



# Biotech Daily

Monday February 2, 2015

*Daily news on ASX-listed biotechnology companies*

- \* JANUARY BDI-40 DOWN 1%, ASX200 UP 3%, BIG CAPS UP 4%
- GENETIC TECHNOLOGIES UP 69%, NEUREN 46%; ALCHEMIA, PHARMAXIS DOWN 21%
- \* TODAY: ASX UP, BIOTECH DOWN: NANOSONICS UP 5%, GENETIC TECH DOWN 20%
- \* INVION COMPLETES INV102 SMOKING CESSATION TRIAL ENROLMENT
- \* ACRUX, ELI LILLY AXIRON SALES RECOVERING FROM CARDIAC SCARE
- \* TISSUE THERAPIES 'CAPITAL RAISING' TRADING HALT
- \* BIONOMICS RESTARTS BNC210 ANXIETY PROGRAM
- \* UNILIFE TO RAISE \$53m
- \* UNIVERSAL BIOSENSORS RETAINS \$US10m LOAN OPTION
- \* MEDIBIO HAS LESS THAN ONE QUARTER CASH; \$2.5m PLACEMENT VOTE
- \* BANK OF AMERICA, MERRILL LYNCH BUY, BORROW 6% OF IDT
- \* IMUGENE PROMOTES CEO CHARLES WALKER TO M-D
- \* CLINICAL GENOMICS: WARREN BINGHAM, MICHELE HOULDSWORTH
- \* PHYTOTECH TO LOSE FOUNDER ROSS SMITH; ERLYN DALE TO CO SEC
- \* BPH APPOINTS BRUCE WHAN DIRECTOR; DEBORAH AMBROSINI CO SEC

## MARKET REPORT

The Australian stock market was up 0.66 percent on Monday February 2, 2015 with the S&P ASX 200 up 37.0 points to 5,625.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and three were untraded.

Nanosonics was the best, up seven cents or 5.2 percent to \$1.42 with 1.4 million shares traded. Benitec, Living Cell and Viralytics climbed more than three percent; Prana, Sirtex and Starpharma rose more than two percent; Bionomics, Ellex, Mesoblast and Optiscan were up more than one percent; with Cochlear, CSL and Psivida up less than one percent.

Genetic Technologies led the falls, retreating from Friday's 108.3 percent jump, down half a cent or 20 percent to two cents with 42.8 million shares traded. Circadian fell 14.3 percent; Admedus lost eight percent; Analytica and GI Dynamics fell more than seven percent; Impedimed, Phosphagenics and Universal Biosensors were down six percent or more; Acrux and Neuren fell more than five percent; Anteo, Antisense and Pharmaxis fell more than four percent; IDT was down 3.3 percent; Clinuvel fell 2.7 percent; with Alchemia, Atcor and Resmed down more than one percent.

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

Despite more Biotech Daily Top-40 Index (BDI-40) stocks climbing than falling, small percentage falls by Mesoblast and Sirtex dragged the January BDI-40 down 0.8 percent.

In January, the S&P ASX200 was up 3.3 percent to 5,588.3, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a further 4.4 percent for the month - up 29.1 percent for the 12 months to January 31, 2015. Cochlear was up 6.8 percent to \$4,738 million, CSL rose 1.3 percent to \$41,679 million while Resmed jumped 16.4 percent to \$11,292 million.

Nineteen of the BDI-40 companies were up in January, 17 fell and four were unchanged.

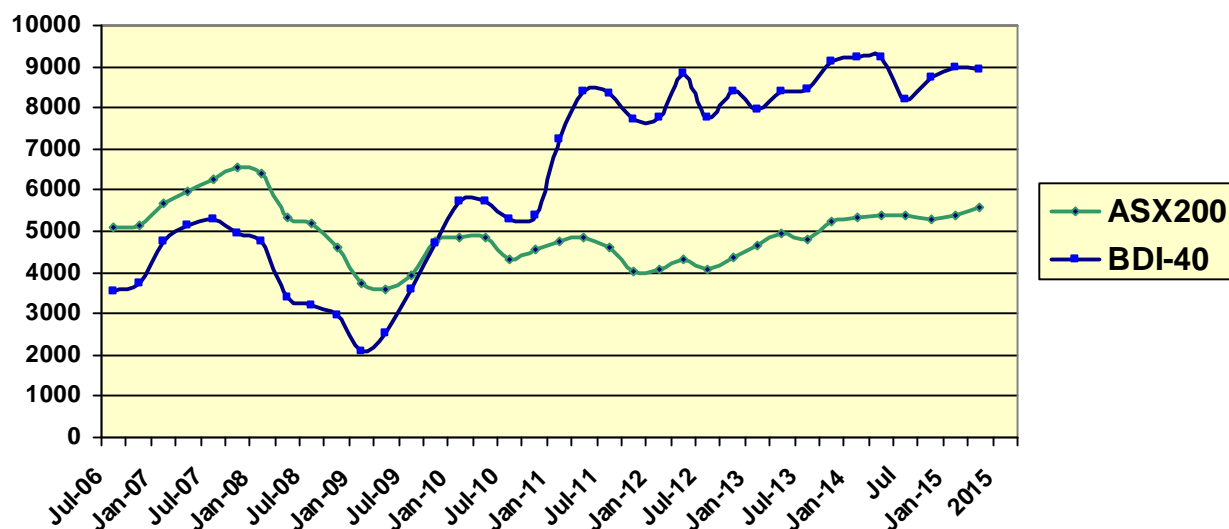
Genetic Technologies had a late recovery last Friday on news of six US centres adopting its Brevagenplus test, taking it up 69.2 percent for the month to a market capitalization of \$22 million, followed by Neuren up a further 46.1 percent to \$279 million having filed US FDA applications for breakthrough therapy and orphan drug status for NNZ-2566 for Rett syndrome. Medical Developments climbed 35.9 percent to \$106 million as it closed in on European approval for Pentrox, followed by Antisense and Compumedics, both up 26.7 percent, Universal Biosensors (25%), Impedimed (19.6%) and GI Dynamics (18.4%).

Mesoblast lost \$120 million (8.4%) and Sirtex fell \$81 million (5.0%), but the deepest percentage fall was Pharmaxis down 21.4 percent to \$33 million followed by Alchemia down 20.7 percent to \$23 million, Benitec (19.1%), Oncosil (16.1%), Starpharma (11.9%) and Prana (10.2%).

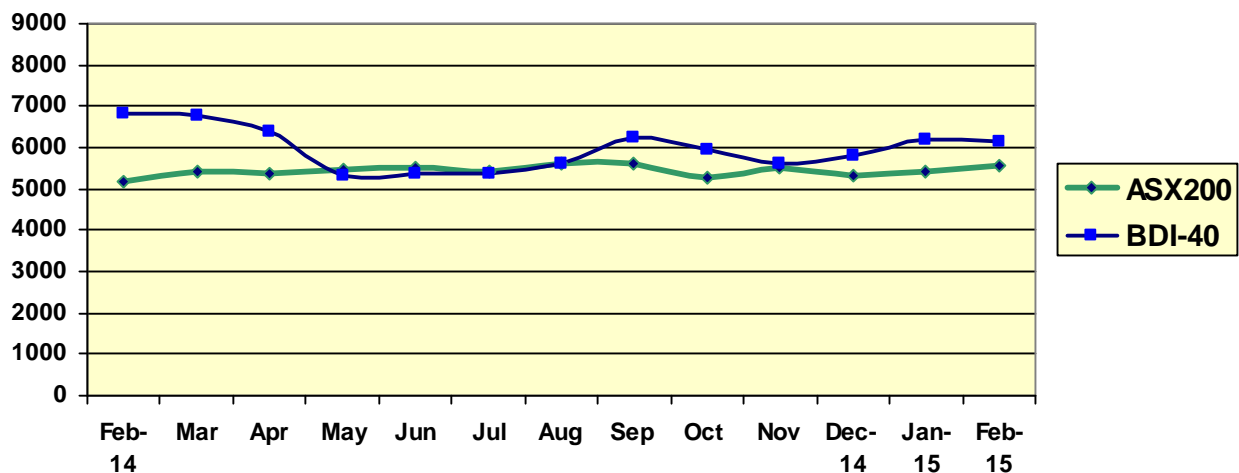
Outside the BDI-40, Reva recovered 20.6 percent to \$164 million, with Actinogen and Unilife making solid progress. On the Nasdaq, the former Australian companies had an exchange rate leg-up, with Biota up 12.5 percent to \$108 million, Heartware up 19.6 percent to \$1,830 million and Sunshine Heart up 28.2 percent to \$109 million.

Circadian chief executive officer Dr Megan Baldwin has overseen a recovery at her company, which returns to the BDI-20 replacing Alchemia, which joins the Second 20.

### **BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2015 - Adjusted**



## BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2014- Jan 31, 2015



### INVION

Invion says it has completed enrolment for its phase II clinical trial of INV102, or nadolol, for respiratory patients trying to quit smoking but have failed multiple times previously. Invion said that patients with chronic bronchitis or a smoker's cough might have a harder time quitting smoking and were more likely to be incapacitated or die from lung disease. The company said that the smoking cessation trial protocol was designed to examine the effect of INV102 in patients with chronic bronchitis who were enrolled in validated smoking cessation programs, with the primary objective to evaluate the efficacy of INV102 in improving rates of smoking cessation over a 10 to 12 week treatment period.

Invion chief medical officer Dr Mitchell Glass said that completing enrolment in the phase IIb smoking cessation study was "a key milestone for Invion since this is the regulatory and commercial target for oral INV102".

"Completion of enrolment enables us to plan for dedicated resources to analyze the study and to prepare for our end of phase II meeting with the [US Food and Drug Administration] as well as other key regulatory agencies during the second half of 2015," Dr Glass said.

"The positive interim data that we recently released validates our approach for treating the airway epithelium even in the face of ongoing insult, such as cigarette smoking," Dr Glass said.

"We will be exploring whether these airway effects relate to successful quitting within this population of patients, who have failed so often previously," Dr Glass said.

"We have been pleased that nearly all patients to date have tolerated titration to a maintenance dose and have remained enrolled in a smoking cessation program," Dr Glass said.

"We know that patient treatment and follow-up should be completed early in the third quarter, at which time we will undertake the intensive analysis of data from the trial, including smoking cessation, biomarkers of airway inflammation and remodelling, and the correlations of these effects with drug treatment and dose," Dr Glass said.

"Safety and tolerability of INV102 in these patients, together with the previously reported results from the NIH-sponsored study of nadolol in mild asthma (NIMA), strongly support our development of inhaled INV102 for the long-term treatment of chronic airway diseases, including COPD, severe asthma and cystic fibrosis," Dr Glass said.

Invion was up 0.2 cents or 4.2 percent to five cents.

## ACRUX

Acrux says that net sales of Axiron fell 4.6 percent to \$US170.5 million (\$A218.96 million) for the 12 months to December 31, 2014 compared to \$US178.7 million in the prior year. In February 2014, the then exchange rate meant that the \$US178.7 million was equivalent to \$A203.4 million, implying a 7.65 percent increase in Australian dollar terms.

Last year, sales fell following news that the US Food and Drug Administration was investigating reported cardio-vascular risks in men taking approved testosterone products (BD: Feb 4, 2014).

In November, Acrux reported that the European Medicines Agency had released a statement, entitled 'No consistent evidence of an increased risk of heart problems with testosterone medicines' (BD: Nov 24, 2014).

Acrux chief executive officer Michael Kotsanis told Biotech Daily that researchers at the Utah-based Intermountain Medical Center Heart Institute last year separately presented a paper entitled 'Testosterone replacement therapy does not increase cardiovascular risks in men with low testosterone levels' at the November 2014 American Heart Association meeting in Chicago.

The study of 5,695 men concluded that testosterone therapy in men with low testosterone was associated with reduced major adverse cardiac events and death over three years compared to no or ineffective supplementation.

An article entitled 'Testosterone Therapy and Cardiovascular Risk: Advances and Controversies' published in the Mayo Clinic Proceedings concluded: "The largest meta-analysis to date revealed no increase in [cardiovascular] risks in men who received [testosterone] and reduced [cardiovascular] risk among those with metabolic disease."

"In summary, there is no convincing evidence of increased [cardiovascular] risks with [testosterone] therapy," the paper said.

"On the contrary, there appears to be a strong beneficial relationship between normal [testosterone] and [cardiovascular] health that has not yet been widely appreciated," the authors concluded.

The paper, authored by Harvard Medical School researchers and colleagues is available at: <http://www.mayoclinicproceedings.org/article/S0025-6196%2814%2900925-2/pdf>.

Today, Acrux said that Eli Lilly reported Axiron net sales of \$US47.6 million (\$A61.115 million) for the three months to December 31, 2014, compared to \$US53.9 million for the three months to December 31, 2013.

Last year, Axiron said that revenue for the three months to September 30, 2014 was \$US36.3 million (\$A41.4 million) (BD: Oct 24, 2014).

The company previously said that it would be entitled to a \$US50 million royalty milestone, believed to be when global sales reached more than \$US200 million in one calendar year (BD: Jan 31, 2014).

Acrux fell eight cents or 5.2 percent to \$1.45 with 1.5 million shares traded.

## TISSUE THERAPIES

Tissue Therapies has requested a trading halt "pending an announcement regarding a proposed capital raising".

Trading will resume on February 4, 2015 or on an earlier announcement.

Tissue Therapies last traded at 29 cents.

## BIONOMICS

Bionomics says it has initiated a phase Ib trial of BNC210 for anxiety and depression in more than 50 healthy volunteers.

Bionomics said the randomized, double-blind, placebo-controlled, ascending dose trial would be conducted by Biotrial International in Rennes, France and to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of BNC210.

The company said that four groups of subjects would be enrolled to receive one of four doses of BNC210 or placebo, twice a day for eight days, with target engagement by BNC210 investigated through the use of a nicotine challenge where the subjects response to nicotine would be monitored by an electroencephalogram (EEG).

Bionomics said that the primary endpoint would be the safety and tolerability of BNC210 following multiple administrations with secondary endpoints investigating the pharmacokinetic and pharmacodynamic profile of BNC210 and its effect on cognitive functions and the response to nicotine.

The company said that a phase IIa BNC210 study in patients suffering anxiety was planned to begin in the UK by April, 2015.

Bionomics chief executive officer Dr Deborah Rathjen said that the company was "eager to get back to the clinic with BNC210 and unlock the potential of this compound."

In 2011, Bionomics said that two phase Ib trials of BNC210 begun in France demonstrated efficacy with reduced sedation and intellectual impairment, in evaluations for panic attacks compared to placebo and against the benzodiazepine lorazepam for side effects such as attention, memory, co-ordination and sedation (BD: Mar 30, 2011).

In January 2012, Bionomics licenced the compound to the Cambridge Massachusetts-based Ironwood Pharmaceuticals, which announced the start of a phase I trial in December of that year (BD: Jan 22, Dec 21, 2012).

With no further announcement about the development path, Bionomics said last year that it had taken back BNC210 from Ironwood (BD: Nov 11, 2014).

"We expect this to be a pivotal year in its development and given the data thus far are confident it will be another Bionomics drug candidate that will attract the interest of big pharma companies," Dr Rathjen said today.

Bionomics said that trial data was expected by October, 2015.

Bionomics was up half a cent or 1.2 percent to 42.5 cents.

## UNILIFE

Unilife Corporation says it hopes to raise up to \$53.02 million through an underwritten US public offering of 11,000,000 US shares the public at \$US3.75 (\$A4.82) per share.

Unilife said the proceeds were expected to be \$US38,792,500 after deducting underwriting discounts and commissions and estimated expenses and in addition the company has granted the underwriters an option for a period of 30 days to purchase up to an additional 1,650,000 shares of its US stock.

The company said that the offer was expected to close on February 4, 2015, subject to customary closing conditions, with Jefferies LLC and Piper Jaffray & Co acting as joint book-running managers for the offering and Griffin Securities acting as a co-manager.

Unilife said it expected to use the proceeds for plant, equipment, systems and personnel to further develop its manufacturing and operational capabilities and general corporate purposes, including working capital, acquisitions and other business opportunities.

Unilife fell 8.5 cents or 9.1 percent to 85 cents with 1.3 million shares traded.

### UNIVERSAL BIOSENSORS

Universal Biosensors says it has chosen not to draw down funds from a loan facility provided US investment adviser Athyrium Capital Management.

Universal Biosensors said that Athyrium had agreed to extend the company's option to draw down a further \$US10 million until July 31, 2015.

The company said that in December 2013 it entered into a five-year term loan with funds managed by Athyrium of up to \$US25 million and it drew down \$US15 million upfront and had the option to draw down two further tranches each of \$US5 million if commercial conditions were achieved prior to January 30, 2015.

Universal Biosensors said it met the conditions to draw down an additional \$US5 million including the achievement of revenue thresholds for Onetouch Verio blood glucose strips and coagulation test strips supplied to Siemens.

The company said that with cash reserves of \$16.3 million at December 31, 2014 and expectations of increasing revenues from quarterly service fees and coagulation test strip production for Siemens, it did not require the additional loan capital.

Universal Biosensors said the additional \$US10 million available under the Athyrium loan provided flexibility to respond to risks and opportunities with cost effective and non-dilutive capital and it had the option to draw down the additional funds within 30 days of any fiscal quarter ending on or before July 31, 2015 in which the existing revenue thresholds were met, subject to customary closing conditions.

The company said that in consideration of granting an extension to the delayed draw tranches, Athyrium would be paid a fee of \$US200,000.

Universal Biosensors fell 1.5 cents or 6.5 percent to 21.5 cents.

### MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says its net operating cash burn for the three months to December 31, 2014 was \$676,000 with cash at the end of the quarter of \$302,000.

Medibio executive director Kris Knauer told Biotech Daily that the company expected the March 6, 2015 extraordinary general meeting to approve the \$2.5 million second tranche of its \$3.5 million placement at 0.3 cents a share (BD: Oct 6, 2014).

Mr Knauer said that the previous quarter included one-off costs associated with the change of business and acquisition of the Invatec cardiac-rhythm based diagnostic for depression and other mental disorders.

Medibio fell 0.05 percent or 14.3 percent to 0.3 cents with 2.3 million shares traded.

### IDT AUSTRALIA

Bank of Australia Corp and related companies including Merrill Lynch have become substantial shareholders in IDT with 11,125,000 shares or 5.82 percent of the company.

The substantial shareholder notice in the name of Bank of America said that Merrill Lynch (Australia) Futures had the "power to control voting and or/disposal of securities ... as ultimate beneficial owner" and Merrill Lynch International (Australia) had the same authority under a prime brokerage agreement.

The notice said that Merrill Lynch (Australia) Futures bought 8,700,000 shares for \$1,305,000 or 15 cents a share and Merrill Lynch International (Australia) had "borrowed" 2,425,000 shares.

IDT fell half a cent or 3.3 percent to 14.5 cents.



### IMUGENE

Imugene says that chief executive officer Charles Walker has been appointed as managing director, effective immediately.

Imugene said that Mr Walker was appointed chief executive officer in August 2014 and had "overseen an important period for the company including the significant advancement of product development activities, in addition to overseeing the recent capital raising".

Imugene was unchanged at 0.9 cents with 1.3 million shares traded.

### CLINICAL GENOMICS

Clinical Genomics says it has appointed Warren Bingham as Asia-Pacific vice-president and Michele Houldsworth as regulatory affairs vice-president.

Clinical Genomics said that Mr Bingham had managed the Australia-New Zealand business of Given Imaging for more than 10 years and he would be responsible for increasing the existing cancer screening and detection business in Australia and opening new markets in the Asia-Pacific.

The company said Ms Houldsworth had been quality manager since 2012, she had been a quality manager for Somnomed and Cathrx and had experience in pre-market approvals and product registrations in the US, Europe, China and Australia and her aim was to win pre-market approval for the company's blood test for colorectal cancer in the US.

The company said that chief executive officer Dr Lawrence LaPointe would relocate from Australia to the US office in New Jersey.

Clinical Genomics is a private company.

### PHYTOTECH MEDICAL

Phytotech says that founder Ross Smith has resigned as a director and Erlyn Dale has replaced company secretary Loren Jones.

Phytotech chairman Peter Wall said that Mr Smith had been "instrumental in bringing together an outstanding team to manage the business [and] the company would not be where it is today without Ross's hard work and perseverance".

"Having achieved what the majority of people said couldn't be done in listing Australia's first medical cannabis company, I am stepping down from the board confident that the world class team we brought together and the company will go on to become a huge success," Mr Smith said.

Phytotech said that Ms Dale had "a broad range of experience in corporate governance and company compliance", had been involved with several ASX listed companies and held a Bachelor of Commerce degree.

Phytotech fell 5.5 cents or 11.6 percent to 42 cents with 4.1 million shares traded.

### BPH ENERGY

BPH says that Deborah Ambrosini has resigned as a director but continues as the company secretary and Bruce Whan has been appointed a director.

BPH said that Mr Whan was an experienced company director and a current director of the Melbourne-based Swinburne Ventures which had established or become involved in 18 start-up companies attracting investment of more than \$16 million.

BPH has investments in several biotechnology companies including the Swinburne University based Cortical Dynamics.

BPH was untraded at 0.6 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT JAN 31, 2015

<b>Company \$Am</b>	<b>Feb-14</b>	<b>Jan-15</b>	<b>Feb-15</b>
Cochlear	3,292	4,435	4,738
CSL	34,306	41,132	41,679
Resmed	7,103	9,699	11,292
<b>BDI-20</b>			
Acrux	391	214	255
Admedus	207	173	180
Benitec	68	110	89
Bionomics	300	180	175
Biotron	20	29	32
Circadian	10	24	26
Clinuvel	46	179	167
GI Dynamics	328	114	135
Impedimed	40	245	293
Mesoblast	1,863	1,423	1,303
Nanosonics	239	362	357
Neuren	152	191	279
Osprey	82	67	62
Pharmaxis	40	42	33
Prima	59	45	50
Psivida	151	145	143
Sirtex	780	1,604	1,523
Tissue Therapies	76	84	76
Universal Biosensors	87	32	40
Viralytics	27	54	56
<b>Second 20</b>			
Alchemia	191	29	23
Analytica	17	25	25
Anteo	147	101	81
Antisense	19	15	19
Atcor	22	16	16
Avita	44	27	28
Cellmid	23	21	20
Compumedics	13	15	19
Ellex	47	30	32
Genetic Technologies	36	13	22
IDT	30	29	29
Living Cell	30	27	25
Medical Developments	63	78	106
Oncosil	47	31	26
Optiscan	10	11	12
Patrys	30	11	12
Phosphagenics	117	95	100
Prana	481	98	88
Starpharma	223	168	148
Uscom	11	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.

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