



Biotech Daily

Monday July 2, 2012

Daily news on ASX-listed biotechnology companies

- * **6-YEAR BDI-40 UP 82%, ASX200 DOWN 19%, BIG CAPS UP 66%**
- 1-YEAR BDI-40 DOWN 12.6%, ASX200 DOWN 11.1%**
 - **NEUREN UP 189%, ANTISENSE 188%, AVITA 69%, PHARMAXIS 65%**
- JUNE BDI-40 DOWN 8.6%, ASX 200 UP 0.5%**
 - **ANTISENSE UP 15%, QRX DOWN 67%**
- * **TODAY: ASX, BIOTECH UP: GENERA UP 9%, VIRALYTICS DOWN 8%**
- * **CBIO, INVERSEON MERGER FOR ANTI-INFLAMMATORY DISEASES**
- * **IMPEDIMED L-DEX LYMPHOEDEMA PREVENTION DATA**
- * **ACRUX CEO RICHARD TREAGUS RETIRES, ROSS DOBINSON EXEC CHAIR**
- * **TISSUE THERAPIES EXPECTS DELAYED CE MARK IN JULY**
- * **BLUECHIIP APPOINTS RON FINKEL NON-EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.94 percent on Monday July 2, 2012 with the S&P ASX 200 up 38.4 points to 4,133.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and seven were untraded. All three Big Caps fell.

Genera was the best, up 1.5 cents or 8.6 percent to 19 cents with 190,532 shares traded.

Prana climbed 6.9 percent; Clinuvel and Optiscan were up more than five percent; Genetic Technologies, Prima and Sunshine Heart were up more than four percent; Psivida, QRX and Sirtex rose more than two percent; Acrux, Bionomics and Starpharma were up more than one percent; with Biota up 0.7 percent.

Viralytics led the falls, down two cents or 7.55 percent to 24.5 cents with 75,800 shares traded.

Cellmid lost 6.25 percent; Neuren and Universal Biosensors Heart fell more than four percent; Phosphagenics, Reva and Tissue Therapies were down more than three percent; Avita shed 2.7 percent; CSL, Mesoblast and Resmed were down more than one percent; with Cochlear and Pharmaxis down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

With six years of data, the Biotech Daily Top 40 Index (BDI-40) is up 82.4 percent since June 30, 2006, compared to the S&P ASX200 falling 19.3 percent (see charts below).

For a more conservative investment, the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up 66.1 percent from a collective market capitalization of \$17,156 million at June 30, 2006 to \$28,501 million at June 30, 2012. CSL was up 105.6 percent, Cochlear up 22.6 percent and Resmed up 7.9 percent.

The Big Caps were up 9.7 percent for the year to June 30, 2012 and climbed 2.6 percent in the month of June, with CSL up \$834 million or 4.3 percent to \$20,099 million, Cochlear up 2.8 percent to \$3,671 million and Resmed down 4.1 percent to \$4,731 million.

The BDI-40 lost 8.6 percent in June, mostly attributable to last week's QRX tumble on the US FDA Moxduo rejection and a \$193 million fall in Mesoblast's value.

For the year to June 30, 2012, the BDI-40 fell 12.6 percent, compared to the ASX200 down 11.1 percent – the first time that the biotechnology index underperformed the ASX200 over 12 months, since November 2008.

It wasn't a good end to the financial year, with QRX receiving the unexpected FDA rebuff and Bioxyne taking two weeks to tell us that HI-164OV hadn't met its endpoints. But the two negatives are instructive. Biotech Daily is conservative in promotion and demotion and despite the attractiveness of Bioxyne's 2006 phase II trial and our respect for chief executive officer David Radford, it is not our policy to promote a company into the Top 40 without seeing some public and published history. Bioxyne listed in April with results just two months away. We decided to wait and see.

On the other hand, despite the FDA's rejection of the QRX Moxduo application – possibly for the same reasons that Biotech Daily has reservations over combining two old opioids – the QRX board and management are highly qualified and determined and QRX has about \$27 million in the bank. QRX remains in the BDI-20, despite last week's bad news.

There are several BDI-40 companies that could be demoted for lack of performance and in no particular order they include: Bionomics, Living Cell, Cellmid, Circadian, Patrys, Phylogica and Compumedics, but every time we look at the lists, those companies have saved themselves with a research and development announcement or a deal and we look at which company could replace them and there are none. In the Second 20, companies like Neuren, Psivida and Reva are just a trial result away from promotion.

Outside the BDI-40, there are several companies that are seriously knocking on the door including the refurbished Biodiem, Bluechiip which has recovered to its listing price and doubled its market capitalization over the past 12 months, along with Biotron, GI Dynamics, Immuron, Mayne Pharma, Medical Developments and Cogstate.

The 12-month data shows the best performers were companies recovering from earlier failures of technology, approval or sales. Pharmaxis recovered 65.1 percent from European refusal (\$192 million) to approval (\$317 million), Neuren was up 188.9 percent from \$9 million to \$26 million, Antisense was up 187.5 percent to \$23 million, Avita was up 69.2 percent to \$44 million and Optiscan closed the year up 62.5 percent to \$13 million.

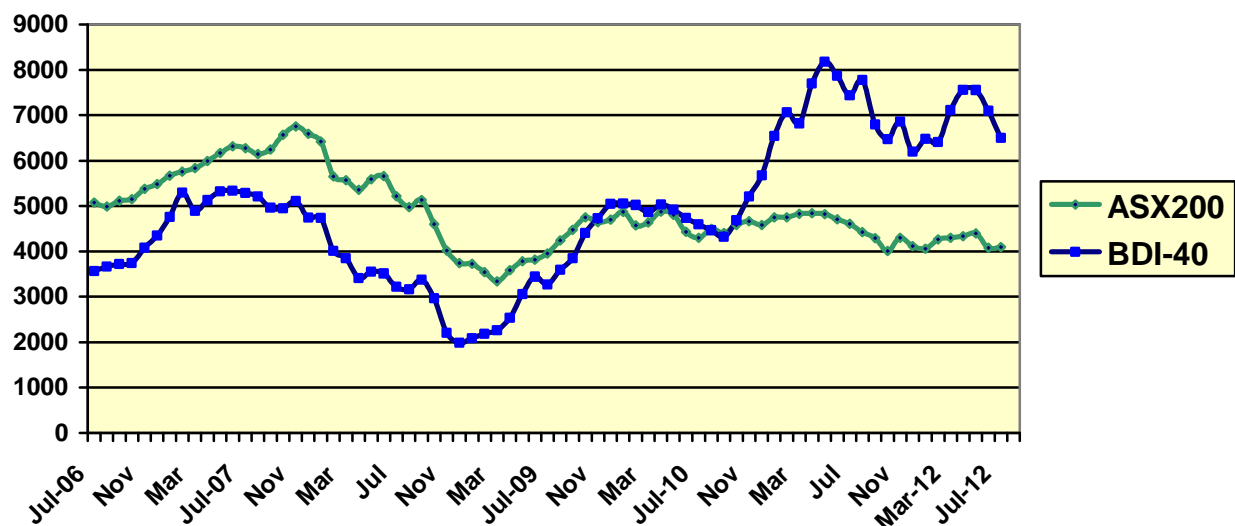
The best organic growth was from Acrux up 24.8 percent to \$704 million, Heartware up 22.8 percent to \$1,221 million, Phosphagenics up 43.7 percent to \$148 million, Sirtex up 24.5% to \$340 million and Starpharma up 9.3 percent to \$388 million.

For the month of June, eight of the BDI-40 stocks were up, 29 fell and three were unchanged.

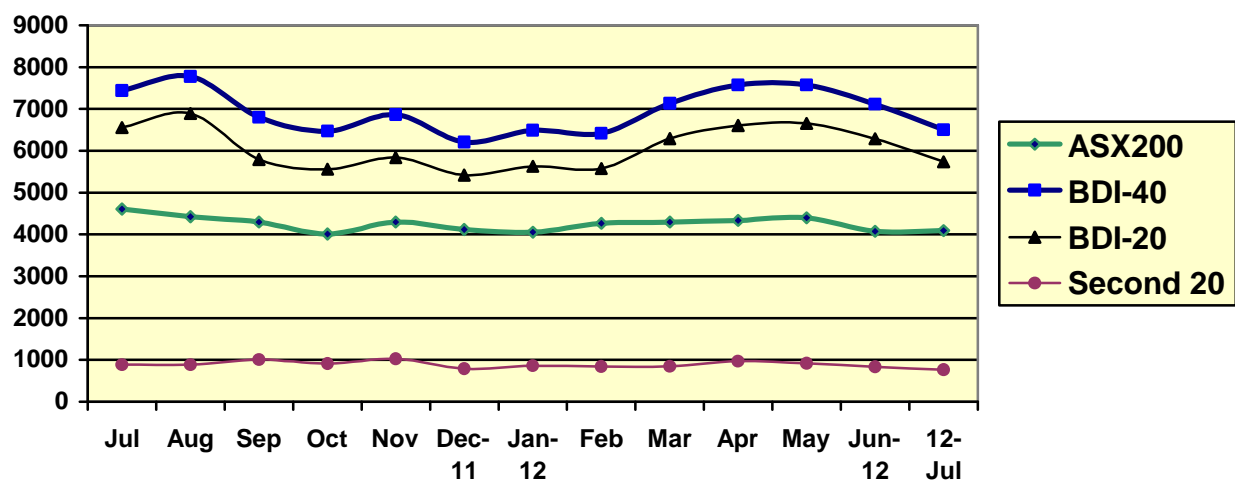
Antisense was up 15.0 percent in June to \$23 million; followed by Anteo up 14.0 percent to \$57 million; Psivida (12.2%); Heartware (6.1%); Nanosonics (3.1%); and Sirtex (1.8%).

QRX led the falls in June, down 67.2 percent to \$87 million; followed by Prima down 33.1 percent to \$107 million; Impedimed (22.8%); Circadian (22.7%); Allied Health (22.2%); Patrys (22.2%); Bionomics (21.8%); Genetic Technologies (21.6%); and Ellex (21.4%).

BDI-40 v ASX200 Jun 30, 2006 To Jun 30, 2012



BDI-40 v ASX200 Jun 30, 2011 To Jun 30, 2012



CBIO

CBio says it will merge with the San Francisco California-based Inverseon Inc to become Invion to develop clinical stage treatments for anti-inflammatory diseases.

CBio said that the acquisition for 143,486,978 CBio shares, worth \$8,609,219 at Friday's closing price of six cents a share, was subject to shareholder approval, but had the unanimous support of the board following a detailed strategic review.

In its previous Appendix 3B statement, CBio said it had 239,144,963 shares on issue and today the company said Inverseon would hold 37.5 percent of the combined entity.

The company said the merger would take place through a 'reverse triangular merger' under Delaware law, with CBio issuing the shares to a newly incorporated subsidiary CBio USA Inc, which would merge with Inverseon and the shares transferred to Inverseon shareholders, resulting with Inverseon being a wholly-owned CBio subsidiary.

CBio said the merged company, Invion, would progress a phase II trial of lead product INV102 for asthma and smoking cessation indications by October 2012.

The company said Inverseon was exploiting the use of beta-2 adrenergic inverse agonism for lung inflammatory conditions such as asthma, chronic bronchitis and cystic fibrosis.

CBio said INV102 was a beta-blocker patented until 2026 known as nadolol and had been used in more than eight million people for high blood pressure, migraine and chest pain.

The company said Inverseon was targeting nadolol for new indications and two phase II clinical trials demonstrated acceptable safety as well as dose-related activity showing a reduction of airway hyper-responsiveness.

CBio said two phase II trials were due to begin by October 2012, including a \$4.4 million phase II asthma study expected to be funded by the US National Institutes of Health.

Inverseon chairman Dr William Garner said the merger was mutually beneficial, marrying two experienced teams to develop anti-inflammatory treatments.

CBio said it planned to continue development work on chaperonin 10 as a potential treatment for the autoimmune disorder Lupus.

Also known as XToll, chaperonin 10 failed to meet its primary endpoint for rheumatoid arthritis in a phase IIa trial (BD: Aug 1, 2011) precipitating the creation of a shareholder action group and the removal of the then board.

Today, CBio chairman Dr Ralph Craven said the merger would create an anti-inflammatory company with a broad skill base and promising intellectual property.

"This merger provides a solid platform for the potential development of a range of new therapies to address the unmet needs of patients," Dr Craven said.

CBio said that Inverseon was founded in 2004 based on intellectual property from the University of Houston using the scientific discoveries of Dr Richard Bond who contributed to the discovery of beta adrenergic inverse agonism and correctly hypothesized this property was predictive for the effective subset of beta blockers for the treatment of heart failure.

The company said Dr Garner would be the chief executive officer, Dr Mitchell Glass would be the chief medical officer, and along with former Chemgenex executive Dr James Campbell, would be executive directors.

CBio said Dr Craven would continue as chair, with Brett Heading and Warren Brown as non-executive directors.

The company said that on completion of the merger, Dr Garner and Dr Glass would hold about 21 percent of CBio's shares, were likely to be considered associates, and would require shareholder approval.

CBio said it expected to hold a shareholder meeting before the end of August with the merger completed by mid-September 2012.

CBio was up 0.9 cents or 15.0 percent to 6.9 cents.

IMPEDIMED

Impedimed says its L-Dex U400 diagnosed 36 of 257 patients with a sub-clinical lymphoedema and with early intervention none progressed beyond sub-clinical.

Impedimed said the data was presented last weekend in New York at the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology's International Symposium on Supportive Care in Cancer.

The company said the clinical outcomes data was directly linked to the use of L-Dex U400 technology in a routine setting for helping lymphoedema prevention in breast cancer patients at Magee-Womens Hospital of the University of Pittsburgh Medical Centre.

Impedimed said the L-Dex U400 was used in the lymphoedema prevention program was as a clinical aid for helping physicians identify sub-clinical lymphoedema in patients with either axillary lymph node dissection or sentinel lymph node biopsy with radiation therapy.

The company said that the L-Dex U400 measurements were obtained pre-operatively for baseline and then post-operatively every three to six months for the first year.

Impedimed said that 497 patients were recorded in the lymphoedema prevention program database and to date none have progressed to clinical lymphoedema.

The company said 128 patients completed L-Dex assessment prior to their surgery, to determine their baseline and all patients had between three and nine months of follow up readings, with 16 detected having sub-clinical lymphoedema

Impedimed said the 16 patients received early intervention, including a compression sleeve, physical therapy, daily exercise and reducing the use of the affected arm.

The company said that a further 129 patients who underwent breast cancer surgery prior to the start of the program were measured by L-Dex as part of their three month follow-up visit and the readings were taken as baseline for patients if no clinical breast cancer related lymphoedema and no symptoms existed.

Combining both groups, of the 257 patients, 36 patients were diagnosed with a sub-clinical lymphoedema (14%) and all sub-clinical patients received early intervention for lymphoedema with no patients progressing beyond a sub-clinical state.

Impedimed said the Magee Women's Hospital found that early detection and intervention gave the greatest promise of reducing the incidence of late-stage lymphoedema.

Impedimed chief executive officer Greg Brown said the data was "the first presentation of clinical outcomes, based on the use of L-Dex in a prospective care model".

Mr Brown said the data helped demonstrate that L-Dex could identify patients with sub-clinical lymphoedema, help prevent progression through early intervention and demonstrate compliance of patients to a prevention program with the use of L-Dex in routine clinical use.

"This outcomes data will strengthen the existing clinical data on technical and diagnostic performance, critical for health insurers to cover for prospective testing and treatment," Mr Brown said.

Impedimed was unchanged at 26 cents.

ACRUX

Acrux chief executive officer Dr Richard Treagus has retired from the company, with chairman Ross Dobinson becoming executive chairman.

The changes were announced earlier this year and Dr Treagus told Biotech Daily that having taken several products to market with Acrux he would be pursuing new challenges (BD: Feb 22, Mar 15, 2012).

Dr Treagus final director's interest notice said he held 2,077,495 shares.

Acrux was up seven cents or 1.7 percent to \$4.27 with 17 million shares traded.

TISSUE THERAPIES

Tissue Therapies says it expects Conformité Européenne (CE) mark approval for its Vitrogro wound treatment this month.

Tissue Therapies said that all the requested additional information had been provided to the British Standards Institute, the notified body reviewing the CE mark application.

Tissue Therapies chief executive officer Dr Steven Mercer said the company had answered in full all questions raised by the Institute.

"There are no outstanding issues or requests and we are confident that CE mark will be granted during July," Dr Mercer said.

"As previously announced, we have Vitrogro ECM [extracellular matrix] product ready for sale as soon as approval is granted," Dr Mercer said.

"We have also taken this opportunity to refine our integrated sales and marketing campaign with some of the most influential wound care key opinion leaders in the EU," Dr Mercer said.

"We will launch this campaign on the first business day after CE mark is granted," Dr Mercer said.

"Despite these minor delays, the expected granting of CE mark during July instead of June will have little commercial impact as there is already substantial and growing interest in Vitrogro ECM from the clinical trial results and other related announcements," Dr Mercer said.

"We are also well advanced in our preparations for applications for reimbursement," Dr Mercer said.

"Regulatory approvals such as CE mark are fundamentally based on the risk of releasing the new product for use by the targeted market," Dr Mercer said.

"A low risk profile like that of Vitrogro ECM assists approval," he said.

Tissue Therapies fell 1.5 cents or 3.2 percent to 46 cents.

BLUECHIIP

Bluechiip has appointed Ron Finkel as an independent non-executive director.

Bluechiip said that Mr Finkel had been involved in the venture capital industry since 1986 including at Pratt Venture Management and as director of investments at the Advent Management Group, where he directed investments in a number of companies across a wide range of innovative technologies.

The company said that with colleague Ergad Gold, Mr Finkel established the Momentum Investment Group in 1997, which was awarded one of the Australian Government's inaugural licences under the Innovation Investment Fund program.

Bluechiip said that Mr Finkel was the chairman of Panviva Pty Ltd and a director of Momentum Investment Group, Momentum Ventures, Benthic Geotech Pty Ltd, Petrecycle Ltd and Alphapet.

Mr Finkel holds a Bachelor of Laws and Bachelor of Commerce degree from the University of Melbourne.

Bluechiip fell two cents or 7.7 percent to 24 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Jul-11	Jun-12	Jul-12
Cochlear	4,086	3,571	3,671
CSL	17,454	19,265	20,099
Resmed	4,436	4,933	4,731
BDI-20			
Acrux	564	723	704
Alchemia	117	123	126
Bionomics	191	124	97
Biota	173	139	129
Clinuvel	50	55	50
Genetic Technologies	85	74	58
Heartware	994	1,151	1,221
Impedimed	89	57	44
Living Cell	22	18	19
Mesoblast	2,420	1,897	1,704
Nanosonics	176	129	133
Pharmaxis	192	354	317
Phylogica	29	21	20
Prima	262	160	107
QRX Pharma	210	265	87
Sirtex	273	334	340
Starpharma	372	445	388
Sunshine Heart	51	30	25
Tissue Therapies	97	86	76
Universal Biosensors	162	98	89
Second 20			
Allied Health	11	18	14
Anteo	53	50	57
Antisense	8	20	23
Avita	26	49	44
Benitec	26	17	17
Bioniche	101	44	41
Cellmid	9	8	7
Circadian	26	22	17
Compumedics	13	12	10
Ellex	15	14	11
Genera	13	15	13
Neuren	9	30	26
Optiscan	8	13	13
Patrys	22	9	7
Phosphagenics	103	179	148
Prana	53	49	43
Psivida	83	41	46
Reva	328	215	205
Uscom	11	5	5
Viralytics	43	22	19

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

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