



Biotech Daily

Monday March 2, 2015

Daily news on ASX-listed biotechnology companies

- * FEBRUARY BDI-40 UP 10%, ASX200 UP 6% - CYNATA UP 254%, GENETIC TECH 200%
- * TODAY: ASX UP, BIOTECH DOWN: VIRALYTICS UP 17.5%, NEUREN DOWN 43.5%
- * VALE DR SIMON MARAIS (17.8.1964 – 26.2.2015)
- * CORRECTION: VIRALYTICS
- * BIOTA \$22m FOR FRANCE'S ANACONDA FOR WART, HPV ANTI-VIRAL
- * NEUREN TUMBLES 44% ON FDA BREAKTHROUGH REFUSAL.
- * EUROPE UPHOLDS AMENDED CSIRO, BENITEC PATENT
- * PHYTOTECH TO FUND CANIGMA VAPORIZER, ROSS SMITH DEVICE QUERY
- * GENERA NOTES RAISE \$615k
- * HEARTWARE 2014 REVENUE UP 34% to \$356m, LOSS DOWN 67% TO \$25m
- * ADMEDUS H1 REVENUE UP 17% to \$5m, LOSS UP 1,333% TO \$11m
- * OFF-SHORE PROCESSING HITS SUDA H1 REVENUE 52% to \$3m, LOSS UP
- * AVITA H1 REVENUE DOWN 23% TO \$1.4m, LOSS UP 6% TO \$3.4m
- * GENETIC TECH H1 REVENUE DOWN 38% TO \$1m, LOSS DOWN 5% TO \$5m
- * CIRCADIAN H1 REVENUE DOWN 8% TO \$366k, LOSS UP 90% TO \$3m
- * BRAIN: 'JOURNAL ARTICLE BACKS DEPRESSION TREATMENT TEST'
- * BIONOMICS TO LIST ON US OTC-QX

MARKET REPORT

The Australian stock market was up 0.51 percent on Monday March 2, 2015 with the S&P ASX 200 up 30.1 points to 5,958.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded.

Viralytics was the best, up seven cents or 17.5 percent to 47 cents with 3.2 million shares traded. Prima climbed 5.7 percent; Ellex and Pharmaxis rose more than four percent; Alchemia, Circadian and IDT were up more than three percent; with Bionomics and Tissue Therapies up more than two percent.

Neuren led the falls, down 7.4 cents or 43.5 percent at 9.6 cents with 68.1 million shares traded. Genetic Technologies lost 13.2 percent; Admedus lost eight percent; Acrux and Universal Biosensors fell more than seven percent; Optiscan lost six percent; Cellmid, Impedimed and Oncosil fell four percent or more; Biotron was down 3.6 percent; with Phosphagenics, Sirtex and Uscom down more than two percent.

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

February proved positively volatile for the Biotech Daily Top-40 Index (BDI-40) stocks with more climbing than falling, and many by double digit percentages. Nineteen of the BDI-40 were up - eight by more than 20 percent - 17 fell and four were unchanged.

While Sirtex neared the \$2 billion market capitalization mark, having crossed \$1 billion just seven months ago, other companies including Mesoblast and Nanosonics helped push the February BDI-40 up 9.85 percent to 6,724, compared to the S&P ASX200 up 6.1 percent to 5,929, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a further 3.3 percent for the month - up 32.7 percent for the 12 months to February 28, 2015.

Cochlear was up 9.9 percent to \$5,208 million, CSL rose 2.9 percent to \$42,869 million with Resmed up 2.3 percent to \$11,554 million.

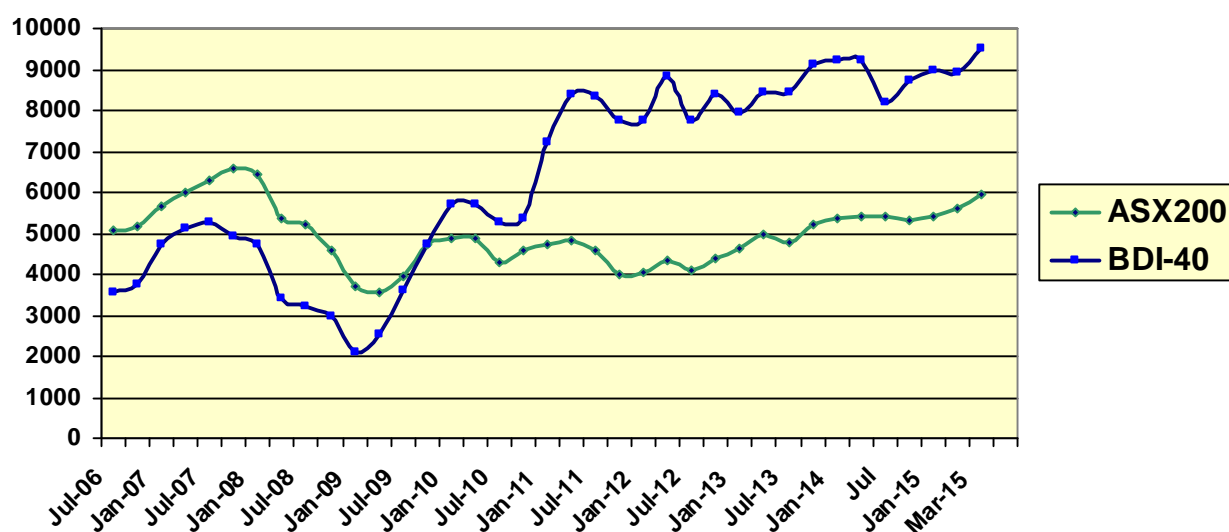
Genetic Technologies was the best of the BDI-40 for two months in a row, up 200 percent to \$66 million in one month. Recovering from a market punishment, Universal Biosensors was up 62.5 percent to \$65 million followed by Optiscan up 58.3 percent from a low base to \$19 million, Biotron (31.25%), Sirtex (30.7%), Nanosonics (30.0%), Oncosil (23.1%), Compumedics (21.05%) and eight more up by more than 10 percent.

From a low base, Patrys fell 33.3 percent to \$8 million, Acrux lost \$69 million or 27.1 percent to \$186 million, followed by Prana (19.3%), Alchemia, (17.4%), Admedus (16.1%), Antisense (15.8%), Clinuvel (12.0%), Analytica (12.0%) and Impedimed (11.9%).

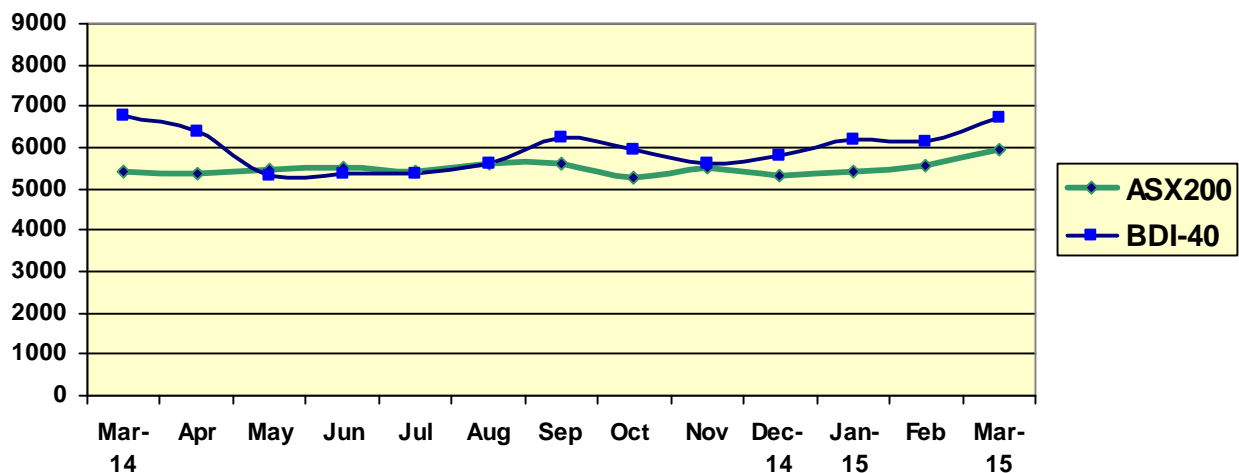
Just outside the BDI-40 Cynata jumped 254.2 percent from \$24 million to \$85 million on news of low-cost large-scale stem cell manufacturing, Reva continued its recovery, up 6.1 percent to \$174 million, Cyclopharm was up 52.9 percent to \$26 million on thin volumes, Actinogen consolidated up 17.2 percent to \$34 million, with OBJ steady at \$142 million.

On the Nasdaq, Biota was up 4.6 percent to \$113 million, Heartware up 1.5 percent to \$1,857 million and Sunshine Heart climbed 14.7 percent to \$125 million.

BDI-40 v ASX200 Jun 30, 2006 to Feb 28, 2015 - Adjusted



BDI-40 (\$m) v S&P ASX 200 – Feb 28, 2014- Feb 28, 2015



[DR SIMON MARAIS \(17.8.1964 -26.2.2015\)](#)

Biotech Daily is deeply saddened to learn that Allan Gray Australia chief executive officer Dr Simon Marais has died of cancer.

Biotech Daily had numerous conversations with Dr Marais about his company's investments in biotechnology, as well as outside the sector, and he was always insightful, sharp and frank, while remaining soft-spoken, gentle and affable.

Under his direction, Allan Gray, formerly Orbis Investment Management, invested in many biotechnology companies including Acrux, Alchemia, Avexa, Chemgenex, Impedimed, Nanosonics, Pharmaxis, Phosphagenics, QRX, Starpharma and Tissue Therapies.

In many cases Biotech Daily noted that he was taking profit on large numbers of shares having sometimes acquired them at very low prices.

Despite being described as a "contrarian" Dr Marais agreed that it was better to buy shares cheaply and sell them at a higher price, rather than the other way around, as a number of funds had been doing.

Dr Marais was often 'bearish' on biotechnology, buying Pharmaxis the first time it was hit from \$3.00 down to 84 cents, and supporting other companies which looked like they were facing difficulties. And he invested for the long term.

According to the Australian Financial Review, Allan Gray's Australian Equity Fund was the top-performing fund for the year to November 30, 2014 with a return of 14.4 per cent and over five years it was second best, with 7.4 per cent.

The Allan Gray website said that before he joined the company in South Africa, he conducted research in theoretical physics and held a Master of Science from Stellenbosch and a Doctor of Philosophy from Cambridge.

Dr Marais leaves a wife and three sons.

[VIRALYTICS](#)

On Friday, Biotech Daily reported that Viralytics was the best on no news but with an ASX Query, up 9.5 cents or 31.15 percent rise to 40 cents with 1.3 million shares traded.

In fact, Viralytics told the ASX that a US investment bank Roth Capital Partners research paper, with a 12-month price target of \$3.84, was posted on its website on Friday.

The mistake was made by the overstretched reporting season sub-editor.

Viralytics was up seven cents or 17.5 percent to 47 cents with 3.2 million shares traded.

BIOTA PHARMACEUTICALS

Biota says it will acquire the Paris, France-based Anaconda Pharma for its AP611074 antiviral for condyloma, or anoogenital warts, and recurrent respiratory papillomatosis. Biota said it would acquire Anaconda for 3.5 million Biota shares and \$US8.0 million in cash, subject to certain closing and post-closing adjustments (about \$A21.5 million).

The company said the deal included payment of up to \$US30.0 million on meeting clinical and regulatory milestones, and a royalty, with completion expected by the end of April 2015, subject French Ministry of Finance and Economics approval and other conditions. Biota said that Anaconda had completed a phase IIa clinical trial of AP611074 five percent gel demonstrating biological activity with a significant reduction in the surface area of condyloma, while exhibiting favorable local skin tolerability.

Biota chief executive officer Dr Joseph Patti said that the company was “very enthusiastic about the global market opportunity for AP611074, and believe it is uniquely positioned to significantly improve the treatment paradigm for ano-genital warts, the most frequent viral sexually transmitted disease worldwide, and [recurrent respiratory papillomatosis], a condition in which tumors grow in the respiratory tract”.

“We are encouraged by both the positive efficacy data as well as the favorable local skin tolerability profile observed in the proof-of-principle Phase IIa clinical trial,” Dr Patti said.

“We are looking forward to the initiation of a randomized, placebo-controlled, double-blind, phase IIb trial in patients with ano-genital warts in the second half of 2015,” Dr Patti said. Biota said that Stifel, Nicolaus & Co acted as financial advisor, with Dechert LLP as legal counsel.

Biota said that condyloma or ano-genital wart infections with human papillomavirus (HPV) was the most frequent viral sexually transmitted disease in adults worldwide, affecting one to two percent of sexually active US adults between the ages of 15 to 49 developing condyloma as the primary clinical manifestation of HPV infection.

The company said that current treatments were either ablative destructive therapies and topical therapies, with the topical therapies associated with mucosal toxicities, while ablative options could be painful, scarring and can lead to sexual dysfunction, both with a high incidence of recurrence.

Biota said that HPV 6 and HPV 11 were associated with recurrent respiratory papillomatosis, a condition of tumors or wart-like lesions of the upper respiratory tract, particularly the larynx, affecting between one and seven per 100,000 persons, with juvenile-onset usually diagnosed between the ages of one and four years, and was believed to be acquired by newborns from their mothers during labor.

The company said the juvenile symptoms were difficulty breathing or swallowing and therefore the lesions could be life-threatening, while adults presented with hoarseness, chronic coughing or breathing problems.

Biota said that in the US, children underwent an average of 19.7 surgical procedures over their lifetime, with a mean frequency of 4.4 procedures per year.

Following the termination of its \$US231 million Biomedical Advanced Research and Development Authority contract, Biota closed its Australian operations (BD: Jun 3, 2014).

Biota was developing its long-acting neuraminidase inhibitor laninamivir octanoate, when it merged with Nabi Pharmaceuticals to access its \$US54 million in cash, eventually settling for \$US27 million in cash (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).

In August, Biota said that top-line data from its phase II trial comparing 40mg and 80mg laninamivir octanoate to placebo showed no significant benefit (BD: Aug 4, 2014).

On the Nasdaq on Friday, February 27, Biota closed down two US cents or 0.79 percent to \$US2.52 (\$A3.23 - equivalent to 40.3 cents prior to the Nabi merger, when it was trading around \$A1.00), with 81,765 shares traded.

NEUREN PHARMACEUTICALS

Neuren fell as much as 43.5 percent following the US Food and Drug Administration rejection of its application for Breakthrough designation for trofinetide for Rett syndrome. Neuren said that the FDA agreed that Rett syndrome met the criteria for a serious or life-threatening condition, but “considered that data from Neuren’s exploratory phase II trial [provided] insufficient evidence to demonstrate substantial improvement over existing therapies using conventional statistical methods”.

The company said it would proceed under the Fast Track designation granted by the FDA and expected to meet with the FDA by July 2015 to agree the remaining requirements for the development of trofinetide, formerly known as NNZ-2566, in Rett syndrome.

Neuren executive chairman Dr Richard Treagus said that “Neuren submitted a strong case for Breakthrough Therapy”.

“Nevertheless we look forward to meeting with the FDA and advancing the development of trofinetide for Rett syndrome under the Fast Track expedited program,” Dr Treagus said.

Neuren said the FDA had granted orphan drug designation to trofinetide for Rett syndrome and it had begun the process of an orphan drug application to the European Medicines Agency.

Neuren closed down 7.4 cents or 43.5 percent at 9.6 cents with 68.1 million shares traded.

BENITEC BIOPHARMA, THE CSIRO

Benitec says that the European Patents Office has upheld an amended form of CSIRO’s Waterhouse platform RNA-interference patent.

Benitec said it was the exclusive worldwide licensee of the patent for human therapeutic applications from the Commonwealth Scientific and Industrial Research Organisation.

The company said that an opposition hearing was held in The Hague on January 7 and 8, 2015 and was attended by CSIRO, Benitec and Bayer representatives which had licenced the patent for plant applications.

Benitec said that the patent was granted on March 31, 2011 and was opposed by four parties, BASF SE, Syngenta International AG, Carnegie Institution of Washington and the University of Massachusetts and Strawman, which was identified as Galapagos NV.

The company said the patent was upheld with amendments to focus the claims to hairpin RNA molecules produced from the genetic constructs of DNA-delivered RNAi (ddRNAi).

Benitec said that the patent from the Waterhouse family complemented the foundational RNAi patents of the Graham patent family, but the Waterhouse patent family had no limitations on the maximum length of the constructs generated by ddRNAi, offering broad protection for the platform technology.

The company said the European Patent Office would hear opposition by BASF SE to a patent in the Graham family on June 17, 2015.

Benitec said the patent was the second filing in a suite of patents filed in Europe for the Graham family and the first European patent was revoked in opposition proceedings in May 2014.

The company said that with CSIRO it appealed the decision in November, 2014, when chief executive officer Dr Peter French said the two organizations were confident it provided strong grounds for the Graham patent to be reinstated (BD: Nov 25, 2014).

Dr French said at that time that Benitec was building its own intellectual property portfolio to protect its position in ddRNAi in general and the pipeline programs under development. Benitec said it expected positive outcomes in both cases.

Benitec was up one cent or 1.2 percent to 86.5 cents.

PHYTOTECH MEDICAL

Phytotech says it has an agreement with the Moshav Shilat, Israel-based Canigma AL to develop a capsule-based vaporizer to administer medical cannabis.

Phytotech said that Canigma held intellectual property interests relating to a vaporizer delivery device for medical cannabis and the company would fund the granting process of a patent for the device, the proof of concept and the development of the prototype.

The company said that if Canigma was granted a patent it would subscribe for 50 percent of Canigma for \$US1 million, less the funds expended, with an option to acquire the remaining 50 percent of Canigma.

Phytotech said that the Canigma vaporizer was based on the Nespresso model so that dispensaries could stock different capsules to treat different indications.

In its prospectus, Phytotech said it had planned to spend \$700,000 to develop a vaporizer invented by founder and recently resigned director Ross Smith, also based in Israel.

Phytotech chairman Peter Wall told Biotech Daily that Canigma was not related to Mr Smith, the company was focusing on the Canigma device, but did not clarify whether the company was paying for two types of vaporizers.

Phytotech was up 1.5 cents or 4.5 percent to 35 cents with 1.7 million shares traded.

GENERA BIOSYSTEMS

Genera says it has placed the final tranche of its series B convertible notes at \$100 a note to raise \$615,000 before costs.

Genera said it had raised \$2.5 million through the issue of 25,000 series B notes with about 80 percent of the previously issued series A convertible notes converted.

The company said it held 1,653 series A convertible notes at a face value of \$100 each.

Genera fell half a cent or 2.3 percent to 21.5 cents.

HEARTWARE INTERNATIONAL

Heartware says revenue for the year to December 31, 2014, was up 33.9 percent to \$US278,420,000 (\$A356,468,860) reducing net loss after tax by 67.3 percent to \$US19,366,000 (\$A24,794,830).

Heartware chief executive officer Doug Godshall said that "with record unit sales in the fourth quarter contributing to more than 2,750 units sold globally during 2014, as well as the addition of more than 50 hospital centers around the world, we continue to be encouraged by the growing adoption of the Heartware system".

"During the year, we completed enrollment in our Japan bridge-to-transplant study, ramped enrollment in the supplemental cohort of our US destination therapy study, advanced our technology pipeline, made significant upgrades to our quality systems, improved our gross margin, and concluded the year by initiating the submission process for our CE marking trial application for our next-generation [miniature ventricular assist device] System," Mr Godshall said.

Heartware said that research and development costs were up 19.5 percent to \$US122,432,000 or 44.0 percent of revenue.

The company said that diluted loss per share fell 69.1 percent to \$US1.14 at December 31, 2014 and it had cash and cash equivalents of \$US102,946,000 at December 31, 2014, compared to \$US162,880,000 at December 31, 2013.

On the Nasdaq, on Friday February 27, Heartware fell \$US1.15 or 1.33 percent to \$US85.23 (\$A109.12) with 347,808 shares traded.

ADMEDUS

Admedus says that revenue for the six months to December 31, 2014, was up 17.4 percent to \$4,795,000 with net loss after tax up 1,333 percent to \$10,688,000.

Admedus said that overall sales revenue for the group for the six months was \$4.8 million, with a closing cash balance of \$9.6 million, including \$1 million in sales for its Cardiocel heart patch as the it continued its launch in Europe and North American and increased its sales teams across Europe and the US.

The company said it continued to invest in the therapeutic vaccine technology, with the herpes simplex virus 2 program progressed towards a phase II study.

Admedus said that basic loss per share increased 973.9 percent to 0.741 for the six months to December 31, 2014, with net tangible assets per share up 11.4 percent to 1.17 cents at December 31, 2014, and held cash and cash equivalents of \$9,602,354 at December 31, 2014, compared to \$19,582,972 at June 30, 2014.

Admedus fell 0.8 cents or 8.0 percent to 9.2 cents with 13.5 million shares traded.

SUDA

Suda says that revenue for the six months to December 31, 2014, fell 52 percent to \$2,999,000 increasing net loss after tax 486 percent to \$1,945,000.

Last year, Suda posted revenue for the six months to December 31, 2013, up 197.7 percent to \$6,242,000 reducing net loss after tax to \$332,000, BD: Feb 27, 2014).

Suda said that most of the revenue related to subsidiary Westcoast Surgical and Medical Supplies which supplied pharmaceuticals, consumables and vaccines.

The company said that "Westcoast was supplying medical products to an organization funded by the Federal Government for the benefit of detention centres in the 2013-'14 financial year but, due to the Government's Operation Sovereign Borders policy, there has been a large decrease in sales activity in the current year".

Suda said that diluted loss per share increased 400 percent from 0.04 cents for the six months to December 31, 2013 to 0.20 cents for the six months to December 31, 2014, with net tangible assets per share down 40 percent from 0.5 cents to 0.3 cents.

The company said it had cash and cash equivalents of \$3,049,688 at December 31, 2014, compared to \$3,990,397 at June 30, 2013.

Suda fell 0.2 cents or 4.9 percent to 3.9 cents.

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2014 fell 23.8 percent to \$1,367,389 with net loss after tax up 5.6 percent to \$3,394,123.

Avita said that Recell global sales for the six months were up 29 percent compared to the previous period, with Recell Asia Pacific sales up 62 percent and sales to Europe, the Middle East and Africa up 15 percent with operating costs down eight percent.

The company said that respiratory device sales fell 14 percent for the six months taking total group sales down two percent to \$1,340,977 compared to same period for 2013.

Avita said the 93.8 percent fall in other revenue from \$423,465 to \$26,412 "was primarily attributable to the reduction in contract revenues from [the US Armed Forces Institute of Regenerative Medicine]".

The company said its net tangible assets per share fell 68.2 percent to 0.7 cents, diluted loss per share increased 1.96 percent to 1.04 cents, with cash and cash equivalents of \$1,705,065 at December 31, 2014 compared to \$3,648,390 at June 30, 2014.

Avita was unchanged at 7.9 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the six months to December 31, 2013 was down 37.9 percent to \$1,252,170, with a net loss after tax down 5.4 percent to \$4,831,493.

Genetic Technologies said the decrease in total revenues and loss "was primarily due to the divestiture of the heritage Australian genetics business".

Genetic Technologies said its net tangible assets per share fell from 0.11 cents at June 30, 2014 to negative 0.06 cents at December 31, 2014, but diluted loss per share fell 32.7 percent from 1.01 cents at December 31, 2013 to 0.68 cents at December 31, 2014.

The company said it had cash and cash equivalents of \$1,274,808 at December 31, 2014 compared to \$2,831,085 at June 30, 2014.

Genetic Technologies fell 0.7 cents or 13.2 percent to 4.6 cents with 17.1 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says revenue for the six months to December 31, 2014 was down 7.7 percent to \$366,215, with a net loss after tax up 90.1 to \$3,018,683.

Circadian said the revenue reflected a fall in cash balances and lower interest rates, with a 3.6 percent fall in royalty and licence fees from \$247,276 at December 31, 2013 to \$238,326 at December 31, 2014.

The company previously said it received income from its VGX-100 cancer and VGX-300 eye disease programs, and licences to Imclone and Healthscope (BD: Feb 19, 2013).

Circadian said its net tangible assets per share fell 27.3 percent to from 22 cents at June 30, 2014 to 16 cents at December 31, 2014, diluted loss per share was up 41.4 percent to 4.58 cents, with cash and cash equivalents of \$18,988,424 at December 31, 2014 compared to \$7,162,020 at June 30, 2014.

Circadian was up half a cent or 3.0 percent to 17 cents.

BRAIN RESOURCE

Brain Resource says its "most important publication to date" details its Depression Treatment Test submitted to the US Food and Drug Administration.

Brain said that the article, entitled 'Toward an online cognitive and emotional battery to predict treatment remission in depression' was published in the journal Neuropsychiatric Disease and Treatment and was available at: <http://bit.ly/17JkC7E>.

The article concluded that the test battery "identified about 50 percent of each medication group as being equal or greater than 10 percent more or less likely to remit than by chance, and identified about 38% of individuals who did not remit with equal or greater than 80 percent certainty".

"Clinicians might choose to avoid this specific medication in these particular patients," the article concluded.

Brain was untraded at 28.5 cents.

BIONOMICS

Bionomics says it expects to begin trading on the US Over-The-Counter Quality Exchange (OTCQX) tonight, under the code BNOEF.

Bionomics said that the move allowed it to provide new and existing US investors with immediate access to trade its shares in US dollars during US market hours.

Bionomics was up one cent or 2.1 percent to 49.5 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT FEB 28, 2015

Company \$Am	Mar-14	Feb-15	Mar-15
Cochlear	3,325	4,738	5,208
CSL	34,813	41,679	42,869
Resmed	6,796	11,292	11,554
BDI-20			
Acrux	350	255	186
Admedus	207	180	151
Benitec	155	89	102
Bionomics	292	175	196
Biotron	17	32	42
Circadian	10	26	24
Clinuvel	59	167	147
GI Dynamics	280	135	138
Impedimed	42	293	258
Mesoblast	1,847	1,303	1,358
Nanosonics	207	357	464
Neuren	146	279	267
Osprey	80	62	74
Pharmaxis	34	33	27
Prima	57	50	53
Psivida	134	143	164
Sirtex	837	1,523	1,990
Tissue Therapies	74	76	68
Universal Biosensors	68	40	65
Viralytics	35	56	56
Second 20			
Alchemia	201	23	19
Analytica	17	25	22
Anteo	130	81	78
Antisense	23	19	16
Atcor	22	16	18
Avita	41	28	25
Cellmid	24	20	20
Compumedics	13	19	23
Ellex	43	32	36
Genetic Technologies	39	22	66
IDT	25	29	26
Living Cell	29	25	25
Medical Developments	72	106	117
Oncosil	45	26	32
Optiscan	10	12	19
Patrys	28	12	8
Phosphagenics	112	100	91
Prana	518	88	71
Starpharma	199	148	166
Uscom	15	16	16

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Alchemia, Atcor, Avita, Circadian, Cochlear, Ellex, IDT, Impedimed, Innate Immunotherapeutics, Pharmaxis, Prana, Resmed and Sirtex. These holdings are liable to change. <http://www.australianethical.com.au/who-we-invest-in>.

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