



Biotech Daily

Wednesday May 1, 2013

Daily news on ASX-listed biotechnology companies

- * APRIL BDI-40 DOWN 3.7%, ASX200 UP 4.5%; BIG CAPS UP 5%
- * TODAY: ASX DOWN, BIOTECH EVEN: PHYLOGICA UP 15%, CELLMID DOWN 10%
- * CSL RESUMES INFLUENZA VACCINE PRODUCTION FOR AUSTRALIA
- * CSIRO TRIAL DEVELOPING ALZHEIMER'S BLOOD TEST
- * US PATENT FOR ALCHEMIA'S VAST PLATFORM
- * ANTISENSE ATL1102 MULTIPLE SCLEROSIS TOXICOLOGY STUDY
- * IMMURON RIGHTS ISSUE RAISES \$284k OF UNDERWRITTEN \$1.9m
- * NUSEP RAISES \$350K TO RAISE \$15m FOR \$50m PRIME FACILITY
- * IMUGENE SHARE PLAN FOR UP TO \$600k
- * USCOM APPOINTS GRUPO SIM MEXICO DISTRIBUTOR
- * M&G GROUP TAKES 13% OF STARPHARMA
- * ACUVAX HAS ONE QUARTER CASH, \$5m PLACEMENT
- * CLINUVEL REQUESTS CAPITAL RAISING TRADING HALT
- * TOM MILICEVIC APPOINTED ADVANCED SURGICAL CEO
- * GI DYNAMICS APPOINTS DR DAVID MAGGS CHIEF MEDICAL OFFICER

MARKET REPORT

The Australian stock market fell 0.48 percent on Wednesday May 1, 2013 with the S&P ASX 200 down 25.0 points to 5,166.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and six were untraded.

Phylogica was the best, up 0.2 cents or 15.4 percent to 1.5 cents, with 474,500 shares traded. Avita climbed 8.7 percent; Neuren was up 6.25 percent; Prana rose five percent; GI Dynamics and Tissue Therapies were up four percent or more; Heartware and Pharmaxis climbed more than three percent; Bionomics rose 2.6 percent; with Psivida, Resmed and Viralytics up more than one percent.

Cellmid led the falls, down 0.3 cents or 10 percent to 2.7 cents with 2.2 million shares traded. Prima fell 7.1 percent; Genetic Technologies lost 5.3 percent; Medical Developments, Optiscan and Phosphagenics fell more than four percent; Nanosonics was down 3.5 percent; Reva shed 2.8 percent; Mesoblast and Starpharma were down more than one percent; with Acrux, CSL, Cochlear and Sirtex down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 index (BDI-40), fell again in the month to April 30, 2013, down 3.7 percent, while the S&P ASX200 climbed 4.5 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40), were up 5.0 percent, with CSL apparently an unstoppable behemoth - up 5.8 percent to \$31,180 million and up 65.3 percent for the year. Resmed also hit a record high on March quarter revenue, up 5.0 percent to \$7,174 million. Cochlear fell 3.0 percent to \$3,764 million – its third consecutive fall. For the year-to-date, the Big Caps were up 52.1 percent

The BDI-40 graph for the year to April 30, 2013 looks like Luna Park's Scenic Railway, but the longer term charts (below) show that for the five years since April 2008, the BDI-40 has almost doubled (up 93.1%) while the ASX200 was down 8.2 percent over five years.

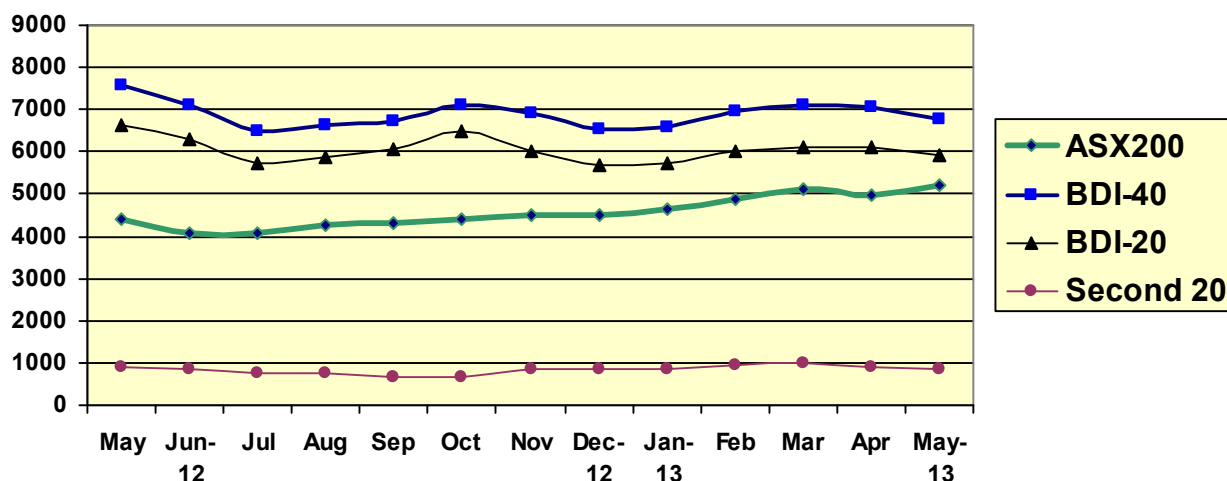
So much for data-mining scraps of good news. At least we didn't have to go into a trading halt. Twenty-eight of the Top 40 stocks fell in April, six were unchanged and six were up.

Heartware's \$86 million (6.3%) increase balanced Mesoblast's \$85 million (4.4%) fall, while the Pharmaxis \$57 million phase III bronchiectasis trial tumble (55.9%) and the Sirtex \$76 million (12.3%) dose sales-related retreat had a far greater impact than Impedimed's 60 percent fall to \$10 million. More importantly, Impedimed has shed 85.1 percent of its value in 12 months, down from \$67 million.

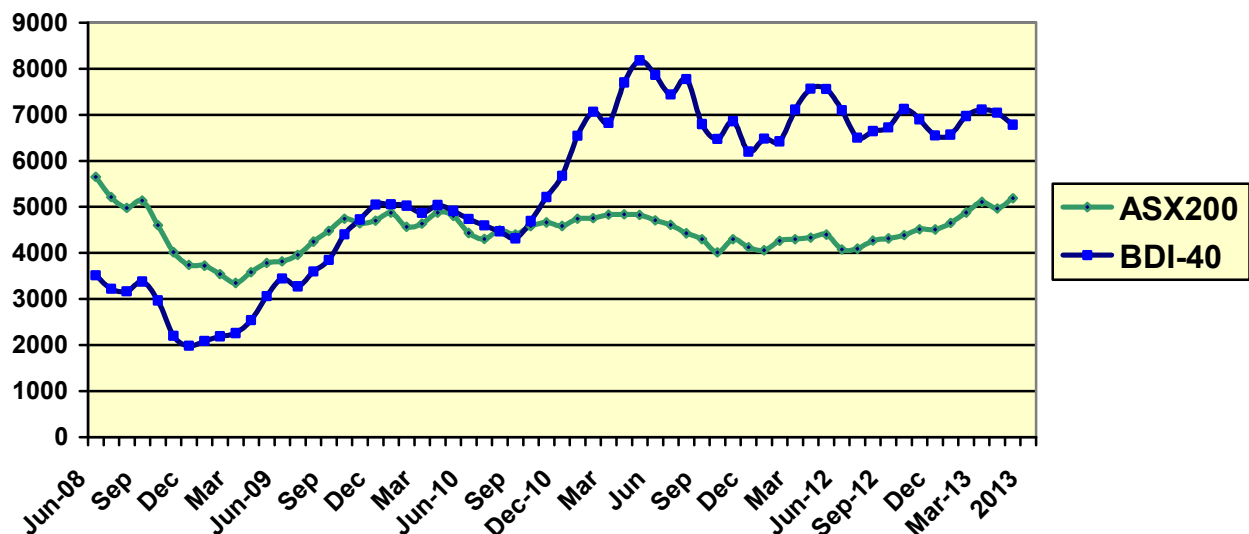
Other deep falls included Phylogica down 40 percent to \$6 million, Clinuvel (23.5%), Osprey (22%), Tissue Therapies (20.6%), Avita (18.9%), Medical Developments (17.9%), Atcor (14.3%) and Optiscan (13.3%).

Alchemia led the six-pack, up 20.2 percent to \$125 million on fondaparinux sales, followed by Antisense (14.3%), Bionomics (12.2%), Heartware (6.3%), Acrux (4.2%) and Allied Health (3.3%). Outside the BDI-40, the AOD9604 sports controversy and positive Polynovo results put the peptide back into Calzada, up 70.6 percent to \$29 million, with Novogen and Suda climbing to market capitalizations of \$24 million. On the Nasdaq, Biota rose 3.6 percent to \$111 million and Sunshine Heart was up 8.8 percent to \$57 million.

BDI-40 v ASX200 April 30, 2012 To April 30, 2013



BDI-40 v ASX200 April 30, 2008 To April 30, 2013



[CSL](#)

CSL says it has restarted production of influenza vaccine for the Australian market in response to higher than expected demand.

CSL said that additional doses were expected to be ready for delivery by the end of May 2013 and would be prioritized for age-appropriate at-risk groups under the National Immunisation Program.

Last year CSL reorganized its divisions with all plasma operations in CSL Behring and vaccines, pharmaceuticals and diagnostics becoming Bio-CSL (BD: Dec 5, 2012).

Bio-CSL general manager, Dr John Anderson said the demand for influenza vaccine had increased significantly in the first two weeks of April in both the public and private markets.

"All our customers are reporting a much earlier and much higher uptake of influenza vaccine this year, compared to the last few years," Dr Anderson said.

CSL said that Bio-CSL was the only manufacturer of influenza vaccine in the Southern Hemisphere and was a major supplier of seasonal and pandemic influenza vaccines to the Australian market, also supplying influenza vaccine to the US, UK and New Zealand.

Dr Anderson said that Bio-CSL was producing a new formulation of influenza vaccine for the coming Northern Hemisphere season when it made the decision to return to production for Australia.

"Restarting production of Southern Hemisphere influenza vaccine is a significant undertaking, but as Australia's only on-shore manufacturer we are committed to responding to local needs," Dr Anderson said.

"Should the extraordinarily high demand for influenza vaccine persist, we are very pleased to be able to support the [Federal] Government in ensuring additional doses are available for age-appropriate at-risk groups," Dr Anderson said.

CSL said the inactivated influenza vaccine was for the prevention of influenza caused by influenza virus types A and B and was indicated for use only in persons aged five years and over and should only be used in children aged five years to under nine years based on consideration of potential risks and benefits.

CSL fell 29 cents or 0.5 percent to \$62.67 with 463,609 shares traded.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says its scientists are closer to developing a screening test for the early detection of Alzheimer's disease.

The CSIRO said the researchers had identified blood-based biological markers associated with the build up of the toxic protein amyloid beta in the brain which occurred years before symptoms appeared and irreversible brain damage had occurred.

The CSIRO said that mathematical models were used to analyze data from 273 participants in the Australian Imaging, Biomarkers and Lifestyle study of ageing (AIBL), which identified nine markers that correlated with brain positron emission tomography imaging measurements of amyloid beta, which deposited as plaques early in the disease's development.

The article, entitled 'A blood-based predictor for neocortical A-Beta burden in Alzheimer's disease: results from the AIBL study' was published in the journal Molecular Psychiatry.

An abstract is at <http://www.nature.com/mp/journal/vaop/ncurrent/full/mp201340a.html>.

The Australian Imaging and Biomarkers Lifestyle Study of Aging is a collaboration between Melbourne's Austin Health, the Commonwealth Scientific and Industrial Research Organisation, Edith Cowan University, the Florey Institute of Neurosciences and Mental Health and the National Aging Research Institute.

The longitudinal study aims to discover which biomarkers, cognitive characteristics and health and lifestyle factors determine subsequent development of symptomatic Alzheimer's disease.

Prana Biotechnology associated researchers Prof Colin Masters and Prof Ashley Bush are co-authors of the article.

Florey Institute for Neuroscience and Mental Health research fellow Dr Noel Faux said that the progressive build-up of amyloid beta was "one of the earliest changes in the brain associated with the development of Alzheimer's disease".

"A recent study from the AIBL team showed that amyloid beta levels become abnormal about 17 years before dementia symptoms appear," Dr Faux said.

"This gives us a much longer time to intervene to try to slow disease progression if we are able to detect cases early," Dr Faux said.

CSIRO Preventative Health Flagship's Dr Samantha Burnham said that early detection was critical in making a difference in treating Alzheimer's disease.

The CSIRO said that Alzheimer's disease was the leading cause of dementia, 250,000 million Australians currently suffering from dementia and given the ageing population, predicted to increase to one million people by 2050.

"We hope our continued research will lead to the development of a low cost, minimally invasive population based screening test for Alzheimer's," Dr Burnham said.

"A blood test would be the ideal first stage to help identify many more people at risk before a diagnosis is confirmed with cognitive tests and [positron emission tomography] imaging or cerebral spinal fluid testing," Dr Burnham said.

Dr Faux told Biotech Daily that the Australian Imaging, Biomarkers and Lifestyle study of ageing was "still actively recruiting volunteers, in particular people who have been diagnosed as having mild cognitive impairment".

Dr Faux said that people wanting to be involved in the research should go to:

www.brainpet.org and for more information on the study, go to: <http://www.aibl.csiro.au>.

ALCHEMIA

Alchemia says it has been granted a US patent, entitled 'Methods of Drug Design' protecting its Versatile Assembly on Stable Templates (Vast) drug discovery platform. Alchemia said the Vast platform included more than 14,000 unique compounds built on the company's internal chemistry expertise that enabled the discovery of small molecule drugs across a range of therapeutic areas.

The company said that it had been granted a patent term adjustment extending protection 864 days, from October 2025 to February 2028; further preserving its advanced position in pyranose drug discovery.

Alchemia intellectual property vice-president Dr Mike West said the additional patent term "provides meaningful protection to our Vast platform and is particularly timely given our recently announced discovery collaboration with Astrazeneca".

Last month, Alchemia said it had a multi-target collaboration with Astrazeneca worth a potential \$240 million in milestone payments, expenses and royalties (BD: Apr 23, 2013). Alchemia was unchanged at 38.5 cents.

ANTISENSE THERAPEUTICS

Antisense says China's Pharmaron will begin a six month toxicology study of ATL1102 for a potential phase IIb trial in multiple sclerosis.

Antisense said that the primate screening by the Pharmaron contract research organization was expected to be finished in time for dosing by the end of May 2013 and to be completed by the end of the year.

The company said the results were expected in early 2014, and it would begin planning a phase IIb study in multiple sclerosis patients.

Antisense said it would fund the study out of its existing cash reserves and any further development of ATL1102 "would most likely be undertaken with a development and funding partner".

In March, Antisense said it would spend up to \$300,000 on the toxicology study despite the joint venture with Tianjin International Joint Academy of Biotechnology and Medicine to develop and commercialize ATL1102 for multiple sclerosis, stem cell mobilization and asthma (BD: Feb 29, 2012; Mar 19, 2013).

Antisense said at that time that the Academy had agreed an extension to the establishment of the joint venture to September 30, 2013.

Antisense was unchanged at 1.1 cents with 1.4 million shares traded.

IMMURON

Immuron says it has raised \$283,917 from applications and over-subscriptions in its \$1,863,810 fully-underwritten, three-for-two rights issue at 0.3 cents a share.

Immuron said it had received applications for 88,641,762 shares and 5,997,082 in additional oversubscriptions.

Immuron said that Patersons Securities had underwritten the issue and would be asked to place the 526,631,242 shortfall, raising a further \$1,579,894.

The company said the funds would be used to continue commercialization efforts, including that of the over-the-counter travelers' diarrhoea treatment Travelan in the US (BD: March 27, 2013).

Immuron was untraded at 0.2 cents.

NUSEP

Nusep says it has raised \$350,000 through the issue of 5,000,000 shares at seven cents a share to a sophisticated Singapore investor as part of its \$15 million Prime plant funding. Nusep said the placement was to provide working capital while it finalized the cornerstone investments for the \$50 million Singapore-based Prime Biologics plasma fractionation business.

Nusep was up 0.6 cents or 10.7 percent to 6.2 cents.

IMUGENE

Imugene hopes to raise up to \$600,000 through a share plan at a 90 percent of the 10-day volume weighted average price to the date of issue, expected to be June 4, 2013.

Imugene is currently trading at one cent and with a limit of issuing 30 percent of its current capital of about 343 million shares could raise up to \$1.14 million.

Imugene executive director Dr Nick Ede told Biotech Daily he would be pleased to see a raising of between \$500,000 and \$600,000.

The company said shareholders eligible at the share plan record date of April 29, 2013 would be able to apply for parcels of shares from \$1,000 to \$15,000, the offer would open on May 7 and close on May 28, 2013.

Imugene said the funds would be used to advance its lead products to regulatory filing in the UK and EU.

The company said it had three priority targets, vitamin D, pain and Parkinson's disease, for its Linguet platform technology which enables drugs to be absorbed into the bloodstream through the cheek, via the buccal mucosa or under the tongue.

Imugene said the first product, a reformulation of vitamin D, had completed feasibility testing and formulation development, and the company expected to file for regulatory approval and licence the product to a third party in 2014.

The company said that the funds would also be used to advance development of reformulation of the over-the-counter pain drug, ibuprofen.

Imugene said that currently marketed products had a global market of \$US5.37 billion a year but had serious side effects including gastric irritation and stomach ulcers, particularly when used at higher doses for extended periods of time.

The company said that positive results from a phase I clinical trial on a Linguet ibuprofen demonstrated improved patient compliance and speed of action.

Imugene was unchanged at one cent.

USCOM

Uscom says it has appointed Grupo SIM as its regional distributor for in Mexico.

Uscom said that the Mexico City-based Grupo SIM distributed medical products to intensive care, pulmonary and respiratory care, diagnostic cardiology, cardiac monitoring, critical care and neonatal and paediatric critical care units in Mexico.

The company said that Mexico had a population of 115 million people and the medical device market was estimated to be \$US3.4 billion in 2012.

Uscom said the medical device market was supported by a rapid population growth, increasing health expenditure, a high incidence of chronic diseases and a commitment to acquisition of new technology in the public health sector and the improved economic outlook for the 2013 - 2017 period further boosted growth prospects.

Uscom was untraded at 20 cents.

STARPHARMA

M&G Investment Funds has increased its substantial shareholding in Starpharma from 34,174,302 shares (12.04%) to 37,069,789 shares (13.06%).

The London-based M&G companies first acquired 18,604,651 shares (6.70%) in November 2011 for \$19,999,999 or \$1.075 a share (BD: Nov 24, 2011).

Today, the M&G Group said it acquired 2,895,487 shares between April 5 and 29, 2013 at a range of prices.

Starpharma fell 1.5 cents or 1.5 percent to 96 cents.

ACUVAX

Acuvax says its net operating cash burn for the three months to March 31, 2013 was \$160,000 with cash at the end of the quarter of \$222,000.

Acuvax is in the process of acquiring and raising \$5 million through the placement of 25,000,000 shares at 20 cents each for phase I/II trials of HER-Vaxx for cancer and for working capital (BD: Dec 20, 2012; Feb 12, 18, 2013).

Acuvax was untraded at 0.1 cents.

CLINUVEL

Clinuvel has requested a trading halt pending “an announcement to the market regarding a proposed capital raising”.

Trading will resume on May 3, 2013 or on an earlier announcement.

Clinuvel last traded at \$1.85.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says that acting chief executive officer Tom Milicevic has been appointed chief executive officer, effective from today.

Last year, then the company’s chief financial officer, Mr Milicevic replaced founder and chief executive officer Dr Greg Roger as acting chief executive officer (BD: Mar 26, 2012).

Advanced Surgical was untraded at 10.5 cents.

GI DYNAMICS

GI Dynamics say it has appointment Dr David Maggs as its chief medical officer.

GI Dynamics said Dr Maggs would oversee clinical development and medical affairs for the Endobarrier for obesity and type 2 diabetes.

The company said that Dr Maggs had worked at Amylin Pharmaceuticals for more than 10 years and held positions of increasing responsibility, led numerous collaborations and was directly engaged with the diabetes and endocrine community.

GI Dynamics said that most recently, Dr Maggs was Amylin’s vice president of medical research and development and prior to Amylin, Dr Maggs was with Parke-Davis (now Pfizer) as the director of diabetes and metabolism.

GI Dynamics said that Dr Maggs at London’s Guy’s Hospital, completed his medical and endocrine training at the University of Nottingham and held faculty appointments at the Yale School of Medicine.

GI Dynamics was up three cents or 4.7 percent to 67 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	May-12	Apr-13	May-13
Cochlear	3,737	3,882	3,764
CSL	18,861	29,459	31,180
Resmed	5,089	6,785	7,174
BDI-20			
Acrux	668	646	673
Alchemia	146	104	125
Benitec	19	14	14
Bionomics	147	139	156
Clinuvel	56	85	65
Heartware	1,059	1,373	1,459
Impedimed	67	16	10
Mesoblast	2,134	1,936	1,851
Nanosonics	118	126	112
Neuren	34	40	38
Osprey	42	50	39
Pharmaxis	407	102	45
Prana	43	74	74
Prima	229	102	91
Psivida	50	52	47
Reva	215	182	177
Sirtex	361	617	541
Starpharma	520	308	277
Tissue Therapies	79	34	27
Universal Biosensors	119	120	107
Second 20			
Allied Health	21	30	31
Anteo	62	45	40
Antisense	17	14	16
Atcor	11	14	12
Avita	48	37	30
Cellmid	8	20	18
Circadian	23	13	13
Compumedics	12	9	8
Ellex	16	16	15
Genetic Technologies	44	36	36
GI Dynamics	280	184	184
Living Cell	25	17	16
Medical Dev	41	106	87
Optiscan	16	15	13
Patrys	12	16	14
Phosphagenics	219	133	122
Phylogica	22	10	6
QRX Pharma	263	169	155
Uscom	5	13	13
Viralytics	26	26	25

* 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.

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