



# Biotech Daily

Monday June 3, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: OPTISCAN UP 12%; COMPUMEDICS DOWN 13%**
- \* **MAY BDI-40 UP 7%, BIG CAPS UP 4% ASX200 UP 1%, NBI DOWN 6%**
- \* **FEDERAL OPPOSITION: CLARE O'NEIL, BRENDAN O'CONNOR INNOVATION**
- \* **VOLPARA TO RAISE \$55m, TO PAY \$21m FOR MRS SYSTEMS**
- \* **SUDA 3-FOR-1 RIGHTS ISSUE FOR \$3.4m**
- \* **UNIQUEST, PFIZER PARTNER FOR CANCER**
- \* **STARPHARMA, ASTRAZENECA 2<sup>nd</sup> ONCOLOGY AGREEMENT**
- \* **CLINUVEL: FDA EXTENDS SCENESSE PDUFA DATE**
- \* **MEDICAL DEVELOPMENTS: MUNDIPHARMA FOR PENTHROX AUSTRALIA**
- \* **OBJ APPOINTS PARAFIX MANUFACTURING PARTNER**
- \* **BARD1 EURO PATENT VALIDATED IN 6 COUNTRIES**
- \* **SMART TOP, XIANHUI MENG TAKE 19% OF USCOM**
- \* **LBT REQUESTS CAPITAL RAISING TRADING HALT**
- \* **MGC REQUESTS 'CUSTOMER CONTRACT' TRADING HALT**
- \* **ALCHEMIA FURTHER EXTENDS 'CHANGE IN ACTIVITIES' SUSPENSION**
- \* **DAVID TERRIBLE REPLACES TOTAL BRAIN DIRECTOR STEPHEN KOSLOW**
- \* **RECCE APPOINTS DR DAVID BOWERS ADVISORY CHAIR**

## MARKET REPORT

The Australian stock market fell 1.2 percent on Monday June 3, 2019, with the ASX200 down 76.4 points to 6,320.5 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and five were untraded. All three Big Caps fell.

Optiscan was the best, up 0.5 cents or 11.6 percent to 4.8 cents, with 842,841 shares traded. Medical Developments, Polynovo and Proteomics were up more than three percent; Neuren, Starpharma and Universal Biosensors rose more than two percent; Oncosil was up 1.6 percent; with Mesoblast up 0.4 percent.

Compumedics led the falls, down 7.5 cents or 12.93 percent to 50.5 cents, with 184,813 shares traded, followed by Impedimed down 12.9 percent. Clinuvel lost 10.1 percent; Benitec and Orthocell fell more than eight percent; Avita and Pro Medicus slipped more than six percent; Antisense shed 5.8 percent; Ellex and Osprey fell more than four percent; Patrys was down 3.7 percent; Cynata, Kazia, Opthea and Uscom shed more than two percent; Dimerix, Nanosonics and Telix were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

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

May continued the Biotech Daily Top 40 Index (BDI-40) run, breaking through the record collective \$10 billion market capitalization mark last month and \$11 billion this month.

The BDI-40 (which does not include the Big Caps of Cochlear, CSL and Resmed) climbed a further 6.5 percent in May, following the April 18.1 percent jump, easily out-performing the ASX200 which was up 1.1 percent.

The three Big Caps of Cochlear, CSL and Resmed rose a collective 4.3 percent and the Nasdaq Biotechnology Index (NBI) fell a further 6.1 percent.

For the year to May 31, 2019 the BDI-40 was up 31.3 percent, the Big Caps were up 10.75 percent, the ASX200 improved 6.4 percent and the NBI fell 7.9 percent.

In May, 16 of the BDI-40 stocks were up; 11 by more than 10 percent and six by more than 20 percent; while 18 fell, with eight losing more than 10 percent; and six were unchanged.

Clinuvel added the most to the market cap index, up \$479 million to \$1649 million, while the percentage best, from a much lower base, was Orthocell on the news of four Celgro patients regaining muscle function and sensation, up a sensational and muscly \$46 million or 418.2 percent to \$57 million in the month.

LBT was second best on an FDA approval for its APAS Independence, up 106.25 percent to \$33 million, followed by Prescient (41.7%), Clinuvel (40.9% for the month and 184.3% for the year), Telix (21.1%), Patrys (20.8%), Compumedics (18.4%), Oncosil (17.6%), Polynovo (15.9%), Pro Medicus (14.8%) and Avita (11.8%).

Actinogen led the falls on non-significance for Xanamem for Alzheimer's disease, down \$45 million or 77.6 percent to \$13 million, followed by Impedimed (40.4%), Osprey (25.4%), Alterity (Prana, 17.1%), Benitec (16.2%), Kazia (13.3%), Nanosonics (12.75%) and Universal Biosensors (12.5%).

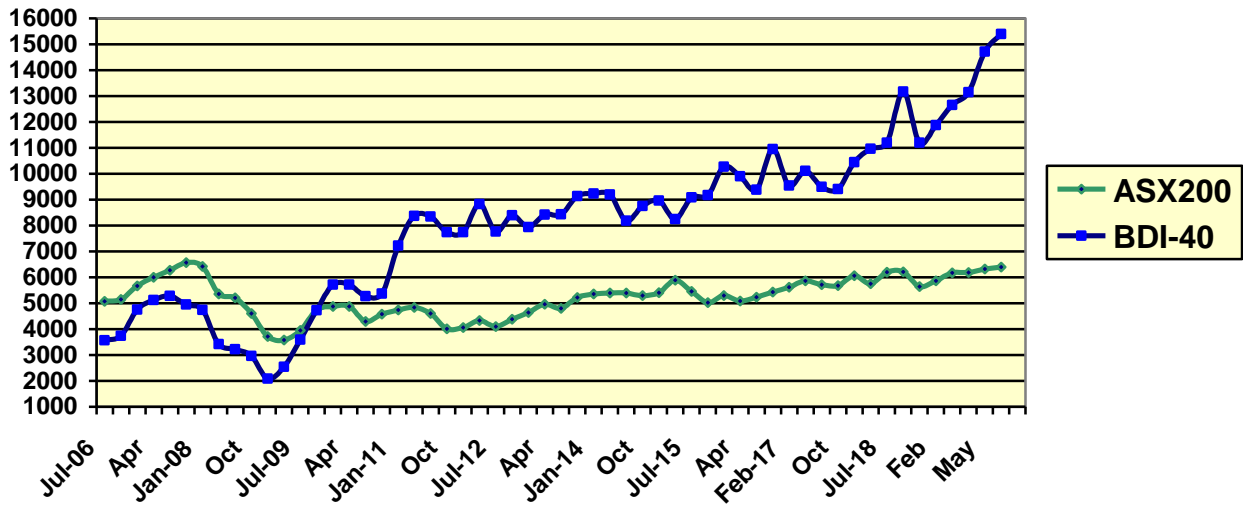
Resmed was up 11.3 percent to \$23,394 million, Cochlear rose 5.0 percent to \$11,353 million, with CSL up 2.5 percent to \$92,240 million.

Outside the Top 40, Alcidion, Elixinol, Medadvisor, Painchek and Resonance were all contenders for promotion.

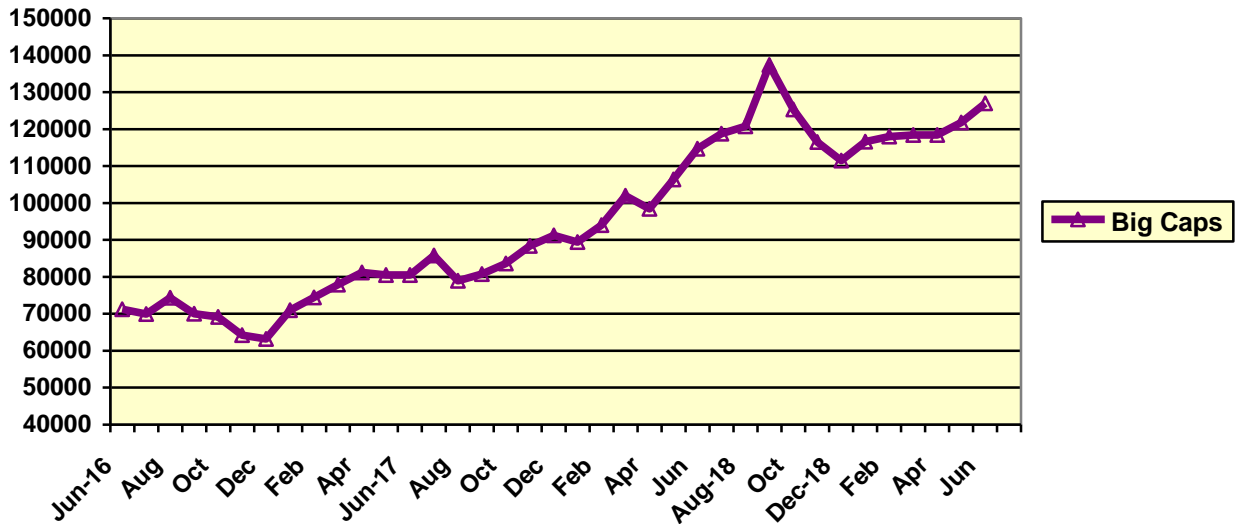
The 16 stocks in Cannabis Corner were up 8.1 percent to a collective market capitalization of \$1,744 million, with 11 companies up, four down and two unchanged.

On the Nasdaq, Vaxart (Biota) recovered from its all-time low, up 66.7 percent to \$15 million, Eyepoint (Psivida) was up 3.9 percent to \$240 million, Queensland's Protagonist lost 0.6 percent to \$339 million and Israel's Redhill (with Australian assets) shed 25.5 percent to \$234 million.

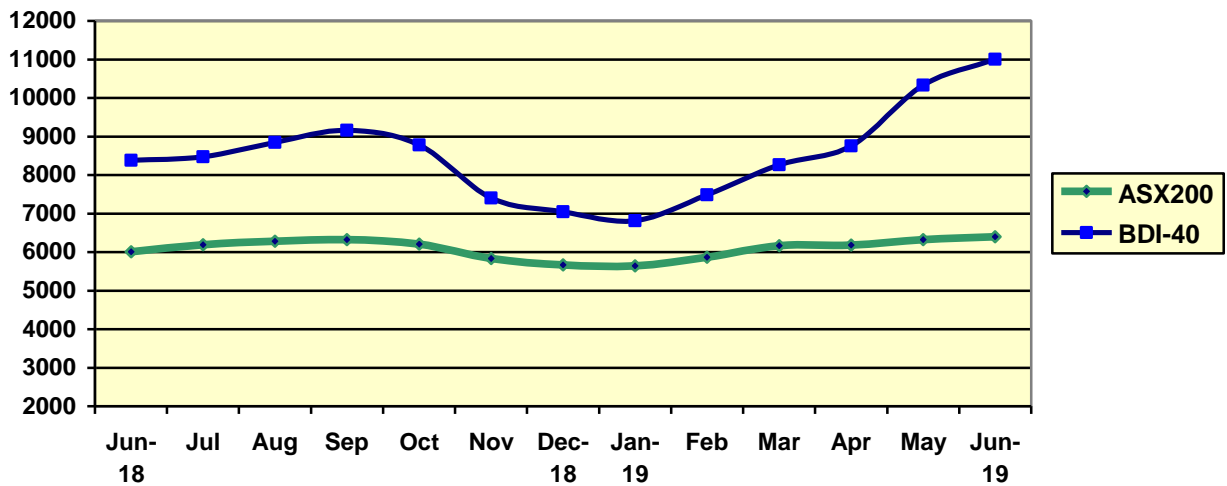
**BDI-40 v ASX200 Jun 30, 2006 to May 31, 2019- Adjusted**



**Big Caps \$m (Cochlear, CSL, Resmed) May 31, 2016 – May 31, 2019**



**BDI-40 (\$m) v S&P ASX 200 – May 31, 2018 - May 31, 2019 (current, raw data)**



## FEDERAL OPPOSITION

The Federal Opposition has appointed Clare O’Neil and Brendan O’Connor the Shadow Ministers responsible for innovation and biotechnology.

The Australian Labor Party Federal Opposition Leader Anthony Albanese announced the Shadow Ministry on Sunday June 2, 2019, appointing Mr O’Connor the Shadow Minister for Employment, Industry and Science, and Small and Family Business and Ms O’Neil as the Shadow Minister for Innovation, Technology and the Future of Work.

Mr O’Connor is a member of the Shadow Cabinet, along with Shadow Treasurer Dr Jim Chalmers, Shadow Minister for Health Chris Bowen and Shadow Finance Minister Senator Katy Gallagher.

The ‘Outer Shadow Ministry’ includes Ms O’Neil and Stephen Jones as Shadow Assistant Treasurer and Shadow Minister for Financial Services, and ‘Assistant Ministers’ Senator Carol Brown as Shadow Minister on Infrastructure, Dr Andrew Leigh as Shadow Assistant Minister for Treasury and Senator Louise Pratt as the Shadow Minister for Manufacturing.

## VOLPARA HEALTH TECHNOLOGIES

Volpara says it expects to raise up \$55 million at \$1.50 a share to buy MRS Systems Inc for \$US14.59 million (\$A21.15 million) and fund further organic growth.

Volpara said the capital raise was “fully underwritten” by Bell Potter Securities with Morgans Corporate as co-lead manager.

The company said the Lynnwood, Washington-based Mammography Reporting System Inc was “a medical software company that provides comprehensive patient tracking and communication, and a radiology reporting platform, for sub-specialty radiology applications including breast and lung imaging”.

Volpara said that MRS was “a leading provider of breast clinic management software” with an estimated 20 percent market share of breast clinics in the US and its software was used in more than 1,700 breast clinics.

The company said that MRS was forecasting annual recurring revenue of about \$US4.5 million for the year to December 31, 2019, and with capital sales, expected total revenue of \$US7.5 million for 2019.

Volpara said the acquisition provided “an expanded and mature presence in the US, with an enlarged sales footprint and technical support, product suites that were “highly complementary” creating cross-selling opportunities for both MRS and Volpara.

The company said the combination of MRS clinical data and Volpara images would enrich its artificial intelligence capability.

Volpara said it had a fully underwritten \$45 million placement and would have a fully underwritten 27-for-one entitlement offer for a further \$10 million.

The company said that the record date for the rights offer was June 5, the offer would open on June 11 and close on June 26, 2019.

Volpara chief executive officer Dr Ralph Highnam said his company had been “talking to MRS for many years and have been extremely impressed with the quality of the people and the products they build”.

“So, I’m very happy to now announce that we are combining to create a world-class entity with a strong US base and an extended range of integrated products which will help detect breast cancer earlier,” Dr Highnam said.

Volpara said the \$1.50 a share offer price was an 18.9 percent discount to the closing price on Friday, May 31 and a 14.9 percent discount to the 30-day volume-weighted average price.

Volpara was in a trading halt and last traded at \$1.85.

## SUDA PHARMACEUTICALS

Suda says it hopes to raise up to \$3.44 million through a partially underwritten, renounceable, three-for-one rights issue at 0.4 cents a share.

Suda said the funds would be used to strengthen the company balance sheets, fund project development and address general working capital requirements.

The company said the rights issue was partially underwritten to \$1 million by the Perth, Western Australia-based CPS Capital Group.

Suda said that for every two new shares subscribed, shareholders would receive one attached listed option, exercisable at 1.5 cents by June 20, 2021.

The company said the record date would be June 6, the offer would open on June 7 and close on June 21, 2018.

Suda fell 0.2 cents or 33.3 percent to 0.4 cents with 55.2 million shares traded.

## UNIQUEST, PFIZER PHARMACEUTICALS

Uniquet says it will partner with Pfizer's Centres for Therapeutic Innovation to develop drug candidates for as yet undecided cancer targets.

Uniquet, the commercialization company of Brisbane's University of Queensland said the collaboration would combine its research expertise in cancer biology and immunology with Pfizer's capability in drug discovery and development.

Uniquet spokesperson Brooke Baskin told Biotech Daily that the type of cancer to be targeted was yet to be decided and that there was "a range of possibilities".

Uniquet chief executive officer Dr Dean Moss said the project was the first in Queensland and second in Australia to be funded under the Centres for Therapeutic Innovation program.

## STARPHARMA

Starpharma says it has signed a second agreement with Astrazeneca, this time to develop a dendrimer enhanced product (DEP) version of an unnamed cancer drug.

Starpharma said the development and option agreement would give Astrazeneca the option to licence the DEP oncology drug for an option exercise fee of \$US5 million (\$A7.2 million) plus commercialization milestones and royalties on sales.

The company said that if Astrazeneca did not exercise the option, Starpharma would gain the option to develop the drug itself or through a sub-licencee, with milestones and royalties paid to Astrazeneca upon commercialization of the product.

Starpharma said it was the second oncology agreement with Astrazeneca, after the 2015 deal, which licenced Starpharma's dendrimer drug delivery technology to Astrazeneca for "potentially more than \$US126 million (\$A180 million), with \$US2 million up-front" (BD: Sep 7, 2015).

The company said the agreement was signed at the American Society of Clinical Oncology meeting, currently underway in Chicago.

Starpharma chief executive officer Dr Jackie Fairley said the agreement followed a research program in which the company "identified a promising DEP candidate with a number of potential benefits".

"Unlike our first DEP agreement with Astrazeneca, which applies DEP to novel oncology drug candidates, this agreement is for an existing major Astrazeneca oncology medicine and provides further validation of the value of the DEP platform and its broad application to both new chemical entities and existing products," Dr Fairley said.

Starpharma was up 3.5 cents or 2.7 percent to \$1.34.

## CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has extended the Prescription Drug User Fee Act (PDUFA) date for a decision on Scenesse to October 6.

Clinuvel said the FDA had extended the PDUFA decision “to allow time to evaluate data” provided by the company on Scenesse which was used for “prevention of phototoxicity and anaphylactoid reactions in adult patients with erythropoietic protoporphyria (EPP)”.

In January, Clinuvel said the FDA had set the PDUFA date for July 8 (BD: Jan 10, 2019).

Today, the company said the FDA had established a new timeline for labelling changes, and post-marketing requirements and commitments of September 6, 2019.

Clinuvel fell \$3.49 or 10.1 percent to \$31.00 with 204,602 shares traded.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Mundipharma will distribute its Pentrox inhaled methoxyflurane analgesic in Australia.

Medical Developments said Pentrox was a self-administered, inhaled analgesic used under the supervision of a healthcare practitioner for short-term pain relief in adult patients.

The company said the agreement contained “minimum volumes” which would guarantee the current rate of sales in Australia and allow for “significant” increase, but did not provide specific details.

Medical Developments chief executive officer John Sharman told Biotech Daily that Pentrox previously was distributed by the Monaco-based Besins Healthcare.

Medical Developments was up 16 cents or 3.1 percent to \$5.26.

## OBJ

OBJ says it has appointed the Parafix Tapes and Conversions to manufacture its Active Kneeguard magnetic transdermal system for osteoarthritis.

OBJ said the manufacturing agreement with the Lancing, West Sussex-based Parafix was part of the business plan to commercialize their patch technology and production of commercial prototypes would begin in the coming weeks.

Last year, the company said that a 24-patient study showed that its Kneeguard patch reduced osteoarthritis pain and improved movement (BD: Mar 9, 2018).

Today, OBJ said it hoped to launch its Kneeguard by June 30, 2020, subject to regulatory approval.

OBJ was unchanged at 1.6 cents.

## BARD1 LIFE SCIENCES

Bard1 says that a granted European patent for lung and colorectal cancers has been validated in France, Germany, Italy, Spain, Switzerland and the UK.

Bard1 said the patent, titled ‘Bard1 isoforms in lung and colorectal cancer and use thereof’ would protect “the sequence of various Bard1 isoforms specific to lung and colorectal cancer” and expire on August 17, 2031.

The company said the patent had been granted on December 26, 2018, but European patents were “not enforceable until validation has been completed in the designated countries”.

Bard1 fell 0.1 cents or 5.0 percent to 1.9 cents with 10.5 million shares traded.

### USCOM

Smart Top Overseas says it has increased its holding in Uscom from 24,608,482 shares (17.88%) to 26,323,649 shares (19.12%).

The substantial shareholder notice, signed by director Xianhui Meng, said the British Virgin Islands-based Smart Top acquired 1,715,167 shares for \$286,735 or 16.7 cents a share between March 27 and May 30, 2019.

Uscom fell half a cent or 2.9 percent to 16.5 cents.

### LBT INNOVATIONS

LBT has requested a trading halt “pending an announcement to the market in relation to a capital raise”.

Trading will resume on June 5, 2019 or on an earlier announcement.

LBT last traded at 16.5 cents.

### MGC PHARMACEUTICALS

MGC has requested a trading halt “pending the release of an announcement by the company regarding a material commercial customer contract”.

Trading will resume on June 5, 2019 or on an earlier announcement.

MGC last traded at 5.2 cents.

### ALCHEMIA

Alchemia has requested a further extension to the suspension requested on March 29, pending a proposed change to the nature and scale of its activities (BD: Mar 29, 2019).

In April, Alchemia requested an extension to the suspension (BD: Apr 30, 2019).

Today, the company said the announcement was expected by July 1, 2019.

Alchemia last traded at 1.1 cents.

### TOTAL BRAIN

Total Brain says it has appointed David Torrible to replace Prof Stephen Koslow as a non-executive director.

Total Brain said Mr Torrible was a former Goldman Sachs head of product sales in Asia with experience in equity capital markets.

The company said Prof Koslow would continue as a scientific advisor.

Total Brain was up 0.1 cents or 3.85 percent to 2.7 cents.

### RECCE PHARMACEUTICALS

Recce says it has appointed Dr David Bowers as chair of its newly-formed clinical advisory committee.

Recce said Dr Bowers was a spinal injury specialist based in Sydney’s Royal North Shore hospital with “a specialist interest in the treatment of complex and life-threatening antibiotic resistant infections, particularly among patients with severe spinal cord injuries”.

Recce said Dr Bowers had “not accepted any remuneration for his ... contributions to date and [would] continue on this basis”.

Recce was up half a cent or 2.4 percent to 21.5 cents.

## BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT MAY 31, 2019

<b>Company \$Am</b>	<b>Jun-18</b>	<b>May-19</b>	<b>Jun-19</b>
Cochlear	11,288	10,812	11,353
CSL	84,079	89,972	92,240
Resmed	19,296	21,019	23,394
<b>BDI-20</b>			
Avita	53	718	803
Clinuvel	580	1,170	1,649
Compumedics	128	87	103
Cyclopharm	69	85	89
Cynata	119	123	128
Ellex	82	85	84
Genetic Signatures	41	120	114
Immutep	112	95	91
Medical Developments	346	361	334
Mesoblast	725	818	713
Nanosonics	796	1,482	1,293
Neuren	307	119	122
Opthea	91	173	161
Paradigm	66	273	279
Pharmaxis	99	114	104
Polynovo	401	684	793
Pro Medicus	765	2,118	2,431
Starpharma	437	468	485
Telix	136	190	230
Volpara	140	333	333
<b>Second 20</b>			
Actinogen	46	58	13
Airxpanders	24	20	20
Alterity (Prana)	25	35	29
Antisense	9	23	22
Benitec	36	37	31
Dimerix	14	13	12
Impedimed	200	99	59
Imugene	86	65	61
Kazia (Novogen)	32	30	26
LBT Innovations	23	16	33
Oncosil	119	34	40
Optiscan	28	19	19
Orthocell	30	11	57
Osprey	53	63	47
Patrys	52	24	29
Prescient	29	12	17
Proteomics	18	23	23
Reva	114	71	71
Universal Biosensors	41	40	35
Uscom	24	23	23

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Amplia, Benitec, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Prana, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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