



Biotech Daily

Monday October 3, 2016

Daily news on ASX-listed biotechnology companies

- * **SEPTEMBER BDI-40 UP 2%, ASX200 UP 0.1%, BIG CAPS DOWN 1%**
- **BIONOMICS UP 92%, OSPREY 42%; BENITEC DOWN 26%, ACTINOGEN 22%**
- * **TODAY: ASX UP, BIOTECH DOWN: ANTEO UP 4%**
- **POLYNOVO, UNIVERSAL BIOSENSORS DOWN 7%**
- * **AUSBIOTECH: 'R&D REVIEW RISKS COMPETITIVE ADVANTAGE'**
- * **RESAPP: 'MORE POSITIVE RESPIRATORY DISEASE ANALYSIS DATA'**
- * **POLYNOVO TO MARKET BTM WOUND TREATMENT DIRECTLY IN THE US**
- * **ASX REMOVES MEDIVAC FROM OFFICIAL LIST**
- * **GENERA: 'US, UK SAMPLE DATA BACKS PAPTYPED HPV TEST'**
- * **GENETIC TECHNOLOGIES PROMOTES BREVAGENPLUS**

MARKET REPORT

The Australian stock market climbed 0.78 percent on Monday October 3, 2016 with the ASX200 up 42.6 points to 5,478.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and four were untraded.

Anteo was the best, up 0.2 cents or four percent to 5.2 cents with 557,038 shares traded.

Acrux and Medical Developments climbed more than three percent; Bionomics and Osprey rose more than two percent; Airxanders was up 1.8 percent; with Clinuvel, Impedimed and Sirtex up less than one percent

Polynovo and Universal Biosensors led the falls, both down two cents or 6.9 percent to 27 cents with 2.4 million shares and 15,950 shares traded, respectively.

Benitec and Living Cell fell more than five percent; Atcor, Cellmid and Pro Medicus were down more than three percent; Neuren shed two percent; Admedus, Factor Therapeutics, Orthocell and Uscom were down more than one percent; with Cochlear, Compumedics, CSL, Ellex, Mesoblast, Nanosonics, Opthea, Reva and Viralytics down by less than one percent.

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

The Biotech Daily Top 40 Index (BDI-40) continued to out-perform the ASX200, up 2.0 percent in September to a collective market capitalization of \$8,446 million.

The ASX200 edged up just 0.1 percent in September, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell a collective 1.25 percent, with Resmed retreating 6.0 percent to \$11,858 million, CSL slipping 0.3 percent to \$49,188 million and Cochlear up 0.5 percent to \$8,114 million.

For the year to September 30, 2016, the BDI-40 was up 32.4 percent, the ASX200 rose 8.2 percent, with the Big Caps up a collective 22.5 percent (see chart below).

In the month of September, 21 of the BDI-40 companies were up, 11 by more than 10 percent, 17 were down, eight by more than 10 percent, with two companies unchanged.

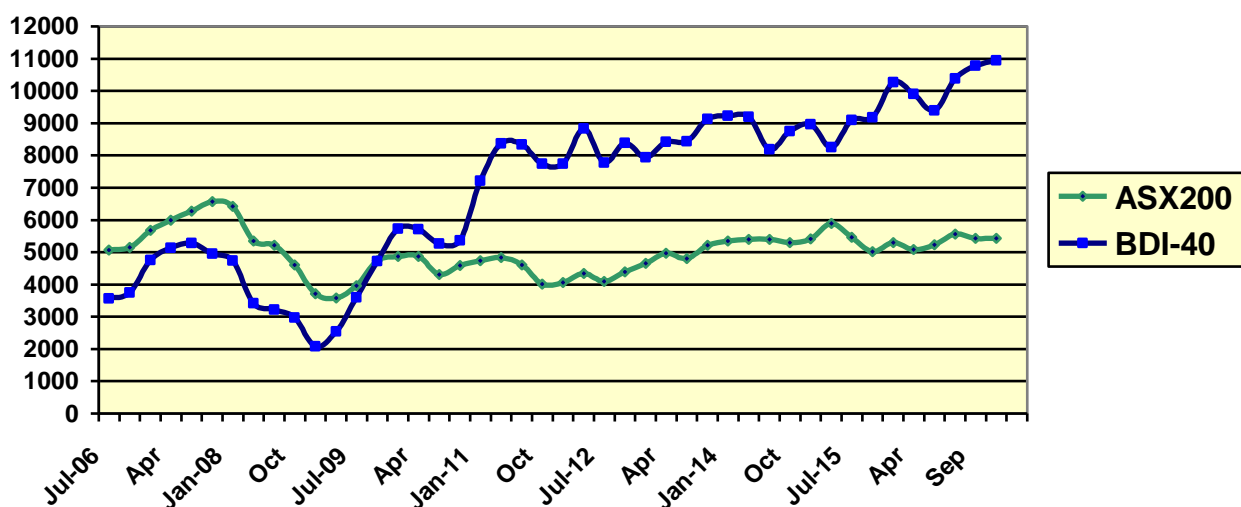
Bionomics was the best, up 92.2 percent to \$221 million on BNC210 trial data, followed by Osprey recovering 42.0 percent to \$98 million, Opthea (37.5%), Dimerix (31.25%), Orthocell (27.3%), Airxpanders (18.75%), Neuren (15.8%) and Clinuvel (15.5%).

Benitec led the falls, down 26.3 percent to \$14 million, followed by Actinogen (21.9%), Psivida (20.6%), Uscom (18.2%), Mesoblast (17.0%) and Anteo (16.2%).

Outside the BDI-40, eight companies have made significant gains in the month and year to September 30: Cynata was up 74.1 percent for the month and 51.5 percent for the year; followed by Phosphagenics (66.7%, 122.2%); Resapp (35.7%, 1,706.25%); Innate Immunotherapeutics (32.1%, 270%); Paradigm (31.8%, 150.0%); Cogstate (29.1%, 320.8%); Dorsavi (21.7%, 170.4%); and Mayne Pharma (10.3%, 269.7%).

The Nasdaq Biotech Index rose 3.0 percent in September (down 4.5 percent for the year to September 30), with Aviragen (Biota) up 27.9 percent to \$97 million, Sunshine Heart falling 31.8 percent to just \$15 million, having dumped its C-Pulse heart pump technology and Israel's Redhill, developing Giacomda's assets, down 8.7 percent to \$231 million. With Heartware's acquisition by Medtronic and Sunshine Heart no longer developing its New Zealand-originated technology, Biotech Daily has ceased its coverage of both companies.

BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2016 - Adjusted



AUSBIOTECH

Ausbiotech says the Review of the R&D Tax Incentive and its recommendations have met with frustration and despondency from the biotechnology industry.

Ausbiotech chief executive officer Glenn Cross said that there was a strong objection to the 'Ferris, Finkel, Fraser' recommendation of a \$2 million cap on the refundable component of the Research and Development Tax Incentive program that would disadvantage a significant portion of the small and medium sized enterprises in the sector. "The R&D Tax Incentive is the most critical centre-piece program in the translation of Australia's world-class research into treatments, cures, diagnostics devices and vaccines," Mr Cross said.

"It is important that the program not be diminished with unnecessary complexity, conditions and carve outs, and instead provide consistency and certainty to the life sciences sector to allow its development," Mr Cross said.

"The review report comes on the back of, and therefore without regard for, the recent passing of the Omnibus Bill, which enacted the 1.5 per cent cut to the program, saving the Government a reported \$600 million," Mr Cross said.

"The Report that was completed in April has not taken account of this saving already removed from the program," Mr Cross said.

The unrelenting threat to the R&D Tax Incentive and efforts to trim and cap is unsettling for an industry that takes many years to develop each treatment, diagnostic, cure and medical device," Mr Cross said.

"Ausbiotech has been arguing to keep the program consistent and stable since its inception, more than seven years ago," he said.

"Overseas companies and investors are already reporting that they are pulling back plans to bring clinical trials and research investment to Australia, causing havoc with planning, creating even greater uncertainty and discouraging the industry from investing," Mr Cross said.

Ausbiotech said that among other recommendations there was a welcome acknowledgement that the \$100 million cap that was placed on the program last year was too low and should be raised, along with the introduction of an intensity measure, which would ensure appropriate preferential treatment to research and development-intensive companies, like biotechnology companies, the detail and the implications were unclear. The industry organization said the report contained positive comment about the much-needed quarterly payments, which it had been advocating for many years. Ausbiotech said that notable in the report was the comment that the estimated cost of implementation was a one-off bring-forward cost, but there would be no on-going cost impact.

"Ausbiotech has been a tireless advocate for quarterly payments, since the first announcement on the tax incentive in 2009," Mr Cross said.

Ausbiotech said its survey showed that the timing of the receipt of payments, that is quarterly or annually, was "a critical factor" in its value as an incentive for additional research and development activities.

"Concern remains over the overstating of the cost of the program, which appears to be the justification driving the narrative for change," Mr Cross said.

"The R&D Tax Incentive has been the shining beacon of encouragement and support to the industry and plays a pivotal role in motivating and attracting research, development and clinical trials to be conducted in Australia as well as local investment," Mr Cross said.

Ausbiotech said it welcomed the Federal Government's willingness to seek submissions and consult widely before finalizing a response by the end of March 2017.

Ausbiotech invited members to comment directly by contacting the deputy chief executive officer Lorraine Chiroiu by email at: lchiroiu@ausbiotech.org.

RESAPP HEALTH

Resapp says that further preliminary results from its adult clinical study shows “high levels of sensitivity, specificity and accuracy on an expanded adult dataset”.

Resapp said that the study of its cough sound-based algorithms was being undertaken at the Perth, Western Australia-based Joondalup Health Campus and the Brisbane-based Wesley Hospital, with the data prepared by a team led by the University of Queensland’s Prof Udantha Abeyratne.

The company said the algorithms achieved between 91 percent and 100 percent accuracy for distinguishing adult patients with chronic obstructive pulmonary disease, asthma or pneumonia from subjects with no discernible respiratory disease.

Resapp said that the new analysis showed “100 percent accuracy for distinguishing patients with an upper respiratory tract infection from the no respiratory disease group [which was] not previously reported”.

The company said that there were 20 patients with an upper respiratory tract infection.

Resapp said that its smart-phone-based technology “correctly detected lower respiratory tract disease in 84 percent of adult patients initially diagnosed as clear by experienced clinicians using stethoscopes”.

The company said that the differential diagnosis of asthma compared to chronic obstructive pulmonary disease, pneumonia versus asthma, and pneumonia compared to chronic obstructive pulmonary disease was between 88 percent and 94 percent accurate. Resapp chief executive officer Dr Tony Keating said the reported “high levels of accuracy in a significantly larger dataset” continued to build the clinical evidence base.

“It is also excellent to note that once again our algorithms outperformed experienced clinicians by correctly detecting lower respiratory tract infection in patients initially diagnosed as clear,” Dr Keating said.

Resapp said that its Smartcough-C US paediatric study was a prospective, multi-site, double-blind study to evaluate the efficacy of the Resappdx software to diagnose childhood pneumonia and other respiratory conditions from cough sounds and three hospitals had been confirmed as study sites.

The company said that study protocol had been finalized and the study would begin following ethics approvals, expected within two to six weeks.

Resapp fell 4.25 cents or 8.7 percent to 44.5 cents with 8.2 million shares traded.

POLYNOVO

Polynovo says it will market its biodegradable temporising matrix wound treatment directly in the US, rejecting partnership options with major medical device companies.

Polynovo said it hoped “to emulate the success of Mimedx which entered the US wound matrix market five years ago with a sales team of five, becoming a \$300 million turnover business”.

The company said that the biodegradable temporising matrix (BTM) wound treatment market was concentrated in fewer than 25 centres and the product margins were high.

Polynovo said that a core team of three well-established sales people could achieve “a rapid market penetration and maximize our margin” and a direct sales force would allow it to establish a close relationship with customers, build a dedicated surgeon support sales model and allow it to directly control the market.

The company said that the sales team would be supported by a third-party logistics company, which would manage a customer service call centre, warehousing, dispatch, accounts receivable and logistics and it expected to generate revenue by the end of 2016.

Polynovo fell two cents or 6.9 percent to 27 cents with 2.4 million shares traded.

MEDIVAC

The ASX says it has removed Medivac from the official list, under listing rule 17.12 from the start of trading today, Monday October 3, 2016.

The ASX said its policy was to automatically remove from the official list any entity whose securities had been suspended from trading for a continuous period of three years.

Last week Medivac said its reverse takeover by Brand TV Media was terminated because the ASX refused a relisting deadline" (BD: Sep 26, 2016).

Medivac was attempting to commercialize its Metamizer medical waste system and Sunnywipes hand hygiene products (BD: May 13, 2011; May 7, 2012).

In 2012, the company merged with Republica Capital and in 2014 sought funds to rebadge itself as Woolwich Capital (BD: Oct 29, 2012; Jan 31, 2014).

Last year, Medivac said it had a \$200,000 converting loan to re-list on the ASX, changed its board and was conducting a review of its business (BD: Aug 10, 2015).

Medivac last traded at 0.3 cents.

GENERA BIOSYSTEMS

Genera said that results from 2,025 cervical screening specimens in a US screening population was consistent with prior data generated by its Papttype in other studies.

Genera said the evaluation was undertaken by the University of New Mexico Health Sciences Centre and it had received an analysis on the data set by the London-based Wolfson Institute of Preventive Medicine's Prof Jack Cuzick group.

The company said the data was consistent with Papttype data from other studies in both atypical cells of undetermined significance (Ascus) referral and screening populations in the detection of cervical intraepithelial neoplasia grade 2 (CIN2+).

Genera chief executive officer Richard Hannebery said he was "very pleased with the data showing sensitive detection of CIN2+ and CIN3+ as it represents the strongest performance of Papttype in an independent clinical study we have delivered to date".

The company said it was undertaking an additional study in about 6,650 patient samples at the Wolfson Institute with the additional data expected in November and it had tendered for an Indian state government-funded project to screen half a million women in the Thane district near Mumbai, over five years.

Genera was untraded at 21 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will conduct a Brevagenplus promotional campaign around the Susan G Komen Race for the Cure events, beginning in Dallas, Texas.

Genetic Technologies said that the Brevagenplus risk assessment test for non-hereditary breast cancer promotional program would begin on October 15, 2016, which coincided with the US national breast cancer awareness month.

According to its website, the Susan Goodman Komen breast cancer charity was founded by Ms Komen's sister Nancy Goodman Brinker in 1982 to fund research, community health outreach, advocacy and programs to reduce breast cancer.

Genetic Technologies chief executive officer Eutillio Buccilli said his company was "pleased to join Susan G Komen in the world's largest fundraising initiative to fight breast cancer".

Genetic Technologies said that breast cancer would affect one in eight women during their lifetime.

Genetic Technologies was untraded at 1.6 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEP 30, 2016

| Company \$Am | Oct-15 | Sep-16 | Oct-16 |
|----------------------|---------------|---------------|---------------|
| Cochlear | 4,772 | 8,073 | 8,114 |
| CSL | 41,472 | 49,347 | 49,188 |
| Resmed | 10,213 | 12,617 | 11,858 |
| BDI-20 | | | |
| Admedus | 116 | 78 | 81 |
| Airxpanders | 151 | 272 | 323 |
| Bionomics | 199 | 115 | 221 |
| Clinuvel | 124 | 251 | 290 |
| Compumedics | 46 | 100 | 107 |
| Ellex | 43 | 122 | 138 |
| Impedimed | 260 | 576 | 601 |
| Medical Developments | 190 | 303 | 317 |
| Mesoblast | 1,066 | 511 | 424 |
| Nanosonics | 374 | 923 | 1,006 |
| Neuren | 138 | 76 | 88 |
| Opthea | 29 | 80 | 110 |
| Pharmaxis | 73 | 94 | 86 |
| Polynovo | 56 | 151 | 156 |
| Prima | 115 | 78 | 79 |
| Pro Medicus | 241 | 640 | 583 |
| Psivida | 147 | 175 | 140 |
| Reva | 270 | 555 | 542 |
| Sirtex | 1,871 | 1,933 | 1,852 |
| Viralytics | 109 | 219 | 219 |
| Second 20 | | | |
| Acrux | 95 | 62 | 57 |
| Actinogen | 36 | 32 | 25 |
| Anteo | 81 | 68 | 57 |
| Atcor | 47 | 22 | 20 |
| Avita | 35 | 58 | 64 |
| Benitec | 64 | 19 | 14 |
| Cellmid | 27 | 29 | 29 |
| Cyclopharm | 32 | 66 | 72 |
| Dimerix | 11 | 16 | 21 |
| Factor Therapeutics | 13 | 36 | 40 |
| Genetic Signatures | 31 | 35 | 38 |
| IDT | 69 | 56 | 52 |
| Living Cell | 16 | 44 | 38 |
| Oncosil | 52 | 63 | 56 |
| Orthocell | 37 | 22 | 28 |
| Osprey | 106 | 69 | 98 |
| Prana | 69 | 59 | 56 |
| Starpharma | 251 | 257 | 240 |
| Universal Biosensors | 61 | 49 | 51 |
| Uscom | 13 | 33 | 27 |

* 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.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au; twitter: @biotech_daily