



# Biotech Daily

Tuesday April 2, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **MARCH BDI-40 DOWN 1%, ASX200 DOWN 2.7%, BIG CAPS DOWN 1.2%  
- PSIVIDA UP 21%, PHARMAXIS DOWN 40%**
- \* **TODAY: ASX UP, BIOTECH DOWN: CLINUVEL UP 4%, PHYLOGICA DOWN 9%**
- \* **REVA STARTS REZOLVE2 CORONARY STENT TRIAL**
- \* **ALLIED LODGES US FDA CARDIOCEL 510K APPLICATION**
- \* **PHOSPHAGENICS EXTENDS NIPPON ZOKI TPM COLLABORATION**
- \* **STARPHARMA BACTERIAL VAGINOSIS TRIAL RESULTS TRADING HALT**
- \* **ENDO RETURNS UROCIDIN SPONSORSHIP TO BIONICHE**
- \* **PRIMA SHARE PLAN, OPTIONS RIGHTS OFFER FOR UP TO \$20m**
- \* **RESMED TAKES APEX, MEDICAL DEPOT TO ITC, US FEDERAL COURT**
- \* **SUNSHINE HEART LOSES DIRECTOR DONAL O'DWYER IN MOVE TO US**

## MARKET REPORT

The Australian stock market was up 0.38 percent on Tuesday April 2, 2013 with the S&P ASX 200 up 19.0 points to 4,985.5 points.

Four of the Biotech Daily Top 40 stocks were up, 21 fell, 11 traded unchanged and four were untraded.

Clinuvel was the best, up 10 cents or 4.2 percent to \$2.50 with 2,300 shares traded, followed by Prana up 2.3 percent, GI Dynamics and Universal Biosensors up more than one percent, and Resmed up 0.7 percent.

Phylogica led the falls, down 0.2 cents or 8.7 percent to 2.1 cents with 164,000 shares traded.

Benitec fell 7.7 percent; Patrys lost 6.45 percent; Atcor and Reva were down more than five percent; Living Cell and QRX fell more than four percent; Acrux, Cochlear, Phosphagenics and Viralytics were down three percent or more; Cellmid, Medical Developments and Neuren shed more than two percent; Anteo, Bionomics, Genetic Technologies, Nanosonics, Prima and Sirtex were down more than one percent; with CSL, Heartware and Mesoblast down by less than one percent.

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

Both the ASX200 and the Biotech Daily Top 40 index (BDI-40), slipped back in the month to March 31, 2013, down 2.7 percent and 1.0 percent, respectively.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40), also fell in the month to March 31, 2013, down a collective 1.2 percent. Cochlear was down a further 3.9 percent, CSL fell for the first time since January 31, 2012, with Resmed reducing the losses, adding \$109 million or 1.6 percent to a record market capitalization of \$6,785 million.

Heartware's \$138 million (11.2%) increase and Mesoblast's \$36 million (1.9%) gain ameliorated the Biotech Daily Top 20 index (BDI-20) falls taking the index up 0.2 percent, but the plethora of smaller falls in the Second 20 dragged the overall BDI-40 down

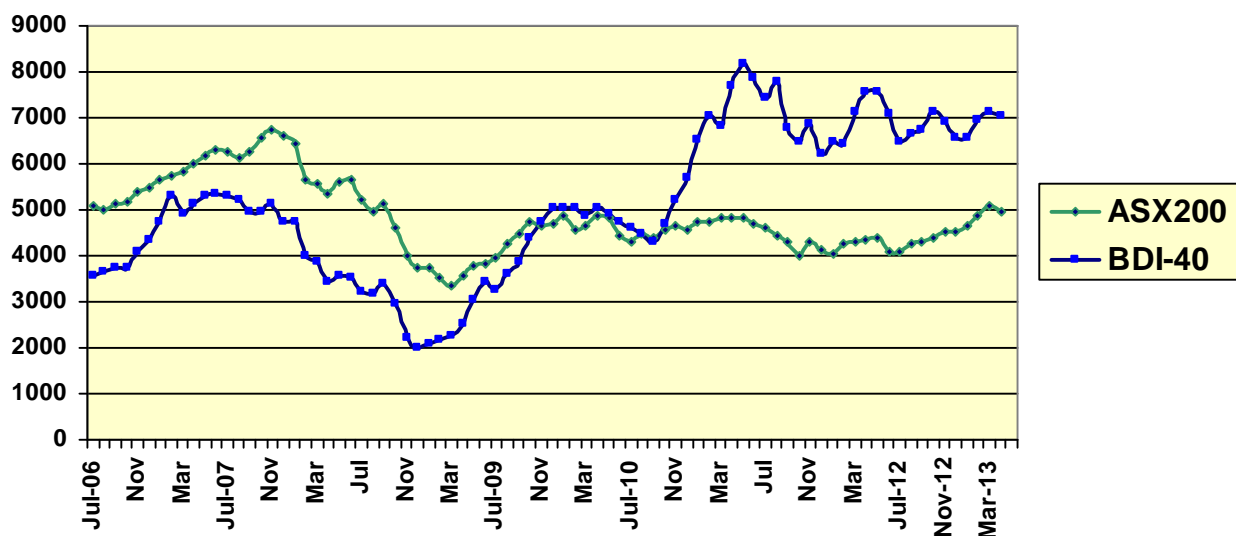
Ten BDI-40 companies were up, 25 fell and five were unchanged. Seven BDI-20 companies were up, with 11 falls and two unchanged.

Pharmaxis led the falls, following the US FDA rejection of Bronchitol for cystic fibrosis (BD: Mar 19, 2013), down 40.4 percent to a market capitalization of \$102 million, followed by Tissue Therapies, down 27.7 percent to \$34 million, Compumedics (25.0%), Optiscan (21.1%), Patrys (20.0%), GI Dynamics (17.9%), Antisense (17.6%) and Prima (17.1%).

Psivida was the best, up 20.9 percent to \$52 million, followed by Cellmid up 17.6 percent to \$20 million, Alchemia (14.3%), QRX (14.2%) and Heartware (11.2%).

Outside the BDI-40, generics manufacturer Mayne Pharma was up 21.6 percent to \$270 million, with Cogstate and Cryosite continuing to improve. On the Nasdaq, Biota and Sunshine Heart were unchanged at \$111 million and \$57 million, respectively.

BDI-40 v ASX200 June 30, 2006 To March 31, 2013



### REVA MEDICAL

Reva says it has begun its 125 patient trial of the Rezolve2 bioresorbable sirolimus-eluting coronary scaffold.

Reva said the Rezolve2 stent was a polymer scaffold designed to provide the benefits of a metal drug-eluting stent, with the advantage of fully resorbing from the body and allowing the artery to return to its natural function.

The company said that the trial would evaluate the safety and performance of Rezolve2 in up to 125 patients at centers in Australia, Brazil, Europe and New Zealand to provide the data required to apply for Conformité Européenne (CE) mark approval.

Reva said the first patient implants were performed at the Sao Paulo, Brazil-based Instituto Dante Pazzanese de Cardiologia by the chief of coronary interventions Dr Alexandre Abizaid and his team.

The company said that Dr Abizaid was the principal investigator for the 2011-'12 clinical trial of the original Rezolve stent (BD: Jan 22, Jul 13, 2012).

"We were pleased with the outcome of the procedures and saw a noticeable improvement in the deliverability of the Rezolve2 scaffold as compared to the original Rezolve device," Dr Abizaid said.

Reva fell three cents or 5.45 percent to 52 cents.

### ALLIED HEALTHCARE GROUP

Allied Health says it lodged its US Food and Drug Administration pre-market notification 510(k) submission for Cardiocel cardiac patch on March 29, 2013.

Allied said that the FDA 510(K) submission was "a major step ... to gain marketing approval for Cardiocel in the US".

The company said that the Cardiocel cardiovascular tissue patch was used to repair heart deformities including repairing and reconstructing heart valves.

Allied managing director Lee Rodne said that the US was the largest market for regenerative medicine and "US opinion leaders are very supportive of our application and key centers are ready to use Cardiocel when approved by the FDA".

The company said it expected Conformité Européenne (CE) mark approval in mid-2013 and Cardiocel was authorized in through the Authorized Prescriber Scheme.

Allied Health said that four years after implanting Cardiocel there had been no calcification of the tissue, a major issue with existing tissue products.

Allied Health climbed as much as 13.8 percent to 3.2 cents before closing unchanged at 2.9 cents with 12 million shares traded.

### PHOSPHAGENICS

Phosphagenics says it has extended its collaboration with Japan's Nippon Zoki Pharmaceutical Co for tocopheryl phosphate mixture or TPM diclofenac.

Last year, Phosphagenics said it had "a pre-licensing agreement" with Nippon Zoki for a material transfer to test and assess TPM diclofenac topical non-steroidal pain formulation for its suitability as a prescription item in the US and Japan (BD: Mar 5, 2012).

Today, Phosphagenics said the collaboration would develop an anti-inflammatory product to treat acute and chronic pain for the US market and a licence would include milestone and royalty payments on completion of an advanced topical product development.

Phosphagenics said Nippon Zoki manufactured and marketed topical diclofenac products without TPM for the Japanese market.

Phosphagenics fell half a cent or 3.85 percent to 12.5 cents.

## STARPHARMA HOLDINGS

Starpharma has requested a trading halt pending an announcement “regarding the results of the ... phase II study of VivaGel for the prevention of recurrence of bacterial vaginosis”. Last year, Starpharma’s phase III trial of Vivagel for bacterial vaginosis failed to meet its primary endpoint of clinical cure (BD: Nov 28, 2012).

Trading will resume on April 4, 2013 or on an earlier announcement.

Starpharma last traded at \$1.085.

## BIONICHE LIFE SCIENCES

Bioniche Life Sciences says that former partner Endo Pharmaceuticals has returned the sponsorship of its phase III bladder cancer product Urocidin.

Last year, Endo discontinued its phase III trial of Urocidin for non-muscle-invasive bladder cancer, with Bioniche saying it had “not been recruiting at the expected rate and, after recent discussions with the US Food and Drug Administration regarding the current clinical trial design, Endo has decided to end the study before its scheduled completion” (BD: Nov 6, 2013).

In 2010, Bioniche raised \$30 million to list on the ASX and develop Urocidin, having run its own registration-directed phase III trial of Urocidin for patients whose cancer was refractory or not responsive to standard treatment with bacillus Calmette-Guérin (BCG) and Endo planned to conduct an additional phase III trial.

In 2011 Bioniche said that Endo had paid an up-front fee of \$US20 million in July 2009, and was eligible for \$US110 million in milestone payments (BD: Feb 17, 2011).

Bioniche said that its first 129-patient phase III trial showed a 25 percent one-year disease-free survival rate, comparing favorably to existing treatments (BD: Feb 18, 2011).

Today, Bioniche said that since December 2012 it had worked with Endo to ensure a smooth transition and Endo had completed all termination activities related to the original licence agreement.

Bioniche chief executive officer Graeme McRae said the return of sponsorship was “an important milestone for Urocidin”.

“With sponsorship back in our hands, we will endeavor to schedule meetings with North American regulatory agencies,” Mr McRae said. “With Health Canada, we will discuss the potential for approval of a regulatory submission under its notice of compliance with conditions policy [and] with the US Food and Drug Administration, we will propose a revised clinical development plan to achieve U.S. registration.”

The Kingston Ontario-based Queen’s University urologist and principal investigator Prof Alvaro Morales said the “urology community recognizes the urgent need for complementary and/or alternative treatments for non-muscle-invasive bladder cancer that fails to respond to BCG”.

“A number of research teams around the world are actively studying a variety of agents, some of which are showing significant promise,” Prof Morales said.

“Currently, Urocidin is the only one that has completed a phase III trial,” Prof Morales said.

Bioniche said that if it was successful in obtaining access to the Canadian market under the notice of compliance with conditions (NOC/c) policy, a new drug submission could be made to Health Canada before the end of 2013.

The company said that about one year of review would follow and if Health Canada was satisfied with the submission, an approval could follow by the end of 2014, generating revenue to offset the cost of additional clinical trial work that could be required for the US and other jurisdictions.

Bioniche was untraded at 23 cents.

### PRIMA BIOMED

Prima will offer a share plan at 10 cents a share to raise \$15 million, as well as an options rights offer at two cents an option to raise up to \$5.3 million.

Prima said it was intended that participants in the share plan could use their new shares for the one-for-four options entitlement offer, to raise up to \$5,330,317, through the issue of up to 266,515,847 options, exercisable at 20 cents within four years of issue.

The company said shareholders eligible at the share plan record date of March 28, 2013 would be able to apply for parcels of shares up to \$15,000.

Prima said that the record date for the option entitlement offer would be May 13, 2013.

The company said that the funds would “co-fund up to three phase II trials of CVac in additional cancer indications and continue the ongoing clinical program; continue CVac manufacturing optimization programs to move toward a commercially successful and global product manufacturing platform; and provide general working capital for the company and add security to the balance sheet”.

Prima fell 0.1 cents or one percent to 9.5 cents with four million shares traded.

### RESMED

Resmed says it has filed parallel legal actions in the International Trade Commission and in the US Federal Court to stop the infringement of its patents.

Resmed said it had filed the actions against Taiwanese manufacturer Apex Medical and its US distributor Medical Depot, doing business as Drive Medical Design and Manufacturing.

Resmed said it alleged that multiple Resmed patents were infringed by several Apex products, including the Apex Wizard 210 and Wizard 220 masks, as well as the identical Freedom 210 and Freedom 220 masks made by Apex and sold by Medical Depot as well as the Apex Ich and XT Fit flow generators.

Resmed said it was asking the International Trade Commission to stop the importation and sales of these products in the US and was asking the US Federal Court to stop the infringement and award damages against the defendants.

Resmed general counsel and chief administrative officer David Pendarvis said the company invested more than “\$100 million dollars in research and development each year ... and other companies should not be allowed to infringe Resmed’s intellectual property by using our technology”.

Resmed was up three cents or 0.7 percent to \$4.39 with 4.6 million shares traded.

### SUNSHINE HEART

Sunshine Heart says Donal O’Dwyer will retire as a directors following the completion of his current term and will not stand for re-election at the annual general meeting.

Sunshine Heart said the move came as the company prepared to de-list from the Australian Stock Exchange on May 6, 2013.

Sunshine Heart chairman John Erb said the company was “incredibly thankful for Donal’s service to Sunshine Heart over the years”.

“Since joining the board in 2004, Donal’s tremendous experience within the medical device industry has been essential to Sunshine Heart’s progression,” Mr Erb said.

Sunshine Heart was untraded at three cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Apr-12	Mar-13	Apr-13
Cochlear	3,458	4,040	3,882
CSL	18,753	29,892	29,459
Resmed	4,622	6,676	6,785
<b>BDI-20</b>			
Acrux	664	674	646
Alchemia	145	91	104
Benitec	17	14	14
Bionomics	169	150	139
Clinuvel	57	84	85
Heartware	890	1,235	1,373
Impedimed	75	17	16
Mesoblast	2,264	1,900	1,936
Nanosonics	130	131	126
Neuren	29	46	40
Osprey	20	50	50
Pharmaxis	416	171	102
Prana	48	72	74
Prima	256	123	102
Psivida	40	43	52
Reva	228	194	182
Sirtex	292	608	617
Starpharma	491	316	308
Tissue Therapies	74	47	34
Universal Biosensors	116	141	120
<b>Second 20</b>			
Allied Health	22	33	30
Anteo	62	50	45
Antisense	19	17	14
Atcor	11	15	14
Avita	57	41	37
Cellmid	6	17	20
Circadian	23	13	13
Compumedics	12	12	9
Ellex	16	18	16
Genetic Technologies	44	41	36
GI Dynamics	291	224	184
Living Cell	27	17	17
Medical Dev	32	119	106
Optiscan	18	19	15
Patrys	12	20	16
Phosphagenics	244	153	133
Phylogica	20	12	10
QRX Pharma	251	145	169
Uscom	5	12	13
Viralytics	29	26	26

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Allied Health, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Alchemia, Atcor, Avita, Circadian, Cochlear, Neuren, Pharmaxis, Sirtex and Universal Biosensors. These holdings are liable to change.

**Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053**  
**email: [editor@biotechdaily.com.au](mailto:editor@biotechdaily.com.au); [www.biotechdaily.com.au](http://www.biotechdaily.com.au); twitter: @biotech\_daily**