



Biotech Daily

Monday May 2, 2022

Daily news on ASX-listed biotechnology companies

- * **ALL APRIL INDICES DOWN: BDI-40 6%, ASX200 1%, BIG CAPS 2%, NBI 10%**
- * **TODAY: ASX, BIOTECH DOWN: USCOM UP 6%; IMUGENE DOWN 14%**
- * **IMUGENE LOSES MERCK KEYTRUDA SUPPLY; TRIAL UNAFFECTED**
- * **BIOTRON: 'BIT225 KILLS ESTABLISHED SARS-COV-2, IN MICE'**
- * **EPSILON \$2.1m PLACEMENT FACILITY FOR SOUTHPORT OPERATIONS**
- * **RESPIRI RAISES \$1.6m FOR US COMMERCIALIZATION**
- * **INOVIQ HIRES MP BIOMEDICALS FOR SUB-B2M PROTEIN**
- * **EMVISION REQUESTS 'STRATEGIC AGREEMENT' TRADING HALT**
- * **CREDIT SUISSE BELOW 5% IN MESOBLAST**
- * **HERAMED 'OUTSTANDING RESULTS' FOR HERABEAT MONITOR TRIAL**
- * **SERVATUS APPOINTS DR UWE BUECHELER DIRECTOR**
- * **RESONANCE APPOINTS LIESL ELLIES CO-CO SEC**

MARKET REPORT

The Australian stock market fell 1.18 percent on Monday May 2, 2022, with the ASX200 down 88.0 points to 7,347.0 points. Five of the Biotech Daily Top 40 stocks were up, 26 fell, seven traded unchanged and two were untraded. All three Big Caps were down.

Uscom was the best, up 0.6 cents or 6.4 percent to 10 cents, with 153,959 shares traded. Alcidion and Opthea climbed two percent or more; Oncosil was up 1.7 percent; with Cyclopharm up by 0.7 percent.

Imugene led the falls, down three cents or 13.6 percent to 19 cents with 71.6 million shares traded, followed by Dimerix down 13.3 percent to 13 cents with 2.5 million shares traded.

Pro Medicus fell 7.8 percent; Telix lost 6.7 percent; Actinogen, Compumedics, Genetic Signatures and Proteomics were down more than five percent; Atomo, Clinuvel, Kazia and Paradigm fell more than four percent; Orthocell and Prescient were down more than three percent; Cochlear, Immutep, Impedimed, Mesoblast, Micro-X, Nanosonics, Neuren, Polynovo and Starpharma shed more than two percent; Avita, CSL, Pharmaxis, Resmed and Universal Biosensors lost more than one percent; with Cynata down by 0.7 percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

It's Autumn in Australia - a season that the Americans call Fall - and that's what the stock markets have done. All indices lost ground in the month of April.

Despite the January and February plunge, a slight easing in March and another fall in April the Biotech Daily Top-40 Index (BDI-40) is still well above the February and March 2020 Covid write-down but at its lowest point since November 2020 (see charts below).

The BDI-40 fell a further 6.1 percent in April to a collective market capitalization of \$15,752 million, but a significant 20.2 percent below April 30 last year.

The ASX200 slipped 0.9 percent in April, but was up 5.8 percent for the year, while the Nasdaq Biotechnology Index (NBI) lost 9.7 percent in April and 22.7 percent for the year.

Resmed dragged the collective value of the three Big Caps (which are not included in the BDI-40) down 2.2 percent for the month but the group was up 5.6 percent for the year. Resmed lost 10.1 percent to \$2,623 million, while Cochlear climbed 1.8 percent to \$15,093 million and CSL edged up 0.3 percent to \$129,502 million.

Thirty-five of the BDI-40 companies fell in April, with 18 down by more than 10 percent; while just five were up, with three up more than 10 percent. Some of the greatest April losses are inexplicable and some expected to fall have weathered the storm.

Universal Biosensors led the April falls, down 22.5 percent to \$117 million, despite good news, followed by Avita (20.9%), Kazia (17.8%), Impedimed (17.4%), Dimerix (17.2%), Imugene (16.0%), Actinogen (15.5%), Amplia (14.3%), Compumedics (13.2%), Clinuvel (12.9%), Polynovo (12.4%), Proteomics (11.8%), Immuteq and Starpharma (11.7%). Oncosil climbed 43.75 percent to \$46 million following months of falls, followed by Pharmaxis (12.8%), Genetic Signatures (11.0%), Paradigm (9.4%) and Telix (1.0%).

But the 12-month data is more informative, underlining the relevance of time-points. Imugene was up 35.4 percent for the year to May 1, because its rise to \$3.1 billion began a year ago. In June, it could be the year's deepest fall, while still being worth more than \$1 billion with no product sales.

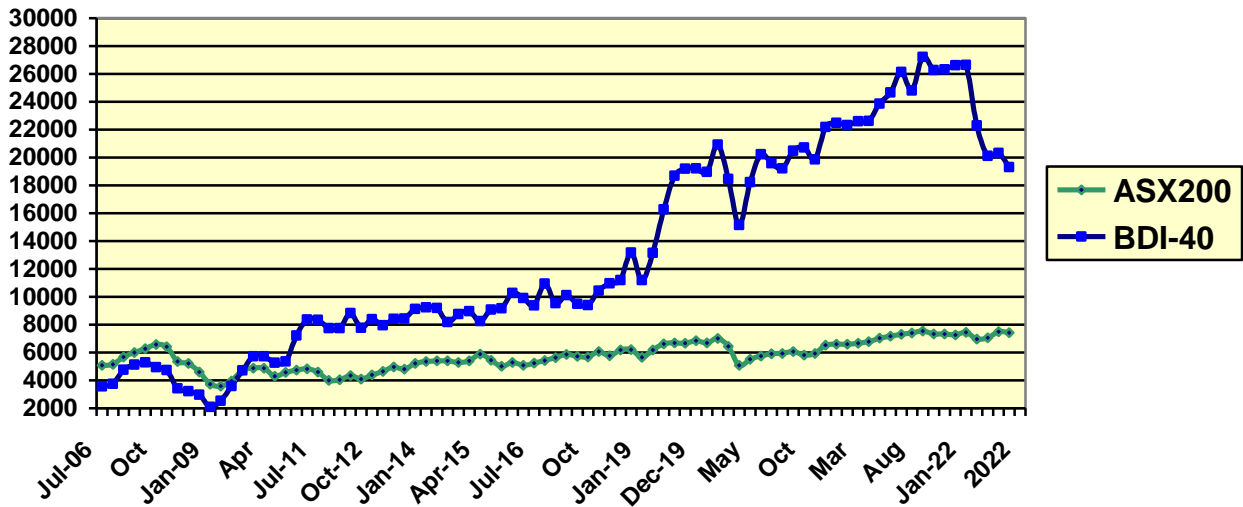
Polynovo lost 69.5 percent for the year to April 30, followed by Avita (64.9%), Starpharma (53.2%), Alcidion and Paradigm (47.3%), Atomo (46.7%), Clinuvel (46.3%) and Next Science (44.5%). These are all good companies, so why the sell off?

The more speculative stocks had deeper falls: Inoviq (Bard1) lost 78.6 percent in 12 months, followed by Oventus (73.1%), Anteo (71.9%), Exopharm (71.7%), Radiopharm (68.3%), Optiscan (67.5%), Bionomics (66.4%), Zelira (65.2%) and Creso (65.0%).

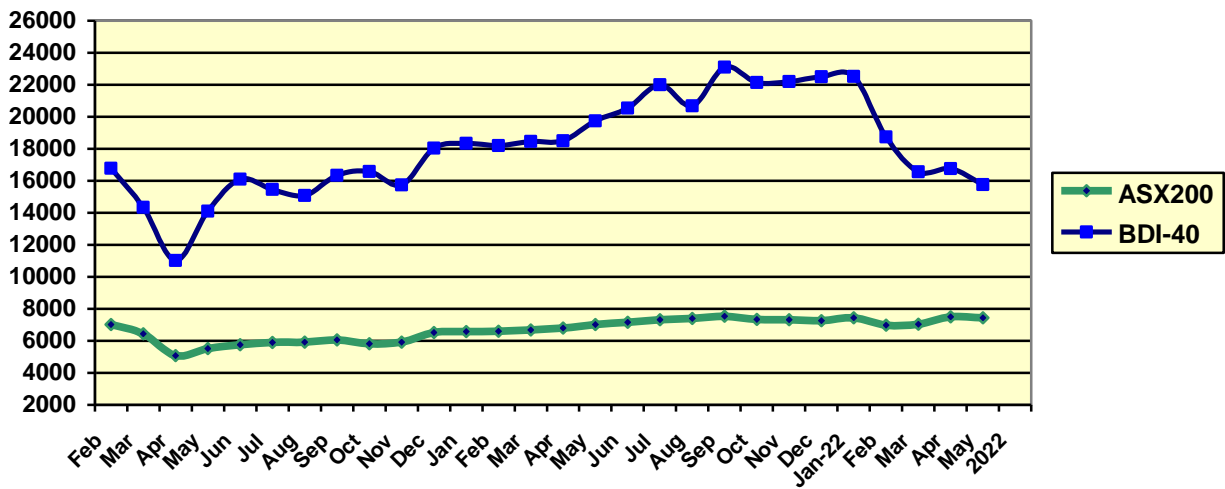
Biotech Daily has observed institutional gambling on biotech, showing that some fund managers are disinterested in the sector, chasing temporary gains. Biotech requires long-term investment and that means putting one's money in and leaving it there for a decade. There is money to be made in biotech but day-trading isn't the way to do it.

The 11 companies in Cannabis Corner fell a further 12 percent in April to \$1,177 million, but 1.4 percent above April 30, 2021. Only Cann Group and Medlab improved in April.

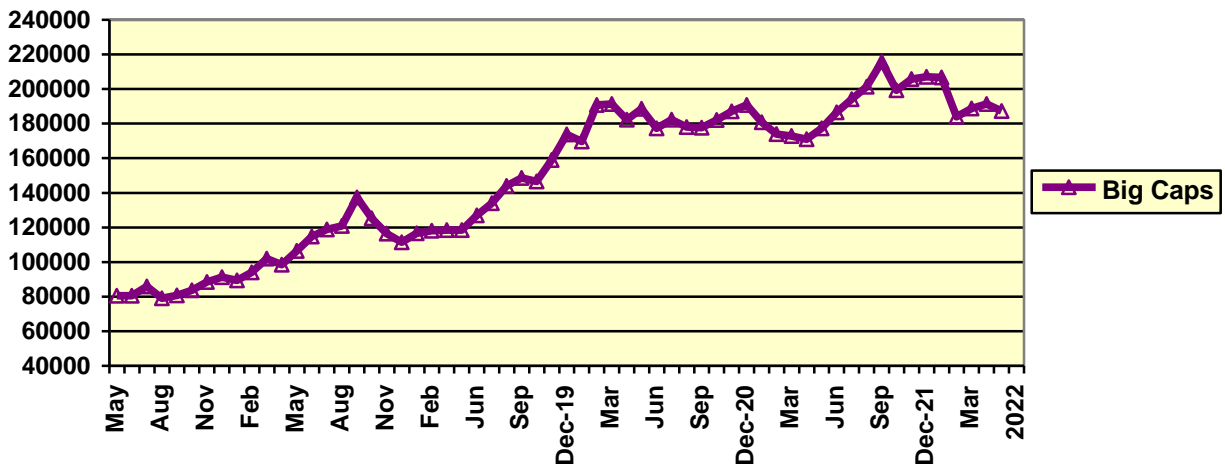
BDI-40 v ASX200 Jun 30, 2006 to Apr 30, 2022- Adjusted



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Apr 30, 2022 (current, raw data)



Big Caps \$m (Cochlear, CSL, Resmed) Apr 30, 2017 – Apr 30, 2022



IMUGENE

Imugene says the pembrolizumab, or Keytruda, supply agreement with Merck & Co has been terminated, but the phase II gastric cancer trial continues unchanged.

Imugene said it would continue with its phase II trial to evaluate the safety and efficacy of HER-Vaxx in combination with anti-programmed death 1 (PD-1) therapy for human epidermal growth factor 2 (HER-2) positive gastric cancer.

In March, Imugene said it would sponsor the study and fund it from its existing budget, while the Kenilworth, New Jersey-based Merck & Co would provide Keytruda for the study (BD: Mar 15, 2022)

Today, Imugene executive chair Paul Hopper told Biotech Daily that “the situation had changed” and the company would source pembrolizumab elsewhere.

Mr Hopper said the trial was “still full speed ahead” and the costs of the drug were not material.

Imugene fell three cents or 13.6 percent to 19 cents with 71.6 million shares traded.

BIOTRON

Biotron says BIT225 shows “effective protection” from established severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in mice.

Biotron said that a study, at the Scripps Research Institute in La Jolla, California, investigated mice infected with Sars-Cov-2 up-to 48 hours before starting treatment with BIT225.

In March, the company said that 300mg of oral BIT225 had shown “substantial and clinically efficacy” against Sars-Cov-2, in mice (BD: Mar 17, 2022).

Today, Biotron said the study had four groups: group one had five mice dosed twice daily for 12 days with vehicle control; group two had five mice dosed twice daily for two days with vehicle control, then 10 days with 300mg/kg BIT225 (24-hour post-dosing group); group three had five mice dosed twice daily for three days with vehicle control, then nine days with 300mg/kg BIT225 (48-hour post-dosing group), and group four had five mice dosed twice daily for 12 days with 300mg/kg BIT225 (pre-dosing group).

The company said that all BIT225 pre-dosed mice and the 24-hour post-dose mice remained “healthy and continued to gain weight as per age expectations ... to day-12 when the study was terminated”.

Biotron said that one of the five animals in the 48-hour post-dosing cohort died on day 11 of the study and that all vehicle control mice showed an “inexorable downward trend in body weight, and all control mice died by day-8”.

The company said that group mean body weights of BIT225-treated mice throughout the studies were “statistically different” to vehicle control mice throughout the study and that while there appeared to be a trend for less weight gain if initiation of BIT225 dosing was delayed, the trend lines were “statistically the same” regardless of whether drug treatment was initiated pre- or post-infection.

Biotron managing-director Dr Michelle Miller said the results were “important as they show a clear clinical benefit for BIT225 regardless of time of commencement of treatment”.

“We believe that BIT225’s extended therapeutic protection window sets it apart from the other approved or in-development agents and further strengthens our confidence in this valuable clinical asset,” Dr Miller said.

Biotron said that in March it submitted a proposal to the US Food and Drug Administration to conduct a human clinical trial to assess the efficacy of BIT225 for the treatment of Covid-19 and that it expected a response shortly.

Biotron was up 2.7 cents or 37.5 percent to 9.9 cents with 60.5 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has secured a capital raising of up to \$2.1 million in two tranches, for the “continued ramp up of operations at Southport facility.

Epsilon said the first tranche \$600,000 placement at 3.4 cents a share was a 9.2 percent discount to the five-day volume-weighted average price and the second tranche, to be completed within 45 days of the first tranche, was expected to be on “similar terms”, subject to sufficient capacity or shareholder approval.

Epsilon fell 0.2 cents or 5.6 percent to 3.4 cents with 1.4 million shares traded.

RESPIRI

Respiri says it raised \$1.6 million in a placement at 4.5 cents a share, a 26.0 percent discount to the five-day volume-weighted average price to April 26, 2022.

Respiri said the funds would be used to accelerate its Wheezo asthma detection commercialization and roll-out strategy in the US.

Respiri was untraded at 5.1 cents.

INOVIQ (FORMERLY BARD1 LIFE SCIENCES, SIENNA CANCER DIAGNOSTICS)

Inoviq says it has a manufacturing agreement with the Irvine, California-based MP Biomedicals for the production of its Sub-B2M protein.

Inoviq said that the agreement was for the provision of contract manufacturing services to produce the Sub-B2M protein to current good manufacturing practice (GMP) at MP Biomedicals’ Singapore facility which has GMP and International Organization for Standardization 13485 certifications.

In April, the company said it had engaged Researchdx to develop and validate its Sub-B2M-based tests for detecting the pan-cancer biomarker Neu5Gc, which it had developed after licencing the B subunit of Subtilase cytotoxin (SubB) from the University of Adelaide in 2020 (BD: Apr 20, 2020; Apr 5, 2022).

At that time, the then Sienna Diagnostics said that Sub-B targeted and bound to Neu5Gc, the tumor biomarkers found in multiple human cancers including breast, ovarian, prostate and others.

Today, Inoviq chief executive officer Dr Leeearne Hinch said that securing commercial supply of the Sub-B2M protein was “a key milestone”.

“MP Biomedicals is a highly respected global supplier of life science and diagnostic products and we are therefore delighted to partner with them to ensure the commercial supply of Sub-B2M protein, which are critical components of our Sub-B2M-based tests for breast and ovarian cancer,” Dr Hinch said.

MP Biomedicals sales and marketing director Ben Kuan Choo said that “we are very excited to be partnering with Inoviq to supply high-quality Sub-B2M protein for the company’s innovative Sub-B2M-based diagnostic tests”.

Inoviq did not disclose the financial terms of the agreement.

Inoviq was up one cent or 1.8 percent to 57 cents.

EMVISION MEDICAL DEVICES

Emvision said it has requested a trading halt “pending an announcement ... regarding a strategic agreement”.

Trading will resume on May 4, 2022, or on an earlier announcement.

Emvision last traded at \$1.94.

MESOBLAST

Sydney's Credit Suisse says it has ceased its substantial holding in Mesoblast. In March, Credit Suisse said it had become substantial in Mesoblast with 32,871,412 shares or 5.05 percent (BD: Mar 29, 2022).

Today, Credit Suisse said that between March 30, and April 20, 2022 it sold, returned and borrowed shares under lending agreements.

Mesoblast fell 2.5 cents or 2.3 percent to \$1.05.

HERAMED

Heramed says it has "outstanding results" for its 103-patient trial of its Herabeat foetal heart rate monitor in prolonged monitoring sessions.

Heramed said the study, by Western Australia's Joondalup Health Campus, was designed to evaluate the accuracy and clinical utility of Herabeat when used to record foetal heart rate, assess the ability of pregnant women to record measurements unsupervised at home, and the obstetrician's ability to review the recordings remotely.

The company said the foetal heart rate was detected on 100 percent of occasions, there was a high level of accuracy compared to hospital-grade cardiotocography machines exceeding accuracy guidelines.

Heramed said that Herabeat accurately detected essential clinical features present in cardiotocography needed for obstetricians to make clinical decisions and that time taken to detect foetal heart rate on smartphones ranged from less than 15 seconds to one minute for 62 subjects and six minutes for one subject.

The company said women using the device at home gave an overall rating of six of seven. Heramed co-founder and chief executive officer David Groberman said the company was "delighted with the results [which shows] that the smart foetal heart rate monitor can not only be used as a screening tool for assessing foetal wellbeing, but it is also highly valuable in pregnancies where more detailed medical examinations are required, including high-risk pregnancies when there is an increased concern about the foetal wellbeing". Heramed fell 4.5 cents or 23.1 percent to 15 cents with 1.4 million shares traded.

SERVATUS

The Coolumb Beach, Queensland's Servatus says it has appointed Dr Uwe Buecheler as a Germany-based non-executive director.

Servatus said Dr Buecheler had more than 30 years of experience in the pharmaceutical industry, was currently chair of the Ulm-headquartered Biopharma Cluster South Germany and had worked for Boehringer Ingelheim, including as head of expansion.

Servatus said that Dr Buecheler held a Master of Science from the University of Hohenheim and a Doctor of Philosophy from the University of Heidelberg, Germany.

Servatus is a public unlisted company.

RESONANCE HEALTH

Resonance says it has appointed Liesl Ellies as a third joint company secretary with chair Mitchell Wells and chief financial officer Nicholas Allan, effective from April 29, 2022.

Resonance said Ms Ellies was a corporate lawyer, advising companies on compliance, capital markets, and mergers and acquisitions and according to LinkedIn, Ms Ellies held a Bachelor of Laws and a Bachelor of Asian Studies from Perth's Murdoch University.

Resonance was unchanged at 12 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT APR 30, 2022

Company \$Am	May-21	Apr-22	May-22
Cochlear	14,774	14,821	15,093
CSL	124,471	129,170	129,502
Resmed	38,079	47,414	42,623
BDI-20			
Avita	647	287	227
Clinuvel	1,479	912	794
Compumedics	81	53	46
Cyclopharm	262	153	140
Cynata	90	59	53
Genetic Signatures	197	173	192
Immutep	309	334	295
Kazia	181	135	111
Medical Developments	393	275	250
Mesoblast	1,187	745	673
Nanosonics	1,837	1,201	1,168
Neuren	148	501	482
Nova Eye	47	36	35
Opthea	506	403	357
Pharmaxis	38	47	53
Polynovo	2,017	725	615
Pro Medicus	4,921	5,113	5,099
Starpharma	696	369	326
Telix	1,052	1,305	1,318
Volpara	334	222	214
Second 20			
Actinogen	110	187	158
Alcidion	421	247	222
Amplia	31	28	24
Antisense	115	84	77
Atomo	122	71	65
Dimerix	50	58	48
Emvision	229	163	150
Impedimed	172	258	213
Imugene	907	1,462	1,228
Micro-X	152	99	92
Next Science	335	187	186
Oncosil	78	32	46
Orthocell	100	84	81
Paradigm	531	256	280
Patrys	47	53	47
Prescient	62	94	85
Proteomics	119	127	112
Resonance	90	60	55
Universal Biosensors	128	151	117
Uscom	23	19	18

* 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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