



Biotech Daily

Friday March 1, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: OPTHEA UP 8%; PRANA DOWN 10%**
- * **FEBRUARY BDI-40 UP 11%, ASX200 UP 5%, BIG CAPS UP 0.4%**
- * **DR BOREHAM'S CRUCIBLE: COCHLEAR**
- * **FEDERAL \$608m FOR NSW CHILDREN'S CANCER CENTRE**
- * **ADMEDUS REVENUE UP 127% TO \$25.6m, LOSS UP 180% TO \$24.7m**
- * **TBG REVENUE DOWN 9% TO \$3.2m, LOSS UP 33% TO \$4.4m**
- * **THC REVENUE UP 45% TO \$2.7m, LOSS UP 237% TO \$8.6m**
- * **CARDIEX H1 REVENUE UP 2% TO \$2m, LOSS UP 26% TO \$1.4m**
- * **PHARMAUST H1 REVENUE UP 44% TO \$1.9m, LOSS DOWN 94% TO \$90k**
- * **DORSAVI H1 REVENUE DOWN 18% TO \$1.8m, LOSS DOWN 3% TO \$1.9m**
- * **OBJ H1 REVENUE DOWN 29% TO \$1.1m, LOSS UP 92% TO \$788k**
- * **W WHITNEY GEORGE TAKES 23% OF RHINOMED**
- * **OCEANIA, HCI REDUCE TO 7.6% OF MACH7**
- * **G MEDICAL REQUESTS FINAL PRELIMINARY REPORT SUSPENSION**
- * **DAMIAN LISMORE REPLACES LBT DIRECTOR DR GLENN HAIFER**
- * **CLARITY APPOINTS DR ROBERT MILLER CMO**
- * **MGC LOSES JOINT CO SEC KATE SAINTY**

MARKET REPORT

The Australian stock market was up 0.38 percent on Friday March 1, 2019, with the ASX200 up 23.7 points to 6,192.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and three were untraded.

Opthea was the best, up six cents or 8.2 percent to 79.5 cents with 176,232 shares traded. Ellex, Genetic Signatures and Pro Medicus climbed more than five percent; Compumedics improved 4.55 percent; Avita, Benitec, Orthocell and Volpara were up more than three percent; Cochlear, CSL, Neuren and Pharmaxis were up one percent or more; with Cynata, Nanosonics and Paradigm up by less than one percent.

Prana led the falls, down 0.4 cents or 10 percent to 3.6 cents with 206,127 shares traded. Optiscan lost 9.6 percent; Proteomics and Universal Biosensors were down more than six percent; Actinogen, Kazia and Polynovo retreated more than five percent; Clinuvel fell 4.1 percent; Immutep was down 3.2 percent; Oncosil and Starpharma shed more than two percent; Dimerix and Medical Developments were down one percent or more; with Impedimed and Resmed down by less than one percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

Australia's hottest Summer on record was also hot for biotechs, with the Billion Dollar Club doing most of the heavy lifting.

Clinuvel, Nanosonics and Pro Medicus added \$659 million to the index.

Matching the weather, February was one of the hottest on record and the Biotech Daily Top 40 Index (BDI-40) climbed 10.8 percent to a collective market capitalization of \$8,262 million compared to the ASX200 up 5.2 percent to 6,169 points.

For the year to February 28, the BDI-40 fell 7.0 percent, the ASX200 was up 2.5 percent, the Nasdaq Biotechnology Index climbed 4.2 percent, and the Big Caps were up 16.1 percent.

The collective three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up just 0.4 percent in February, struggling with punters unimpressed with a collective half-year record revenue of \$8.762 billion and record net profit after tax of \$2.065 billion. Just like Billy Idol, the market wanted "more, more, more".

For the month of February, Cochlear fell 11.8 percent to \$9,841 million, CSL slipped half a percent to \$87,771 million, with Resmed defying the odds and climbing 11.6 percent to \$20,790 million.

Eighteen of the BDI-40 stocks were up, 10 by more than 10 percent, while 16 fell with just five losing more than 10 percent.

From a dangerously low base, Airxpanders was the best in February, up \$5 million or 31.25 percent to \$21 million, followed by Benitec (26.9%), Nanosonics (24.3%), Clinuvel (23.8%), Polynovo (16.0%), Kazia (13.8%), Genetic Signatures (13.1%), Cynata (11.8%), Impedimed (11.8%) and Imugene (10.8%).

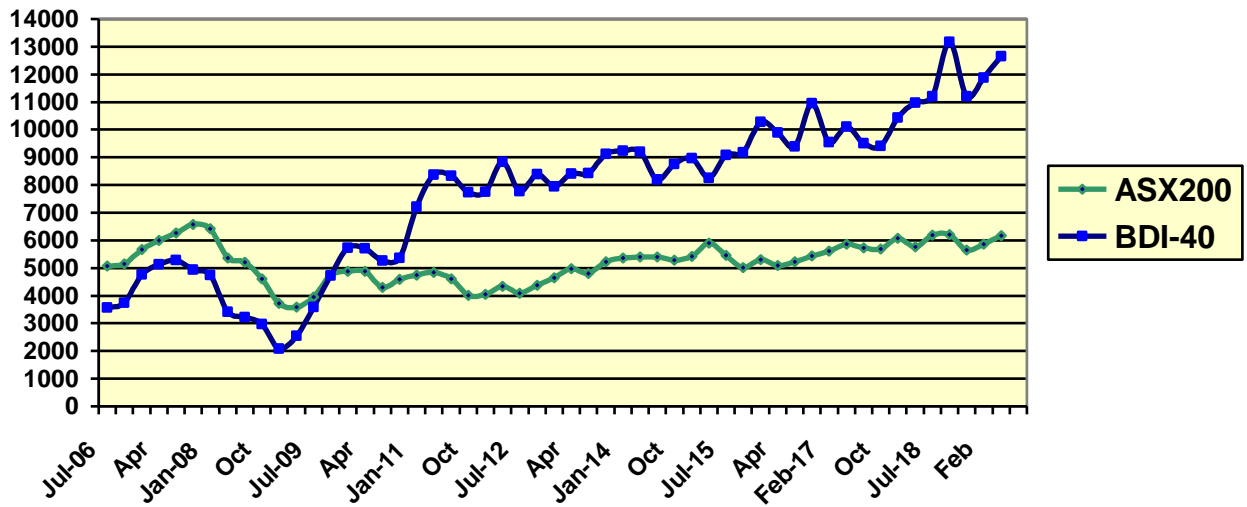
Osprey led the falls, down \$11 million or 20.4 percent to \$43 million, followed by Reva (18.4%), Antisense (17.6%), Neuren (13.0%) and LBT (12.5%).

Outside the Top 40, Cardiex and Resonance were at their peak market capitalization for the second month in a row, along with Bluechiip, while Bionomics' slow recovery was boosted in February with a 106.3 percent jump to \$131 million. Cogstate continued its downward trajectory, and at \$43 million, was worth less than half of its value of 12 months ago.

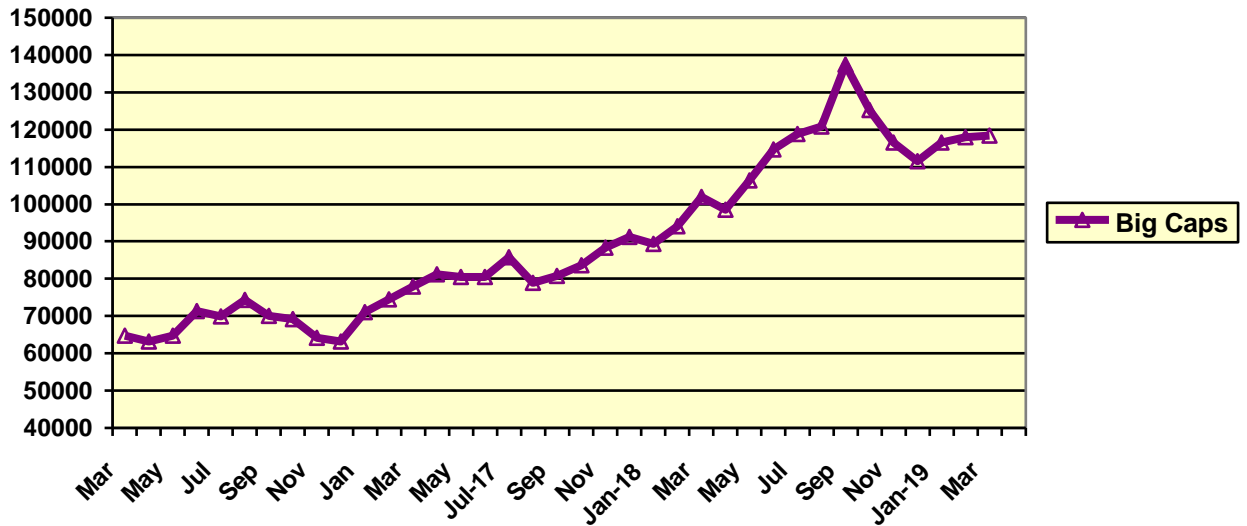
The now 16 stocks in Cannabis Corner fell a collective 1.3 percent to \$1,397 million. Elixinol Global added \$51 million or 13.7 percent to \$428 million, while former leader Cann Group – not to be confused by the rebadged Queensland Bauxite, now trading as Cann Global - lost \$48 million or 20.4 percent to \$187 million.

In the US, the NBI was up 0.3 percent in January, with Eyepoint (formerly Psivida) up 20.9 percent to \$347 million, Israel's Redhill (developing Australian assets) down 5.6 percent to \$306 million, Brisbane's Protagonist up 1.4 percent to \$285 million, and Vaxart (formerly Aviragen and Melbourne's Biota) at an all-time low, down 15.0 percent to \$17 million.

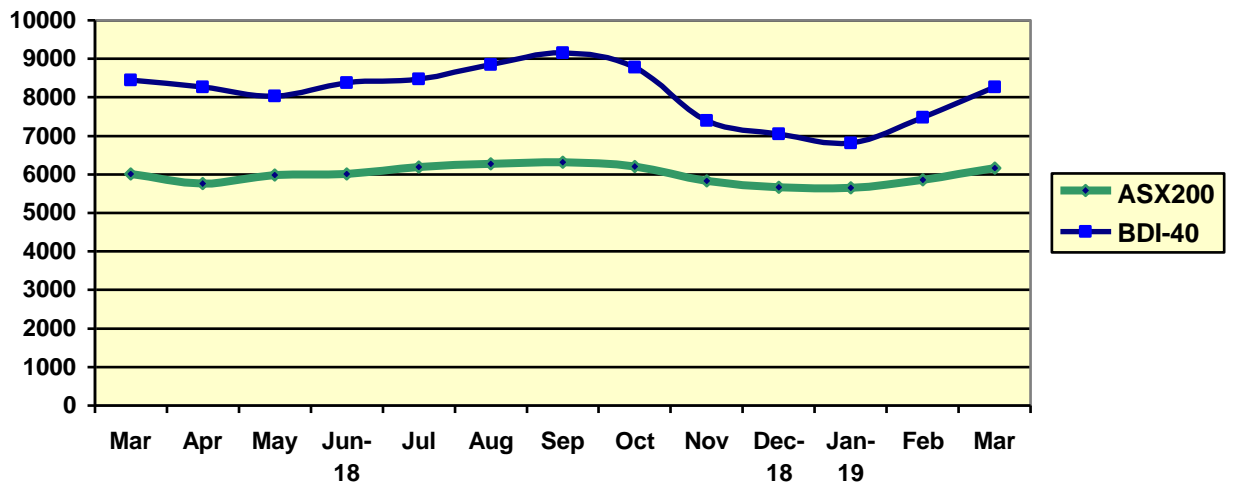
BDI-40 v ASX200 Jun 30, 2006 to Feb 28, 2019- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Feb 28, 2016 – Feb 28, 2019



BDI-40 (\$m) v S&P ASX 200 – Feb 28, 2018 - Feb 28, 2019 (current, raw data)



[DR BOREHAM'S CRUCIBLE: COCHLEAR](#)

By Tim Boreham

ASX code: COH

Share price: \$172.92; **Shares on issue:** 57,715,821; **Market cap:** \$9.98 billion

Chief executive officer: Diggory Howitt

Board: Rick Holliday-Smith (chair), Dig Howitt, Shah Abbas Hussain, Yasmin Allen, Glen Boreham*, Alison Deans, Donal O'Dwyer, Andrew Denver, Prof Bruce Robinson.

Identifiable major shareholders: Baillie Gifford & Co 7.9%, Black Rock Group 6%, Vanguard 5%.

Financials (December half): revenue \$712m (up 11%), net profit \$128.6m (up 26%), earnings per share \$2.23 (up 16%), dividend \$1.55 per share (up 11%), cash of \$92.3m (up 11%).

*No relation (as far as we know)

Even when you're an established device outfit turning over \$1.45 billion a year, seemingly trivial product tweaks on the part of a competitor can upset the sales momentum.

In Cochlear's case, arch-rival Advanced Bionomics launched a hearing implant called Hires Ultra 3D which is magnetic resonance imaging (MRI) compatible: wearers don't have to remove the batteries if they are undergoing a scan.

This small advantage over Cochlear's state-of-the-art Nucleus 7 implant and processor range cost Cochlear crucial sales, especially in Germany where more MRIs are carried out per capita than anywhere else.

"That has affected our market share in the US and Germany, our two biggest markets for Cochlear implants," rues CEO Dig Howitt.

A compote of other factors saw Cochlear generate only anaemic growth in its core developed country markets in the half year - notably the US, the country's most important market.

Deaf to Cochlear's longer term potential, irate investors marked Cochlear shares down eight percent after the company's February 19 results briefing.

The devil is in the detail

Cochlear's reported net profit - a 16 percent increase to \$128.6 million - looked acceptable enough. Management also reaffirmed full-year earnings guidance of \$265 million to \$275 million, an increase of eight to 12 percent.

Services revenue - which encompasses sound processor upgrades, spare parts and sundry items such as shake-awake alarm clocks and travel insurance - surged 28 percent to \$207 million.

This segment - which management has targeted for growth in recent years - now accounts for 29 percent of Cochlear's revenue.

However, investors couldn't forgive the sub-par performance of implants, which remain Cochlear's core market, accounting for 58 percent of revenue (the acoustic and bone implant range, known as Baha, accounts for a further 13 percent of turnover).

Mr Howitt attributes the sales malaise in developed countries not just to Advanced Bionics' new product, but to reimbursement caps in some western European markets. A nuance of that geography is that hospitals have a combined funding cap for implants and upgrades, which means that sales of the former could cannibalize the latter (and vice versa).

Mr Howitt notes that as Cochlear launched Nucleus 7 in the prior comparative half, it was 'cycling' tough comparative numbers this time around. He maintains that Cochlear continues to see a strong demand for Nucleus 7, the company's latest product iteration that is now compatible with both android phones and Apple iPhones.

Among the emerging countries, Mr Howitt calls out Argentina and Turkey as significant opportunities, despite currency devaluation and generally dodgy economies. Back in the first world, Cochlear saw only three percent growth in the US market.

"We do expect developed world market growth over the medium to long run," Mr Howitt says, adding that the uptake is difficult to predict.

Patent appeal pending

In November last year, the US District Court awarded \$US268 million (\$A380 million) against Cochlear in a long-running patent breach dispute.

The company is appealing the decision, brought by Advanced Bionics (yes, that name again) and the Alfred E Mann Foundation for Scientific Research. The plaintiffs are also demanding \$US123 million in pre-judgment interest, which Cochlear opposes. Naturally.

Because it expects to win an appeal, the company is treating the amount as a contingent liability and has expunged a \$A21.3 million provision on the balance sheet, but a \$A19.6 million provision for legal and other costs remains.

Mr Howitt says the judgment relates to expired products and does not affect Cochlear's current range.

Innovation and opportunity

Cochlear has a 60 percent share of the global children's market and is hell-bent on protecting that share.

But there are other segments where the company is not so prevalent, notably the over 65s market.

As anyone with elderly relatives would know, they either wear hearing aids or simply try to get by - often with less than optimal effect in terms of having a decent conversation. (There's also a phenomenon called selective hearing but we won't go there ...)

The company also cites links between hearing loss, ageing and cognitive decline, depression and the risk of falls.

Cochlear also has only 10 percent penetration of the children's market in developing countries, which is not surprising as the products are without a reimbursement system in place.

Still, Cochlear can't be accused of complacency, with 12 percent of revenue (\$160 million) devoted to research and development.

In a collaboration with GN Hearing Solutions, called the Smart Hearing Alliance, Cochlear aims to develop the latest connectivity and wireless technology. The alliance is relevant to "bimodal" patients, that is, those with a Nucleus 7 sound processor in one ear and a GN's Resound hearing aid in another. The devices are paired with an Iphone or Ipod to control the functionality of both devices.

Harnessing the consumer

With a sales and marketing background, newly-minted CEO Chris Smith introduced a 'direct to consumer' focus when he took over from long-running CEO Chris Roberts in September 2015. This strategy involved sharpening the appeal of Cochlear's products to its target audience.

As it happened, the Denver based Chris The Second quit in July 2017 after he realized that an agreed plan to move to Sydney HQ would not work for family reasons.

Under Mr Howitt - Cochlear's chief operating officer who took over from Mr Smith - the strategy remains unchanged.

One successful innovation has been a "member recipient" program called Cochlear Family. The loyalty-style club has now signed up 120,000 users whom, it is hoped, will become advocates of the product on online forums and such.

Finances and performance

Despite the headwinds, Cochlear's results showed sound cash generation which enabled investors to be awarded with an 11 percent dividend increase to \$1.55 a share, fully franked.

This is also despite \$80 million to \$100 million being earmarked for long-term projects including a new manufacturing facility in China.

With cash of \$92 million and net debt of only \$72 million, Cochlear is in a sound position to pursue further acquisitions into areas that expand its repertoire.

In May 2017, Cochlear paid \$US78 million for Sycle LLC, the world's dominant supplier of audiology practice management software.

Via its innovation fund, in November the company announced an EUR13 million (\$A20 million) investment in the Copenhagen Nasdaq-listed Nyxoah, to develop and commercialize a best-in-class nerve stimulation therapy for obstructive sleep apnoea.

While finding a cure for snoring may seem far removed from Cochlear's core technology, the therapy is based on an implant to modulate the hypoglossal nerve, which controls the functions of the tongue.

Then again, perhaps some spouses of locomotive-grade snorers would rather remain hard of hearing.

Performance wise, Cochlear shares over the last 12 months have traded in a range of \$155.22 and \$221.44

Dr Boreham's diagnosis:

Since 1981, Cochlear has provided more than 500,000 implants in more than 100 countries. As a company, you know you have made it when your brand is synonymous with the broader product, a la Eskys or Hoovers.

Despite this, Cochlear has only scratched the surface of the addressable market. The company estimates 15 million people could benefit from a Cochlear bone conduction implant, which implies it has penetrated only 3.3 percent of the global market.

Globally, 460 million people suffer hearing loss, with one in three over 65 years having impaired hearing to a disabling degree.

Strategy wise, Cochlear is targeting the "hundreds and thousands" of people with profound hearing loss who use hearing aids and have not transitioned to implants.

Meanwhile, it's hard to know what to make of the court judgment and Cochlear's chances of ultimate victory.

Investors can only hope that Cochlear's legal eagles are right and that the balance sheet won't have to be deployed to fund the massive court judgment.

As fellow home-grown global hero CSL would attest, patent disputes are part and parcel of doing business in the litigation trigger-happy US.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He does not head a global biotech company but when it comes to career advancement is all-ears to the possibilities.

FEDERAL GOVERNMENT

The Federal and New South Wales Governments say they will fund a \$608 million Comprehensive Children's Cancer Centre and rebuild the Randwick Children's Hospital. A media release from Federal Health Minister Greg Hunt said \$428 million would be provided by the NSW Government, \$100 million from the Federal Government, \$30 million from the University of New South Wales, \$25 million from the Sydney Children's Hospital Foundation and \$25 million from the Children's Cancer Institute.

Mr Hunt's media release said the funding would add more than 50 percent to the size of the Children's Hospital in Randwick, including a new emergency department.

Mr Hunt said the cancer centre would be on two levels, with a ground floor emergency department and short stay units, with the Cancer Centre on the first floor.

The media release said the expanded Children's Hospital would be integrated with a new Acute Services Building and the University of New South Wales Translational Hub.

The funding was announced ahead of the NSW election to be held on March 23, 2019, according to the NSW Electoral Commission.

ADMEDUS

Admedus says revenue for the year to December 31, 2018 was up 126.5 percent to \$25,601,000 with net loss after tax up 179.7 percent to \$24,699,000.

In reports filed after the close of market, Admedus said revenue came from sales of its Infusion and Adapt cardiac patch and valve businesses.

The company said that basic loss per share was up 113.9 percent, net tangible asset backing per share fell 22.9 percent to 2.7 cents and it had cash and cash equivalents of \$12,036,301 at December 31, 2018 compared to \$8,254,823 at December 31, 2017.

Admedus was up 0.1 cents or three percent to 3.4 cents.

TBG DIAGNOSTICS

TBG says revenue for the year to December 31, 2018 was down 8.7 percent to \$3,152,830 with net loss after tax up 32.9 percent to \$4,393,330.

TBG said revenue came from technical services and product sales, primarily for sequence-based typing and sequence specific primer.

The company said net tangible asset backing per share was down 18.5 percent to 5.3 cents, diluted loss per share was up from 0.8 cents to 2.0 cents at December 31, 2018, and it had cash and cash equivalents of \$5,647,021 at December 31, 2018 compared to \$7,918,213 at December 31, 2017.

TBG was up 0.8 cents or 19.5 percent to 4.9 cents.

THC GLOBAL GROUP

THC says revenue for the year to December 31, 2018 was up 44.5 percent to \$2,664,094 with net loss after tax up 236.6 percent to \$8,611,270.

THC said revenue was from sales of its hydroponic equipment for growing marijuana and other plant material.

The company said net tangible asset backing per share was up 58.3 percent to 19 cents, basic loss per share was up from 3.09 cents to 6.93 cents at December 31, 2018, and it had cash and cash equivalents of \$6,333,540 at December 31, 2018 compared to \$11,037,689 at December 31, 2017.

THC was up one cent or two percent to 51.5 cents.

CARDIEX

Cardiex says revenue for the six months to December 31, 2018 was up 2.2 percent to \$2,007,925 with net loss after tax up 26.3 percent to \$1,365,391.

In reports filed after the close of market, Cardiex said revenue came from sales of its medical devices for health management, including its Sphygmocor system.

The company said diluted loss per share was down 39 percent to 0.25 cents, net tangible asset per security was up 11.5 percent to 0.97 cents and it had cash and cash equivalents of \$4,735,364 at December 31, 2018 compared to \$724,671 at December 31, 2017.

Cardiex fell 0.2 cents or 3.3 percent to 5.8 cents with 1.6 million shares traded.

PHARMAUST

Pharmaust says revenue for the six months to December 31, 2018 was up 43.8 percent to \$1,871,053 with net loss after tax down 94 percent to \$89,930.

Pharmaust said revenue came primarily from subsidiary Epichem's chemistry contracts.

The company said net tangible asset backing per share was down 17.3 percent to 1.96 cents, diluted loss per share fell to 0.05 cents, and it had cash and cash equivalents of \$961,976 at December 31, 2018 compared to \$2,945,646 at December 31, 2017.

Pharmaust was up 0.2 cents or 6.25 percent to 3.4 cents.

DORSAVI

Dorsavi says revenue for the six months to December 31, 2018 was down 18.2 percent to \$1,831,096 with net loss after tax down 3.3 percent to \$1,907,290.

The company said diluted loss per share fell 5.1 percent to 1.12 cents, net tangible asset backing per share fell to 0.03 cents, and it had cash and cash equivalents of \$4,866,818 at December 31, 2018 compared to \$6,749,478 at December 31, 2017.

Dorsavi was untraded at 3.4 cents.

OBJ

OBJ says revenue for the six months to December 31, 2018 was down 28.8 percent to \$1,146,000 with net loss after tax up 92.2 percent to \$788,400.

OBJ said revenue came from licence fees from Procter & Gamble for its micro-array and magnetic transdermal technology.

The company said net tangible asset backing per share was down 25 percent to 0.3 cents, diluted loss per share was up from 0.02 cents to 0.04 cents at December 31, 2018, and it had cash and cash equivalents of \$2,900,934 at December 31, 2018 compared to \$4,776,854 at December 31, 2017.

OBJ was unchanged at two cents with 3.6 million shares traded.

RHINOMED

W. Whitney George says he has increased his holding in Rhinomed from 25,667,050 shares (21.81%) to 32,528,955 (22.92%).

The Carlsbad, California-based Mr George said that between November 5, 2018 and February 27, 2019 he bought 6,861,905 shares for \$US997,624 (\$A1,407,378) or 20.5 cents a share.

Rhinomed was up half a cent or 3.45 percent to 15 cents.

MACH7 TECHNOLOGIES

Oceania Capital and HCI say they have reduced their Mach 7 holding from 11,428,541 shares (8.79%) to 11,242,455 shares (7.62%).

In the substantial shareholder notice, the Sydney-based Oceania Capital, HCI Australian Operations and HCI Investments said that between December 11, 2018 and February 27, 2019 they bought the shares for prices ranging from 17.5 cents a share to 21 cents a share.

Mach7 was unchanged at 19.5 cents.

G MEDICAL INNOVATIONS

G Medical says it has requested a voluntary suspension pending the release of its preliminary final report, expected next week.

G Medical last traded at 29.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Robert Miller as its part-time consultant chief medical officer.

Clarity said Dr Miller had provided medical management and clinical development support to pharmaceutical and biotechnology companies and was currently a managing partner at Artemida Pharma.

The company said Dr Miller was a fellow at the Royal College of Surgeons, Faculty of Pharmaceutical Medicine and the Royal Society of Medicine.

Clarity said Dr Miller was a member of the European Society of Medical Oncologists and an affiliate member of the American Society of Clinical Oncologists.

The company said he was trained at the London Hospital Medical College and held surgical and medical roles in hospitals across the UK.

Clarity is a public unlisted company.

LBT INNOVATIONS

LBT says it has appointed former Biota chief financial officer Damian Lismore as a non-executive director, effective from March 25, 2019.

LBT said Mr Lismore was based in Melbourne and held chief executive officer, chief financial officer and company secretary roles at a number of listed companies.

The company said that director Dr Glenn Haifer would retire, effective immediately, "due to increased time commitments in a company he acquired at the end of 2018".

LBT was unchanged at seven cents.

MGC PHARMA

MGC says joint company secretary Kate Sainty has resigned, effective from February 28, 2019.

MGC said Rachel Kerr would return as company secretary following maternity leave.

MGC was up 0.1 cents or 2.6 percent to four cents with 1.5 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT FEB 28, 2019

Company \$Am	Mar-18	Feb-19	Mar-19
Cochlear	10,583	11,163	9,841
CSL	73,797	88,201	87,771
Resmed	17,576	18,624	20,790
BDI-20			
Avita	61	252	252
Clinuvel	417	1,033	1,279
Compumedics	64	60	58
Cyclopharm	66	82	81
Ellex	120	86	79
Impedimed	287	85	95
LBT Innovations	29	16	14
Medical Developments	459	247	268
Mesoblast	842	586	616
Nanosonics	793	1,002	1,245
Neuren	345	131	114
Opthea	127	191	183
Pharmaxis	101	103	103
Polynovo	330	450	522
Immutep	54	98	105
Pro Medicus	857	1,255	1,425
Reva	175	87	71
Starpharma	535	399	401
Telix	107	157	156
Volpara	69	194	193
Second 20			
Actinogen	38	60	63
Airxpanders	141	16	21
Antisense	7	17	14
Benitec	40	26	33
Cynata	104	144	161
Dimerix	17	14	14
Genetic Signatures	31	84	95
Imugene	69	65	72
Kazia (Novogen)	32	29	33
Oncosil	71	114	114
Optiscan	37	20	22
Orthocell	26	12	12
Osprey	100	54	43
Patrys	41	24	25
Paradigm	36	168	161
Prescient	15	15	14
Prana	29	23	22
Proteomics	16	28	26
Universal Biosensors	52	41	40
Uscom	38	17	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.

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