



# Biotech Daily

Tuesday July 1, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **JUNE TOP 20 BEATS ALL ORDS; CHEMGENEX UP 30%, PORTLAND DOWN 57%**
- \* **ASX DOWN, BIOTECHS UP: PHYLOGICA UP 48%, VENTRACOR DOWN 8%**
- \* **CHEMGENEX SUBMITS NON-CLINICAL OMACETAXINE NDA**
- \* **SANOFI-AVENTIS PAYS \$16m PLUS COSTS FOR UNILIFE'S SYRINGE**
- \* **RESMED 'NO COMMENT' ON LINDE TAKEOVER RUMORS**
- \* **VICTORIA FUNDS \$7m MONASH MICRO NANOPHYSICS LABORATORY**
- \* **UK REIMBURSES FERRISCAN, RESONANCE WANTS AUSTRALIA, TOO**
- \* **QRX LISTS ON US OTCQX**
- \* **BIO-MELBOURNE: LEVERAGE EARLY RESULTS FOR MARKET SUCCESS**
- \* **LABTECH, INVETECH, BIOMERIEUX TO DISCUSS AUTOMATIC TESTING**
- \* **FEDERAL GOVERNMENT DEVELOPS PATENT, TRADE MARK ATTORNEYS**

## MARKET REPORT

The Australian stock market fell 1.3 percent on Tuesday July 1, 2008 with the All Ordinaries down 71.8 points to 5,261.1 points.

Twenty of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and two were untraded.

Phylogica was best, up 3.9 cents or 48.15 percent to 12 cents on moderate volumes, followed by Novogen up 20 cents or 17.24 percent to \$1.36 on small volumes, Clinuvel up 11.29 percent to 34.5 cents and Starpharma up 10.91 percent to 30.5 cents.

Polartechncis climbed eight percent; Chemgenex was up 7.14 percent; Genetic Technologies, Living Cell and Resmed were up more than six percent; Cathrx, Labtech and Phosphagenics all climbed five percent; Neuren was up 4.55 percent; Universal Biosensors put on 3.53 percent; Acrux, Agenix, Benitec and Biota rose more than two percent; with Bionomics up 1.47 percent.

Ventracor led the falls, down two cents or eight percent to 23 cents, followed by Progen down 7.97 percent to \$1.27. Impedimed and Psivida lost more than five percent; Optiscan shed 2.13 percent; with Antisense, Cellestis and Mesoblast down more than one percent.

## BIOTECH DAILY TOP 40 INDEX

While it is hard to find much positive to say about any sector, the Biotech Daily Top 20 Index (BDI-20) outperformed the All Ordinaries in June falling 6.4 percent compared to the ASX's top 500 companies falling 7.6 percent.

The Second 20 fell 13.2 percent, contributing to the overall Biotech Daily Top 40 Index (BDI-40) loss of 8.4 percent for the month.

For the financial year to June 30, 2008 the BDI-40 was down 39.2 percent compared to the All Ordinaries' 15.5 percent fall.

The three Big Caps of Cochlear, CSL and Resmed, which are not included in the BDI-40, fell a collective 11.4 percent for the month, with CSL recording its first monthly fall since January 2008, down \$2,257 million or 10.3 percent to \$19.7 billion. Cochlear lost 19.4 percent to \$2,428, while Resmed lost 11.5 percent to \$3148 million. For the year to June 30, the Big Caps were up 7.3 percent, all due to CSL alone.

Ten of the BDI-40 stocks were up, 28 fell with two unchanged for the month of June.

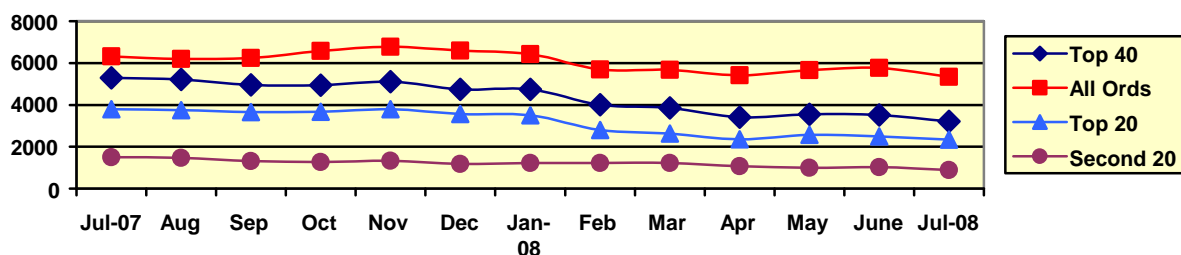
Chemgenex was best up 29.6 percent to a market capitalization of \$210 million followed by Acrux up 29.3 percent to \$194 million, followed by Mesoblast up 25.3 percent to \$109 million. Impedimed climbed 12 percent with Avexa up 10.5 percent for the month.

Thirteen companies fell by more than 20 percent, with Portland Orthopaedic the worst, down 57.1 percent for the month to a market capitalization of \$3 million, down 94 percent for the year. Agenix lost 52.9 percent to \$16 million, Psivida lost 49.5 percent to \$50 million, Cytopia was down 32 percent to \$17 million, with Ventracor down 27.9 percent to \$75 million, a 68 percent fall for the year.

Changes to the Top 40 this month are led by the promotion of Mesoblast to the Top 20 at the expense of Ventracor, which will go to the Second 20. It is with great reluctance that Biotech Daily demotes a company with a heart pump that works and is in phase III trials, but Ventracor is underperforming. That chief executive officer Peter Crosby was paid \$2.45 million according to the company's 2007 annual report is hard to overlook.

Portland Orthopaedics and Tissue Therapies have fallen dramatically over the year and will be replaced in the Second 20 by Labtech and Viralytics. Neuren has only just retained its place in the Top 20 as has Phylogica in the Second 20.

Biotech Daily Top 40 (\$m) v ASX All Ordinaries 2007-08



## CHEMGENEX

Chemgenex has submitted the non-clinical section of its rolling submission for a new drug application for omacetaxine mepesuccinate to the US Food and Drug Administration. Chemgenex's chief executive officer Dr Greg Collier said the non-clinical section of the NDA was the first of three parts necessary to complete the submission of omacetaxine (formerly known as Ceflatonin).

Dr Collier said it brought the company "one step closer to commercialization".

The next submission will be the chemistry and manufacturing controls section due in the first half of 2009, followed by the clinical section, which the company plans to submit to complete the filing in mid-2009.

"This is a significant milestone for the company and it follows the presentation of positive clinical data for omacetaxine at international conferences and the acquisition of global [intellectual property] and European commercialization rights from Stragen Pharma over the past month," Dr Collier said.

The FDA has granted fast track designation for omacetaxine for chronic myeloid leukemia patients who had failed treatment with imatinib mesylate (Gleevec) and have the T315I Bcr-Abl point mutation. No approved therapy has been efficacious for these patients. Chemgenex said the fast track program expedited the review of drugs that treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The rolling submission process enables companies to submit sections of the NDA as they become available, allowing the review to begin before the complete dossier has been submitted.

Chemgenex climbed to \$1.25 before closing up eight cents or 7.14 percent at \$1.20.

## UNILIFE MEDICAL SOLUTIONS

Sanofi-Aventis will pay Unilife Medical Solutions a licence fee of \$16.4 million (EUR10 million) for rights to the Unilife Ready-to-Fill Syringe for five years.

Payment is expected by July 31, 2008.

The prefilled safety syringe has automatic, user-controlled needle retraction features to help protect those at risk of needle-stick injury.

All safety features for the RTFS are fully integrated into the device.

Unilife said the parties agreed to negotiate in good faith to finalize an industrialisation agreement between Unilife and Sanofi Winthrop Industrie to be signed by December 31, 2008.

Sanofi Winthrop Industrie will bear the industrialisation costs for the product estimated by Unilife to be approximately \$24-\$27 million (EUR15-17 million) upon the achievement of key milestones scheduled to occur between July 1, 2008 and the end of 2011.

The parties have agreed that Sanofi Winthrop Industrie will make the initial payment toward the industrialisation agreement of \$2.45 million (€1.5 million) upon completion of certain milestones by September 30, 2008, separate from the \$16.4 million licence fee.

Unilife is responsible for expanding pilot production of the syringe at its US subsidiary Integrated Biosciences to support the supply of an initial one million units to Sanofi-Aventis at a price to be agreed by both parties.

Unilife commenced pilot production of the Ready-to-Fill Syringe at its US facility earlier this year, to support the completion of product evaluation activities by Sanofi-Aventis.

Unilife is reviewing a number of opportunities to increase production of the RTFS up to, and beyond, 400 million units per year with commercial supply to Sanofi-Aventis expected to begin by the end of 2011.

Unilife fell seven cents or 15.22 percent to 39 cents with 5.5 million shares traded.

## RESMED

Resmed says it won't comment on reports in The (Melbourne) Age and Australian Financial Review.

Resmed said The Age reported the company was "being stalked by German industrial and medical gases giant the Linde Group" and quoted the Australian Financial Review saying there were "rumors of an agreed cash bid" under the headline 'Sceptics doubt Resmed rumour'.

Resmed told the ASX that it was not aware of any information that would require disclosure to the ASX in terms of listing rule 3.1.

"Further, the company has a policy of not commenting on market rumors," Resmed said. Resmed climbed 25 cents or 6.89 percent to \$3.88.

## VICTORIAN GOVERNMENT

The Victorian Government says the \$7 million Monash Micro-Nanophysics Research Laboratory will help to improve the effectiveness of drug treatments.

Innovation Minister Gavin Jennings said the nanotechnology research facility would develop "breakthrough drug delivery systems which will assist in the treatment of conditions like diabetes".

A Victorian Government spokesman told Biotech Daily the \$7 million investment in the laboratory comprised 60 percent from the Federal Government, 15 percent from private investment, 15 percent from Monash University and 10 percent from the Victorian Government through Nanovic.

The Commonwealth Scientific and Industrial Research Organisation, Minifab, the Small Technologies Cluster and Nanovic have also provided in-kind support through consultation services.

"The Laboratory is a joint-venture between the Monash Medical and Engineering Faculties to develop new nano-engineered materials and devices for therapeutic applications," Mr Jennings said.

He said it was working on a pulmonary drug delivery project to allow inhalation of drug, vaccine and hormone treatments, initially for the treatment of diabetes.

Mr Jennings said the micro-nano-lab was developing "a fast, safe, pain-free and cost effective method of treating diseases using Victoria's growing strengths in nanotechnology".

"Since 1999, the Victorian Government has invested over \$2 billion into science, technology and innovation, including over \$250 million in nanotechnology and related activities," Mr Jennings said.

"The Brumby Government is taking action on innovation and is the first Australian Government to create a strategic framework for the development of this revolutionary technology, the 2008 Victorian Nanotechnology Statement," Mr Jennings said.

"As part of our support for nanotechnology we provided \$12 million to establish Nanotechnology Victoria (Nanovic) to drive proof of concept and commercialization initiatives.

"Nanovic has helped fund the micro-nano-lab, while one of its commercial arms, Interstitial NS, is now working with investors and pharmaceutical companies to take this technology to full commercialisation.

"The actual delivery device, developed with support from the Brumby Government's Design Victoria Strategy and Business Immersions program, is also a breakthrough product in its own right," Mr Jennings said.

## RESONANCE HEALTH

With its first British reimbursement agreement Resonance Health has asked the Australian Medical Services Advisory Committee for reimbursement for Ferriscan in Australia.

Resonance said that the Whittington Hospital in London had achieved funding approval from the UK National Health Service for Ferriscan, enabling the clinicians to use the equipment in the routine clinical care of patients with iron overload.

The company said there were more than 15,000 people suffering from sickle cell disease, thalassemia major or myelodysplastic syndromes in the UK.

Many of these patients require regular blood transfusions in the management of their disease and suffer from iron overload as a result.

The company said that patients at the Whittington Hospital would have access to “a cost effective, non-invasive and accurate measurement of their liver iron loading” enabling their clinicians to optimize the management of their treatment.

Resonance said it was “an important acknowledgement of the clinical importance of Ferriscan and a significant revenue opportunity”.

Consultant haematologist at the Whittington Hospital Dr Farrukh Shah said that having access to Ferriscan would “greatly improve the efficiency of monitoring the body iron burden in our iron-loaded patients in a cost effective manner and will enable us to minimize the use of liver biopsy”.

Resonance Health is working with other hospitals in the UK to achieve similar funding success, enabling Ferriscan to be more widely available across Britain.

Reimbursement continues to be a key area of focus for Resonance Health and an important step in the commercialization of the test, the company said.

Resonance was up 0.1 cents or 10 percent to 1.1 cents.

## QRX PHARMA

QRX Pharma has initiated a Level 1 American depository receipt program and has been listed on the US International over-the-counter exchange (OTCQX).

QRX's American depository receipts began trading yesterday, June 30 on the International PrimeQX under the ticker QRXPY.

The International OTCQX is an electronic trading, quotation and disclosure venue to the US over-the-counter market.

QRX said it provided issuers with a platform on which to list securities “and access some of the deepest pools of liquidity in the world”.

The company said its ADR program listing on the International OTCQX would enable its shares to be more accessible to US institutions and private investors, including those permitted to buy only US-based securities.

QRX chief executive officer Dr John Holaday said that as the company prepared to initiate final phase III studies of its lead dual-opioid product candidate, Q8003IR, for new drug application submission to the US Food and Drug Administration in 2009, “we are working proactively to diversify and extend our shareholder base”.

“With the company achieving its critical development milestones as projected and reporting positive clinical data to date, this initiative is part of a broad strategy to maximize value, provide access to US investors and increase international liquidity,” Dr Holaday said.

US investment bank Merriman Curhan Ford will be QRX Pharma's principal American liaison on the International OTCQX, responsible for providing guidance on listing requirements.

QRX was up four cents or 6.78 percent to 63 cents.



## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says companies need product and development strategies that will attract expansion, investors and licencing partners.

The Network said its July 15, 2008 Bio-Breakfast, sponsored by Kendle Australia, will provide an overview of market entry and clinical strategic planning.

The industry organization said executives need to plan late phase clinical development and market entry programs, to maximize commercial success.

Kendle Australia's director of regulatory development and commercialization Judy Bingham and Acrux's director of clinical development Dr Tina Soulis will examine market entry strategies, product competitiveness, interpretation of early phase data in the design of a phase III trial program and how to plan for a phase III trial including countries, sites, budgets and product processes.

For more information visit: [www.biomelbourne.org](http://www.biomelbourne.org), call Nicole Pitcher +613 9650 8800 or email: [npitcher@biomelbourne.org](mailto:npitcher@biomelbourne.org) by July 9 2008.

## LABTECH, INVETECH, BIOMERIEUX

Labtech Systems, Invetech and Biomerieux will discuss the automation of sample testing in association with the Australian Society of Microbiology conference.

A Biomerieux media release said automated testing of human, food and veterinary samples would make testing "faster, more reliable, cheaper and frees up staff from routine, often boring, tasks for other activities, reducing staff attrition".

A seminar on the subject will be held at the Melbourne Exhibition Centre on July 7 from 10:30am followed by a lunch.

Speakers include Labtech chief executive officer Dr Lusia Guthrie, the chief scientist at South Australia's Institute of Medical and Veterinary Science Dr John Glasson who developed Labtech's automated Microstreak system for streaking agar plates. Microstreak was commercialized by Labtech, built by Invetech and is being marketed by Biomérieux. Invetech's chief executive officer Fred Davis and Biomerieux's Australian CEO Paul Wilson will also present at the seminar chaired by the director of microbiology at Melbourne Pathology Dr Rob Baird

The media release said more than six billion agar plates used for a range of diagnostic purposes were processed manually every year around the world.

The Australian Society of Microbiology conference will be in Melbourne, July 7-10, 2008.

## FEDERAL GOVERNMENT

The Minister for Innovation, Industry, Science and Research Senator Kim Carr has announced significant changes to the way patent and trade mark attorneys operate.

A Federal Government media release said new regulations change the pre-registration requirements for patent attorneys with a focus on a more skills-based approach, resulting in attorneys being better placed to provide high-quality assistance.

Registered patent and trade marks attorneys will need to undertake compulsory continuing professional development activities each year to ensure they remain skilled to provide the best intellectual property advice to Australian innovators.

Senator Carr said it was "important that innovators have access to professional services which keep pace with these changes. Continuing professional development is essential".

For more details go to the Professional Standards Board website [www.psb.gov.au](http://www.psb.gov.au) or IP Australia's Smart Start website [www.smartstart.gov.au](http://www.smartstart.gov.au).

Labtech climbed one cent or five percent to 21 cents.

## BIOTECH DAILY TOP 40 WITH MARKET CAP

<b>Big Caps \$Am</b>	<b>Jul-08</b>	<b>Jun-08</b>	<b>May-08</b>
Cochlear	2,428	3,014	3,154
CSL	19,649	21,906	21,900
Resmed	2,787	3,148	3,524
<b>Top 20</b>			
Acrux	194	150	132
Alchemia	48	56	69
Arana	260	241	249
Avexa	126	114	118
Bionomics	80	85	85
Biota	139	182	193
Chemgenex	210	162	178
Cellestis	235	248	237
Cytopia	17	25	25
Living Cell	58	74	69
Neuren	24	22	26
Novogen	113	154	162
Peplin	66	68	87
Pharmaxis	296	338	317
Phosphagenics	66	83	106
Progen	83	82	91
Proteome	27	29	30
Sirtex	167	217	209
Starpharma	49	59	61
Ventracor	75	104	119
<b>Second 20</b>			
Agenix	16	34	42
Antisense	42	39	42
Benitec	22	25	27
Cathrx	34	43	53
Circadian	35	39	38
Clinuvel	94	121	126
Genetic Tech	33	38	36
Heartware	99	124	89
Impedimed	56	50	59
Mesoblast	109	87	88
Optiscan	27	26	26
Phylogica	12	13	13
Polartechnics	30	35	53
Portland Ortho	3	7	9
Prana	85	87	82
Psivida	50	99	73
Stem Cell Sci	9	11	11
Sunshine Heart	15	15	16
Tissue Therapies	3	3	5
Universal Biosensors	110	123	104

\* Biotech Daily editor, David Langsam, owns shares in Alchemia, Biota, Chemgenex and Stem Cell as well as non-biotechnology stocks. These are liable to change at any time.

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