



Biotech Daily

Tuesday April 1, 2014

Daily news on ASX-listed biotechnology companies

- * **MARCH BDI-40 DOWN 5%, ASX200 DOWN 0.2%, BIG CAPS DOWN 3%
- VIRALYTICS UP 66%, ANTEO UP 56%, REVA DOWN 54%**
- * **TODAY: ASX, BIOTECH DOWN: REVA UP 6%, PRANA DOWN 74%**
- * **PRANA FALLS AS PBT2 FAILS TO REDUCE ALZHEIMER'S PLAQUES**
- * **ANTISENSE COMPLETES ATL1102 MS TOXICOLOGY STUDY**
- * **LIVING CELL'S DR ANDREA GRANT, 55 STAFF TO JV; DR KEN TAYLOR CEO**

MARKET REPORT

The Australian stock market fell 0.1 percent on Tuesday April 1, 2014 with the S&P ASX 200 down 5.6 points to 5,389.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and five were untraded.

Reva was the best, recovering from two trading days of falls, up one cent or 6.45 percent to 16.5 cents with 1.7 million shares traded.

Benitec climbed 6.2 percent; Bionomics was up 3.8 percent; Phosphagenics and Sirtex rose more than two percent; with Alchemia, Resmed and Viralytics up by more than one percent.

Prana led the falls, down as much as 80.5 cents or 77.4 percent to 23.5 cents before, closing down 76.5 cents or 73.6 percent to 27.5 cents with 39.9 million shares traded, followed by Atcor down 16.7 percent to 10 cents with 2.0 million shares traded, Antisense down 16.3 percent to 18 cents with 7.9 million shares traded and Anteo down 10.2 percent to 22 cents with 10.5 million shares traded.

Neuren lost 6.8 percent; GI Dynamics fell 5.3 percent; Prima and QRX were down more than four percent; Admedus, Mesoblast, Oncosil, Pharmaxis and Uscom were down more than three percent; Patrys, Starpharma and Tissue Therapies shed more than two percent; Nanosonics and Universal Biosensors were down more than one percent; with Acrux, Clinuvel, Cochlear and CSL down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Beware the Ides of March, they told Caesar, and so it was. Let's hope that April is not the cruellest month.

All indices fell in March with the Biotech Daily Top-40 Index (BDI-40) down 5.2 percent, the S&P ASX200 down 0.2 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) down a collective 2.9 percent.

CSL fell 3.4 percent to \$33,640 million, Cochlear lost 2.2 percent to \$3,253 million with Resmed down 1.0 percent to \$6,726 million.

Fourteen of the BDI-40 companies were up, 24 companies fell and two were unchanged.

The deepest falls included Bionomics failing to meet its BNC105 renal cell carcinoma primary endpoint, Reva effectively going back to the laboratory bench having been overtaken on coronary stents and Acrux suffering collateral damage from US litigation against competitor testosterone replacements.

Prana's 73.6 percent fall today on news that PBT2 failed to meet its primary endpoint for Alzheimer's disease, as well as minimal efficacy for Huntington's disease (see below), has the company's eight-year tenure in the BDI-20 under review.

Reva led the falls for the second month in a row, down 22.2 percent in February and a further 53.6 percent in March to \$52 million, followed by Bionomics (25.3%), Optiscan (20.0%), Acrux (18.3%), GI Dynamics (17.1%), Ellex (16.3%), Alchemia (15.9%), Admedus (15.0%), Pharmaxis (14.7%) and Phosphagenics (14.3%).

The good news was that Viralytics continued to consolidate on trial data and a \$27 million capital raising, taking it up \$23 million or 65.7 percent for the month to a market capitalization of \$58 million, with Anteo sticking like molecular glue, up \$73 million or 56.2 percent to \$203 million.

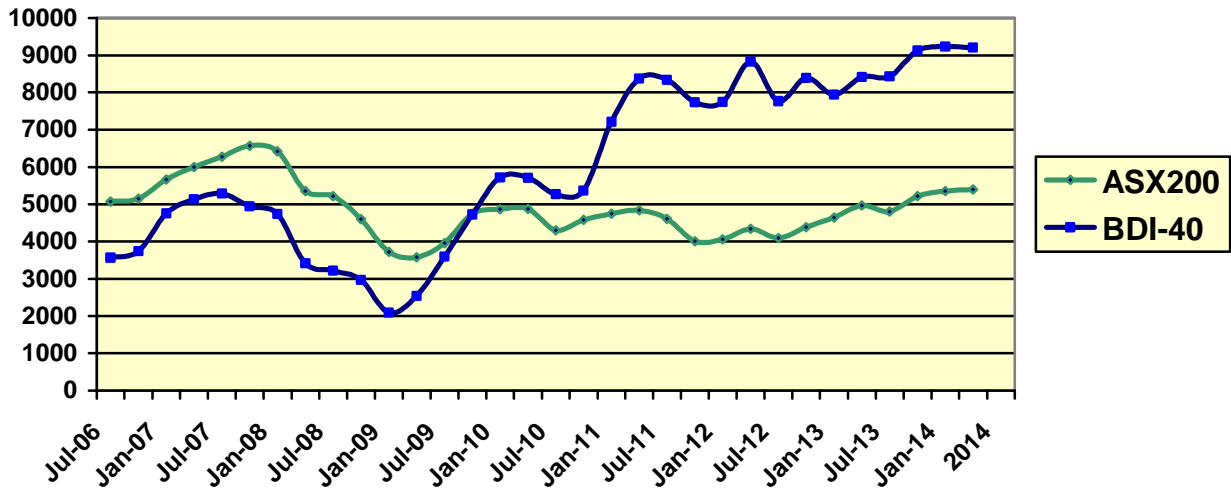
Uscom was up 53.3 percent to \$23 million, followed by Compumedics up 38.5 percent to \$18 million, Tissue Therapies (24.3%), Medical Developments (12.5%), Circadian (10%) and Nanosonics (9.7%).

Outside the BDI-40, Progen was up 121.4 percent in March to \$62 million (a rise of 933.3 percent for the year) with Calzada up 50 percent to \$54 million and Biotron up 47.1 percent to \$25 million.

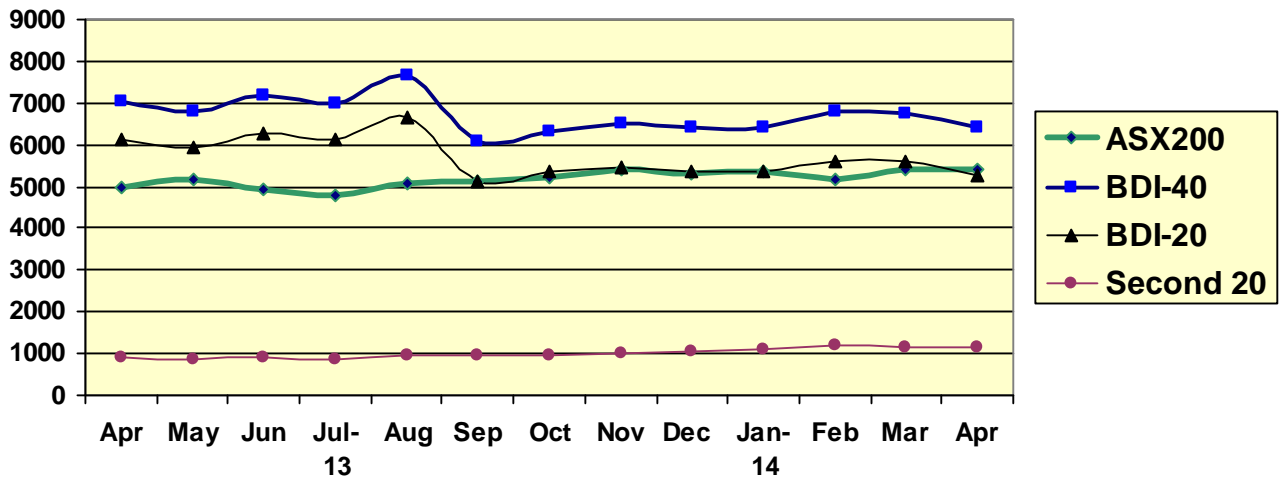
On the Nasdaq, Biota fell 11.15 percent to \$231 million, Heartware fell 5.6 percent to \$1,715 million and Sunshine Heart lost 34.6 percent to \$106 million.

Viralytics will be promoted into the BDI-20, with Reva relegated to the Second 20.

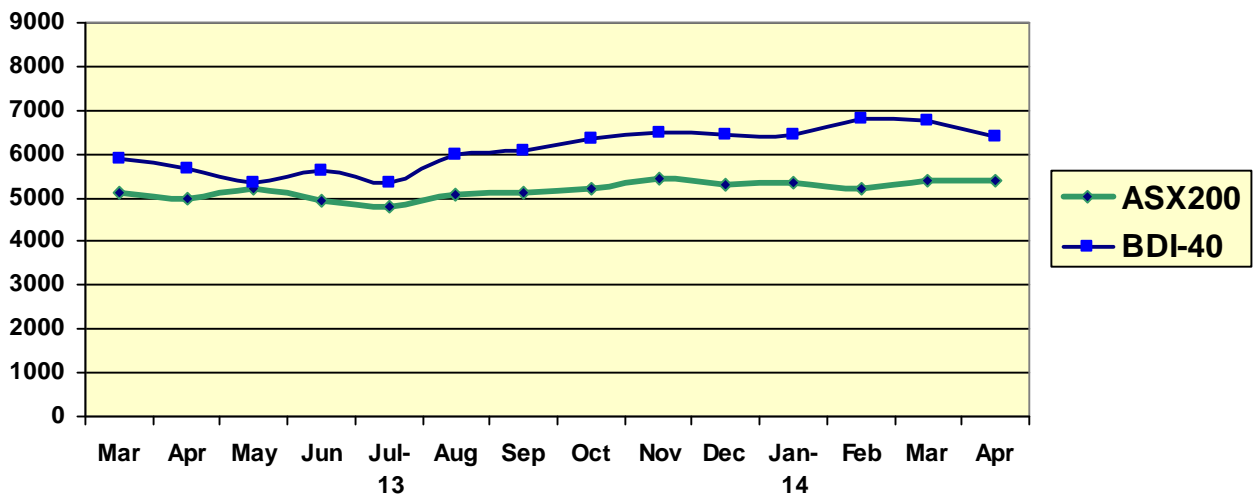
BDI-40 v ASX200 Jun 30, 2006 to Mar 31, 2014 - Adjusted



BDI-40 (\$m) v S&P ASX 200 – Mar 31, 2013- Mar 31, 2014



BDI-40 (\$m) v S&P ASX 200 – Mar 31, 2013- Mar 31, 2014 – Adjusted



PRANA BIOTECHNOLOGY

Prana fell more than 70 percent on news that its imaging trial of PBT2 for Alzheimer's disease did not meet its primary endpoint of reducing amyloid beta plaques.

In February, Prana climbed when a phase II trial of PBT2 for Huntington's disease met the primary endpoint of safety and tolerability but only met one secondary endpoint for cognitive efficacy of several (BD: Feb 18, 19, 2014)

Today, Prana said that while there was a reduction in the overall levels of amyloid beta plaques in Alzheimer's patients treated with PBT2, "the results were confounded by an atypical reduction of levels ... in the placebo group as well".

Prana said that the 'Imagine' 12-month, phase II, imaging trial of PBT2 for Alzheimer's disease draft results showed the drug did not meet its primary endpoint of a statistically significant reduction in the levels of beta-amyloid plaques in the brains of prodromal or mild Alzheimer's disease patients, as measured using Pittsburgh compound B (PiB) positron emission tomography (PET) standardized uptake value ratio (SUVR).

The company said that no improvement was observed on the secondary endpoints of brain metabolic activity, cognition and function, but there was a trend towards preserving hippocampal brain volume in the PBT2 group.

The company said there was less atrophy in PBT2-treated patients relative to placebo (2.6% and 4.0%, respectively), consistent with published measures of atrophy in Alzheimer's disease patients versus healthy controls (4.7% and 1.4%, respectively).

Prana executive chairman Geoffrey Kempler the Imagine trial was "the first time that Prana has looked at PiB-PET in a study with PBT2 to measure its effect on insoluble amyloid plaques".

Mr Kempler said a previous study looked at levels of unaggregated soluble amyloid beta peptides in spinal fluid, which were significantly reduced with PBT2 treatment.

"So in the Imagine trial we looked for an impact on the insoluble plaques as well, but did not see it differ significantly from the placebo," Mr Kempler said.

"It is possible the result may point to PBT2 targeting soluble species of [amyloid beta] including toxic oligomers rather than plaques," Mr Kempler said.

"[Amyloid beta] oligomers are not visible in the PiB-PET scans which can only detect amyloid plaques," Mr Kempler said. "Alternatively, what we are seeing is simply the result of an inconclusive imaging readout in a small sample size with 42 participants [with] 15 on placebo [and] 27 on PBT2."

Prana said it was tracking measures of brain volume and cognition in the 12 month extension study that would be completed at the end of 2014.

The company said that PBT2 was safe and very well tolerated over the 52 weeks, with the adverse event profile equivalent between placebo and treated groups and 40 of the 42 enrolled participants completed the 52-week treatment period.

"This result does not deter us from the future development of PBT2," Mr Kempler said.

"Our scientists and those from other institutes have developed a strong body of evidence for the efficacy of PBT2 in Alzheimer's disease."

Mr Kempler said the suggestion of beneficial effect of PBT2 on brain volumes in the Huntington's disease trial and in the Imagine trial was "intriguing" and Prana was consulting with experts to further assess these results and consider how best to progress PBT2 in Alzheimer's disease along with the continuing Imagine extension trial.

Prana said it had \$A25.4 million in cash at March 31, 2014.

On the Nasdaq overnight, Prana fell \$US7.06 or 71.6 percent to \$US2.80 (equivalent to 30.2 cents per Australian share) with 23,640,882 shares traded.

On the ASX, Prana fell as much as 80.5 cents or 77.4 percent to 23.5 cents before closing down 76.5 cents or 73.6 percent to 27.5 cents with 39.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that a chronic toxicity study in monkeys shows that subcutaneous ATL1102 was well-tolerated at 1.5mg/kg and 3mg/kg doses levels over six months. Antisense said that ATL1102 was in development for multiple sclerosis and data should allow ATL1102 dosing at or above the 1.5 mg/kg/dose level.

The company said that based on histologic findings in common with a previous monkey study at doses exceeding 1.5mg/kg/dose, it continued to evaluate the monkey data for human relevance and safety biomarkers that might be useful in future studies.

Antisense said it expected a final review of the data by June this year and discussions with the US Food and Drug Administration at a pre-investigational new drug application meeting by October 2014.

Antisense managing director Mark Diamond said the company was “continuing to generate new data on ATL1102 which we believe will support positive interactions with the FDA in relation to our plans for a future phase IIb trial in [multiple sclerosis] patients”.

Antisense fell 3.5 cents or 16.3 percent to 18 cents with 7.9 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says 55 staff, led by former chief executive officer Dr Andrea Grant, have transferred to its joint venture, with Dr Ken Taylor appointed acting chief executive officer. Living Cell said that Dr Grant had been appointed as chief executive officer of Diatranz Otsuka, a joint venture created in 2011 with Otsuka Pharmaceutical Factory to develop the company’s original assets, the encapsulated porcine islets of Langerhans derived from its specialist Auckland Island pig herd (BD: Apr 12, Oct 19, 2011).

The company said the staff would continue with pre-clinical and clinical development, manufacturing, pig husbandry, quality assurance and administrative functions.

Living Cell said that until now, it provided the staff and functions for Diabecell development to Diatranz Otsuka on a fee-for-service basis and as a result of the changes its revenue would reduce and be offset by reductions in expenses, while its assets and equity in Diatranz Otsuka was unchanged.

The company said that Dr Grant had resigned as managing director and from the board, while NTCCell program director Dr Taylor would be the acting chief executive officer.

Living Cell said the changes strengthened Diatranz Otsuka and enabled Living Cell to develop new products from its existing technology and intellectual property portfolio.

Living Cell chairman Roy Austin told Biotech Daily that the Diabecell program was the company’s most important assets and would be better placed through the restructure.

Mr Austin said he hoped the NTCCell trial program would be revived in the near future.

The company said that 12 staff would continue its research and development activities for the phase I clinical trials of NTCCell encapsulated pig choroid plexus cells as a potential treatment for Parkinson’s disease as well as progressing additional projects from a pre-clinical stage into clinical trials.

The phase I trial implanted the first patient in September 2013, but was halted in December when a pre-clinical rat trial paper was withdrawn (BD: Sep 20, Dec 19, 2013).

In the media release to the ASX, Mr Austin said the restructure was “a natural evolution for Living Cell and Diatranz Otsuka”.

“It is not [Living Cell’s] long term vision to be a services business,” Mr Austin said. “As Diabecell moves closer to market, it is important that [Diatranz Otsuka] controls its essential functions within its own corporate structure rather than by contracting services from [Living Cell],” Mr Austin said.

Living Cell was unchanged at eight cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Apr-13	Mar-14	Apr-14
Cochlear	3,882	3,325	3,253
CSL	29,459	34,813	33,640
Resmed	6,785	6,796	6,726
BDI-20			
Acrux	646	350	286
Alchemia	104	201	169
Admedus	30	207	176
Benitec	14	155	162
Bionomics	139	292	221
Clinuvel	85	59	60
Impedimed	16	42	40
Mesoblast	1,936	1,847	1,757
Nanosonics	126	207	227
Neuren	40	146	136
Osprey	50	80	74
Pharmaxis	102	34	29
Prana	74	518	447
Prima	102	57	50
Psivida	52	134	118
Sirtex	617	837	871
Starpharma	308	199	216
Tissue Therapies	34	74	92
Universal Biosensors	120	68	60
Viralytics	26	35	58
Second 20			
Anteo	45	130	203
Antisense	14	23	31
Atcor	14	22	19
Avita	37	41	39
Cellmid	20	24	21
Circadian	13	10	11
Compumedics	9	13	18
Ellex	16	43	36
Genetic Technologies	36	39	34
GI Dynamics	184	280	232
IDT	11	25	23
Living Cell	17	29	29
Medical Developments	106	72	81
Oncosil	4	45	45
Optiscan	15	10	8
Patrys	16	28	30
Phosphagenics	133	112	96
QRX Pharma	169	141	126
Reva	182	112	52
Uscom	13	15	23

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

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