



# Biotech Daily

Wednesday July 1, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **9-YEAR BDI-40 UP 155%; ASX200 UP 8%, BIG CAPS UP 221%**
- 12-MONTH BDI-40 UP 17%, ASX200 1.2%, BIG CAPS 28%**
  - IMPEDIMED UP 477%, PHARMAXIS 245%; ALCHEMIA DOWN 94%, TISSUE THERA 87%
- \* **TODAY: ASX, BIOTECH UP: BIOTRON UP 12%, COMPUMEDICS DOWN 2%**
- \* **CIRCADIAN STARTS US PHASE I OPT-302 WET AND TRIAL**
- \* **SIRTEX RELEASES MORE SIRFLOX SUB-GROUP ANALYSES**
- \* **ALCHEMIA TO SELL HYACT, ONCOLOGY TO PANTHER FOR UP TO \$21m**
- \* **PRANA PBT2 EXTENSION STUDY DOSE SAFE AFTER 2 YEARS**
- \* **BVF PARTNERS, MARK LAMPERT TAKE 12% OF PHARMAXIS**
- \* **ANATARA REQUESTS CAPITAL RAISING TRADING HALT**
- \* **OBJ PLEADS SCHULTZ TO ASX 19% QUERY**
- \* **NOVOGEN APPOINTS IAN PHILLIPS INTERIM CHAIRMAN**
- \* **BIO-MELBOURNE 'THINK GLOBAL' BIO-BREAKFAST**

## MARKET REPORT

The Australian stock market climbed 1.04 percent on Wednesday July 1, 2015 with the ASX200 up 56.7 points to 5,515.7 points. Twenty-one of the Biotech Daily Top 40 stocks were up, six fell, six traded unchanged and seven were untraded. All Big Caps were up.

Biotron was the best, up 1.5 cents or 12 percent to 14 cents with 626,915 shares traded. Avita climbed 11.1 percent; Genetic Technologies, GI Dynamics and Optiscan were up 10 percent or more; both Analytica and Pharmaxis were up 9.1 percent; Viralytics was up 7.9 percent; Prima rose 6.35 percent; Actinogen, Atcor, Benitec, Circadian, Oncosil, Sirtex and Universal Biosensors were up five percent or more; Mesoblast and Prana rose more than three percent; Bionomics, CSL and Tissue Therapies climbed more than two percent; Cochlear and Resmed were up more than one percent; with Impedimed up 0.6 percent.

Compumedics led the few falls, down half a cent or 1.85 percent to 26.5 cents with 53,335 shares traded, with Anteo, Nanosonics and Starpharma down more than one percent and Acrux and Medical Developments down by less than one percent.

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

In the nine years since the establishment of the Biotech Daily Top-40 Index (BDI-40) the leading companies have improved 155.1 percent in adjusted terms and 76.6 percent comparing the raw collective market capitalization of June 30, 2006 to last night.

In the same period, the ASX200 has climbed just 7.6 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed 220.6 percent between June 30, 2006 and June 30, 2015.

While the three Big Caps eased a collective 6.5 percent in June, for the year to June 30, 2015 they were up 28.3 percent, with Cochlear climbing 29.9 percent to \$4,575 million, CSL up 26.9 percent to \$40,194 million and Resmed up 33.2 percent to \$10,240 million.

For the 12 months to June 30, 2015, the BDI-40 climbed 16.7 percent compared to the ASX200 up just 1.2 percent.

Twelve of the Top 40 companies climbed more than 100 percent in the 12 months, led by Impedimed up 477.3 percent to \$254 million. Pharmaxis recovered 245 percent to \$69 million, followed by Reva (236.2%), Circadian (200%), IDT (193.3%), Viralytics (180%), Nanosonics (131.25%), Prima (124.5%), Atcor (120%), Genetic Technologies (118.2%), Medical Developments (103.9%), Optiscan (100%), Clinuvel (76.4%) and Sirtex (73.4%).

Alchemia led the year's falls, down 94.4 percent from \$180 million to just \$10 million and followed by Tissue Therapies losing 87.2 percent, also to \$10 million, GI Dynamics (74.2%), Phosphagenics (71.9%), Analytica (71.4%), Patrys (71.4%) and Anteo (57.6%). Alchemia and Phosphagenics were demoted from the BDI-40 in April (BD: Apr 1, 2015).

Viralytics was the best in June, up 38.6 percent to a market capitalization of \$140 million, followed by Cellmid up 33.3 percent to \$24 million, Circadian (22.7%), Biotron (15.6%), Medical Developments (14.8%) and Sirtex up \$134 million or 8.8 percent to \$1,642 million.

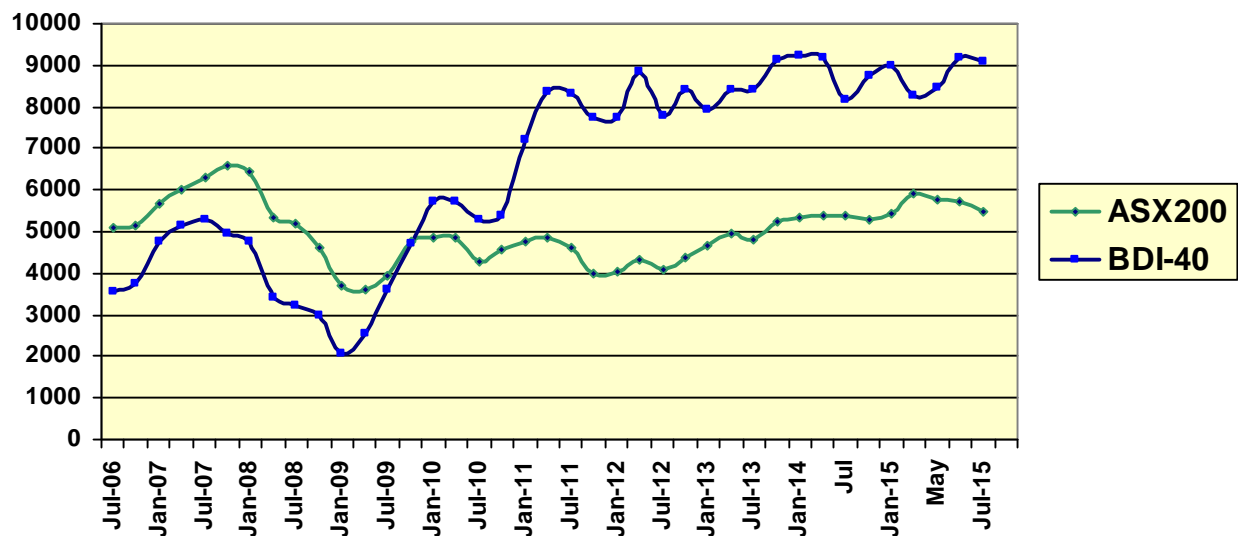
The month of June 2015 saw a plethora of small falls in the BDI-40, with Tissue Therapies leading the retreat, down a further 50 percent to \$10 million, followed by Prima (41.5%), Patrys (25.0%), Genetic Technologies (23.8%), Optiscan (23.1%) and Living Cell (16.0%).

Outside the BDI-40, Novogen was the best for the year, up 279.2 percent to \$91 million followed by Cynata up 238.9 percent, Cyclopharm (166.7%), Pro Medicus (145.5%) and Mayne Pharma (55.3%). Progen fell 77.3 percent and Isona shed 71.4 percent.

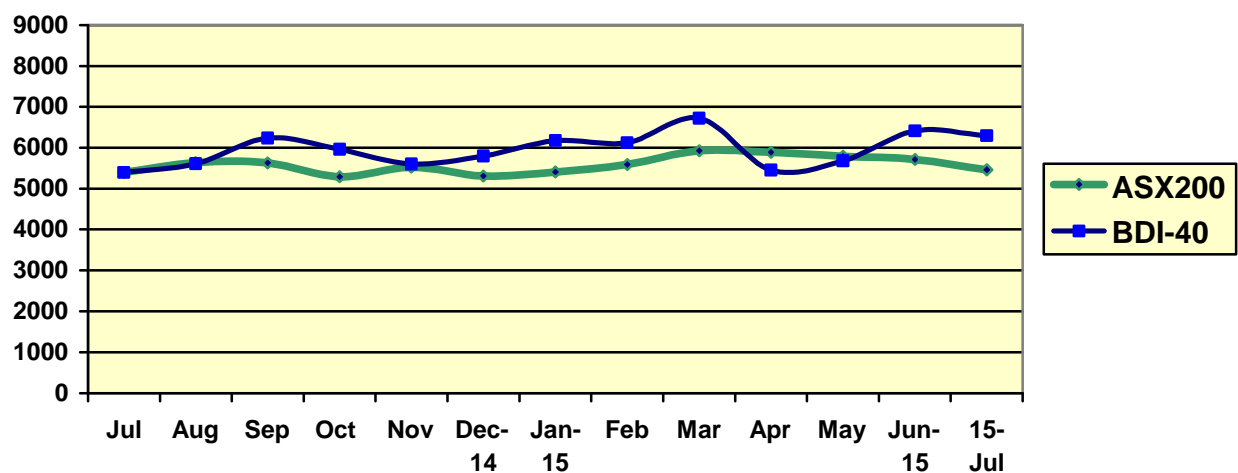
On the Nasdaq, Biota lost 11.3 percent for the year to \$94 million, Heartware was up 2.1 percent to \$1,629 million and Sunshine Heart fell 18.0 percent to \$82 million.

Reva and Medical Developments are promoted to the BDI-20, with GI Dynamics and Tissue Therapies joining the Second 20. Patrys will be demoted from the Second 20 to be replaced by Polynovo, which has focused on its CSIRO-originated Novosorb wound treatment and has jettisoned the anchor of Metabolic's AOD9604. Originally called Metabolic before it became Calzada, Polynovo returns to the BDI-40 after a brief 7.5 year absence (BD: Jan 21, 2008).

### BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2015 - Adjusted



### BDI-40 (\$m) v S&P ASX 200 – Jun 30, 2014- Jun 30, 2015



### [CIRCADIAN TECHNOLOGIES](#)

Circadian says it has begun its US phase I study of OPT-302 in patients with wet age-related macular degeneration and five sites had begun recruitment.

Circadian said that the first-in-human, multi-centre, dose-escalation, clinical trial would investigate OPT-302 administered either alone or in combination with ranibizumab, marketed as Lucentis, on a monthly basis for three months by ocular injection, and would treat patients who had either not been treated previously or who had a sub-optimal response to prior anti-vascular endothelial growth factor-A therapy.

Circadian said the endpoints included the safety of OPT-302 and preliminary measures of efficacy, including evaluation of visual acuity as well as changes in wet age-related macular degeneration lesions, with dose escalation data analysis expected by April 2016.

Circadian chief executive officer Dr Megan Baldwin there was “a great need for novel therapies to improve outcomes for wet [age-related macular degeneration] patients [and] approval and commencement of patient recruitment and screening for this clinical program is an important step in the development of OPT-302 for the management of this disease”.

Circadian was up one cent or 5.4 percent to 19.5 cents.

## SIRTEX MEDICAL

Sirtex says that additional data from its 530-patient Sirflox trial has been released ahead of a European Society for Medical Oncology meeting from July 1 to 4, 2015.

Sirtex said that the abstract for the World Congress on Gastrointestinal Cancer in Barcelona, Spain was available on the Annals of Oncology journal website at:

[http://annonc.oxfordjournals.org/content/26/suppl\\_4.toc](http://annonc.oxfordjournals.org/content/26/suppl_4.toc).

Since the trial results were first posted in March, Sirtex has said that although the trial failed to meet its primary endpoint, SIR -Spheres significantly increased liver tumor progression-free survival (BD: Mar 17, May 14, Jun 1, 2015).

Today that company said that, patients were stratified according to the presence or absence of extra-hepatic metastases, liver-dominant and liver-only, respectively, and the use of bevacizumab.

Sirtex said that 60 percent of patients were liver-only and 40 percent were liver-dominant and for bevacizumab, 55 percent of all patients were stratified to receive bevacizumab and 45 percent were stratified to not receive bevacizumab.

Sirtex chief executive officer Gilman Wong said that the sub-group analysis "continued to reinforce the significant effect of SIR-Spheres microspheres in combination with first-line Folfox chemotherapy with or without the biologic agent bevacizumab in the liver".

Mr Wong said that from a clinical practice perspective the conference data releases "demonstrated the first-line use of SIR-Spheres microspheres delivered a 7.9 month extension of tumor control in the liver, while at the same time having no negative impact on the duration of systemic therapy".

Sirtex said that in patients with liver-only metastases, a significant 70.2 percent improvement in median progression-free survival in the liver and a 36 percent reduction in the risk of tumor progression in the liver was reported.

The company said that for liver-dominant patients, a 32.5 percent improvement in median progression-free survival in the liver and a 23 percent reduction in the risk of progression was reported.

Sirtex said that in patients stratified according to an intention or no intention to be treated with bevacizumab, the addition of SIR-Spheres microspheres showed a significant improvement in median progression-free survival in the liver of 8.3 months and a 31 percent lower risk of progression in both groups and the clinical benefit of SIR-Spheres microspheres was not dependent on a patient receiving bevacizumab.

The company said that in patients with liver-only metastases, the median progression-free survival in the liver was 21.1 months in the SIR-Spheres with Folfox and bevacizumab arm compared to 12.4 months in the Folfox and bevacizumab arm without SIR-Spheres ( $p = 0.003$ ).

Sirtex said that in patients with liver and extra-hepatic metastases, the median progression-free survival in the liver was 16.7 months in the SIR-Spheres microspheres treated group compared to 12.6 months for the Folfox and bevacizumab without SIR-Spheres arm ( $p = 0.147$ ).

The company said that the study authors concluded that "in first-line treatment of patients with non-resectable [colorectal cancer] liver metastases, the addition of SIRT to a standard chemotherapy regimen failed to improve overall [progression-free survival]".

"However, major gains in [progression-free survival] in the liver were achieved," Sirtex quoted the authors saying.

"The addition of SIRT was associated with acceptable toxicity," Sirtex quoted the authors saying.

Sirtex climbed \$1.66 or 5.7 percent to \$30.71 with 410,845 shares traded.

## ALCHEMIA

Alchemia says that Panther Biotechnology will buy its oncology assets including the Hyact platform for cash and stock worth more than \$US16 million (\$A20.7 million).

Alchemia said the Bannockburn, Illinois-based Panther had agreed to reimburse oncology operational costs incurred in the exclusivity period including all existing staff employment expenses, excluding contractual commitments for the ACO-002 phase III trial, up to a maximum of \$US300,000, accelerating its cost cutting program.

Last year, Alchemia fell as much as 86 percent on news that the Hyact-platform hyaluronic acid-formulated irinotecan, or HA-irinotecan, for metastatic colorectal cancer failed to meet its phase III primary endpoint (BD: Oct 27, 2015).

Today, Alchemia said that it would receive \$US15 million in Panther stock on Panther listing on the Nasdaq and the potential for a \$US1 million milestone payment on commencement of a phase III clinical trial and royalties on world-wide net sales of Hyact products and it would keep any Australian Federal Government R&D Tax Incentive refunds.

The company said that the sale was subject to conditions including regulatory and shareholder approvals.

Alchemia said it would also be entitled to mid-single digit royalties on world-wide net sales of Hyact products.

The company said that it expected Panther to offer on-going employment to key members of the oncology team.

Alchemia said it had agreed to grant Panther the right, at Panther's election, to close out any unpaid milestone payment and royalty stream payable with respect to the phase III HA-irinotecan product and this option had an exercise price of \$US20 million payable in Panther's Nasdaq-listed stock and would expire on the day immediately prior to the first US sale of the HA-irinotecan asset.

Alchemia was up 0.3 cents or 9.4 percent to 3.5 cents with 3.6 million shares traded.

## PRANA BIOTECHNOLOGY

Prana says that the 250mg dose of PBT2 for Alzheimer's disease in its Imagine extension study was safe and well tolerated over a two year period.

Last year, Prana's imaging trial of PBT2 for Alzheimer's disease did not meet its primary endpoint of reducing amyloid beta plaques (BD: Apr 1, 2014).

Today, Prana said that the independent data safety monitoring board did not identify any safety concerns related to PBT2.

The company said the extension study allowed the 40 participants in the original 12 month trial to receive PBT2 for a further 12 months and 33 patients elected to continue onto the open label extension study with 27 patients completing the study.

Prana said that clinical and scientific experts were reviewing the effects of PBT2 taken for two years and while there was no placebo group, the experts were interested in better understanding how treatment with PBT2 would differ from the anticipated outcome without treatment.

The company said that the safety data would form part of the package presented to the US Food and Drug Administration as part of the goal to remove the partial clinical hold placed on PBT2 in the US (BD: Feb 13, 2015).

Prana said it would continue to work with the FDA and other agencies to initiate a phase III trial for PBT2 for Huntington's disease and PBT2 had orphan designation in both Europe and the US for that indication.

Prana was up half a cent or 3.3 percent to 15.5 cents.

### PHARMAXIS

BVF Partners and Mark Lampert say they have increased their substantial holding in Pharmaxis from 30,000,000 shares (9.54%) to 37,715,848 shares (11.98%).

The San Francisco, California-based BVF Partners and Mr Lampert said they acquired the shares in 16 trades between June 18 and 29, 2015, with the single largest purchase 259,160 shares for \$59,607 or 23 cents a share.

Pharmaxis was up two cents or 9.1 percent to 24 cents with 1.9 million shares traded.

### ANATARA

Anatara has requested a trading halt "pending an announcement regarding a proposed capital raising".

Trading will resume on July 3, 2015 or on an earlier announcement.

Anatara last traded at \$1.00.

### OBJ

OBJ has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 19.4 percent from 4.9 cents on June 30 to 5.85 cents, today, July 1, 2015, and noted an increase in trading volume.

OBJ was up 0.4 cents or 8.2 percent to 5.3 cents with four million shares traded.

### NOVOGEN

Novogen says that Ian Phillips has replaced executive chairman Dr Graham Kelly as interim chairman, with Dr Kelly continuing as chief executive officer.

"Splitting the roles of chairman and chief executive officer has to come at any time during a company's growth and it is good corporate governance," Dr Kelly told Biotech Daily.

Last month, Novogen appointed Mr Phillips and Bryce Carmine as non-executive directors and said that Mr Phillips had worked in New York, London, Sydney, Singapore and Wellington, New Zealand in banking, financial markets and corporate finance for more than 30 years and was the chairman of Nutraceutical and Natural Products AG and studied at Otago University, the University of Colorado and the London School of Economics (BD: Jun 3, 2015).

Novogen was up half a cent or 2.3 percent to 22 cents.

### BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that Blamey Saunders Hears managing director Dr Elaine Saunders and Circadian chief executive officer Dr Megan Baldwin will discuss strategies for international positioning at the July 'Think Global' Bio-Breakfast.

Bio-Melbourne chief executive officer Dr Krystal Evans said that positioning globally in the healthcare market was essential for biotechnology and medical technology success.

The July 7, 2015 Bio-Breakfast will be held at The Cube, at the Australian Centre for the Moving Image, Federation Square, Melbourne.

Registration is from 7.15am for a networking breakfast from 7.30am and presentation from 8:00am to 9:00am.

To register go to: <http://www.biomelbourne.org/events/view/372>.



## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT JUN 30, 2015

<b>Company \$Am</b>	<b>Jul-14</b>	<b>Jun-15</b>	<b>Jul-15</b>
Cochlear	3,521	4,995	4,575
CSL	31,667	43,161	40,194
Resmed	7,688	10,677	10,240
<b>BDI-20</b>			
Acrux	167	148	142
Admedus	195	127	129
Benitec	132	95	80
Bionomics	230	167	174
Biotron	24	32	37
Circadian	9	22	27
Clinuvel	72	141	127
Impedimed	44	279	254
Medical Developments	76	135	155
Mesoblast	1,438	1,325	1267
Nanosonics	208	499	481
Neuren	129	143	129
Osprey	69	102	92
Pharmaxis	20	75	69
Prima	49	188	110
Psivida	124	147	147
Reva	47	170	158
Sirtex	947	1,508	1642
Universal Biosensors	35	53	49
Viralytics	50	101	140
<b>Second 20</b>			
Actinogen	2	48	44
Analytica	35	10	10
Anteo	158	70	67
Antisense	20	22	20
Atcor	15	39	33
Avita	33	33	31
Cellmid	19	18	24
Compumedics	24	44	45
Ellex	40	36	36
Genetic Technologies	22	63	48
GI Dynamics	275	69	71
IDT	15	44	44
Living Cell	18	25	21
Oncosil	36	39	36
Optiscan	5	13	10
Polynovo	44	33	38
Prana	108	85	80
Starpharma	165	249	233
Tissue Therapies	78	20	10
Uscom	18	17	16

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Mesoblast, Nanosonics, Neuren 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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