



# Biotech Daily

Monday February 3, 2014

*Daily news on ASX-listed biotechnology companies*

- \* JANUARY BDI-40 UP 6%, ASX200 DOWN 3%, BIG CAPS UP 1%  
- PRANA UP 50%, BENITEC UP 39%, ELLEX UP 34%, ATCOR DOWN 19%
- \* TODAY: ASX, BIOTECH DOWN: TISSUE THERA UP 7%, CLINUVEL DOWN 8%
- \* ADMEDUS, CORIDON: 'INTERIM PHASE I HSV-2 VACCINE SAFE, EFFICACY'
- \* WEHI: 'B-CELL ELIMINATION COULD LEAD TO LYMPHOMA TEST'
- \* BIONOMICS BNC105 OVARIAN CANCER PHASE I IDENTIFIES DOSE
- \* CAPITAL GROUP TAKES 7% OF MESOBLAST
- \* GERMAN INSURANCE CODE FOR GI DYNAMICS ENDOBARRIER
- \* VICTORIA PREMIER'S AWARD FOR HEALTH AND MEDICAL RESEARCH
- \* PRANA PLEADS SCHULTZ, PRESENTATIONS TO ASX 19% QUERY
- \* ISONEA REQUESTS MORE BOARD CHANGES TRADING HALT
- \* NOVOGEN APPOINTS DR JUSTINE STEHN, PROF PETER GUNNING
- \* BLUECHIIP APPOINTS EX-QBF MATTHEW MORGAN DIRECTOR

## MARKET REPORT

The Australian stock market slipped 0.04 percent on Monday February 3, 2014 with the S&P ASX 200 down 2.1 points to 5,187.9 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and two were untraded. All three Big Caps fell.

Tissue Therapies was the best, up two cents or 6.9 percent to 31 cents with 78,930 shares traded. Antisense and Prana climbed four percent or more; Avita, Ellex and Medical Developments were up more than three percent; Benitec, Mesoblast and Viralytics rose more than two percent; with QRX up 1.8 percent.

Clinuvel led the falls, down 11.5 cents or 8.1 percent to \$1.30 with 76,727 shares traded. Prima lost six percent; Starpharma fell five percent; Patrys and Reva fell more than four percent; Atcor, Bionomics, Genetic Technologies, GI Dynamics, Oncosil and Uscom were down more than three percent; Circadian, IDT and Neuren shed two percent or more; Living Cell and Nanosonics were down more than one percent; with Alchemia, Cochlear, CSL, Psivida and Resmed down by less than one percent.

### BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) continued to outstrip the S&P ASX200 in January, up 5.8 percent compared to the benchmark index down 3.0 percent.

While the raw BDI-40 index (which includes the September departure of the \$1,365 million Heartware) is down 2.3 percent for the year to January 31, 2014, the cumulative value of the 40 companies currently comprising the index was up 20.2 percent, compared to the ASX200 up 6.4 percent. Calculating the BDI-40 using similar methodology to the S&P indices, the BDI-40 is up 24.1 percent for the 12-month period (see charts below).

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a collective 0.9 percent, with CSL up 2.6 percent to \$34,306 million, Cochlear down 2.1 percent to \$3,292 million and Resmed down 5.7 percent to \$7,103 million.

Twenty-two of the BDI-40 companies were up (12 by more than 10%), with 14 companies down (five by more than 10%) and four unchanged.

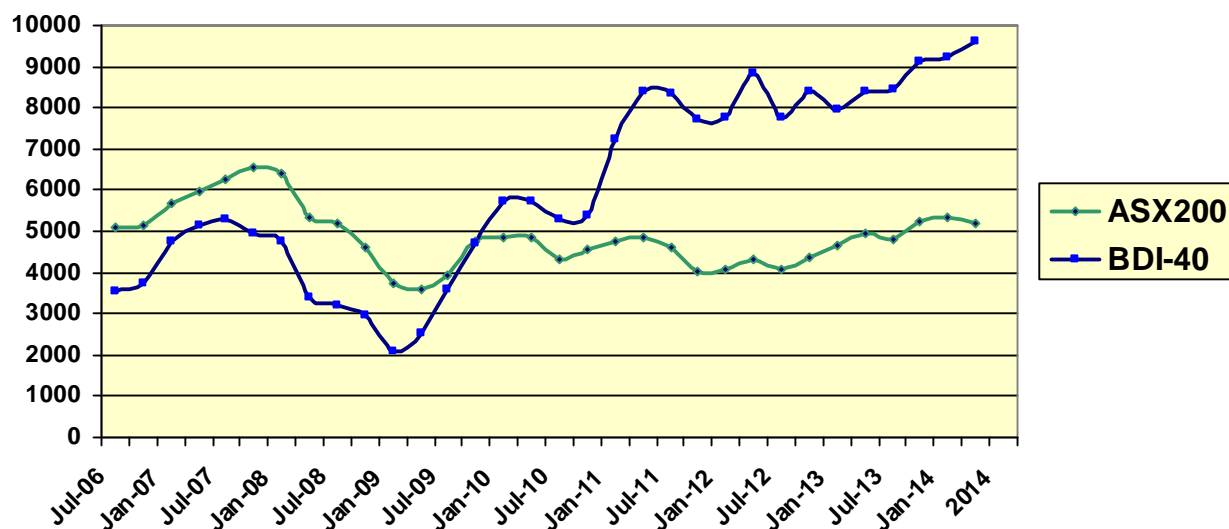
Prana was January's best, up \$160 million or 49.8 percent to \$481 million and up 568.1 percent from its \$72 million market cap 12 months ago, primarily on US presentations by executive chairman Geoffrey Kempler.

Benitec was up 38.8 percent to \$68 million on the start of its hepatitis C trial, followed by Ellex (34.3%), Clinuvel (27.8%), Pharmaxis (25.0%), Psivida (23.8%), Prima (22.9%), Sirtex (18.5%), Genetic Technologies (16.1%), Anteo (13.1%) and QRX (13.1%).

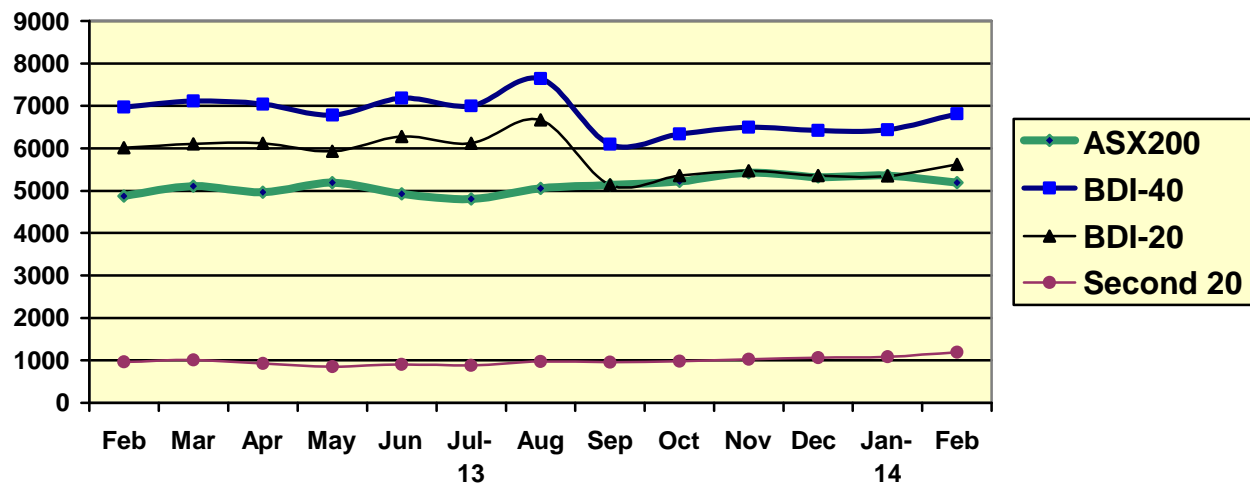
Atcor led the January falls, retreating 18.5 percent to \$22 million, followed by Antisense (13.6%), Patrys (11.8%), Neuren (11.6%) and Reva (10.0%).

Outside the BDI-40, Phylogica's December capital raising took it up 130 percent to \$23 million and Progen improved 114.2 percent to \$30 million. On the Nasdaq, Biota was up 21.8 percent to \$162 million, Heartware climbed 7.6 percent to \$1,865 million and Sunshine Heart was up 4.4 percent to \$191 million.

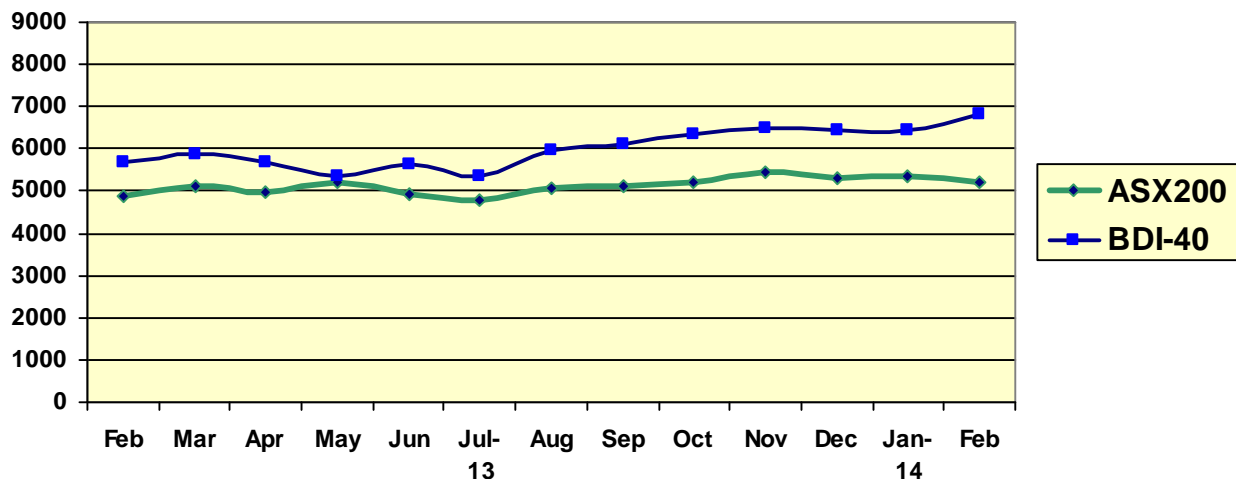
### **BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2014 - Adjusted**



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



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



### [ADMEDUS \(FORMERLY ALLIED HEALTH\)](#)

Admedus says 54 percent subsidiary Coridon's interim phase I trial results show its therapeutic vaccine for herpes simplex virus-2 is safe and generates a T-cell response. Admedus said that dosing of 20 patients was completed in December 2013 and a full data analysis was expected later in 2014 (BD: Sep 3, Oct 17, 2013).

Admedus chief executive officer Lee Rodne said the interim data was "an encouraging result for the core vaccine technology and provides us with the basis for not only progressing the herpes therapeutic vaccine program, but also preparing the human papillomavirus vaccine for initial clinical studies as a therapeutic against [human papillomavirus vaccine] and cervical cancer".

Admedus said the technology was based on work by Coridon's Prof Ian Frazer and his team to stimulate an immune response to enable a patient to fight diseases.

"The results are very encouraging and we believe we should progress these programs forward," Prof Frazer said. "Once we complete our analysis the team will be looking to take this program into a second clinical study in patients infected with the herpes virus."

Admedus said that there was no cure for herpes simplex virus-2 and its incidence was high with one in six people in the US between the age of 14 and 49 with the infection.

Admedus was unchanged at 16 cents with 17.95 million shares traded.

## THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the immune system's elimination of immune B-cells in their early stages could lead to a diagnostic for B-cell lymphomas.

The Institute said that immune B-cells underwent spontaneous changes on a daily basis that could lead to B-cell lymphomas, also known as non-Hodgkin's lymphomas, but surveillance by T-cells enabled early detection and elimination of the cancerous and pre-cancerous cells.

WEHI said that the T-cell immune surveillance accounted for what its researchers described as the "surprising rarity" of B-cell lymphomas in the population, given how often these spontaneous changes occur.

The Institute said that the discovery could lead to the development of an early-warning test that identified patients at high risk of developing B-cell lymphomas, enabling proactive treatment to prevent tumors from growing.

The Institute said that Prof David Tarlinton, Dr Axel Kallies, Dr Stephen Nutt and colleagues made the discovery while investigating the development of B-cell lymphomas and how B-cells changed when lymphoma developed.

Dr Kallies said the discovery provided an answer to why B-cell lymphomas occurred in the population less frequently than expected.

"Each and every one of us has spontaneous mutations in our immune B-cells that occur as a result of their normal function," Dr Kallies said.

"It is then somewhat of a paradox that B-cell lymphoma is not more common in the population," Dr Kallies said.

"Our finding that immune surveillance by T-cells enables early detection and elimination of these cancerous and pre-cancerous cells provides an answer to this puzzle, and proves that immune surveillance is essential to preventing the development of this blood cancer," Dr Kallies said.

WEHI said that B-cell lymphoma was the most common blood cancer in Australia, with about 2,800 people diagnosed each year and patients with a weakened immune system were at a higher risk of developing the disease.

"As part of the research, we disabled the T-cells [in mice] to suppress the immune system and, to our surprise, found that lymphoma developed in a matter of weeks, where it would normally take years," Dr Kallies said.

"It seems that our immune system is better equipped than we imagined to identify and eliminate cancerous B-cells, a process that is driven by the immune T-cells in our body," Dr Kallies said.

Prof Tarlinton said the research would enable scientists to identify pre-cancerous cells in the initial stages of their development, enabling early intervention for patients at risk of developing B-cell lymphoma.

"In the majority of patients, the first sign that something is wrong is finding an established tumor, which in many cases is difficult to treat," Prof Tarlinton said.

"Now that we know B-cell lymphoma is suppressed by the immune system, we could use this information to develop a diagnostic test that identifies people in early stages of this disease, before tumors develop and they progress to cancer," Prof Tarlinton said.

There are already therapies that could remove these aberrant B-cells in at-risk patients, so once a test is developed it can be rapidly moved towards clinical use," Prof Tarlinton said.

The research, entitled 'Fas ligand-mediated immune surveillance by T cells is essential for the control of spontaneous B cell lymphomas', was published in Nature Medicine and an abstract is at: <http://www.nature.com/nm/journal/vaop/ncurrent/full/nm.3442.html>.

## BIONOMICS

Bionomics says 10 of 15 patients in its phase I trial of BNC105 for ovarian cancer had “a positive response” as measured by standard criteria.

Bionomics said the patients were treated with escalating doses of BNC105 in combination with the current standard therapy of carboplatin and two doses of gemcitabine.

The company said that the phase I trial endpoint was to determine the recommended dose and 12mg per square metre was identified as the for the 110-patient phase II trial.

Bionomics said that biomarker analyses of blood samples taken within four hours of administration of BNC105 demonstrated that the 12mg dose induced a pharmacodynamic response indicative of BNC105 activity.

The company said that the same biomarkers had been observed in association with BNC105 activity in previous clinical trials.

Bionomics said one patient had completed the protocol-prescribed 12 cycles of treatment comprised of six cycles of combination therapy and six cycles of BNC105 monotherapy, the patient had clinical benefit and continued on BNC105 as a monotherapy.

Bionomics said that 12 of the 15 patients completed six cycles of combination therapy and began BNC105 monotherapy and three patients were continuing with treatment.

The company said that the mean number of treatment cycles across the study so far was 8.8 cycles, with each cycle of treatment representing three weeks.

Bionomics chief executive officer Dr Deborah Rathjen said that the phase I trial was “very positive reinforcement of what we have come to expect for BNC105”.

“Ovarian cancer is the fifth leading cause of cancer-related deaths in women and we are extremely grateful to the patients who participated in this study,” Dr Rathjen said.

“The market for drugs to treat ovarian cancer is valued at over \$2 billion per annum and there remains significant unmet need for effective treatments,” Dr Rathjen said.

“With these results we anticipate that we will be able advance our partnering strategy for BNC105,” Dr Rathjen said.

Bionomics chief medical officer Dr José Iglesias said that “Some adverse effects were witnessed in patients, but these were of haematological origin consistent with the backbone of the carboplatin and gemcitabine drug combination”.

The head of medical oncology at Melbourne’s Peter MacCallum Cancer Centre and principal investigator Dr Danny Rischin said the results “support continued development of BNC105 in the ovarian cancer setting to further investigate the potential of BNC105 as a new drug that may have a clinically significant impact”.

Bionomics said that in 2013 about 22,240 new cases of ovarian cancer were diagnosed in the US and about 14,000 women would die of the disease.

The company said that ovarian cancer was often diagnosed at an advanced stage after the cancer had spread and despite some improvements in patient outcomes the majority of patients relapse after surgery and chemotherapy and die from their disease.

Bionomics said the trials were being conducted at six sites in Australia, New Zealand and the US.

Bionomics fell 2.5 cents or 3.5 percent to 69.5 cents.

## MESOBLAST

The Los Angeles, California-based Capital Group Companies has increased its substantial holding in Mesoblast from 18,116,901 shares (5.64%) to 21,466,599 shares (6.683%).

Capital Group said that between January 8 and 30, 2014, it bought 3,349,698 shares at an average price of \$5.8943 a share.

Mesoblast was up 13 cents or 2.2 percent to \$6.01 with 875,797 shares traded.

## GI DYNAMICS

GI Dynamics says the German Institute for the Hospital Remuneration System has assigned its Endobarrier Neue Untersuchungs und Behandlungsmethoden status 1. GI Dynamics said the process was intended to introduce medical products prior to reimbursement and was the preferred way to bring the procedure cost of a treatment, such as Endobarrier for obesity and type II diabetes to German reimbursement. The company said status 1 was the highest level available and entitled participating hospitals to negotiate with insurance companies for additional funding for procedures. GI Dynamics said that when the negotiation was completed, a hospital would be authorized to perform an agreed number of procedures in that year, valid for one year and hospitals needed to reapply, with subsequent status historically granted for multiple years. GI Dynamics chief executive officer Stuart Randle said the decision was "significant step forward in our national reimbursement efforts in Germany". GI Dynamics fell three cents or 3.7 percent to 79 cents.

## VICTORIA GOVERNMENT

Victoria Premier Denis Napthine says applications are open for the 2014 Premier's Award for Health and Medical Research.

A media release from Mr Napthine said the award would celebrating its twentieth year of recognizing exceptional achievements of Victoria's early career medical researchers.

"Early career researchers bring new ideas and a fresh approach that will make a vital contribution to the livelihood of media research in Victoria," Dr Napthine said.

"Victoria has an outstanding reputation for our depth of knowledge in medical research and we must continue to acknowledge the young and talented individuals that will change the lives of so many," Dr Napthine said.

The media release said award was worth \$40,000, with the winner receiving \$16,000, and the three commendees \$8,000 to further their post-graduate research studies.

Dr Napthine said the Victoria Government was committed to supporting the future of health and medical research.

"Since its inception by the Kennett Government in 1995, the Premier's Award has honored more than 70 individuals across a variety of fields including public health, health services, and clinical research," Dr Napthine said.

"It is essential that we continue to foster the ambition and drive of these emerging leaders," Dr Napthine said.

Applications close on March 14, 2104 with the winners announced in the middle of the year. For more information go to [www.business.vic.gov.au/premiersaward](http://www.business.vic.gov.au/premiersaward).

## PRANA BIOTECHNOLOGY

Prana has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 19.1 percent from \$1.15 on January 30 to \$1.37 on January 31, 2014 and noted an increase in trading volume.

Prana said it lodged a presentation with the ASX on January 22, 2014, associated with a US roadshow, which referred to the results of clinical trials for Alzheimer's disease and Huntingdon's disease with final results due in March 2014 and early 2014, respectively.

Prana was up 5.5 cents or 4.4 percent to \$1.305 with 1.4 million shares traded.



## ISONEA

Isona has requested a trading halt pending the release of “an announcement to the market in relation to board changes”.

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

Isona recently announced the departure of chief executive officer Michael Thomas followed by the resignation of chairman Dr Stewart Washer, with Ross Haghighat promoted to chairman, director Jerry Korten appointed chief executive officer and Dr Tim Oldham appointed as a director (BD: Nov 13, 2013; Jan 19, 2014).

In September 2013, Investment Holdings, an entity owned by gambling machine operator Bruce Mathieson held 48,000,000 shares or 18.59 percent (BD: Sep 23, 2013).

Isona last traded at 32 cents.

## NOVOGEN

Novogen says it has appointed Dr Justine Stehn as the director of its anti-tropomyosin program and Prof Peter Gunning to its scientific advisory panel.

Novogen said that Dr Stehn and Prof Gunning were the co-inventors of the anti-tropomyosin drug technology platform it acquired in 2013 and that anti-tropomyosins were “a safer and more effective alternative to taxane chemotherapy”.

Prof Gunning is the associate dean of research in the Faculty of Medicine at the University of New South Wales and holds a Bachelor of Science degree and Doctorate of Philosophy from Monash University.

The company said that Prof Gunning had published more than 140 research papers, and his research focused on diseases of childhood, primarily cancer and muscle damage.

Novogen Prof Gunning’s research group discovered that tropomyosins were used to specify the spatial and temporal properties of the cell cytoskeleton in all cells of the body. Novogen said that Dr Stehn was drug development coordinator and group leader of the anti-tropomyosin drug development group in Prof Gunning’s Oncology Research Unit at the University of New South Wales.

The company said that Dr Stehn received her Doctorate of philosophy from the Garvan Institute of Medical Research.

Novogen fell half a cent or 2.6 percent to 19 cents.

## BLUECHIIP

Bluechiip says it has appointed former Queensland Biotechnology Fund investment manager Matthew Morgan as a non-executive director.

Bluechiip said that Mr Morgan was currently the principal of advisory company Millers Point Co, which works with emerging companies to implement growth programs.

The company said that Mr Morgan had six years experience investing venture capital funds and seven years in executive operating roles for private equity-funded companies.

Bluechiip said that Mr Morgan had experience investing in, developing and commercializing new products and services, was a non-executive director of Diversa, was formerly Integra Healthcare’s head of business development and QBF’s senior investment manager.

The company said that Mr Morgan held a Bachelor of Commerce degree from Griffith University and a Bachelor of Applied Sciences and a Masters of Business Administration from Queensland University of Technology.

Bluechiip was up 0.8 cents or 13.3 percent to 6.8 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

| Company \$Am         | Feb-13 | Jan-14 | Feb-14 |
|----------------------|--------|--------|--------|
| Cochlear             | 4,604  | 3,362  | 3,292  |
| CSL                  | 27,371 | 33,423 | 34,306 |
| Resmed               | 6,505  | 7,529  | 7,103  |
| <b>BDI-20</b>        |        |        |        |
| Acrux                | 574    | 426    | 391    |
| Alchemia             | 93     | 185    | 191    |
| Admedus              | 24     | 195    | 207    |
| Benitec              | 16     | 49     | 68     |
| Bionomics            | 146    | 311    | 300    |
| Clinuvel             | 83     | 36     | 46     |
| Impedimed            | 19     | 44     | 40     |
| Mesoblast            | 1,717  | 1,879  | 1,863  |
| Nanosonics           | 137    | 221    | 239    |
| Neuren               | 41     | 172    | 152    |
| Osprey               | 70     | 84     | 82     |
| Pharmaxis            | 210    | 32     | 40     |
| Prana                | 72     | 321    | 481    |
| Prima                | 112    | 48     | 59     |
| Psivida              | 33     | 122    | 151    |
| Reva                 | 152    | 160    | 144    |
| Sirtex               | 674    | 658    | 780    |
| Starpharma           | 356    | 246    | 223    |
| Tissue Therapies     | 50     | 80     | 76     |
| Universal Biosensors | 151    | 81     | 87     |
| <b>Second 20</b>     |        |        |        |
| Anteo                | 49     | 130    | 147    |
| Antisense            | 20     | 22     | 19     |
| Atcor                | 13     | 27     | 22     |
| Avita                | 41     | 44     | 44     |
| Cellmid              | 11     | 21     | 23     |
| Circadian            | 16     | 10     | 10     |
| Compumedics          | 12     | 14     | 13     |
| Ellex                | 14     | 35     | 47     |
| Genetic Technologies | 38     | 31     | 36     |
| GI Dynamics          | 221    | 300    | 328    |
| IDT                  | 11     | 28     | 30     |
| Living Cell          | 17     | 28     | 30     |
| Medical Developments | 113    | 67     | 63     |
| Oncosil              | 3      | 45     | 47     |
| Optiscan             | 17     | 9      | 10     |
| Patrys               | 18     | 34     | 30     |
| Phosphagenics        | 148    | 117    | 117    |
| QRX Pharma           | 145    | 122    | 138    |
| Uscom                | 13     | 11     | 11     |
| Viralytics           | 25     | 26     | 27     |

\* 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](mailto:editor@biotechdaily.com.au); [www.biotechdaily.com.au](http://www.biotechdaily.com.au); twitter: @biotech\_daily**