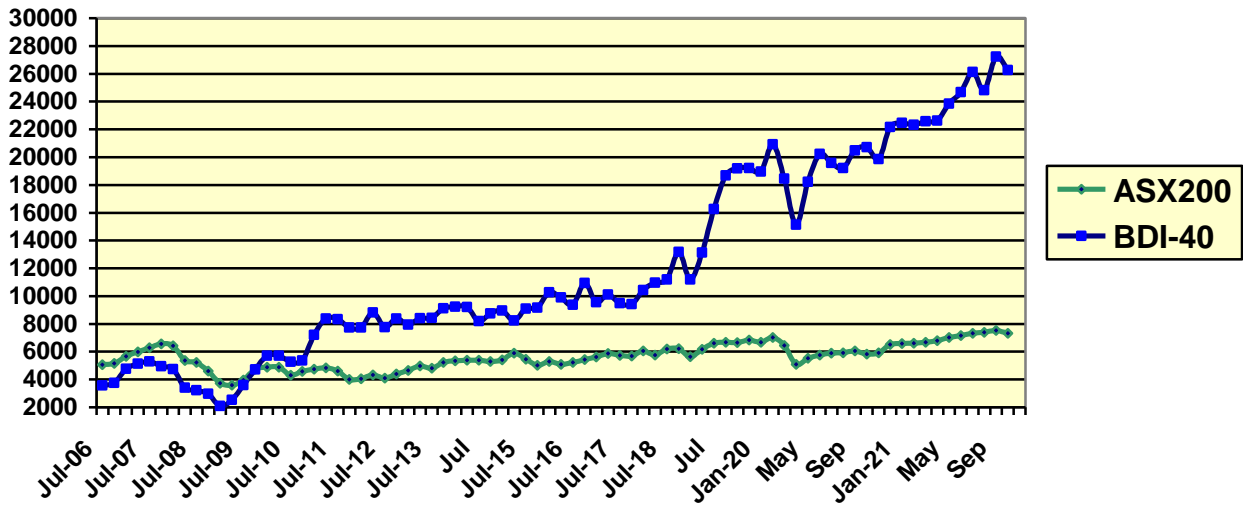
On the Nasdaq, both Queensland's Protagonist and Redhill (with Australian assets) fell sharply on news that the US Food and Drug Administration had placed a hold on the former's rufertide (PTG-300) cancer trials; and the latter's opaganib failed to meet its endpoints for hospitalized patients with severe Covid-19 pneumonia.

Protagonist fell 63.0 percent to \$1,166 million and Redhill lost 54.1 percent to \$296 million. Eyepoint (formerly Psivida) looked good by retreating just 3.5 percent to \$415 million.

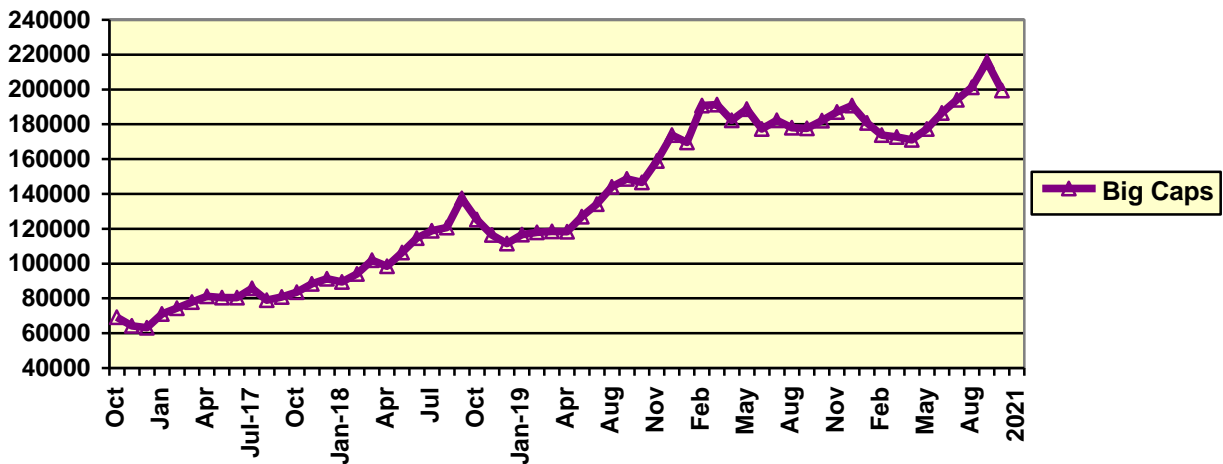
With a raft of new listings over the past year, the BDI-40 is under review – a task that no longer can be put off. Deciding who to promote is easier than deciding who to demote.

Among the contenders for promotion are 4D Medical, Aroa, Atomo, Clarity, Emvision, Imagion, Imricor, Lumos, Pacific Edge and Trajan, with only three or four companies on the potential demotions list.

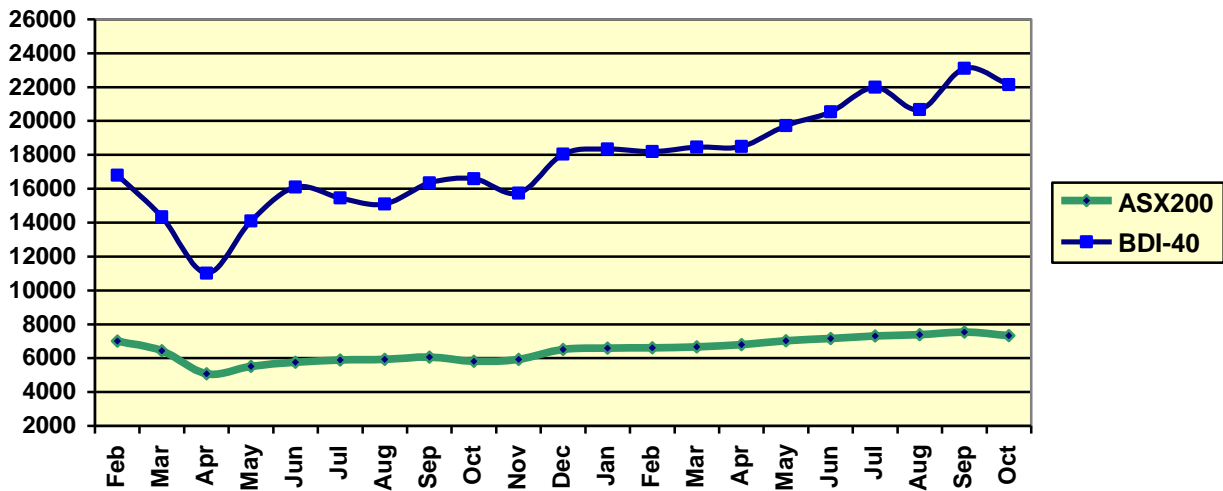
BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2021- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Sep 30, 2016 – Sep 30, 2021



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Sep 30, 2021 (current, raw data)



[BIOTECH CALL TO ARMS: DAVID BLAKE](#)

The founder and editor of Bioshares, David Blake, needs our help

In February, David was diagnosed with brain and lung cancer and he has been having treatment in Melbourne.

With David's family, biotechnology investor and public relations executive Andrew Geddes has established a 'Gofundme' page to support David, his wife Sonya and daughter Aletha, as they face significant challenges including the ongoing cost of care.

Mr Geddes said that exacerbating the difficulties, David's extended family are in Queensland and not able to travel to Melbourne.

David and Bioshares co-founder Mark Pachacz have made a significant contribution to the development of a thriving medical device and biotechnology sector in Australia.

All funds raised will go directly towards providing David and his family with in-home nursing support and the care needed.

To donate, go to: <https://gofund.me/9c2dff05>.

Biotech Daily owes David Blake a debt of gratitude for his support and assistance in establishing this publication in 2005, and many times since.

We know that many others in the industry have been assisted over many years by David and Mark.

Please donate, generously.

David Langsam, Editor

[NEUREN PHARMACEUTICALS](#)

Neuren says the US Food and Drug Administration has placed a "clinical hold" on its NNZ-2591 for Angelman syndrome investigational new drug application.

Neuren said the FDA hold would remain until the changes to the protocol were agreed.

The company said a formal notification on the hold would be issued after 30 days, after which Neuren would seek to discuss and agree the necessary protocol amendment with the FDA.

Neuren said the FDA "specified additional clinical assessments to be added to the phase II trial protocol to enhance safety monitoring during this first trial in patients".

The company said it had submitted investigational new drug (IND) applications for NNZ-2591 for Pitt Hopkins syndrome following earlier applications for Phelan McDermid syndrome and Angelman syndrome.

Neuren chief executive officer Jon Pilcher said the Angelman syndrome trial delay was "disappointing, however we will work with the FDA to amend the protocol as quickly as possible, as well as confirming any necessary amendment to the protocols for the Phelan-McDermid and Pitt Hopkins phase II trials".

"We will also take this into account for our IND application and phase II trial protocol in Prader-Willi syndrome, which we plan to submit in the first half of 2022," Mr Pilcher said.

Neuren fell one cent or 0.5 percent to \$2.09.

PRO MEDICUS

Pro Medicus says it has signed a \$40 million, seven-year contract with Novant Health to replace legacy picture archiving and communications systems.

Pro Medicus said the contract through its US subsidiary Visage Imaging would provide the Winston-Salem, North Carolina-based Novant Health the Visage 7 enterprise imaging platform including the Visage 7 workflow module, providing a “unified diagnostic imaging platform across the network”.

The company said planning for the implementation of the Visage 7 platforms would begin immediately, with initial use targeted by July 2022, using Microsoft’s Azure internet cloud. Pro Medicus said that Novant was a community-based network in three US states, with 15 medical centres and serving more than six million patients a year.

Pro Medicus chief executive officer Dr Sam Hupert said Novant Health was “our seventh major North American contract in less than 18 months and our equal largest deal to date, underpinning the strong momentum we continue to build in the market”.

“Like several of our other recent deals, it includes more than one of our products, in this case, Visage 7 Workflow as well as Visage 7 Viewer, validating our strategy of providing clients maximum flexibility by offering a highly modular, multi-product solution,” Dr Hupert said.

“Deals like this confirm our view that Visage 7, with its proven cloud-native technology and modular design, provides us with a significant strategic advantage that enables us to address opportunities across a growing segment of the market both in North America and other regions,” Dr Hupert said.

Pro Medicus fell 52 cents or 0.95 percent to \$54.09 with 554,169 shares traded.

DIMERIX

Dimerix says it has completed an “oversubscribed” share plan at 20 cents a share, raising \$4 million and taking the total to \$24 million.

In August, Dimerix said it completed a \$20 million placement at 20 cents a share and hoped to raise \$2 million more through a share plan (BD: Aug 16, 2021).

Today, the company said that because of the oversubscriptions it “resolved to accept \$4 million” and scale-back applications.

Dimerix said about 20 million ordinary shares would be issued at 20 cents each with 10 million attaching unlisted options.

The company said that the options would be exercisable at 40 cents each by the earlier of July 30, 2024 or 20 business days after the acceleration trigger date.

Dimerix was up half a cent or 1.7 percent to 30.5 cents.

PHARMAUST

Pharmaust says will conduct a pro-rata, non-renounceable 1-for-four rights offer of up to 79,228,096 options at one cent each to raise \$792, 281.

Pharmaust said the options would be exercisable at 20 cents each, by October 31, 2023. The company said the primary purpose of the offer was to “reward eligible shareholders with an attractively priced options offer”.

Pharmaust said the funds would be used as additional working capital and to meet offer expenses.

Pharmaust said the rights offer record date would be October 7, it would open on October 12 and close on November 2, 2021.

Pharmaust was up 0.2 cents or 2.2 percent to 9.2 cents.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

A report commissioned by the Australian Therapeutic Goods Administration says that psychedelic drugs “show promise” but require cautious administration.

The report, titled ‘An evaluation of the therapeutic value, benefits and risks of methylenedioxy-meth-amphetamine (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders: A report to the Therapeutic Goods Administration’ was authored by Metro South Health, Queensland’s Steve Kisely, Macquarie University’s Mark Connor and the University of Adelaide’s Andrew Somogyi and is available at:

<https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin>.

The report concluded that “MDMA and psilocybin may show promise in highly selected populations but only where these medicines are administered in closely clinically supervised settings and with intensive professional support”.

The report said that it combined the results from nine studies for either beneficial or adverse effects and showed statistically significant differences of the two psychedelic agents between both inactive and active treatments for either continuous scores or dichotomous responses.

“However, it is important to note that this was in highly supportive and structured environments including intense psychotherapy sessions in many cases,” the report said. The report said that both agents were well-tolerated but trial quality including blinding and follow-up was variable and only a small proportion of potential participants were included in the randomized phase”.

MEDIBIO

Medibio says it has launched its Luca mobile telephone application to help measure, monitor and manage stress.

Medibio said Luca was a biometric tool to measure sleep stress, activity stress and cardiac stress, allowing consumers to monitor their daily stress levels through a wearable device and receive “science-based learning modules to help manage their stress”.

Medibio was up 0.1 cents or 10 percent to 1.1 cents with 19.2 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has appointed Melbourne-based Bio101’s Hamish George as its chief financial officer to replace Jeff Carter, effective from October 1, 2021.

Amplia said Mr Carter who had been chief financial officer for more than eight years. Amplia chief executive officer Dr John Lambert thanked Mr Carter “for his exemplary service to Amplia”.

Amplia was up one cent or 4.8 percent to 22 cent.

EXOPHARM

Exopharm says David Franks will replace company secretary Elizabeth McGregor effective from September 30, 2021, with Ms McGregor continuing as a director.

Exopharm said Mr Franks was a principal of Melbourne’s Atomic Group and had more than 20 years of experience in finance, governance and accounting.

The company said Mr Franks held a Bachelor of Economics from Macquarie University.

Exopharm said Ms McGregor resigned as company secretary following her departure from the Atomic Group.

Exopharm fell four cents or 6.8 percent to 54.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEPTEMBER 30, 2021

Company \$Am	Oct-20	Sep-21	Oct-21
Cochlear	13,325	15,339	14,404
CSL	134,457	141,973	130,713
Resmed	34,346	58,540	54,257
BDI-20			
Avita	741	672	614
Clinuvel	1,205	1,867	2,048
Compumedics	76	73	74
Cyclopharm	193	155	156
Cynata	121	75	83
Ellex	47	61	57
Genetic Signatures	244	212	207
Immutep	122	451	468
Medical Developments	346	259	369
Mesoblast	3,044	1,080	1,077
Nanosonics	1,748	1,996	1,864
Neuren	127	250	261
Opthea	781	460	474
Paradigm	623	450	493
Pharmaxis	34	57	59
Polynovo	1,514	1,475	1,253
Pro Medicus	2,861	6,584	5,488
Starpharma	598	489	540
Telix	422	1,912	1,608
Volpara	327	294	298
Second 20			
Actinogen	30	183	209
Alterity	54	79	72
Amplia	19	24	26
Antisense	71	109	118
Dimerix	60	87	75
Impedimed	70	187	187
Imugene	206	2,212	2,622
Kazia	91	183	207
LBT Innovations	37	38	35
Next Science	236	291	265
Oncosil	108	38	38
Optiscan	49	139	139
Orthocell	74	88	98
Osprey	39	28	20
Patrys	21	73	79
Prescient	44	125	168
Proteomics	48	116	94
Resonance	73	53	41
Universal Biosensors	49	155	137
Uscom	27	23	21

* 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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