



Biotech Daily

Wednesday February 1, 2017

Daily news on ASX-listed biotechnology companies

- * **BDI-40 DOWN 12%, ASX200 UP 3%, BIG CAPS UP 12%**
- **MESOBLAST UP 40%; LIVING CELL 37%; SIRTEX DOWN 48%, IMPEDIMED 39%**

- * **TODAY: ASX UP, BIOTECH DOWN: LIVING CELL UP 9%, USCOM DOWN 6%**

- * **OVENTUS 02VENT T RECALL; ZHUHAI BLUE CHINA COLLABORATION**

- * **ACRUX, ELI LILLY AXIRON 2016 SALES DOWN 6% TO \$192m, 'NO GENERIC'**

- * **SHAREHOLDER CLAIM FORESHADOWS SIRTEX LEGAL ACTION**

- * **CANADA, EUROPE APPROVE NUHEARA IQBUDS**

- * **GI DYNAMICS WINS GERMAN ENDOBARRIER REIMBURSEMENT**

- * **ADALTA RELEASES 27m ESCROW SHARES**

- * **NOXOPHARM, HONG KONG UNI RESEARCH NOX66 FOR BRAIN CANCER**

- * **RESPIRI COMPLETES CORE TECHNOLOGY, AGAIN**

- * **CHARLES BRODERICK, UJI TAKE 5% OF MMJ PHYTOTECH**

- * **MEDIBIO APPOINTS ANDREW MAXWELL DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.57 percent on Wednesday February 1, 2017 with the ASX200 up 32.3 points to 5,653.2 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 13 traded unchanged and one was untraded.

Living Cell was the best, up one cent or 9.1 percent to 12 cents with 1.6 million shares traded. Opthea climbed 8.9 percent; Acrux and Genetic Signatures were up more than three percent; Anteo and Atcor rose more than two percent; Bionomics, Factor Therapeutics and Osprey were up more than one percent; with Cochlear, CSL and Medical Developments up by less than one percent.

Uscom led the falls, down 1.5 cents or 6.1 percent to 23 cents with 50,406 shares traded. Reva lost 5.5 percent; Avita, Cyclopharm and Viralytics fell more than four percent; Clinuvel, Ellex and Pro Medicus were down more than three percent; Prima shed 2.9 percent; Oncosil, Prana and Sirtex were down one percent or more; with Airxpanders, Compumedics, Mesoblast, Resmed and Starpharma down by less than one percent.

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

The Biotech Daily Top 40 Index (BDI-40) fell 12.3 percent in the two months of the Australian Summer Holiday period.

Biotech Daily was unable to compile data for December 31, 2016, so today's figures cover November 30, 2016 to January 31, 2017, as well as the year to January 31, 2017.

The ASX200 was up 3.3 percent for the two month period, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a collective 12.3 percent, with the Nasdaq Biotechnology Index up 1.6 percent.

For the year to January 31, 2017, the BDI-40 fell 1.1 percent, the ASX200 was up 12.3 percent, the Big Caps rose 9.7 percent and the NBI was up 4.1 percent.

Nearly all of the BDI-40's \$970 million tumble was due to Sirtex down \$764 million or 47.9 percent to \$830 million and Impedimed's \$176 million (38.5%) retreat to \$281 million.

Interestingly, 19 of the BDI-40 companies were up, with 11 up by more than 10 percent, while 18 fell, with 10 down by more than 10 percent.

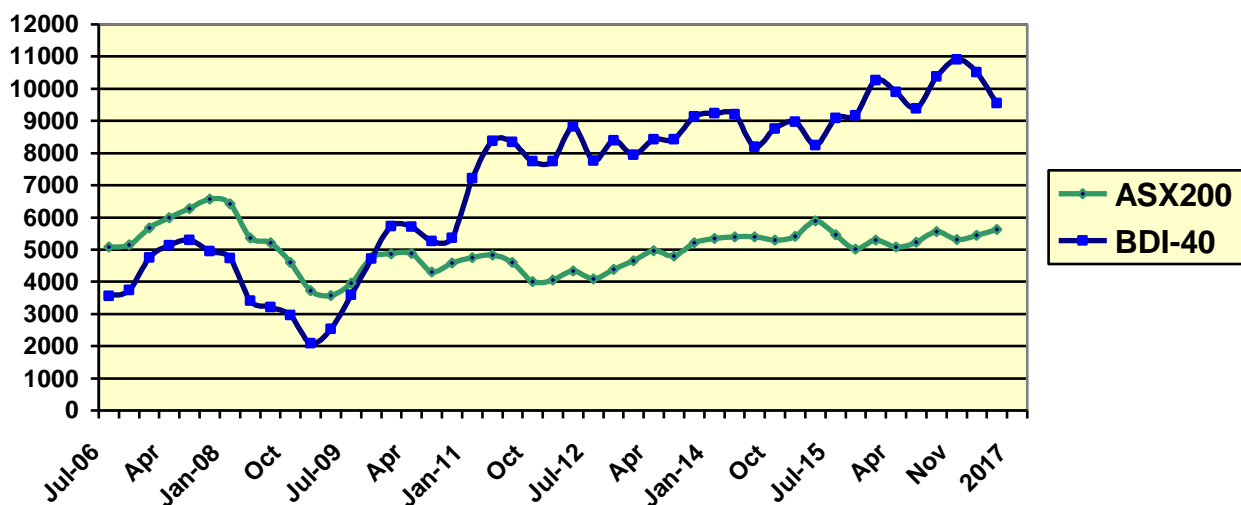
Following Sirtex and Impedimed down were: Factor Therapeutics (20.7%), Anteo (17.0%), Avita (15.1%), Nanosonics (14.3%), Airxpanders (13.4%) and Ellex (13.3%). Nanosonics has overtaken Sirtex as Australia's largest market cap biotech after the Big Caps.

Mesoblast was the best, up 40.0 percent to \$647 million, followed by Living Cell (37.0%), Uscom (21.7%), Opthea (20.5%), Medical Developments (17.8%) and Benitec (17.6%).

Outside the BDI-40, the President Trump-related Innate Immunotherapeutics has been on an upward roller coaster, climbing 62.7 percent for the two months to January 31, but up 708.8 percent for the year, while waiting for multiple sclerosis trial results. Medlab Clinical jumped 387.5 percent for the year, with Medibio up 194.7 percent, Cogstate up 139.7 percent and Phylogica up 133.3 percent.

On the Nasdaq, Aviragen (Biota) fell a further 9.6 percent to \$66 million, while Israel's Redhill was up 13.3 percent to \$213 million.

BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2017- Adjusted



OVENTUS MEDICAL

Oventus has issued a product recall for some of its O2Vent T mouth-guard anti-snoring and moderate sleep apnoea devices, citing a fault in the adjuster assembly.

The O2Vent T was approved by the US Food and Drug Administration in September last year with first sales announced last month (BD: Sep 26, 2016; Jan 22, 2017).

Oventus said that the recall was undertaken following consultation with the Australian Therapeutic Goods Administration.

Biotech Daily understands that the recall letter was dispatched to customers earlier this week but Oventus chief executive officer Neil Anderson said the company had legal advice that the recall was “not material” in terms of making an announcement to shareholders through the ASX. The company filed an announcement late today. The ASX Listing Rule 3.1 on transparency says that an entity must inform the ASX once it “becomes aware of any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity’s securities” and further defines that as information that would be likely to influence persons who commonly invest in securities in deciding whether or not to buy or sell those securities.

Oventus began a 40-patient trial of the device in Brisbane last year to investigate the comfort and efficacy of the inclusion of an airway into an oral appliance and the trial was expected to be completed by April 2017 (BD: Jul 26, 2016).

Oventus chairman Dr Mel Bridges told Biotech Daily that about 400 O2Vent T devices had been made available to the public through sales or trials but “only a small proportion” were affected by the recall.

Mr Anderson told Biotech Daily that the recall applied to one batch of 191 O2Vent T devices manufactured between September 1 and November 30, 2016.

Mr Anderson said that 12 had been returned to the company, prompting the recall and all would be examined for correct adhesion of the adjustment assembly.

Mr Anderson said that at the very worst case, if all devices needed repair, that the cost including shipping would be less than \$5,000.

Oventus said told customers that the manufacturer had “determined that a correction to the adjuster assembly part of the O2Vent T device [was] necessary and must be returned for corrective safety improvement”.

The company said that “the performance of the device and risk to patient safety [was] affected by the faulty adhesion of the adjuster assembly part”.

Oventus said that the adjuster assembly allowed adjustment of the screw and hook for adjustment by mandibular, or lower jaw, advancement for optimized treatment.

Oventus said that customers were advised to stop using the device and return them for corrective work which would take about 10 working days.

The company said it sincerely regretted any inconvenience the recall caused.

In a separate announcement, Oventus said it had a distribution and collaboration deal with the Zhuhai, Guangdong, China-based Zhuhai Blue Ocean Strategy Medical Co.

Oventus said that agreement included clinical trials, staff training, achievement of regulatory clearances and marketing preparations for China.

The company said that Zhuhai Blue Ocean Strategy Medical Co had 633 network hospitals across 400 cities in China and many of the hospitals had sleep clinics, some of which had continuous positive airway pressure (CPAP) as the first line of treatment, with the O2Vent T intended as an alternative to CPAP treatment.

The company said that China had more than 70 million obstructive sleep apnoea sufferers and it was a growing problem due to the aging population and obesity.

Oventus said that a formal distribution agreement was expected by the end of 2017.

Oventus was up 10 cents or 14.3 percent to 80 cents.

ACRUX

Acrux says that net sales of Axiron fell 6.0 percent to \$US145.2 million (\$A191.8 million) for the 12 months to December 31, 2016 compared to \$US154.5 million in the prior year. The US net sales figure has fallen for three years in a row since the high point of \$US178.7 million for the 2013 year.

In 2014, sales fell following news that the US Food and Drug Administration was investigating reported cardio-vascular risks in men taking approved testosterone products, despite a European Medicines Agency statement, entitled 'No consistent evidence of an increased risk of heart problems with testosterone medicines' (BD: Feb 4, Nov 24, 2014). Today, Acrux said that sales rose in the three months to December 31, 2016 compared to the three previous quarters increasing \$US900,000 or 2.3 percent in the three months to December 31 compared to the three months to September 30, 2016, but down 4.1 percent compared to the previous corresponding period.

The company said that despite a challenge in the US to its intellectual property "to date there has been no launch of a generic of Axiron".

Acrux was up one cent or 3.2 percent to 32 cents with 1.9 million shares traded.

SIRTEX MEDICAL

Sirtex says it has received a letter and draft statement of claim, foreshadowing legal proceedings in the Federal Court of Australia.

The letter, from Portfolio Law's Anthony Zika in the Pascoe Vale office, was sent on behalf of client Todd Hayward who acquired 340 Sirtex shares for \$9,449 on December 1, 2016 and held them at the time that the company share price fell following a profit warning on December 9, 2016.

Sirtex said the statement of claim alleged breaches by the company of its continuous disclosure obligations and alleged misleading and deceptive conduct, arising from a statement on August 24, 2016, regarding "double digit dose sales growth".

The company said the class of members identified in the statement of claim was "all persons who acquired ordinary shares in the [company] on or after August 24, 2016 and who were at the commencement of trading on December 9, 2016 holders of any of those shares" and said that if the foreshadowed proceeding was commenced, it would "vigorously defend the proceeding".

The letter from Mr Zita said that in compliance with the provisions of the Civil Dispute Resolution Act 2011, the purpose of the letter and its enclosure was to notify Sirtex of the issues in dispute and to offer to enter into settlement discussions.

"Unless Sirtex Medical Limited notifies me by 12pm on February 6, 2017 that it wishes to enter into settlement discussions, a proceeding will be commenced in the Victorian Registry of the Federal Court of Australia thereafter," Mr Zita wrote.

Sirtex said it had acknowledged receipt of the letter and asked for an extension of time until February 13, 2017 to respond.

Sirtex fell 16 cents or 1.1 percent to \$14.22 with 1.1 million shares traded.

NUHEARA

Nuheara says that its Iqbuds sound filtering and device ear buds mobile telephone application have Conformité Européenne (CE) mark and Canadian certification.

Nuheara said it was approved to fill European and Canadian pre-orders and then begin broader retail sales.

Nuheara was unchanged at 10.5 cents with 1.8 million shares traded.

GI DYNAMICS

GI Dynamics says the German Institute for the Hospital Remuneration System has awarded its Endobarrier for obesity and type 2 diabetes NUB Status 1 for 2017.

GI Dynamics said that the Neue Untersuchungs und Behandlungsmethoden (NUB) system provided additional payments for new diagnostic and treatment methods and allowed for the introduction of new and innovative medical devices prior to reaching reimbursement eligibility, as well as a supplemental payment for new technologies in the German reimbursement system (BD: Nov 23, 2016).

The company said that NUB Status 1 was the highest of four levels, allowing for full reimbursement for the 143 participating hospitals in 2017, with payers at the hospitals obligated to cover the gaps in treatment costs for the Endobarrier procedure.

GI Dynamics chief executive officer Scott Schorer said that the NUB 1 designation was “an important step towards full reimbursement for Endobarrier in Germany, where there is a significant need for additional therapeutic options for patients with type 2 diabetes and obesity”.

GI Dynamics said that the Endobarrier was currently approved for sale in several countries outside the US.

Last year, the Australian Therapeutic Goods Administration cancelled the Endobarrier listing on the Australian Register of Therapeutic Goods (BD: Sep 14, Oct 24, 2016)

In 2014, Europe stopped Endobarrier shipments pending a review of vigilance and reporting systems, allowing a restart later that year (BD: Oct 6, Dec 1, 2014).

In 2015, the company closed its 500-patient trial with 325 patients enrolled, following seven cases of the bacterial liver infection hepatic abscess (BD: Jul 30, 31, 2015).

GI Dynamics was up 0.3 cents or 12.5 percent to 2.7 cents.

ADALTA

Adalta says that 26,354,040 shares will be released from voluntary escrow on February 22 and 576,967 shares from ASX escrow on February 23, 2017.

Adalta said that after the release there would be 77,002,725 shares available for trading with a further 207,571 shares in ASX escrow until September 27, 2017 and 23,900,594 shares in ASX escrow until August 2018.

Adalta was untraded at 21 cents.

NOXOPHARM

Noxopharm says it has an agreement with the University of Hong Kong to conduct research into the use of idronoxil for brain cancer.

Noxopharm said that idronoxil was the active ingredient of its NOX66 which was the subject of “a number of previously undisclosed oncology and non-oncology pre-clinical activities, all intended to add to the company’s drug development pipeline”.

The company said that the Hong Kong research objective was to take idronoxil to the clinic for the treatment of both primary and secondary brain cancers.

Noxopharm said the collaboration aimed to confirm the ability of NOX66 to sensitise brain cancer cells to the chemotherapy drug temozolomide and demonstrate that NOX66 would lead to significantly higher response rates in both adult and paediatric brain cancers.

The company said that the pre-clinical study, including animal studies using human brain cancer xenografts, was planned to run for 12 months and lead to a phase I trial of NOX66 in combination with temozolomide for glioblastoma multiforme in 2018.

Noxopharm was up one cent or two percent to 51 cents.

[RESPIRI \(FORMERLY ISONEA, KARMELSONIX\)](#)

Respiri says it has completed its core technology software platform and the latest generation of the Airsona smart mobile telephone application for asthma.

Respiri said the application was “designed to help asthmatics better monitor and manage their asthma, stay in control of symptoms and feel well”.

The company said the core technology was an essential component of negotiations and the primary focus for the rest of the year was the completion of partnership transactions.

Respiri said the core technology provided the basis for the development of a “state-of-the-art wireless overnight monitoring product”.

“Using sensors, proprietary algorithms and analytics to quickly, easily and objectively measure the major symptom of asthma, wheeze, the latest generation Airsona [application] allows users to set preventer medication reminders, log symptoms, allergic triggers and reliever medication doses,” Respiri said.

The company said that the Airsona application allowed patients to “view all trends and graphs seamlessly so the relationship between asthma symptoms and triggers and response to medication can be understood in an instant”.

Respiri said that physicians lacked “the tools to understand how their patients are doing between visits and adjust therapy ... [and the] Airsona diary features provide healthcare professionals with invaluable data to help in the design of essential asthma action plans”.

The company said that wheeze measurements and diary data were automatically sent through Wifi servers to the secure Respiri cloud-based internet storage system where users could track and share their results.

Karmelsonix listed on the ASX in 2006 to develop the respiratory diagnostics originally invented by the Haifa, Israel-based Dr Noam Gavriely (BD: Nov 24, 2006).

In 2011, Karmelsonix changed its name to Isona and by January 2015 had appointed its fourth chief executive officer in 12 months, changing its name to Respiri and starting a 90-patient Chicago trial (BD: Aug 30, 2011; Jan 23, Oct 27, Nov 25, 2015).

With investment from poker machines operator Bruce Mathieson, Isona’s market capitalization peaked at \$194 million at September 30, 2013, with a share price above 80 cents, but fell to \$9 million at January 31, 2016.

Respiri was unchanged at 5.2 cents.

[MMJ PHYTOTECH](#)

The New York based Uji Capital LLC says it has become a substantial shareholder in MMJ Phytotech with 9,631,419 shares (5.0%).

The substantial shareholder notice was signed by Uji managing director Charles Broderick and said the shares were acquired for \$2,250,081 or 23.4 cents a share.

MMJ was up four cents or 14.8 percent to 31 cents with 5.9 million shares traded.

[MEDIBIO](#)

Medibio says that it has appointed Andrew Maxwell as a non-executive director replacing Dr Franklyn Prendergast moving to chairman of its advisory board.

Medibio said that Mr Maxwell was previously the managing-director of Global Kinetics Corp developing the approved Parkinson’s Kinetigraph product for the remote measurement and reporting of the movement disorder symptoms of Parkinson’s disease.

The company said that Mr Maxwell was previously the chief executive officer of Escor Private Equity, a Smorgon family company, managing a \$40 million investment fund.

Medibio was unchanged at 38 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JAN 31, 2017

Company \$Am	Feb-16	Dec-16	Feb-17
Cochlear	5,362	6,817	7,188
CSL	48,132	44,684	51,144
Resmed	11,233	11,694	12,646
BDI-20			
Admedus	124	91	88
Airxpanders	267	268	232
Bionomics	156	176	164
Clinuvel	131	384	384
Compumedics	70	131	117
Ellex	85	181	157
Impedimed	311	457	281
Medical Developments	226	258	304
Mesoblast	578	462	647
Nanosonics	543	1,000	857
Neuren	189	116	131
Opthea	53	112	135
Pharmaxis	101	88	91
Polynovo	140	155	155
Prima	95	77	73
Pro Medicus	317	553	508
Psivida	151	85	80
Reva	437	475	430
Sirtex	2,155	1,594	830
Viralytics	177	274	257
Second 20			
Acrux	117	52	52
Actinogen	31	30	35
Anteo	72	53	44
Atcor	39	15	16
Avita	56	86	73
Benitec	41	17	20
Cellmid	19	31	32
Cyclopharm	35	54	57
Dimerix	8	12	13
Factor Therapeutics	12	58	46
Genetic Signatures	54	47	42
IDT	77	47	45
Living Cell	20	46	63
Oncosil	90	45	47
Orthocell	33	29	33
Osprey	46	111	113
Prana	42	29	30
Starpharma	235	243	278
Universal Biosensors	67	52	59
Uscom	17	23	28

* Biotech Daily editor, David Langsam, owns shares in Acrux, Admedus, Benitec, Mesoblast, Nanosonics, Neuren, 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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