



# Biotech Daily

Tuesday December 1, 2020

*Daily news on ASX-listed biotechnology companies*

- \* NOVEMBER BDI-40 UP 15%, ASX200 UP 10%, BIG CAPS UP 2%, NBI 11%
- \* TODAY: ASX, BIOTECH UP: OPTISCAN UP 14%; OSPREY DOWN 9%
- \* POLYNOVO DETAILS US BURNS TRIAL
- \* POLYNOVO TAKES BACK BREAST PROGRAM
- \* CORRECTION: TELIX
- \* IMUGENE STARTS PHASE I PD1-VAXX LUNG CANCER STUDY
- \* SPAIN CE MARK FOR IMEX HIRUKO IMAGING
- \* NOXOPHARM REQUESTS CAPITAL RAISING TRADING HALT
- \* BARD1 REQUESTS 'ASX INFORMATION' TRADING HALT
- \* ALTHEA, PEAK DEAL FOR CANADA MARIJUANA DRINKS
- \* GENETIC TECHNOLOGIES TO SELL TALIAZ ANTI-DEPRESSANT PREDICTIX TEST
- \* LIFE BIOSCIENCES DILUTED TO 13% OF ALTERITY
- \* REGAL FUNDS REDUCES TO 15% OF ELIXINOL
- \* MEMPHASYS CHAIR ALISON COUTTS ON \$350k
- \* AVITA APPOINTS KATHY MCGEE COO

## MARKET REPORT

The Australian stock market was up 1.08 percent on Tuesday December 1, 2020, with the ASX200 up 70.7 points to 6,588.5 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell and eight traded unchanged. All three Big Caps were up.

Optiscan was the best, up 1.5 cents or 14.3 percent to 12 cents, with one million shares traded. Imugene climbed 8.3 percent; Medical Developments was up 7.3 percent; Immutep, Polynovo and Starpharma improved more than five percent; Cyclopharm and Proteomics were up more than four percent; Telix improved 3.9 percent (joining the \$1 billion club); Nanosonics rose 2.1 percent; Avita, Cochlear, Next Science, Orthocell, Paradigm, Prescient, Pro Medicus, Resmed and Universal Biosensors were up one percent or more; with CSL, Kazia and Genetic Signatures up by less than one percent.

Osprey led the falls, down 0.2 cents or 9.1 percent to two cents, with 17.15 million shares traded. Impedimed lost 6.1 percent; Uscom was down 5.9 percent; Actinogen and Amplia fell more than four percent; Alterity and Cynata were down more than three percent; Neuren and Oncosil shed more than two percent; Nova Eye lost 1.4 percent; with Clinuvel, Mesoblast and Volpara down by less than one percent.

## BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) fully recovered from the Sars-Cov-2 pandemic in November, up \$2,303 million to an all-time high of \$18,049 million.

The benchmark S&P ASX200 was up 9.95 percent in November and down 4.8 percent for the year to November 30. The BDI-40 (which does not include the three Big Caps of Cochlear, CSL and Resmed) climbed 19.5 percent for the 12 months.

The collective market capitalization of the Big Caps was up 1.95 percent in November (and 9.7 percent for the year) to \$190,744 million, just \$594 million (0.3%) below the all-time high of \$191,338 million at the end of February, just before the pandemic took hold of the markets.

Cochlear and Resmed both hit record highs, up 1.15 percent to \$14,491 million and 2.0 percent to \$40,953 million, respectively, with CSL also up 2.0 percent to \$135,300 million.

The Nasdaq Biotechnology Index was up 11.1 percent in November and 21.3 percent for the year to November 30, 2020.

In possibly the BDI-40's best month on record, 31 companies were up, two by more than 100 percent and 12 by more than 20 percent, while just eight fell and one was unchanged.

Telix was the best, on a series of acquisitions and partnerships, up \$563 million or 132.5 percent to \$988 million, last night, and joining the \$1 billion club in trading earlier today.

Imugene was up \$292 million or 118.2 percent, partly on impressive cancer results the company claimed were "statistically significant" but did not conform to conventional methodology. Impedimed almost doubled in value, up 97.8 percent to \$178 million, followed by Kazia (74.0%), Universal Biosensors (43.9%) Mesoblast (32.0%), Immutep (29.7%), Nanosonics (26.9%), Compumedics (26.0%), Oncosil (23.3%), Medical Developments (21.1%) and Orthocell (20.0%).

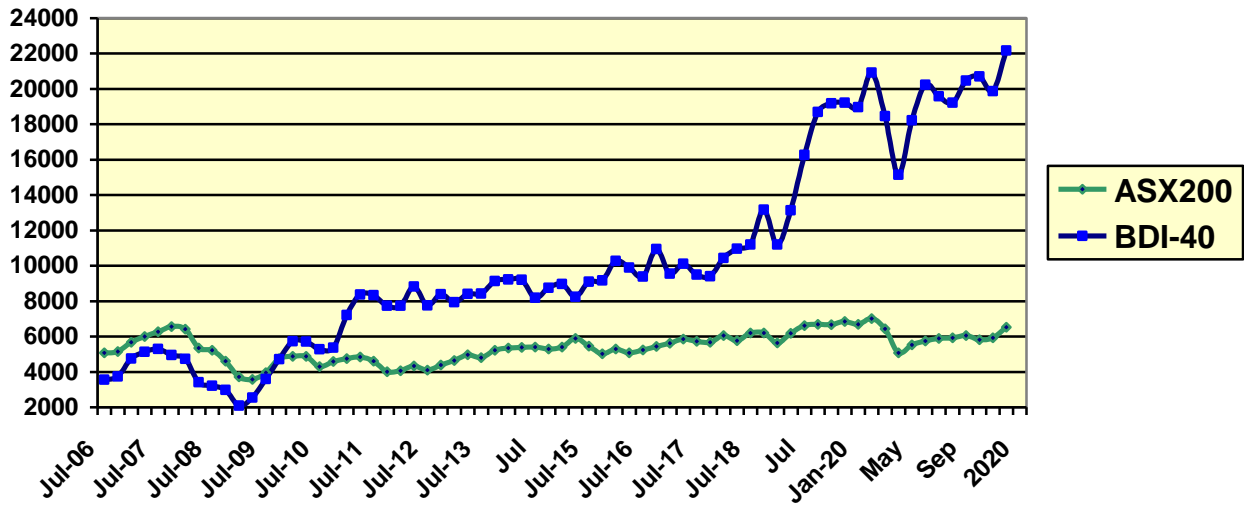
Pro Medicus led the falls, slipping 10.3 percent or \$353 million from last month's record high to \$3,078 million, followed by Starpharma (10.1%), Patrys (8.8%), Genetic Signatures (5.9%), Clinuvel (5.5%), Cynata (3.1%), Avita (2.0%) and Dimerix (1.96%).

Outside the Top 40, Imagion was up 115 percent for the month but 1,333 percent for the year to \$129 million. For the 12 months to November 30, Race Oncology was up 1,235 percent to \$267 million, followed by Rhythm Bio (1,155.5%), Emvision (471.4%), Recce (424.3%), Noxopharm (226.2%), Micro-X (200%), Mach7 (184.8%) and 4D (115.2%).

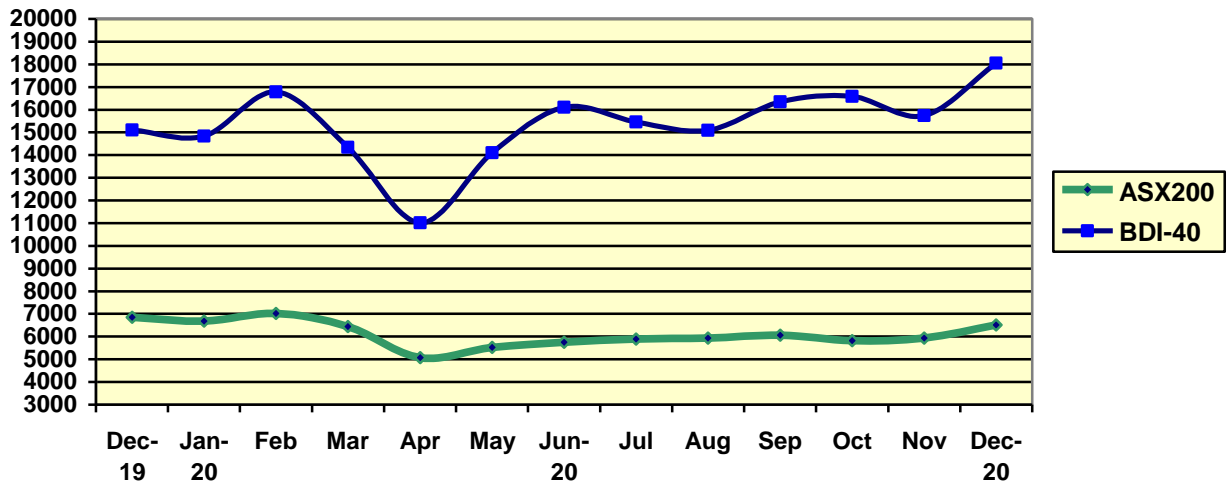
Cannabis Corner recovered 25.6 percent to a collective \$1,450 million, down 8.3 percent for the year to November 30.

On the Nasdaq, Eyepoint (Psivida) was up 49.3 percent to \$106 million, Queensland's Protagonist rose 26.8 percent to \$1,258 million and Redhill (with Australian assets) edged up 2.0 percent to \$454 million.

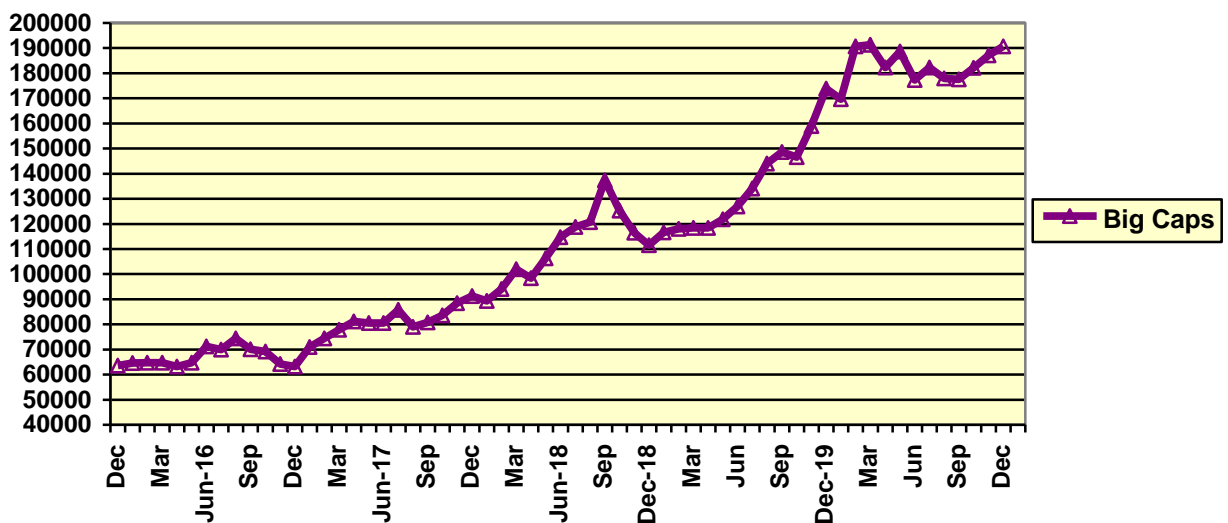
**BDI-40 v ASX200 Jun 30, 2006 to Nov 30, 2020- Adjusted**



**BDI-40 (\$m) v S&P ASX 200 – Nov 30, 2019 – Nov 30, 2020 (current, raw data)**



**5-Year Big Caps \$m (Cochlear, CSL, Resmed) Nov 30, 2015 – Nov 30, 2020**



## POLYNOVO

Polynovo says its 150-patient Novosorb biodegradable temporizing matrix (BTM) trial for full thickness burns will have a multi-center, randomized, adaptive design.

Last month, Polynovo said it had investigation device exemption approval from the US Food and Drug Administration for a 150-patient pivotal trial of its Novosorb biodegradable temporizing matrix (BTM) for full thickness burns (BD: Nov 13, 2020).

Today, the company said the trial would compare safety and effectiveness to the standard-of-care in patients with burns to five to 50 percent of total body surface area.

Polynovo said the primary efficacy endpoint was a comparison of the total percent wound closure between the BTM and standard-of-care groups, with the primary safety objective to compare the type, severity and incidence of adverse events.

The company said that one secondary endpoint was a comparison of the proportion of wounds achieving closure at four weeks after split-thickness skin grafting.

Polynovo said the study would be held at up-to 25 US and Canadian sites, with 12 sites pre-qualified to participate, and recruitment expected to begin in early 2021 following ethics approval.

Polynovo said that the University of California Davis Medical Centre burn unit director Dr Tina Palmieri would be the principal investigator.

Polynovo managing-director Paul Brennan said the data generated from the trial would “provide powerful clinical evidence to support what many surgeons around the world are already seeing with Novosorb BTM”.

“We are very pleased that Dr Palmieri and her team at UC Davis will be supporting the program because they will bring their extensive research rigour and experience to the trial,” Mr Brennan said.

Mr Brennan said the company acknowledged the ongoing support from the US Biomedical Advanced Research and Development Authority (BARDA) for the clinical program.

Polynovo was up 17 cents or 5.3 percent to \$3.38 with 9.4 million shares traded.

## POLYNOVO

Polynovo says its Establishment Labs Novosorb breast device development program “will be brought in-house effective immediately”.

In 2018, Polynovo said it would develop Novosorb polymer-based medical devices for breast aesthetics and reconstruction with the Alajuela, Costa-Rica-based Establishment Labs (BD: Jan 18, 2018).

Today, Polynovo managing-director Paul Brennan said the company was “excited to progress our development of these breast reconstructive and aesthetic devices with our own research and development team”.

“We also see significant cross-fertilization opportunities with our Syntrel hernia devices and other products in development,” Mr Brennan said.

Mr Brennan told Biotech Daily that the breast scaffold work had not “kept pace with the in-house hernia program”.

“We’ve brought it back in-house to accelerate the program,” Mr Brennan said. “We have a lot of detailed work to do, to get the program back on-track.”

At the company’s annual general meeting, Polynovo chairman David Williams said the company intended “to ramp up our in-house research and development capability”.

“We believe we can develop breast and a number of other devices more quickly on our own,” Mr Williams said.

“The size of Polynovo and the new product development and extension opportunities in front of us dictate that we need to build our research and development team and efforts”.

## CORRECTION: TELIX PHARMACEUTICALS

Last night's edition incorrectly described Telix acquisition Therapharm GmbH as based in Klug in the Czech Republic.

The over-enthusiastic Monday sub-editor mistook a company of the same name for the subsidiary of the Zug, Switzerland-based Scintec Diagnostic GmbH that is to be acquired by Telix.

Biotech Daily apologizes unreservedly and has organized a secondment for the sub-editor at the China-Australia Peace and Cooperation Friendship Journal to learn the difference between haste and speed.

Telix was up 14 cents or 3.9 percent to \$3.72 with 1.1 million shares traded.

## IMUGENE

Imugene says it has dosed the first patient in its 32-patient, patient, first-in-human trial of the PD1-Vaxx checkpoint immunotherapy candidate for non-small cell lung cancer.

Imugene said the multi-centre, dose escalation study began in Melbourne and was recruiting patients with non-small cell lung cancer to test three different doses of PD1-Vaxx, with at least three patients in each cohort.

The company said the primary aim of the study would be to determine safety and an optimal biological dose, but it would also measure efficacy, tolerability and immune response.

Imugene said the cohort review committee was co-chaired by chief medical officer Dr Rita Laeufle and would meet to review safety and tolerability data after the last patient in each cohort had completed 30 days of treatment in order to approve the next dose level.

Imugene chief executive officer Leslie Chong said the start of the study was "a significant milestone for Imugene and clinicians treating Australians faced with the challenge of lung cancer".

"The concept of teaching and inducing the body to generate its own antibodies targeting PD-1 expressing cells represents a paradigm shift in oncology, and is a novel treatment method for cancer," Ms Chong said.

Imugene said that about 12,800 Australians were diagnosed with lung cancer each year. Imugene was up one cent or 8.3 percent to 13 cents with 56.0 million shares traded.

## IMEX HEALTH SERVICES

Imex says Spain's Ministry of Health has granted it Conformité Européenne (CE) mark approval for its Hiruko imaging software platform as a class I medical device.

Imex said the certification meant that it could now sell its Hiruko platform in Europe.

The company said the European radiology information system (RIS) and picture archive and communication system (PACS) was expected to be worth about \$US570 million (\$A774.7 million), by 2023.

Imex said it was a leading imaging software as a service and ancillary products company with the internet "cloud"-based, vendor neutral and zero footprint Hiruko platform not requiring installed software.

The company said that Hiruko included a next generation PACS, integrated medical imaging systems, including an RIS, a cardiology information system and an anatomical pathology laboratory information system.

Imex was up 1.5 cents or one percent to \$1.50.

### [NOXOPHARM](#)

Noxopharm has requested a trading halt “pending the release of an announcement relating to a capital raising program”.

Trading will resume on December 3, 2020 or on an earlier announcement.

Noxopharm last traded at 64 cents.

### [BARD1 LIFE SCIENCES](#)

Bard1 has requested a trading halt pending “an announcement to respond to the ASX’s request for further details of the ... announcement made November 23, 2020”.

Last week, Bard1 said it had gained an unnamed high-volume Texas-based customer for its hTERT adjunct urine cytology test for bladder cancer (BD: Nov 23, 2020).

Trading will resume on December 3, 2020 or on an earlier announcement.

Bard1 is conducting a 30-to-one consolidation and last traded at 2.2 cents, or a post-consolidation 66 cents.

### [ALTHEA GROUP HOLDINGS](#)

Althea says subsidiary Peak Processing Solutions has a three-year agreement with Tinley Beverage Company for non-alcoholic marijuana drinks in Canada.

Althea said it would exclusively manufacture and distribute Tinley’s Coconut Cask, Cinnamon Cask and Almond Cask products, including an initial order for more than \$CA100,000 (\$A104,758), with a planned delivery by April 2021.

The company said exclusivity in Canada would last until Tinley’s had met established minimum quantities.

Althea was up three cents or 6.2 percent to 51.5 cents with 1.4 million shares traded.

### [GENETIC TECHNOLOGIES](#)

Genetic Technologies says it has a three-year agreement with Israel’s Taliáz to distribute its Predictix depression test in Australia, New Zealand and the US.

Genetic Technologies said Taliáz’s Predictix artificial intelligence-based decision support and management platform for anti-depression selection improved “anti-depressant prescribing accuracy by 47 percent”.

The company said it had committed to a minimum 7,000 tests for \$30,000, subject to regulatory clearances in Australia and the US, and it expected to make Predictix available in Australia and New Zealand by October 2021.

Genetic Technologies interim chief executive officer Dr George Muchnicki said his company was “at the forefront of providing personalized and predictive products to empower patients to make informed decisions about their health”.

“This distribution agreement is our first external product partnership and our first product within the mental health vertical,” Dr Muchnicki said.

“Mental health has remained at the forefront of media discussions and government initiatives within Australia, New Zealand and globally due to the ongoing social and economic impact and given the impact from the current global pandemic,” Dr Muchnicki said.

“We look forward to working closely with the Taliáz team to deliver their product into these markets at this critical time,” Dr Muchnicki said.

Genetic Technologies was up 0.15 cents or 21.4 percent to 0.85 cents with 24.8 million shares traded.



### ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Life Biosciences says its 269,905,533 share-holding in Alterity has been diluted from 19.9 percent to 13.3 percent.

The Boston, Massachusetts-based Life Biosciences said it was diluted on November 24, 2020 following the \$35 million placement at 3.7 cents a share (BD: Oct 16, 2020).

In 2018, the then Prana said Life Biosciences had agreed to invest up to \$US29.4 million (\$41.8 million) and in 2019, the company approved Life Biosciences taking 63 percent and the name change to Alterity (BD: Jan 20, Mar 6, Apr 5, 2019).

Alterity fell 0.1 cents or 3.1 percent to 3.1 cents with 80.1 million shares traded.

### ELIXINOL GLOBAL

Regal Funds Management says it has reduced its substantial shareholding in Elixinol from 38,936,269 shares (16.15%) to 36,426,732 shares (15.11%).

The Sydney-based Regal Funds said that between November 23 and 26, 2020 it sold 2,509,537 shares for \$472,422 or 18.8 cents a share.

Elixinol was unchanged at 19 cents with 1.9 million shares traded.

### MEMPHASYS

Memphasys says it has renewed executive chairman Alison Coutts' contract effective from today to a base salary of \$350,000 including superannuation.

Memphasys said Ms Coutts would also receive a short-term cash incentive of up to 27.5 percent of her base salary and a long-term incentive based on key performance indicators, including commercial sales of its Felix sperm separation device, the progress of regulatory submissions and the development of other reproductive medicine technologies.

Memphasys was up one cent or 8.3 percent to 13 cents.

### AVITA THERAPEUTICS

Avita says it has appointed Kathy McGee as chief operative officer, effective from today.

Avita said Ms McGee had more than 25 years of biopharmaceutical and life sciences experience, most recently as the president of the CNA Consulting Group.

The company said Ms McGee was previously Shire Pharmaceuticals head of West Coast regenerative medicine operations and worked for Smith and Nephew and Advanced Tissue Sciences.

The company said Ms McGee held a Bachelor of Science from Ireland's University College Galway and a Master of Business and Management from the St Louis, Missouri-based Webster University.

Avita was up nine cents or 1.55 percent to \$5.90 with 706,041 shares traded.

## BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT NOVEMBER 30, 2020

<b>Company \$Am</b>	<b>Dec-19</b>	<b>Nov-20</b>	<b>Dec-20</b>
Cochlear	13,517	14,326	14,491
CSL	128,440	132,624	135,300
Resmed	31,888	40,140	40,953
<b>BDI-20</b>			
Avita	1,323	637	624
Clinuvel	1,416	1,058	1,000
Compumedics	138	73	92
Cyclopharm	79	163	193
Cynata	117	96	93
Ellex	88	47	51
Genetic Signatures	134	271	255
Immutep	99	128	166
Medical Developments	450	356	431
Mesoblast	974	1,848	2,440
Nanosonics	2,048	1,580	2,005
Neuren	252	116	139
Opthea	683	750	777
Paradigm	747	612	668
Pharmaxis	95	35	36
Polynovo	1,236	1,785	2,122
Pro Medicus	2,589	3,431	3,078
Starpharma	491	576	518
Telix	429	425	988
Volpara	393	334	347
<b>Second 20</b>			
Actinogen	50	23	32
Alterity	22	39	65
Amplia	4	24	25
Antisense	33	54	59
Dimerix	21	51	50
Impedimed	87	90	178
Imugene	159	247	539
Kazia	46	100	174
LBT Innovations	44	35	36
Next Science	389	221	240
Oncosil	117	116	143
Optiscan	21	58	63
Orthocell	88	65	78
Osprey	17	32	36
Patrys	23	34	31
Prescient	34	37	43
Proteomics	30	47	55
Resonance	81	69	71
Universal Biosensors	36	57	82
Uscom	18	26	26

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Alcidion, Alterity, Amplia, BTC Health, Cochlear, Cynata, Mesoblast, 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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