



Biotech Daily

Monday September 2, 2013

Daily news on ASX-listed biotechnology companies

- * **AUGUST BDI-40 DOWN 1.6%, ASX200 UP 1.6%; BIG CAPS UP 1.35%
- HEARTWARE GOES; ALLIED HEALTH, IDT PROMOTED**
- * **TODAY: ASX UP, BIOTECH DOWN: PHYLOGICA UP 7%, OPTISCAN DOWN 10%**
- * **MIMETICA \$8m BACKDOOR INTO TELESSO FOR MTC896 FOR ACNE**
- * **CLINUVEL: 'COMBINATION SCENESSE BETTER FOR VITILIGO'**
- * **PRANA FILES SEC FORMS TO RAISE UP TO \$52.5m**
- * **PHARMAUST REVENUE UP 6% to \$1.7m, LOSS DOWN 88% TO \$515k**
- * **OPTISCAN REVENUE UP 132% to \$1m, LOSS DOWN 74% TO \$643,950**
- * **USCOM REVENUE DOWN 26% TO \$639k, LOSS DOWN 25% TO \$1.4m**
- * **ADVANCED SURGICAL REVENUE DOWN 12% TO \$7m, LOSS UP TO \$571k**
- * **UNILIFE REVENUE DOWN 50% TO \$3m, LOSS UP 21% TO \$70m**
- * **PHOSPHAGENICS H1 REVENUE DOWN 39% TO \$1m, LOSS UP 20% TO \$6m**
- * **NEUREN LOSES DIRECTOR JOHN HOLADAY, GAINS COO JAMES SHAW**

MARKET REPORT

The Australian stock market climbed 1.04 percent on Monday September 2, 2013 with the S&P ASX 200 up 53.3 points to 5,188.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and two were untraded.

Phylogica was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 910,000 shares traded. IDT debuted up 6.8 percent to 39.5 cents; Allied Health and Phosphagenics were up more than five percent; Neuren was up 4.3 percent; Alchemia, Bionomics, Circadian, Pharmaxis and Reva were up more than three percent; Acrux, Patrys and Sirtex rose two percent or more; with CSL, Mesoblast and Tissue Therapies up more than one percent.

Optiscan led the falls, down 0.7 cents or 9.7 percent to 6.5 cents with 167,500 shares traded. Anteo lost 8.5 percent; Atcor and Prana fell more than seven percent; Antisense, Ellex and Viralytics fell six percent or more; both Avita and Living fell four percent; Benitec and Heartware were down more than three percent; Impedimed, Prima and Starpharma shed more than two percent; with Nanosonics, Psivida and Resmed down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) fell 1.6 percent in August, but 22 companies were up, 15 fell and three were unchanged.

The S&P ASX200 was up 1.6 percent for the month, with the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up a collective 1.35 percent.

Heartware is due to leave the ASX this month and its \$211 million fall for the month, along with Mesoblast's \$127 million drop, was the primary reason the index was down. Removing Heartware left the other 39 companies up 1.7 percent for the month.

Biotech Daily has been struggling to decide what to do when the \$1.5 billion company leaves the index. There is no company anywhere near that size involved in Australian life sciences to fill the gap and the index is set to fall from the current \$7,533 million level to \$6,095, with IDT Australia promoted into the BDI-40. The drug manufacturing and contract research company has renewed itself with an excellent board and management and along with its drug master files and generic oncology assets is likely to acquire new assets.

The S&P ASX indices correct for changes by resetting the index, so if the ASX200 was at 5,000 points and Rio, BHP and the Commonwealth Bank all left to be replaced by three small companies, the index would remain at 5,000. Biotech Daily uses cumulative market capitalizations, so next month will appear to be a sudden fall. Previous departures of Chemgenex, Arana, Peplin, Cellestis, Biota and Sunshine Heart have been less dramatic.

Even with the loss of Heartware, over five years the BDI-40 is up 80.5 percent with the ASX200 virtually unchanged, down one point from 5136 points.

For the year to August 31, 2013, the BDI-40 was up 12.0 percent, the ASX200 climbed 19.0 percent and the Big Caps were up 39.3 percent (see charts below).

Allied Health was the best-performing company in the BDI-40, up 65.5 percent to \$91 million and will be promoted into the BDI-20 replacing Heartware. Tissue Therapies was up 49.0 percent to \$73 million, IDT was up 46.2 percent to \$19 million, Prana improved 40 percent to \$203 million, followed by Compumedics (25.0%), Osprey (24.1%), Ellex (23.8%), Viralytics (23.1%), Nanosonics (19.6%), Circadian (18.2%) and Psivida (16.3%).

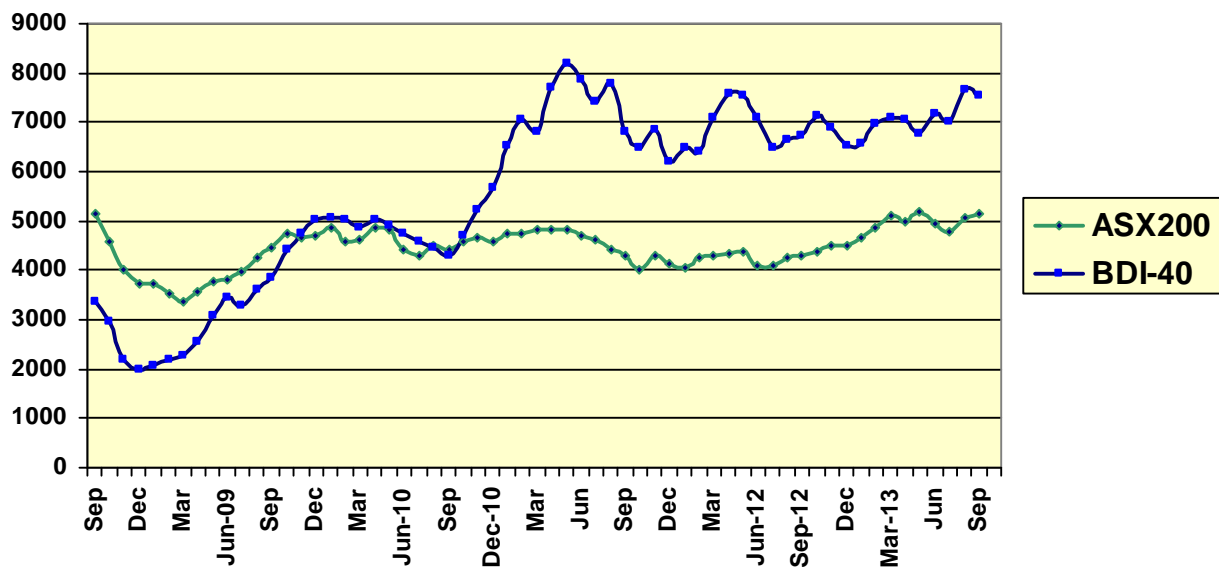
Antisense led the falls, down 23.1 percent to \$20 million. From a decreasingly low base Phylogica fell a further 22.2 percent to \$7 million, followed by QRX (15.9%), Patrys (14.3%), Heartware (12.6%) and Prima (12.3%).

Outside the BDI-40, Oncosil was up 52 percent to \$38 million, Eco Quest was up 57.1 percent to \$11 million, Invion rose 32 percent to \$33 million and Biotron was up 26.3 percent to \$24 million.

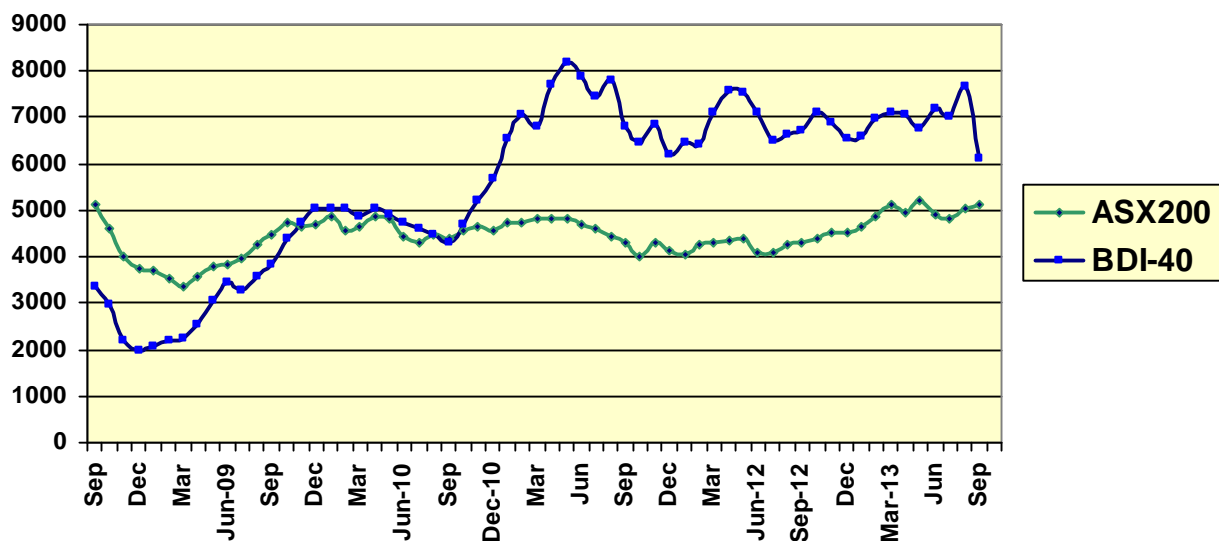
On the Nasdaq, Biota was up 7.0 percent to \$137 million and Sunshine Heart was up 51.5 percent to \$153 million.

Last month, Biotech Daily reported Invion – rather than Isona - up 105.1 percent to \$162 million, from \$6 million, a year ago. Isona was up 4.3 percent to \$169 million in August.

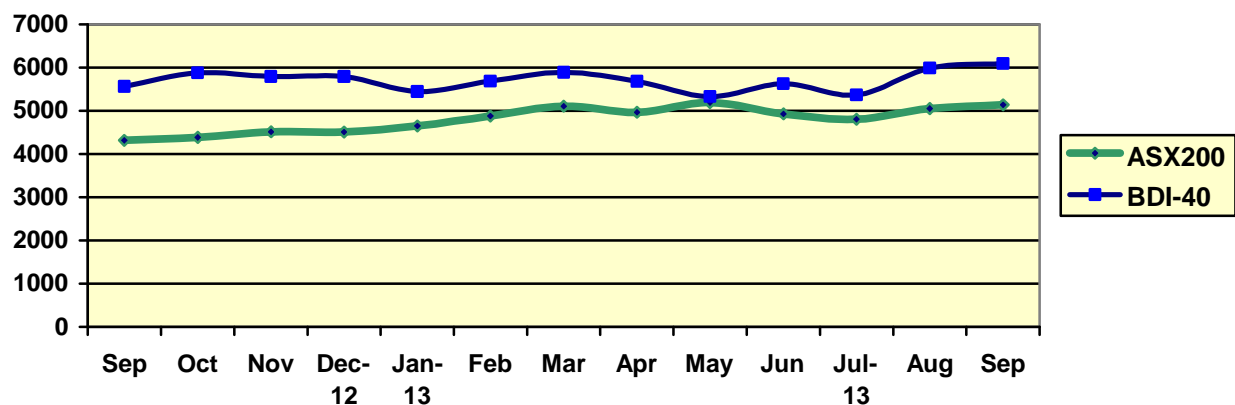
BDI-40 v ASX200 Aug 31, 2008 to Aug 31, 2013 (Five Year Data, with HIN)



BDI-40 (\$m) v ASX 200 –Aug 31, 2008 to Aug 31, 2013 (Five Year Data, ex-HIN)



BDI-40 (\$m) v ASX 200 –Aug 31, 2012- Aug 31, 2013 (12-Month Data, Adjusted)



TELESSO TECHNOLOGIES, MIMETICA

Telesso Technologies hopes to raise up to \$8 million for the backdoor listing of Mimetica to take its MTC896 topical acne treatment into phase II trials.

Mimetica director Dr Cherrell Hirst told Biotech Daily that Telesso was hoping to raise a minimum of \$6.5 million and up to \$8 million.

Dr Hirst said that Queensland Investment Corporation through QIC Bioventures would invest \$1.5 million in the raising.

Dr Hirst said that Telesso chairman Michael Hoy would retire and she would be the chair of the new company, with Starfish Ventures and Mimetica director Nick Peace and Telesso director Dr Ross Macdonald continuing as directors in the merged entity.

Dr Macdonald told Biotech Daily that Telesso company was formerly named Eiffel and was then developing super-critical fluid technology for drug manufacture

In a joint media release, Telesso and Mimetica said that Melbourne's Starfish Ventures recently invested \$1.5 million in Mimetica.

The media release said that MTC896 was a small molecule therapeutic designed to reduce excess sebum or oil production.

The media release said there was "a well documented correlation between excess sebum production and acne" and the companies were seeking to demonstrate that MTC896 was effective in reducing sebum production and, therefore, reducing or preventing the occurrence of acne.

The media release said that there was no currently approved topical acne treatment that reduces the excess sebum production.

The companies said the topical formulation of MTC896 had demonstrated a favorable safety profile with positive initial indications of its ability to reduce sebum production.

The companies said that the planned US phase II trial would seek to demonstrate clinical efficacy in reducing acne in 240 subjects with moderate-to-severe acne in a 12-week double blind, randomized controlled study.

The media release said that the demand for improved acne therapeutics was high with few treatment innovations or improvements in the past 10 years, but the acne market in 2010 accounted for about \$2.8 billion in prescription drug sales across the seven major target markets of the US, Japan, Germany, France, Italy, UK and Spain.

The media release said that Telesso planned to raise \$6.5 million through the placement of 26 million shares at 25 cents a share, giving the company a post-initial public offer market capitalization of \$24.5 million.

The companies said that the funds were expected to see it through the phase II clinical trial with completion due by July 2015.

The companies said that the offer opened to investors today and was scheduled to close in four weeks with an expected ASX re-listing on about October 15, 2013, subject to re-compliance with chapters 1 & 2 of the ASX listing rules.

The media release said Telesso would issue scrip to Mimetica shareholders to acquire all the shares in Mimetica and existing Telesso shares would be consolidated at a ratio of about 6.7 shares for one.

The companies said that following completion of the capital raising and the acquisition of Mimetica, Telesso intended to change its name to Mimetica, subject to shareholder approval.

Mr Hoy said that about \$15 million had been spent developing MTC896 to the proof-of-concept stage including trials on about 400 people.

The companies said that the capital raising was being managed by Phillip Capital.

CLINUVEL PHARMACEUTICALS

Clinuvel says follow-up results show that Scenesse with narrowband ultraviolet B light therapy is superior for vitiligo re-pigmentation than narrowband ultraviolet B alone.

Clinuvel said the 54-patient trial (CUV102) compared Scenesse (afamelanotide 16mg) in the pigmentary disorder vitiligo and re-pigmentation of patients following treatment with Scenesse was higher than with the narrowband ultraviolet B group at 11 months since the start of the treatment ($p = 0.032$).

The company said re-pigmentation for the combination group was maintained at the 11 month follow-up, vitiligo did not reoccur and no safety concerns were identified during combination treatment.

Clinuvel said that final efficacy results were published late last year (BD: Dec 19, 2012).

The company said that vitiligo affected about 45 million people, in which melanocytes or pigment producing cells of the skin appeared to become dysfunctional, with lighter depigmented patches of skin appearing, with therapy primarily intended to arrest depigmentation and stimulate re-pigmentation.

The company said that the current standard of care was narrowband ultraviolet B light, given in two or three sessions a week over up to 18 months, but the response rate was low, re-pigmentation was incomplete and many patients had a recurrence of depigmentation following cessation of therapy.

Clinuvel said that 41 patients of the 54 recruited for the trial completed the treatment at day-168 and 35 patients presented for follow up at day-336 and total body pigmentation at the two time points was compared.

Re-pigmentation in patients who received the combination of Scenesse with narrowband ultraviolet B light was statistically higher at each interval (day-224, day-280 and day-36) than narrowband ultraviolet B light alone (respectively $p = 0.025, 0.037, 0.032$).

Clinuvel said that there was clinical significance in the results found in patients with darker skin complexions and that although vitiligo affected patients of all skin types, those with darker skin complexion were often the most stigmatized due to the visible contrast between vitiliginous lesions and dark skin.

Analyses at day-224, day-280 and day-336 in patients with skin types IV to VI showed that the combination therapy was more effective than narrowband ultraviolet B light alone (respectively $p = 0.049, 0.049, 0.047$).

Clinuvel acting chief scientific officer Dr Dennis Wright said that the follow-up results "together with the earlier efficacy analyses show that Scenesse has the potential to become the main pharmaceutical agent used in the treatment of vitiligo".

Dr Wright said the next trial would focus on patients with darker skin complexion because vitiligo was most conspicuous and had a large social impact.

Clinuvel said it hoped to begin an Asian phase IIb study of Scenesse in vitiligo before the end of 2013, subject to regulatory approval.

Clinuvel fell 1.5 cents or 0.8 percent to \$1.795.

PRANA BIOTECHNOLOGY

Prana has filed US documents allowing it to raise up to US\$47,184,400 (\$A52,568,255) for general research purposes and working capital.

A 'Prospectus Supplement' said the company hoped to raise \$US47,184,400 and it intended to use the proceeds for ongoing and future research programs into the development of its compounds, including PBT2, and for working capital purposes".

Prana had a total market capitalization of \$203 million at August 31, 2013.

Prana fell 4.5 cents or 7.7 percent to 54 cents.

PHARMAUST

Pharmaust says that revenue for the year to June 30, 2013, was up six percent to \$1,721,000 reducing net loss after tax 88 percent to \$515,000.

Pharmaust said that the revenue came from its Epichem synthetic chemistry services business and it had recently merged with Pitney Pharmaceuticals (BD: Jul 23, 2013).

Pharmaust said that diluted loss per share fell 90.3 percent from 93 cents in the previous year to 0.09 cents for the year to June 30, 2013 and net tangible assets per share fell 80 percent to 0.05 cents at June 30, 2013.

The company said it had cash and cash equivalents of \$362,874 at June 30, 2013, compared to \$122,905 at June 30, 2012.

Pharmaust was up 0.1 cents or 11.1 percent to one cent with one million shares traded.

OPTISCAN

Optiscan says that revenue for the year to June 30, 2013, was up 132 percent to \$984,726 reducing net loss after tax 74 percent to \$643,950.

Optiscan said that the 144 percent increase in sales revenue to \$931,920 primarily was from the "sales of pre-clinical systems to collaboration partner, Carl Zeiss".

Optiscan develops, manufactures and sells confocal microscopes.

Optiscan said that diluted loss per share fell 78.9 percent from 1.9 cents in the previous year to 0.4 cents for the year to June 30, 2013 and net tangible assets per share increased 200 percent to 0.6 cents at June 30, 2013.

Optiscan said it had cash and cash equivalents of \$429,927 at June 30, 2013, compared to \$578,900 at June 30, 2012.

Optiscan fell 0.7 cents or 9.7 percent to 6.5 cents.

USCOM

Uscom says its net loss after tax for the 12 months to June 30, 2013 was reduced 25 percent to \$1,371,683 on revenue down 26 percent to \$638,734.

Uscom said that sales fell 26 percent, primarily in the US.

Uscom said that net tangible asset per share fell 40.0 percent from 0.02 cents at June 30, 2012 to 0.012 cents at June 30, 2013.

The company said diluted loss per share was reduced from 3.5 cents at June 30, 2012 to 2.2 cents at June 30, 2013.

Uscom said it had cash and equivalents of \$541,195 at June 30, 2013 compared to \$544,463 at June 30, 2012.

Uscom was untraded at 20 cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical says its net loss after tax for the 12 months to June 30, 2013 was up 230.1 percent to \$571,000 on revenue down 11.6 percent to \$7,175,000.

Advanced Surgical said that net tangible asset backing per share fell 13.5 percent to 9.26 cents at June 30, 2103 compared to 10.71 cents in the previous period.

The company said diluted loss per share was up 115.25 percent to 1.27 cents compared with 0.59 cents in the previous corresponding period.

Advanced Surgical said it had cash and equivalents of \$287,000 at June 30, 2013 compared to \$1,000 at June 30, 2012.

Advanced Surgical was untraded at six cents.

UNILIFE CORP

Unilife says its net loss after tax for the 12 months to June 30, 2013 was up 21 percent to \$US63,198,000 (\$A70,349,020) on revenue down 50 percent to \$US2,743,000.

The company said diluted loss per share was constants at 78 US cents.

Unilife said it had cash and equivalents of \$US5,736,000 at June 30, 2013 compared to \$US11,410,000 at June 30, 2012.

Unilife was up three cents or 4.8 percent to 66 cents.

PHOSPHAGENICS

Phosphagenics says revenue for the six months to June 30, 2013 was down 39 percent to \$929,000, with a net loss after tax up 20 percent to \$6,072,000.

Phosphagenics said that sales of goods, primarily its Elixia cosmetics range including the fat-buster cream was "\$485,000, which were 40 percent lower than \$729,000 reported for the first half [of] 2012".

Phosphagenics said its net tangible assets per share fell 28.1 percent to 1.69 cents and diluted loss per share was up 0.01 cents to 0.59 cents.

The company said it had cash and cash equivalents of \$14,095,000 at June 30, 2013 compared to \$16,912,000 at June 30, 2012.

Phosphagenics was up half a cent or 5.9 percent to nine cents.

NEUREN PHARMACEUTICALS

Neuren says director Dr John Holaday has resigned, chief executive officer Larry Glass has been appointed chief science officer, with James Shaw as chief operating officer.

Neuren said that Mr Glass had been chief executive officer since 2009 and would remain on the board and would be responsible for its scientific and regulatory strategies, management of relationships with key stakeholders such as the US Army, the International Rett Syndrome Foundation and regulatory authorities, as well as interaction with the broader scientific and pharmaceutical industry communities.

The company said that Mr Glass was "the chief architect of Neuren's chronic neuro-developmental program as well as the lead in our relationship with the US Army".

Neuren said it had "progressed from an emphasis on acute indications to now include chronic indications, from a single clinical trial in traumatic brain injury to an ongoing trial in Rett syndrome and now planned studies in Fragile X syndrome and concussion."

The company said that the resources had been realigned to respond better to the needs of shareholders as well as strategic partners and the US Food and Drug Administration.

Neuren said that Mr Shaw had spent the last 10 years with clinical research organizations including Quintiles, where he held senior roles in clinical operations and business development.

The company said Mr Shaw held a Bachelor of Science from the University of Warwick, England and a Master of Business Administration from the Australia Graduate School of Management.

QRX Pharma chief executive officer Dr John Holaday said he had resigned as a non-executive director effective from August 30, 2013 "due to other business commitments".

QRX has faced a series of delays in the regulatory process for its Moxduo dual opioid product (BD: Aug 28, 2013).

Former Acrux chief financial officer Jon Pilcher joined Neuren last month.

Neuren was up .04 cents or 4.3 percent to 9.7 cents with three million shares traded.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Sep-12	Aug-13	Sep-13
Cochlear	3,874	3,484	3,237
CSL	22,286	32,182	32,645
Resmed	5,634	8,030	8,404
BDI-20			
Acrux	566	561	553
Alchemia	149	120	136
Allied Health	22	55	91
Benitec	17	24	24
Bionomics	102	226	255
Clinuvel	54	73	67
Impedimed	33	27	28
Mesoblast	1,821	1,852	1,725
Nanosonics	130	194	232
Neuren	27	120	117
Osprey	37	54	67
Pharmaxis	336	51	40
Prana	54	145	203
Prima	144	122	107
Psivida	38	92	107
Reva	182	186	197
Sirtex	429	699	720
Starpharma	421	275	278
Tissue Therapies	74	49	73
Universal Biosensors	92	131	119
Second 20			
Anteo	42	44	45
Antisense	23	26	20
Atcor	9	16	17
Avita	33	44	41
Cellmid	9	18	20
Circadian	18	11	13
Compumedics	17	12	15
Ellex	16	21	26
Genetic Technologies	56	40	43
GI Dynamics	227	259	292
IDT Australia	10	13	19
Living Cell	17	19	19
Medical Dev	64	79	86
Optiscan	13	12	10
Patrys	10	21	18
Phosphagenics	133	107	99
Phylogica	12	9	7
QRX Pharma	100	145	122
Uscom	9	12	12
Viralytics	20	26	32

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Allied Health, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Acrux, Alchemia, Atcor, Avita, Circadian, Cochlear, Ellex, Neuren, Pharmaxis, Prana, Sirtex and Universal Biosensors. These holdings are liable to change.

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