

Biotech Daily

Friday February 1, 2019

Daily news on ASX-listed biotechnology companies

- * ASX EVEN, BIOTECH UP: PATRYS UP 9%; PRANA DOWN 9.5%
- * JANUARY BDI-40 UP 10%, ASX200 UP 4%, BIG CAPS UP 1%, NBI UP 13%
- * DR BOREHAM'S CRUCIBLE: RESMED
- * NEUREN: ACADIA ROW OFFER 'NOT IN SHAREHOLDERS INTERESTS'
- * GENETIC TECHNOLOGIES, MSK, CAMBRIDGE UNI BREAST CANCER TEST
- * GENERA RIGHTS OFFER FOR \$11.4m
- * MESOBLAST H1 RECEIPTS UP 296% TO \$28.5m
- * THC RECEIPTS UP 61% TO \$2.6m
- * NUHEARA H1 RECEIPTS DOWN 19% TO \$1.4m
- * INVITROCUE HAS ONE QUARTER CASH
- * MGC GROWS 700kg MARIJUANA CROP, MORE THAN 35% THC
- * CARDIEX TAKES 41% OF INHEALTH
- * E-SENSE LAB TO RELEASE 44m ESCROW CDIs
- * CRESO REQUESTS 'SHARE ISSUE, TRANSACTIONS' TRADING HALT
- * REGENEUS CEO LEO LEE STARTS ON \$325k
- * AUSCANN APPOINTS CFO, COO QUENTIN MEGSON JOINT CO SEC
- * CRESO APPOINTS COLOMBIA'S DR RICARDO SALAZAR ADVISOR

MARKET REPORT

The Australian stock market slipped 0.03 percent on Friday February 1, 2019, with the ASX200 down 1.9 points to 5,862.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and two were untraded.

Yesterday's 8.3 percent worst, Patrys, was the best, up 0.2 cents or 9.1 percent to 2.4 cents with 1.7 million shares traded. Orthocell climbed 7.7 percent; Optiscan improved 6.4 percent; Benitec and Prescient were up five percent or more; Pro Medicus was up 4.9 percent; Pharmaxis was up 3.85 percent; Volpara rose 2.8 percent; Actinogen, Cynata, Dimerix, Immutep and Opthea were up more than one percent; with Cochlear, Paradigm, Resmed and Telix up by less than one percent.

Yesterday's 20 percent best, Prana, led the falls, down 0.4 cents or 9.5 percent to 3.8 cents with 422,474 shares traded. Antisense lost 8.9 percent; Osprey and Uscom fell four percent or more; Avita and Neuren were down more than three percent; Polynovo shed 2.2 percent; Clinuvel, Kazia and Medical Developments were down more than one percent; with CSL, Ellex, Mesoblast and Nanosonics down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Summer shone on biotech following a particularly cold Winter and Spring, with the Biotech Daily Top 40 Index (BDI-40) up 9.9 percent in January compared to the ASX200 up 3.9 percent. (See charts below.)

For the year to January 31, the BDI-40 fell 11.9 percent, the ASX200 lost 2.9 percent, the Nasdaq Biotechnology Index (NBI) shed 3.9 percent, but the Big Caps were up 25.5 percent.

The collective three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up 1.2 percent for the month, with Cochlear up 11.4 percent to \$11,163 million, CSL up 5.2 percent to \$88,201 million, but Resmed retreating 17.9 percent to \$18,624 million, following its half-year report.

Twenty-three of the BDI-40 stocks were up, 14 by more than 10 percent and seven by more than 20 percent, while 14 fell with seven losing more than 10 percent.

Clinuvel and Nanosonics returned to the BDI-40 Billion Dollar Club, with Pro Medicus up a further 11.4 percent to \$1,255 million.

Avita was January's best, up \$118 million or 88.1 percent to \$252 million, followed by Antisense (70.0%), Reva (40.3%), Opthea (31.7%), Prana (27.8%), Kazia (26.1%), Actinogen (20.0%), Clinuvel (19.3%), Impedimed (18.1%), Nanosonics (17.6%), Polynovo (14.5%), Paradigm (14.3%), Pro Medicus (11.4%) AND Cynata (10.8%).

Patrys led the falls, down \$5 million or 17.2 percent to \$24 million, followed by Compumedics (15.5%), Uscom (15.0%), Orthocell (14.3%), Medical Developments (14.2%), Ellex (13.1%), LBT (11.1%) and Starpharma (9.3%).

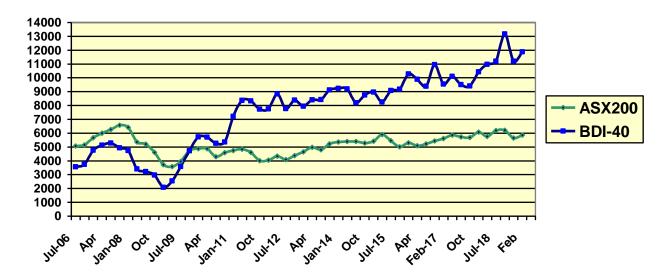
Outside the Top 40, Cardiex and Resonance were at their peak market capitalization for a year or more, up 255.5 percent to \$32 million and 222.2 percent to \$29 million, respectively, with Elixinol Global finally announcing medical uses for its marijuana (along with strong revenue for its hemp seed food additives and other non-medical products), up 19.9 percent to \$373 million.

Unfortunately, there are a number of companies whose market capitalization over the past year indicate that they might want to consider different technologies or perhaps changes to their boards and/or management.

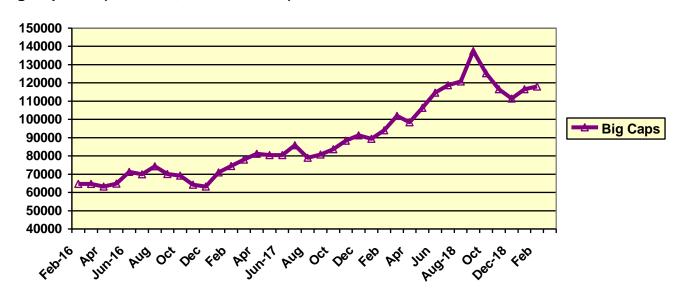
Elixinol provided half of the total increase for the 15 stocks in Cannabis Corner which were up a collective \$122 million or 10.4 percent to \$1,298 million, the highest high in four months.

In the US, the NBI was up 13.4 percent in January, with Israel's Redhill (developing three Australian assets) up 61.2 percent to \$324 million, Brisbane's Protagonist was up 21.6 percent to \$281 million, Eyepoint (formerly Psivida) improved 13.0 percent to \$287 million and Vaxart (formerly Aviragen and Melbourne's Biota) languished at \$20 million, up 5.2 percent.

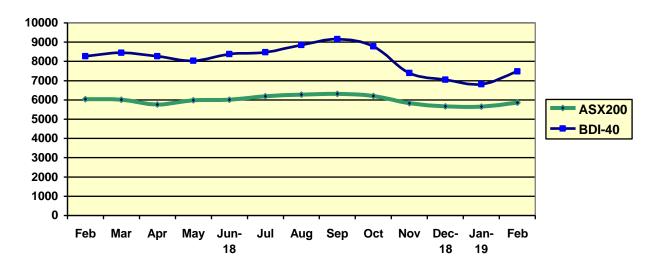
BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2019- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Jan 31, 2016 – Jan 31, 2019



BDI-40 (\$m) v S&P ASX 200 - Jan 31, 2018 - Jan 31, 2019 (current, raw data)



DR BOREHAM'S CRUCIBLE: RESMED

By TIM BOREHAM

ASX and New York Stock Exchange Code: RMD

Share price: \$13.11

Market cap: \$18.7 billion

Shares on issue: 142,494,116 (NYSE), 1,424,941,161 (ASX)

(Ten Chess depository instruments are the equivalent of one NYSE ordinary share)

Financials (December quarter): \$US651 million (up 8%), net income \$US144.5 million (up 0.4%)**, earnings per share \$US1 (steady), dividend per share 37 US cents (steady).

(December half): revenue \$US1,239 million (up 10%), net income \$US260.7 million (up 10%)**, earnings per share \$US1.81 (up 9%), cash balance \$US149 million (down 82%)

** net income is a non-GAAP (US accounting standards) measure excluding amortization on acquired intangibles, acquisition-related items and the impact of US tax reforms.

Chief executive officer: Michael Farrell

Board: Dr Peter Farrell (founder, chairman), Michael Farrell (Peter's son), Carol Burt, Dr Gary Pace, Richard Sulpizio, Ron Taylor, John Wareham, Karen Drexler.

Identifiable major shareholders (US stock): Vanguard 10%, Capital World Investors 8.54%, Black Rock Inc 8.51%, Fidelity Management 6.03%

Company chieftains love to wax lyrical about a "transformational year" in their glossy material, if only for want of something more positive and concrete to say. But in the case of our third-biggest home grown but globalized healthcare outfit, there's more than a kernel of truth about the 2018 year being, well, transformational.

While the San Diego-based Resmed has always been a keen acquirer, in the last nine months it has shelled out \$US1.1 billion for three businesses in the US that stray beyond the company's previous remit of tackling sleep and respiratory disorders.

The acquired operations are all in the broader game of digital health: that is, gathering and analyzing patient data to improve the standard and efficacy of clinical support. They also broaden Resmed's presence in chronic obstructive pulmonary disease (COPD), which is an ever-expanding market as the wheezing populace ages.

While an extension of Resmed's increasing emphasis on cloud-based monitoring of its sleep devices, the purchases also diversify the nature of company at a time when cheaper and more convenient alternatives are emerging to Resmed's continuous positive air pressure (CPAP) masks and pumps.

"The acquisitions are driven by our strategy to be the world leader in digital health for sleep apnoea and COPD and out-of-home software," CEO Mick Farrell says.

CPAPs deliver pressurized air through a nasal mask to prevent obstruction of the upper airway - and thus snoring - during sleep. But many users find them uncomfortable and compliance rates in the past have been low, which hasn't stopped the company from selling in 120 countries with coverage of six million cloud-connected devices.

While Resmed is no spring chicken it's still only lightly penetrating the global market: according to Mr Farrell, 836 million people "suffocate" with sleep apnoea every night. Despite the perception that snoring is largely the claim of fat. Middle-aged men, 40 percent of patients are women.

A sleeper awakes

Resmed's technology is based on the CPAP intellectual property developed by the Baxter Centre for Medical Research and acquired by Resmed founding father Dr Peter Farrell in 1989. Baxter had sold the masks in Australia from 1988.

Up until then, a tracheotomy was the standard treatment for dangerous snoring, which supports the adage that the cure can be worse than the disease.

Incorporated in Delaware (where else?), Resmed was formed as a holding company and admitted to the Nasdaq in June 1995. But in September, Resmed changed its home exchange to the New York Stock Exchange.

Along the way, Resmed has acquired businesses in ventilation devices and diagnostics, dental devices, portable oxygen generators and cloud-based software informatics.

Mick Farrell took over from old man Peter as CEO in 2013, but Dad remains chairman.

Resmed turns Pacman

With Resmed gobbling up so many targets, the investor relations department's mergers and acquisitions announcement template is fast wearing out.

In December, Resmed unveiled the purchase of Propeller Health, a Wisconsin-based asthma and pulmonary health specialist, for \$US225 million. Propeller markets sensors that attach to an asthma inhaler or COPD drug delivery devices and pairs with a mobile application to track medication use (successfully achieving what Adherium had hoped).

In mid-November last year, Resmed completed the \$US750 million purchase of Minnesota's Matrix Care, "a leader in software solutions for more than 15,000 providers across skilled nursing, life plan communities, senior living [retirement homes] and private duty [home based care]".

Matrix Care provides to 13,000 facilities run by 2,500 home and hospital operators.

Early in the September quarter, Resmed closed the \$US126 million acquisition of Healthcarefirst, which provides services to home health and hospice agencies.

A new joint venture with Verily combines Resmed's expertise in sleep apnoea with Verily's advanced health data analytics, to study the financial and health aspects of undiagnosed untreated sleep apnea.

Resmed's big-ticket splurge started with the \$US800 million purchase of software-as-a-service business Brightree in April 2016.

In early 2016, Resmed entered the COPD market with its first own-branded portable oxygen compressor unit, the Mobi (two years previously Resmed acquired the Texasbased Inova Labs and sold Inova's Activox range of compressors).

Despite the digital penetration - so to speak - Resmed hasn't exactly been ignoring its core products, having unleashed several iterations of the existing masks.

For instance, the Airfit F30 minimal contact full face CPAP mask is suited to customers who need to wear glasses to bed and the Airfit N20 nasal mask that sits lower on the face and leaves fewer facial marks.

Financials and performance

Investors last week accorded Resmed's December quarter (and first half) results the all-round raspberry, sending the shares down 12 percent on the day (from \$16.45 to \$14.47) and then a subsequent nine percent over the ensuing week.

Using Resmed's internally deployed non-GAAP accounting measure, earnings were steady at \$US144.5 million, while revenue increased eight percent to \$US651 million.

As usual, there were a variety of gripes including slow non-US device sales - up three percent on a constant currency basis - with sales in France and Japan especially sluggish because the company has lost an earlier revenue boost from device upgrades.

Some commentators bemoaned the cessation of share buy-backs, which should not be surprising given the acquisition spree. Resmed last year bought back 200,000 shares, at a cost of \$US22.8 million

Overall, mask sales grew 10 percent and device sales crept up three percent. With the exception of France and Japan, the company reports "excellent" growth in masks and devices in the Asia Pacific and Western Europe.

The Matrixcare purchase is expected to generate \$US122 million of proforma revenue and earnings before interest, taxation, depreciation and amortization (Ebitda) of \$US30 million in 2018 (that is, assuming the business was owned for the full year).

Despite last week's slump, Resmed shares have performed okay, given the general global market meltdown of late 2018, with the ASX-listed shares gaining 17 percent over the last 12 months.

Longer term performance has been solid rather than spectacular: a \$US100 parcel of shares acquired in June 2013 was worth \$US253 as of June 2018, exceeding the performance of the S&P500 healthcare index (\$US175).

This performance is consistent with the Dow Jones US medical device index (\$US264) and outperforms the S&P500 healthcare index (\$US175)

To keep ahead of pesky sleep device rivals such as Respironics (Philips) and Fisher & Paykel Healthcare, Resmed spent \$US155 million on research and development in 2018 and plans to spend close to \$US200 million this year.

Dr Boreham's diagnosis:

Despite the acquisitive splurge into non-sleep apnoea activity, Resmed remains focused on the "globally underpenetrated" sleep and respiratory markets.

While management hasn't ruled out further purchases, we get the impression that the company will focus on its existing assets, in terms of increasing operating leverage and interoperability between the businesses.

The quarterly results show the growing importance of the digital side of the business, with software-as-a-service revenues gaining 63 percent to \$63.2 million.

Resmed's overall revenue for the quarter increased eight percent to \$US651 million, which means the software-as-a-service side now accounts for just under 10 percent of turnover compared with six percent a year earlier.

"We are now moving to the point where software-as-a-service has become a big enough segment to talk about," Mr Farrell says.

Resmed cites a global market of 936 million people with mild to severe sleep apnoea, fewer than 20 percent of whom have been diagnosed and treated.

On a geographic note, 62 percent of Resmed's revenue derived from the US in 2018 and the company expects this to remain similar "in the foreseeable future".

From local sleeper to global health leader, Resmed's growth over the years has been extraordinary. Given the shares are trading on a price-earnings multiple of around 33 times - well above the industrial average - investors expect more growth to continue.

Management's challenge is not to fall asleep at the wheel as it squeezes as much as it can from the acquisitions.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He admits to the occasional day-dream but so far has never been caught asleep on the job.

NEUREN PHARMACEUTICALS

Neuren says the Acadia Pharmaceuticals offer for the rights to trofinetide for Rett syndrome outside North America "would not be in the interests of ... shareholders". Last year, Neuren said the San Diego-based Acadia would pay up to \$630 million for the North American rights to trofinetide for neurological indications including Rett syndrome and Fragile X and Acadia had the first option for other territories (BD: Aug 7, 2018). Today, Neuren said that in anticipation of discussions with third parties in the US Europe and Japan it had appointed New York investment bank Torreya as its corporate advisor. The company said it was collaborating with Acadia to develop trofinetide for North America, including preparations for a phase III trial.

Neuren fell 4.5 cents or 3.45 percent to \$1.26.

GENETIC TECHNOLOGIES

Genetic Technologies says New York's Memorial Sloan Kettering Cancer Centre and England's University of Cambridge will assess its breast cancer test.

Genetic Technologies said that the collaboration with Sloan Kettering and the University of Cambridge would "assess whether the provision of individual risk information informed by a polygenic risk score reduces decisional conflict among BRCA mutation carriers considering preventive surgery"

The company said the study would be led by Sloan Kettering's breast medicine service chief Dr Mark Robson.

Genetic Technologies executive chairman Dr Paul Kasian said the study's resulting data "has the potential to inform the design of future pipeline products".

The company said that it would be responsible for the development and validation of the new genetic assay and the fundamental technology was similar to the existing Brevagenplus breast cancer test.

Genetic Technologies was up 0.1 cents or 12.5 percent to 0.9 cents with 4.1 million shares traded.

GENERA BIOSYSTEMS

Genera says it hopes to raise up to \$11,446,428 through a pro-rata, non-renounceable four-for-five entitlement offer at 13 cents a share.

Genera said that the record date for the rights issue was February 6, with the offer opening on February 11 and closing on March 1, 2019.

The company said the proceeds would be used to reduce debt, support the roll-out of its Ampasand test menu and for working capital.

Genera was untraded at 16 cents.

MESOBLAST

Mesoblast says that receipts from customers for the six months to December 31, 2018 increased 295.7 percent to \$US28,510,000 (\$A39,253,994).

Mesoblast did not disclose the nature of the revenue.

The company said that receipts from customers increased 300.0 percent to \$US26,915,000 for the three months to December 31, it had \$US77,022,000 in cash and cash equivalents at December 31 and expected to spend \$US22,884,000 for the three months to March 31, 2019.

Mesoblast fell half a cent or 0.4 percent to \$1.17 with 1.2 million shares traded.

THC GLOBAL (FORMERLY HYDROPONICS)

THC says that receipts from customers for the twelve months to December 31, 2018 increased 61.4 percent to \$2,588,000 compared to the previous corresponding period. THC said that receipts from customers for its cannabidiol products and hydroponics equipment fell 21.2 percent to \$647,000 for the three months to December 31, it had \$6,334,000 in cash and cash equivalents at December 31 and expected to spend \$2,216,000 for the three months to March 31, 2019.

THC was up 1.5 cents or 3.3 percent to 46.5 cents.

NUHEARA

Nuheara says that receipts from customers for the six months to December 31, 2018 fell 19.1 percent to \$1,386,000 compared to the previous corresponding period. Nuheara said that receipts from customers for its wireless earbuds fell 14.6 percent to \$725,000 for the three months to December 31, it had \$8,090,000 in cash and cash equivalents at December 31 and expected to spend \$4,750,000 for the three months to March 31, 2019.

Nuheara was up 0.1 cents or 1.4 percent to 7.4 cents with 3.6 million shares traded.

INVITROCUE

Invitrocue says its expects a net operating cash burn for the three months to March 31, 2019 is \$930,000 with cash at December 31, 2018 of \$1,151,000.

Invitrocue said it had receipts from customers for the three months to December 31, 2018 of \$85,000.

The company did not provide any further explanation.

Invitrocue was untraded at 7.4 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its 2018 marijuana crop in the Czech Republic has produced 700kg of biomass and 30 percent more flowers than the previous year.

MGC said the crop was in storage in the Czech Republic and would be transported to its Ljubljana, Slovenia-based extraction facility.

The company said it had developed a new proprietary genetic strain MXC-10, which contained more than 35 percent tetrahydrocannabidiol (THC).

MGC was up 0.3 cents or 7.7 percent to 4.2 cents with 1.1 million shares traded.

CARDIEX

Cardiex says it will take up the \$US3 million second tranche Inhealth option, taking its holding to 41.03 percent, with three of its executives appointed to the company. Cardiex said the investment converted to a 33.33 percent Inhealth interest and a previous \$US250,000 convertible note converted to 7.7 percent (BD: Oct 16, 2018).

The company said that a third tranche option would allow it to move to 50.5 percent. Cardiex said that chief executive officer Craig Cooper and head of corporate strategy Zihan Li had been appointed Inhealth directors and chief financial officer Jarrod White was appointed of Inhealth chief financial officer "to assist in financial oversight and business plan execution".

Cardiex was up 0.4 cents or eight percent to 5.4 cents with 11.7 million shares traded.

ESENSE-LAB

Esense-Lab says 44,398,808 Chess depository instruments, 32,891,608 performance rights and 5,638,689 options will be released from ASX escrow on February 14, 2019. The company's most recent Appendix 3B new share announcement said it had 141,278,103 CDIs quoted on the ASX, implying that 185,676,911 CDIs would be available following the release.

Esense-Lab was unchanged at 2.7 cents.

CRESO PHARMA

Creso has requested a trading halt "pending further detail on the disclosures in the recent cleansing statement".

Creso's most recent cleansing statement was issued after the trading halt and referred to the issue of 555,555 placement shares, 185,185 listed options and 750,000 performance rights which "may be subject to a subsequent offer for sale"

The company said it was in negotiations on the spin-out of its food additive and other cannabidiol assets and the acquisition of a European health food and beverage business "with a possible subsequent listing on the Nasdaq".

Trading will resume on February 4, 2019, or on an earlier announcement.

Creso last traded up half a cent or 1.2 percent to 41.5 cents.

REGENEUS

Regeneus says chief executive officer Leo Lee will be paid \$325,000 a year PLUS 9.5 percent superannuation (BD: Jan 23, 2019).

Regeneus said that Mr Lee would be entitled to a short-term incentive up to 100 percent of his base salary and would be granted up to 5,000,000 options in four equal tranches, with 2,500,000 exercisable at 20 cents a share and 2,500,000 exercisable at 25 cents a share within five years, pending vesting conditions.

Regeneus was untraded at 15.5 cents.

AUSCANN GROUP

Auscann says chief operating and financial officer Quentin Megson has been appointed as joint company secretary with existing company secretary Susan Hunter.

Auscann said Mr Megson joined the company in October and held "non-executive directorships with several companies".

The company said Mr Megson held a Bachelor of Commerce from the University of Western Australia.

Auscann fell two cents or 3.2 percent to 61 cents.

CRESO PHARMA

Creso says it has appointed Dr Ricardo Salazar as its primary medical advisor in Colombia, in partnership with the Bogota-based National University of Colombia. Creso said Dr Salazar was a Colombian medical practitioner, a member of the National University of Colombia, the director of the Education Commission of the Colombian National Academy of Medicine and a teacher at the National University of Colombia, Javeriana University and Del Rosario University.

The company said Dr Salazar was a member of the Colombian Academy of Medicine.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JANUARY 31, 2019

| Company \$Am | Feb-18 | Jan-19 | Feb-19 |
|----------------------|--------|--------|--------|
| Cochlear | 9,997 | 10,018 | 11,163 |
| CSL | 66,221 | 83,870 | 88,201 |
| Resmed | 17,819 | 22,685 | 18,624 |
| BDI-20 | · | | |
| Avita | 57 | 134 | 252 |
| Clinuvel | 425 | 866 | 1,033 |
| Compumedics | 74 | 71 | 60 |
| Cyclopharm | 63 | 76 | 82 |
| Ellex | 135 | 99 | 86 |
| Impedimed | 302 | 72 | 85 |
| LBT Innovations | 29 | 18 | 16 |
| Medical Developments | 452 | 288 | 247 |
| Mesoblast | 634 | 577 | 586 |
| Nanosonics | 847 | 852 | 1,002 |
| Neuren | 292 | 140 | 131 |
| Opthea | 127 | 145 | 191 |
| Pharmaxis | 86 | 104 | 103 |
| Polynovo | 314 | 393 | 450 |
| Immutep | 55 | 94 | 98 |
| Pro Medicus | 833 | 1,127 | 1,255 |
| Reva | 200 | 62 | 87 |
| Starpharma | 585 | 440 | 399 |
| Telix | 111 | 142 | 157 |
| Volpara | 67 | 197 | 194 |
| Second 20 | | | |
| Actinogen | 31 | 50 | 60 |
| Airxpanders | 193 | 15 | 16 |
| Antisense | 8 | 10 | 17 |
| Benitec | 47 | 27 | 26 |
| Cynata | 81 | 130 | 144 |
| Dimerix | 15 | 14 | 14 |
| Genetic Signatures | 33 | 83 | 84 |
| Imugene | 39 | 65 | 65 |
| Kazia (Novogen) | 35 | 23 | 29 |
| Oncosil | 80 | 117 | 114 |
| Optiscan | 41 | 19 | 20 |
| Orthocell | 28 | 14 | 12 |
| Osprey | 107 | 50 | 54 |
| Patrys | 19 | 29 | 24 |
| Paradigm | 39 | 147 | 168 |
| Prescient | 14 | 15 | 15 |
| Prana | 29 | 18 | 23 |
| Proteomics | 17 | 31 | 28 |
| Universal Biosensors | 48 | 39 | 41 |
| Uscom | 28 | 20 | 17 |
| | | | |

^{*} Biotech Daily editor, David Langsam, owns shares in Acrux, Amplia, Benitec, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Prana, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: http://www.australianethical.com.au/who-we-invest-in. These holdings are liable to change.