



Biotech Daily

Tuesday June 1, 2021

Daily news on ASX-listed biotechnology companies

- * **IMUGENE 117% JUMP TAKES MAY BDI-40 UP 4%; ASX200 UP 2%, BIG CAPS 5%**
- * **TODAY: ASX, BIOTECH DOWN: USCOM UP 3%; ACTINOGEN DOWN 9%**
- * **APPLICATIONS OPEN FOR \$2.5m CSL CENTENARY FELLOWSHIPS**
- * **IMMUTEP, MERCK IMP321-M7824 PHASE I/IIa SOLID TUMOR TRIAL**
- * **ANTISENSE: 'FDA EXPECTS 9-MONTH ATL1102 MONKEY TOX TRIAL'**
- * **IMAGION RECEIVES \$2.6m FEDERAL R&D TAX INCENTIVE**
- * **NEUREN: FDA 'MINOR MODIFICATIONS' FOR 3 PHASE II TRIALS**
- * **STARPHARMA: 'VIRALEZE ACTIVE AGAINST UK SARS-COV-2 STRAIN'**
- * **ADHERIUM: US HAILIE FDA SUBMISSION**
- * **GENETIC TECHNOLOGIES, INFINITY LAUNCH COVID-19 TEST**
- * **AVECHO AGM 17% OPPOSE 14m DIRECTOR OPTIONS**
- * **MEDADVISOR LOSES JOINT CO-SEC CARLO CAMPICIANO**
- * **EPSILON APPOINTS EDWARD JONES MARIJUANA MANAGER**

MARKET REPORT

The Australian stock market fell 0.27 percent on Tuesday June 1, 2021, with the ASX200 down 19.0 points to 7,142.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell and 10 traded unchanged. All three Big Caps fell.

Uscom was the best, up 0.5 cents or 2.9 percent to 18 cents, with 550,000 shares traded. Genetic Signatures and LBT climbed more than two percent; Avita, Oncosil and Opthea were up more than one percent; with Cyclopharm, Kazia, Medical Developments, Starpharma and Telix up by less than one percent.

Actinogen led the falls, down one cent or 8.7 percent to 10.5 cents, with 9.7 million shares traded. Antisense lost 7.3 percent; Compumedics and Imugene were down more than six percent; Dimerix and Polynovo fell more than four percent; Impedimed, Next Science, Nova Eye, Proteomics and Universal Biosensors were down three percent or more; Amplia, Clinuvel, Mesoblast, Nanosonics, Paradigm and Resonance shed more than two percent; Orthocell was down 1.8 percent; with Cochlear, CSL, Pro Medicus and Resmed down by less than one percent.

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

For the first time since initiating the Biotech Daily Top-40 Index (BDI-40) in June 2005, we welcome a \$2 billion early-stage company with no revenue.

The inexplicable 117.0 percent rise of Imugene from a market capitalization of \$907 million on April 30 to \$1,968 million last night, on no significant news, may cause doubts about one company skewing an index of 40 companies.

Imugene's share price has soared from 10 cents in March to 40 cents, with the strongest news confirmation that its HER-Vaxx gastric cancer trial met its pre-determined progression-free survival numbers. The program was acquired in October 2013, the trial began in November 2016 and the results published last November claimed a "one-sided" p-value of 0.083, with some observers questioning the use of that measure.

Imugene has acquired several programs, including a B-cell technology, as well as the CF33 program, and on May 18, said it had licenced the CD19 oncolytic virus for chimeric antigen receptor t-cell therapy. Clearly, investors are impressed.

Among the companies with revenue, the three Big Caps of Cochlear CSL and Resmed (which are not included in the BDI-40, so as not to skew the data) were up 5.15 percent to a collective market capitalization of \$186,455 million, not far from the \$191,338 million all-time high at the beginning of the coronavirus pandemic (see charts below).

The benchmark S&P ASX200 was up 1.9 percent to 7,162 points, up 24.4 percent compared to 12 months ago, finally exceeding the pre-Covid 7,125-point record.

In May, the BDI-40 climbed 4.1 percent, including Imugene, but eased 1.2 percent if Imugene's value is kept at the April 30 level.

Seventeen of the BDI-40 stocks were up, six by more than 10 percent; and 22 companies fell, 10 by more than 10 percent; with one unchanged.

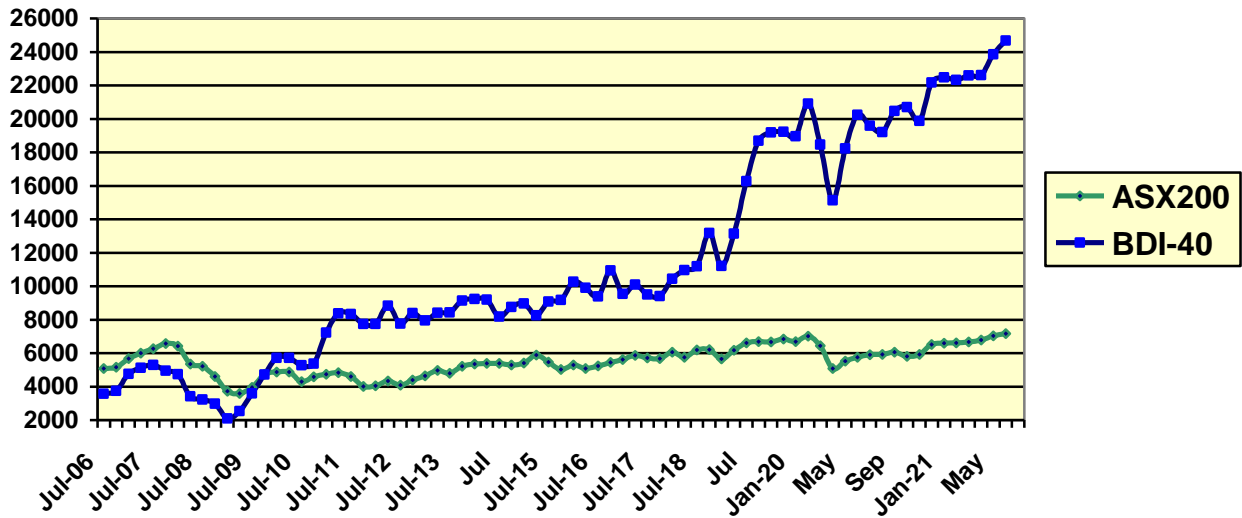
Imugene jumped \$1,061 million or 117.0 percent to \$1,968 million, followed by Actinogen (73.6%), Immutep (57.6%), Telix (20.3%), Uscom (17.4%) and Impedimed (12.8%).

Oncosil led the falls, down 20.5 percent to \$62 million, followed by Optiscan (19.9%), Genetic Signatures (17.8%), Compumedics (17.3%), Amplia (16.1%), Medical Developments (14.0%), Avita (12.8%), Polynovo (11.2%), Cynata (11.1%) and Osprey (10.9%).

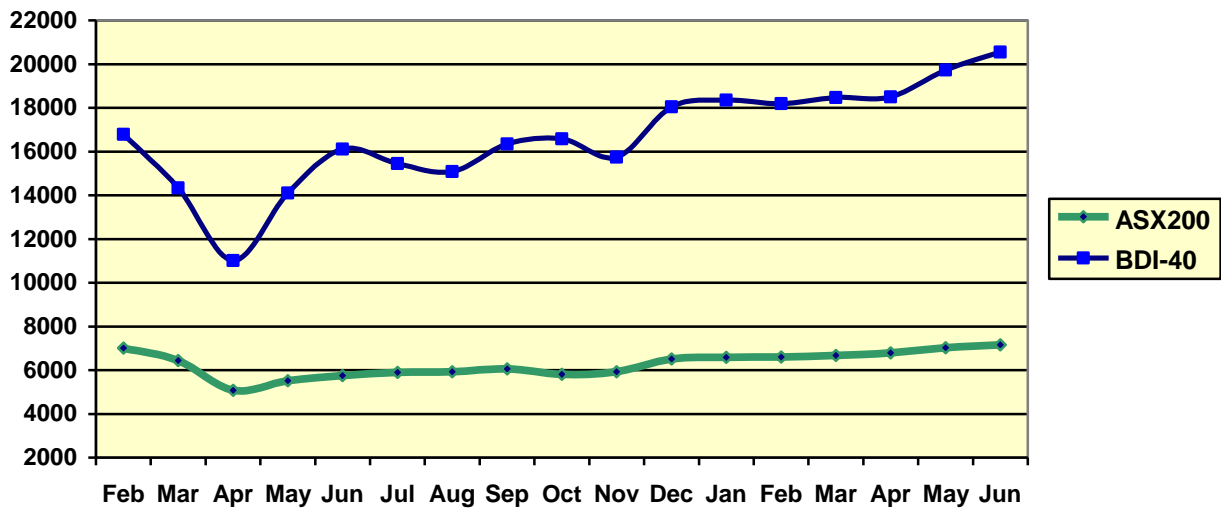
Outside the BDI-40, Alcidion continued its climb to a record \$482 million. The 22 companies in Cannabis Corner eased 17.8 percent from last month's record market capitalization of \$1,973 million to \$1,621 million.

On the Nasdaq, Queensland's Protagonist climbed 21.0 percent to \$1,993 million, Israel's Redhill with Australian assets was up 6.1 percent to \$437 million, but Eyepoint (Psvivida) fell 8.3 percent to \$365 million, while the Nasdaq Biotechnology Index (NBI) fell 2.0 percent for the month.

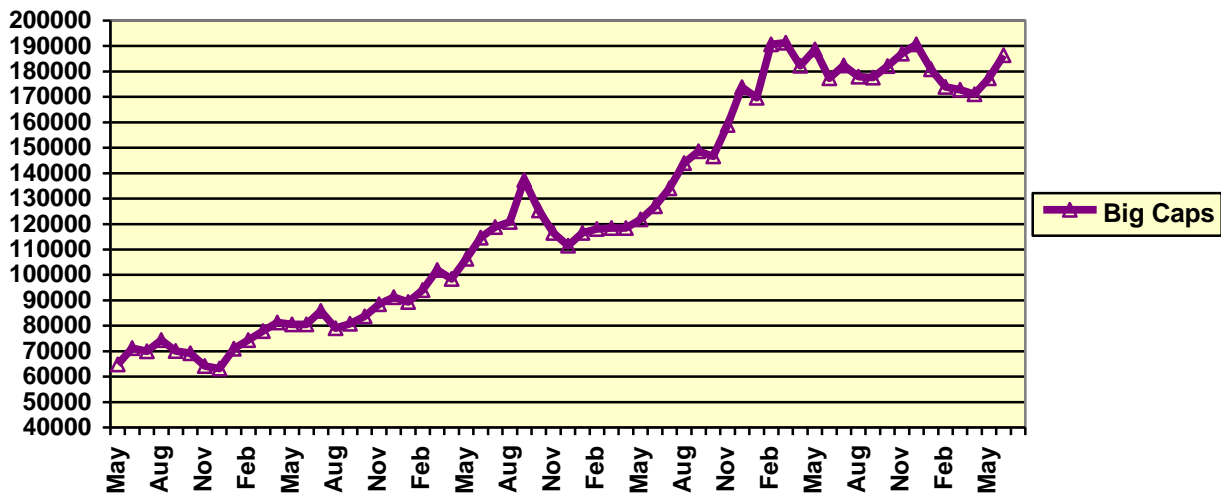
BDI-40 v ASX200 Jun 30, 2006 to May 31, 2021- Adjusted



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



Big Caps \$m (Cochlear, CSL, Resmed) May 31, 2016 – May 31, 2021



CSL

CSL says applications have opened for two Centenary Fellowships, each worth \$1.25 million over five years for discovery and translational research.

CSL said the fellowships were offered to “outstanding mid-career scientists seeking to undertake world-class medical research at an Australian academic institution”.

The company said the fellowships paid tribute to its origins and aimed “to foster a thriving medical research community by supporting the development of Australian science”.

CSL chief scientific officer Dr Andrew Nash said, “following a year of news lead by the Covid-19 pandemic, biomedical science has further demonstrated its importance and ability to save and improve people’s lives”.

“We are honored to be able to support Australian scientists with these fellowships and contribute to the future success of Australia’s research and development and biomedical research community,” Dr Nash said.

For more information and to apply go to www.cslfellowships.com.au.

CSL was down \$2.22 or 0.8 percent to \$287.99 with 343,139 shares traded.

ANTISENSE THERAPEUTICS

Antisense says the US Food and Drug Administration “expects” it to conduct a nine-month monkey toxicology trial of ATL1102 for Duchenne muscular dystrophy.

Antisense said that its nine-patient trial at Melbourne’s Royal Children’s Hospital, which the company said at the time showed safety and efficacy, was adequate to support larger studies (BD: Dec 17, 2019).

The company reported the FDA saying that “it could consider the exploration of higher doses of ATL1102 beyond 25mg per week subject to adequate justification”.

In 2008, Antisense and its then partner Teva reported safety and efficacy of ATL1102 in a phase IIa trial for multiple sclerosis at a dose of 400mg per week, with the only concern a reduction in blood platelets, or thrombocytopenia, which was reversed after treatment interruption (BD: Jun 30, 2008).

Antisense managing-director Mark Diamond told Biotech Daily at that time, the company previously expected future trials of ATL1102 be at a dose of 200mg or lower per week.

Today, the company said the FDA noted that its proposed design of the phase IIb/III single, randomized double-blind, placebo-controlled study and its primary endpoint of performance of upper limb function “appears acceptable”.

Antisense said the FDA expected it to conduct a nine-month monkey toxicology study but because of the seriousness of the indication it might begin the phase IIb/III human study “prior to submission of a nine-month toxicology study, provided that a draft study report is submitted before the duration of dosing in patients exceeds six months”.

The company said it was consulting with US regulatory advisors on next steps and to “fine-tune” the phase IIb/III study design as well as evaluate the cost and feasibility of the nine-month monkey study and supporting other clinical applications of ATL1102 beyond Duchenne muscular dystrophy.

Antisense fell 1.5 cents or 7.3 percent to 19 cents, with 2.9 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has received \$2,612,159 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imagion said the rebate related to expenditure for the year to June 30, 2020.

Imagion fell half a cent or 4.35 percent to 11 cents, with 12.1 million shares traded.

IMMUTEP

Immutep says it has a collaboration with Merck KGaA to evaluate IMP321 with M7824 in a phase I/II trial of 12 previously-treated patients, with different solid tumors.

Immutep said M7824, or bintrafusp alfa, was an investigational bifunctional fusion protein immunotherapy developed by the Darmstadt, Germany-based Merck and the Brentford, England-based Glaxosmithkline.

The company said the 'Insight-005' trial would evaluate the feasibility, safety and efficacy of IMP321 or eftilagimod alpha in combination with M7824.

Immutep said its IMP321 activated antigen presenting cells and M7824 aimed to block two immunosuppressive pathways, TGF-beta and PD-L1.

Immutep chief executive officer Marc Voigt said the trial intended "to explore the effect of releasing the brakes and pushing the accelerator of the body's immune system in three different positions of the cancer immunity cycle".

The company said the trial would be conducted by the Institute of Clinical Cancer Research at Frankfurt's Krankenhaus Nordwest, it would support the trial financially while Merck would contribute to the biomarker-related work and it expected to enrol the first patient in mid-2021, with the first data expected in early 2022.

Immutep was unchanged at 70 cents with 7.1 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration suggested 'minor modification' for its phase II trials of NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndromes. Neuren said that it expected the trials of NNZ-2591 on 10 to 20 paediatric patients over 13 weeks to begin this year, with the Angelman syndrome trial to be conducted in Australia and the Phelan-McDermid and Pitt Hopkins syndrome trials to be conducted in the US.

The company said the primary objective would be safety and tolerability of dosing with a secondary objective to assess efficacy.

Neuren chief executive officer Jon Pilcher said the dialogue with FDA was "very helpful and with only minor modifications" confirming the plans for the three disorders with urgent unmet need.

"NNZ-2591 has ideal attributes," Mr Pilcher said. "[It has] a unique mechanism of action, consistent and compelling results in the model of each disorder, a clearly identified optimum dose and proprietary manufacturing with high purity and yield."

"The final piece of the jigsaw is to demonstrate its impact in patients, so we are eager to expedite that data from these three phase II trials," Mr Pilcher said.

Neuren was unchanged at \$1.30.

STARPHARMA HOLDINGS

Starpharma says its Viraleze, SPL7013, has shown "potent" anti-viral activity against the UK severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) strain.

Starpharma said that the SPL7013 showed anti-viral activity by achieving more than 98 percent reduction of the UK B1.1.7 strain of the virus.

The company said the study would be at the San Diego, California-based Scripps Research Institute, which previously showed anti-viral activity against the US strain.

Starpharma chief executive officer Dr Jackie Fairley said that "SPL7013 has consistently shown high levels of antiviral activity, not only against multiple Covid-19 variants, but also against a broad spectrum of other respiratory viruses, including influenza".

Starpharma was up 1.5 cents or 0.85 percent to \$1.79, with 874,303 shares traded.

ADHERIUM

Adherium says it has submitted a 510(k) clearance application to the US Food and Drug Administration for its Hailie smart-inhaler, which allows remote patient monitoring.

Adherium said the next generation Hailie sensor monitored asthma and chronic obstructive pulmonary disease (COPD) medication use and was designed for use with AstraZeneca's Symbicort aerosol corticosteroid and beta2-agonist inhaler.

The company said the addition to the Hailie range of products would "allow access to reimbursement in the US for the remote monitoring of patients".

Adherium said the company intended to release four new sensors with physiological measures over the next 18 months, taking expected asthma and COPD coverage in the US to more than 80 percent by volume supporting 18 drugs.

Adherium was up 0.1 cents or 6.25 percent to 1.7 cents, with 7.15 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says its Covid-19 serious disease risk test has been launched by the Piscataway, New Jersey-based Infinity Biologix LLC.

Genetic Technologies said Infinity would produce and sell the tests across its network which included labs in New Jersey and Minnesota and partners across the US.

The company said the test retailed at \$US175 (BD: Mar 3, 2021).

Genetic Technologies fell two cents or 20 percent to 0.8 cents, with 47.2 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says that all of its annual general meeting resolutions were passed but there was dissent against granting of 13,977,753 director options and placement facility.

Avecho said votes relating to David Segal were withdrawn (BD: May 5, 2021).

The company said Dr Ross Murdoch's options were opposed by 89,331,748 votes (17.24%), with 428,723,427 votes (82.76%) in favor, with the issue of options to director Matt McNamara and chair Dr Greg Collier opposed by similar numbers.

The remuneration report had 93.99 percent in favor, the prior issue of shares and options passed more easily, with the placement capacity opposed by 15.99 percent.

The company's most recent Appendix 2A announcement said it had 1,828,894,679 shares on issue, meaning that the votes against Dr Murdoch's options amounted to 4.88 percent of the company, not sufficient to requisition extraordinary general meetings.

Avecho fell 0.1 cents or 5.3 percent to 1.8 cents, with 1.3 million shares traded.

MEDADVISOR

Medadvisor says its joint company secretary Carlo Campiciano has resigned, effective from today, with Naomi Lawrie continuing as its sole company secretary.

Medadvisor fell two cents or 6.1 percent to 31 cents.

EPSILON HEALTHCARE

Epsilon says it has appointed Edward Jones as its divisional manager of marijuana operations to manage marijuana producing assets THC Pharma and Canndeo.

Epsilon said Mr Jones was previously worked for Cannvalate, Canopy Farms and CSL.

Epsilon was up one cent or 6.45 percent to 16.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT MAY 31, 2021

Company \$Am	Jun-20	May-21	Jun-21
Cochlear	12,708	14,774	14,927
CSL	130,544	124,471	132,081
Resmed	34,102	38,079	39,447
BDI-20			
Avita	1,013	647	564
Clinuvel	1,119	1,479	1,437
Compumedics	89	81	67
Cyclopharm	122	262	242
Cynata	74	90	80
Ellex	71	47	45
Genetic Signatures	272	197	162
Immutep	90	309	487
Medical Developments	517	393	338
Mesoblast	2,143	1,187	1,271
Nanosonics	2,101	1,837	1,673
Neuren	169	148	149
Opthea	799	506	525
Paradigm	652	531	501
Pharmaxis	35	38	37
Polynovo	1,712	2,017	1,792
Pro Medicus	2,922	4,921	4,805
Starpharma	415	696	721
Telix	349	1,052	1,266
Volpara	347	334	326
Second 20			
Actinogen	21	110	191
Alterity	19	63	60
Amplia	9	31	26
Antisense	36	115	118
Dimerix	45	50	48
Impedimed	80	172	194
Imugene	147	907	1,968
Kazia	44	181	164
LBT Innovations	37	25	26
Next Science	264	335	364
Oncosil	71	78	62
Optiscan	21	277	222
Orthocell	66	100	104
Osprey	18	46	41
Patrys	14	47	49
Prescient	20	62	64
Proteomics	31	119	125
Resonance	80	90	90
Universal Biosensors	39	128	115
Uscom	33	23	27

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, 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.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au; twitter: @biotech_daily