



Biotech Daily

Thursday May 1, 2014

Daily news on ASX-listed biotechnology companies

- * **APRIL BDI-40 DOWN 17%, ASX200 UP 2%**
- **QRX DOWN 88%, PRANA DOWN 80%, ACRUX DOWN 40%, OBJ UP 75%**
- * **TODAY: ASX, BIOTECH DOWN: LIVING CELL UP 7%, CELLMID DOWN 10%**
- * **BARDA EXPLAINS BIOTA STOP-WORK ORDER**
- * **MEDICINES AUSTRALIA: 'COMMISSION OF AUDIT FLAWED ON PBS'**
- * **ADMEDUS CARDIOCEL PATIENT REACHES SIX-YEARS WITH NO ISSUES**
- * **SUDA'S WESTCOAST EXPANDS TO EAST COAST**
- * **AMP REDUCES TO 7.4% IN ACRUX**
- * **VIRAX REQUESTS 'MATERIAL TRANSACTION' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.73 percent on Thursday May 1, 2014 with the S&P ASX 200 down 40.3 points to 5,448.8 points.

Seven of the Biotech Daily Top 40 stocks were up, 16 fell, 13 traded unchanged and four were untraded.

Living Cell was the best, up 0.4 cents or 7.1 percent to six cents with 46,737 shares traded.

Analytica and Antisense climbed more than three percent; Neuren, Pharmaxis and Starpharma rose more than one percent; with CSL and Sirtex up by less than one percent.

Cellmid led the falls, down 0.3 cents or 10.3 percent to 2.6 cents with 10.7 million shares traded.

Biotron lost 7.2 percent; Oncosil fell six percent; Circadian and Psivida were down five percent or more; Benitec, Bionomics and Phosphagenics were down more than four percent; Genetic Technologies and Nanosonics were down more than three percent; Alchemia, Anteo, Impedimed and Medical Developments shed two percent or more; Universal Biosensors was down 1.3 percent; with Acrux, Cochlear and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

TS Eliot was right. April was the cruellest month, adding Acrux, Prana, Biota and QRX to the biotechnology wasteland, not to mention the impending departure of Bio-Melbourne Network chief executive officer Michelle Gallaher.

The April downturn saw just four of the Biotech Daily Top-40 Index (BDI-40) companies up, five unchanged and 31 fell, with 18 down more than 10 percent. Close to \$1 billion was lost by Acrux, Mesoblast, Prana and QRX, alone.

The BDI-40 (which does not include the three Big Caps of Cochlear, CSL and Resmed) fell 17.1 percent in April to a cumulative market capitalization of \$5,312 million, its lowest level in raw data terms since October 30, 2010, and on an adjusted basis, the worst since December 28, 2012.

For the year to date, the BDI-40 fell 26.0 percent on raw data and in adjusted terms was down 5.7 percent, while the S&P ASX200 climbed 1.7 percent in April and 11.4 percent for the year to April 30, 2014.

The three Big Caps were up a cumulative 0.7 percent in April and 4.3 percent for the year to April 30, 2014, with CSL slipping 2.2 percent to \$32,892 million, Cochlear up 2.9 percent to \$3,349 million and Resmed up 14.1 percent to \$7,674 million.

QRX had the deepest percentage fall, down 88.1 percent, losing \$111 million to just \$15 million, followed by Prana shedding \$357 million or 79.9 percent of its market capitalization to \$90 million, and Acrux down 39.9 percent, losing \$114 million to \$172 million. Mesoblast fell \$260 million or 14.8 percent to \$1,497 million. Antisense lost 38.7 percent to \$19 million, followed by Living Cell (31%), Benitec (27.2%), Oncosil (22%), Patrys (20%), Circadian (18.2%) and Pharmaxis (17.2%).

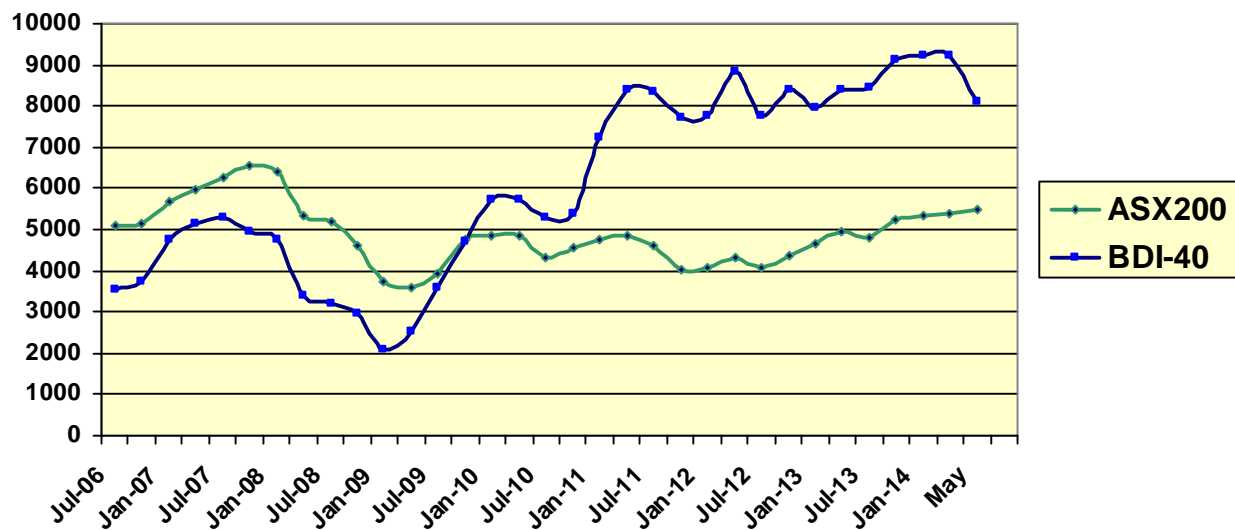
It was not all doom and gloom, with the privately-owned Spinifex raising \$48 million for its EMA401 pain drug and, outside the BDI-40, OBJ signed a major, if confidential, deal with Proctor and Gamble sending its share price up 127.5 percent in two days, 75.3 percent for the month and 814.3 percent for the year.

Impedimed and Universal Biosensors were the best of the few BDI-40 stocks to rise, both up 10 percent to \$44 million and \$66 million respectively, followed by Alchemia up 1.8 percent and Sirtex improving 1.4 percent. Avita, Cellmid, Compumedics, Genetic Technologies and Optiscan looked relatively heroic by remaining unchanged.

The only good news outside the BDI-40 was OBJ (see above). On the Nasdaq, Biota fell 39.8 percent to \$139 million, Heartware fell 9.5 percent to \$1,552 million and Sunshine Heart lost 0.9 percent to \$105 million.

There are a number of changes to the indices this month and the demotions were very difficult decisions. A founding member of the BDI-20, Starpharma, will be demoted to the Second 20 along with Prana, while GI Dynamics and Biotron will be promoted into the BDI-20. Biotron is cash-strapped but has produced promising phase I/II results and expects to complete a 60-patient phase II hepatitis C trial this year. QRX and Reva will be demoted into the Third 20, with Analytica promoted into the Second 20.

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



[BIOTA BIOPHARMACEUTICALS](#)

The US Biomedical Advanced Research and Development Authority (BARDA) says a range of project concerns prompted the 'stop-work' order issued to Biota.

Yesterday, Biota fell 34 percent following a stop-work order on its \$US231 million BARDA laninamivir octanoate anti-influenza drug contract (BD: Apr 1, 2011; Apr 30, 2014).

Biota said yesterday it had not been given specific reasons for the stop-work order.

Through a public affairs officer, BARDA director Dr Robin Robinson told Biotech Daily: "It's important to keep in mind that a stop-work order is not a contract termination."

"We have concerns about the project with regard to the product manufacturing, clinical study enrollment pace, costs, and contractor performance," Dr Robinson said.

"Since the project is at a natural pause following the end of the 'flu seasonal for the Northern Hemisphere, we are considering what is the best next step for the Biota project and the overall program on influenza antiviral drug development before going forward with clinical studies in the Southern Hemisphere and manufacturing optimization and validation," Dr Robinson said.

BARDA gave no indication of the time it would take to make a final determination.

"The program team has expressed concerns with Biota in monthly meetings, and the [in-process review] panel expressed concerns during the [question and answer] session," Dr Robinson said.

"A more consolidated list of concerns will ensue following our final internal deliberations," Dr Robinson said.

Yesterday, Biota chief executive officer Russell Plumb said in a filing to the US Securities and Exchange Commission: "We are surprised by this stop-work order and unfortunately, do not have any additional visibility or understanding at this time as to the nature of [the Assistant Secretary for Preparedness and Response and] BARDA pending decision related to the [in-process review]".

Following inquiries by Biotech Daily, Biota filed an "Update on the development of laninamivir octanoate" quoting Dr Robinson's response to Biotech Daily.

Biota said it expected that "the final decision regarding the outcome of the [in-process review] should be forthcoming within the next week".

Last night on the Nasdaq, was up one US cent or 0.27 percent to \$US3.69 (\$A3.97, equivalent to 49.6 cents pre-merger) with 243,749 shares traded.

MEDICINES AUSTRALIA

Medicines Australia says National Commission of Audit recommendations on the Pharmaceutical Benefits Scheme (PBS) "is a fundamentally flawed analysis".

Medicines Australia chief executive Dr Brendan Shaw said that the recommendations "show an ignorance of what's really happening in Australia and in other countries where these types of policies have been introduced".

"Some of the recommendations on the PBS suggest the Commission of Audit has been drinking the Kool-Aid."

"The fact is the PBS is sustainable and needs no further savings measures, as demonstrated by the Commission of Audit's own numbers," Dr Shaw said.

Dr Shaw told Biotech Daily that several inter-related Commission recommendations would create a New Zealand-style system, which would be counterproductive to innovative biotechnology companies, pharmaceutical companies and patients.

Dr Shaw said that three specific recommendations for a capped scheme, tendering for a single source supply for pharmaceuticals and the creation of a pharmaceutical management agency would harm the industry and patients.

"Those three together basically give the New Zealand system causing delays for approvals for pharmaceutical products and treatments for patients".

In a media release, Dr Shaw said that "access to life-saving medicines means Australian patients can afford and receive new medicines coming into the country, but these new medicines may not even make it to Australia if some of the recommendations in the Commission's report are implemented".

"As well as being dangerous for Australian patients, the Commission of Audit has completely misunderstood the economics driving the pharmaceutical market in Australia," Dr Shaw said.

"The Commission would have been better-off spending time talking to cancer patients in New Zealand, Europe and the US who have missed out on cancer medicines because of policies flagged by the Commission," Dr Shaw said.

"A number of the policies recommended by the Commission risk Australia's access to medicines in the future," Dr Shaw said.

"The Commission has also completely ignored the impact of its recommendations on the Australian medicines industry which contributes \$4 billion in exports and \$1 billion in research and development," Dr Shaw said.

"If the New Zealand system is implemented in Australia, as effectively recommended by the Commission, you can kiss the Australian medicines industry goodbye," Dr Shaw said.

"It would also lead to the loss of hundreds of millions of dollars in investment and thousands of high-paying, high-skilled jobs," Dr Shaw said.

"We know this because that's exactly what happened in New Zealand," Dr Shaw said.

"These types of reforms were introduced there and now there is no longer a manufacturing or research industry in New Zealand," Dr Shaw said.

"If the Government is relying on this industry to drive economic growth, this is not the way to do it," Dr Shaw said.

"Disappointingly, the report has failed to acknowledge the work the industry has done with governments over the years to make the PBS a sustainable part of the health system," Dr Shaw said.

Biotech Daily research shows that "Drinking the Kool-Aid" refers primarily to the inclusion of potassium cyanide in the flavored drink at the Jonestown massacre in 1978, implying one should not follow instructions from cult leaders, as well as Tom Wolfe's 'Electric Kool-Aid Acid Test' on experiments with lysergic-acid diethylamide.

ADMEDUS

Admedus says that six years post-implantation its Adapt-treated bovine cardiac tissue Cardiocel “continues to show no level of calcification or any other issues”.

Admedus said that the first patient from the South African phase II study has had their six-year follow up and the results showed there was no detectable calcification of Cardiocel with no follow-up repair surgery required and no other issues (BD: Oct 9, 2008).

Today, Admedus said that the patient was initially implanted at three weeks of age and has successfully reached their sixth birthday with no implant issues.

Admedus chief executive officer Lee Rodne said the result was “great progress for patients in not having to have additional surgeries and it represents huge potential for the future treatment of congenital heart disease and other cardiac defects”.

The company said that all other patients in the study continued to show no signs of calcification or follow-up surgeries after three to five years and it expected continued data from the ongoing monitoring of these patients.

“We have always believed that Cardiocel has enormous potential in the future of cardiac surgery and this data highlights the longer term benefits of using Cardiocel and its superiority over alternatives,” Mr Rodne said.

Admedus said Cardiocel had both US Food and Drug Administration clearance and Conformité Européenne (CE) mark approval (BD: Aug 26, 2013; Feb 10, 2014)

Admedus was unchanged at 12.5 cents with 5.1 million shares traded.

SUDA

Suda says 110 percent subsidiary Westcoast Surgical and Medical Supplies is expanding to Australia’s East coast, which could increase revenue by up to \$4 million a year.

Suda said that Westcoast was a sales and logistics operation for medical devices and consumables, based in Western Australia and three national clients, including a Federal Government-funded organization, had encouraged it to supply the East coast.

Suda said that Westcoast would establish a warehouse in Brisbane with distribution capabilities on the Eastern seaboard to service the demand and source new business.

Suda chief executive officer Stephen Carter said that the demand from existing customers alone justified the expansion.

Suda was unchanged at 5.2 cents with 2.7 million shares traded

ACRUX

AMP and related bodies have reduced their shareholding in Acrux from 14,717,740 shares (8.84%) to 12,254,545 shares (7.36%).

The shares were sold between February 24 and April 30, 2014 in scores of small to medium-sized trades at a range of prices, with the single largest sale 328,955 shares for \$343,347 or \$1.044 a share on April 30, 2014.

Acrux fell half a cent or 0.5 percent to \$1.03 with 4.3 million shares traded.

VIRAX HOLDINGS

Virax has requested a trading halt “pending the release of an announcement in relation to a material transaction”.

Trading will resume on May 5, 2014 or on an earlier announcement.

Virax last traded at one cent.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	May-13	Apr-14	May-14
Cochlear	3,764	3,253	3,349
CSL	31,180	33,640	32,892
Resmed	7,174	6,726	7,674
BDI-20			
Acrux	673	286	172
Alchemia	125	169	172
Admedus	31	176	157
Benitec	14	162	118
Bionomics	156	221	196
Biotron	22	25	22
Clinuvel	65	60	56
GI Dynamics	184	232	212
Impedimed	10	40	44
Mesoblast	1,851	1,757	1,497
Nanosonics	112	227	214
Neuren	38	136	134
Osprey	39	74	62
Pharmaxis	45	29	24
Prima	91	50	44
Psivida	47	118	117
Sirtex	541	871	883
Tissue Therapies	27	92	78
Universal Biosensors	107	60	66
Viralytics	25	58	53
Second 20			
Analytica	12	19	24
Anteo	40	203	170
Antisense	16	31	19
Atcor	12	19	18
Avita	30	39	39
Cellmid	18	21	21
Circadian	13	11	9
Compumedics	8	18	18
Ellex	15	36	34
Genetic Technologies	36	34	34
IDT	8	23	20
Living Cell	16	29	20
Medical Developments	87	81	72
Oncosil	9	45	35
Optiscan	13	8	8
Patrys	14	30	24
Phosphagenics	122	96	94
Prana	74	447	90
Starpharma	277	216	202
Uscom	13	23	21

* 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.

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