



# Biotech Daily

Thursday October 1, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **SEPTEMBER BDI-40 DOWN 1%, ASX200 DOWN 4%, BIG CAPS DOWN 2%**
  - **ONCOSIL UP 48%, IDT 38%, MEDICAL DEVELOPMENTS 38%**
  - **BIOTRON DOWN 36%, TISSUE THERAPIES 24%, BENITEC 22%**
- \* **TODAY: ASX, BIOTECH UP: ELLEX UP 22.5%, ANTISENSE DOWN 9%**
- \* **ELLEX REDUCES GLAUCOMA SURGERY TO 5-MIN PROCEDURE**
- \* **CORRECTION: ANALYTICA**
- \* **ADHERIUM : 'THREE UK STUDIES BACK SMARTINHALER'**
- \* **PARANTA RAISES \$7m FOR PB01 FOR CYSTIC FIBROSIS**
- \* **REVA ENROLS FIRST 110-PATIENT FANTOM II COHORT**
- \* **PATRY'S SHUTS GERMAN PLANT, COO ROGER MCPHERSON GOES**
- \* **GENETIC SIGNATURES DIRECTOR PATRICK NOLAND RESIGNS FOR US**

## MARKET REPORT

The Australian stock market climbed 1.8 percent on Thursday October 1, 2015 with the ASX200 up 90.5 points to 5,112.1 points. Twenty of the Biotech Daily Top 40 stocks were up, nine fell, six traded unchanged and five were untraded. All three Big Caps were up.

Ellex was the best, up as much as 14 cents or 35 percent to 54 cents, before closing up nine cents or 22.5 cents at 49 cents with 367,855 shares traded, followed by Oncosil up 20.7 percent to 17.5 cents with 11.4 million shares traded.

Genetic Technologies climbed 5.9 percent; Impedimed was up 4.5 percent; Cellmid, Clinuvel, Medical Developments and Prana were up more than three percent; Anteo, Atcor, Benitec, Circadian and Neuren rose more than two percent; Acrux, Admedus, Bionomics, Resmed, Sirtex, Universal Biosensors and Viralytics were up more than one percent; with Cochlear, CSL and Osprey up by less than one percent.

Antisense led the falls, down 0.8 cents or 9.3 percent to 7.8 cents with 150,000 shares traded. Optiscan lost 4.1 percent; Actinogen was down 3.3 percent; Orthocell and Reva shed more than two percent; Nanosonics and Pro Medicus were down more than one percent; with Mesoblast and Starpharma down more than one percent.

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

Despite the tumble of world markets, the BDI-40 slipped 0.85 percent in September to \$6,281 million compared to the S&P ASX200 falling 3.55 percent. For the year to September 30, the BDI-40 was up 7.1 percent while the ASX200 fell 5.1 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell a cumulative 2.4 percent for the month, but were up 19.8 percent for the year. Cochlear slipped 2.2 percent to \$4,772 million, CSL shed 2.9 percent to \$41,472 million with Resmed down 0.5 percent to \$10,213 million.

Fifteen of Biotech Daily Top-40 Index (BDI-40) companies were up, 23 fell and two were unchanged, but only seven falls were by 10 percent or more, while 11 rises were by more than 10 percent, with five up more than 30 percent.

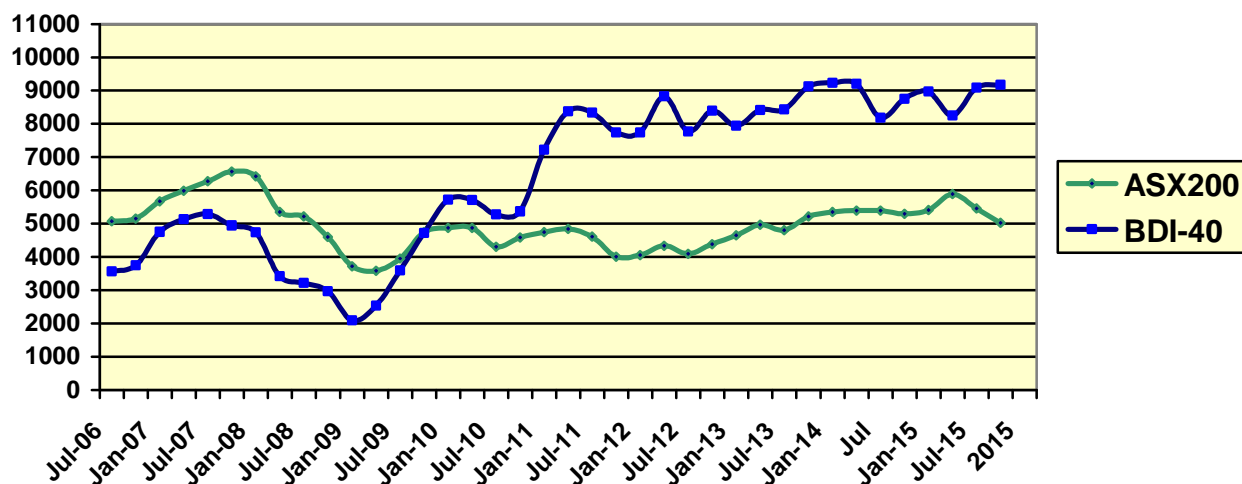
Oncosil was September's best, on a European review of its pancreatic cancer treatment, next week, up 44.4 percent to \$52 million, followed by IDT (38%), Medical Developments (37.7%), Starpharma (36.4%), Polynovo (33.3%), Atcor (23.7%), Bionomics (19.2%), Prima (16.2%), Orthocell (15.6%), Actinogen (12.5%) and Pharmaxis (12.3%).

Biotron led the falls, on yesterday's hepatitis C trial results, down 35.5 percent to \$20 million, followed by Tissue Therapies (23.5%), Benitec (21.95%), Genetic Technologies (19.4%), Impedimed (14.75%), Prana (10.4%) and Cellmid (10%).

Outside the BDI-40, Pro Medicus resumed its stellar rise, up 5.2 percent to \$241 million, but climbing 162.0 percent for the 12 months to September 30, 2015. Pro Medicus joins the BDI-40 today, replacing Analytica.

On the Nasdaq, Biota was up 2.8 percent to \$109 million, Heartware fell 38.0 percent to \$1,292 million and Sunshine Heart lost 24.7 percent to \$58 million. According to Google Finance data, the Nasdaq Biotechnology Index fell 18.7 percent in the past five days, but was up 235.2 percent over five years, with the Nasdaq Composite Index down 6.4 percent over five days, but up 89.7 percent over five years. The BDI-40 was up 71.0 percent and the ASX200 rose 9.6 percent for the five years to September 30, 2015 (see chart below).

### **BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2015 – Adjusted**



## ELLEX MEDICAL LASERS

Ellex says its Itrack canaloplasty micro-catheter can reduce up-to 45 minute surgery for glaucoma with a five-minute procedure.

Ellex chief executive officer Tom Spurling told Biotech Daily that the launch of its new ab-interno, or within the colored part of the eye, canaloplasty surgical procedure, followed clinical investigations and was based on three-year trial data,

The company said that it acquired the patented and US Food and Drug Administration approved Itrack canaloplasty micro-catheter on December 31, 2013 from Iscience Interventional (BD: Dec 20, 2013, Jan 19, 2014).

Mr Spurling said that traditional canaloplasty was designed as an ab-externo, or outside, meaning the white of the eye, procedure, typically taking 30 to 45 minutes to perform and requiring significant surgeon training.

The company said that it had collaborated with leading physicians to develop an ab-interno canaloplasty (ABIC) procedure, which was "much faster and more streamlined adaption of the traditional canaloplasty procedure ... [and] ideally suited to patients suffering from glaucoma in its earlier stages".

"Performed with our proprietary Itrack micro-catheter, ABIC is a five-minute procedure designed for use by cataract surgeons during cataract surgery," Mr Spurling said.

"It is also suitable for use by glaucoma surgeons and cataract surgeons as a stand-alone procedure," Mr Spurling said.

"With the introduction of ABIC we now have access to the fast-growing [minimally invasive glaucoma surgery] device market, in addition to Ellex's existing Blebless Ab externo glaucoma surgery market," Mr Spurling said.

Mr Spurling said that the ABIC opened a significantly larger market for the Itrack, with about 3.9 million cataract operations performed each year in the US and 23 million globally and 20 percent of US patients having cataract surgery also suffering glaucoma. Ellex said that in the US, the new ABIC procedure would be covered by existing insurance reimbursement codes already secured by Ellex and the combined market was valued at \$US90 million for 2015 and expected to grow to \$US686 million by 2020.

The company said that there were three major industry participants in the combined market, with Glaukos Corp having an 85 to 90 percent market share, Ellex at five to six percent of market share and Allergan with three to four percent.

"This market offers a transformational growth opportunity for our business, with companies ... achieving significant valuations," Mr Spurling said. "We are confident the Itrack will compete strongly in this market and accordingly will result in a significant boost to Ellex's value as a leading ophthalmic device company."

Ellex was up as much as 35 percent, closing up nine cents or 22.5 cents at 48 cents.

## ANALYTICA

Last night's edition described the company as having low sales of its Pericoach intra-vaginal, pelvic floor strength diagnostic and monitor system.

Analytica chief executive officer Geoff Daly has told Biotech Daily today that he is not disappointed with the current level of sales.

"They are as expected for a product like this at this early stage," Mr Daly said.

"Pericoach only became available in Australia in January and the roll-out in the US has only just begun," Mr Daly said.

Biotech Daily apologizes unreservedly for the misinterpretation. The mistake was made by the Spring sub-editor who has taken up a new position selling the AFL Football Record.

Analytica was untraded at 0.6 cents.

## ADHERIUM

Adherium says that data from three independent UK studies demonstrate the efficacy of its Smartinhaler platform in paediatric asthma management.

Adherium said that the presentations were made at the European Respiratory Society International Congress, in Amsterdam, September 26 to 30, 2015 and showed an increase in adherence, an increase in lung function and a reduction in oral steroids indicating reduced severe exacerbations.

The company said that the clinical outcomes built on data published in Lancet Respiratory Medicine in January 2015, which showed use of the Smartinhaler platform increased adherence to preventative medication by 180 percent and reduced use of reliever medication by 45 percent.

Adherium chief executive officer Garth Sutherland said the studies "clearly show the impact that the application of Adherium's Smartinhaler platform can have on the health outcomes of children with asthma".

"Most notably, the Sheffield study showed a substantial reduction in the need for oral steroids, indicating a significant reduction in severe attacks, and an increase in lung function," Mr Sutherland said.

Adherium said that University of Sheffield clinical research fellow Dr Robert Morton presented a study entitled 'Randomised control trial to investigate whether electronic adherence monitoring with reminder alarms and feedback can improve clinical outcomes in childhood asthma' which showed that use of the Smartinhaler platform increased adherence by 144 percent, reduced oral steroid use by 37 percent, with a 14.9 percent increase in lung function as measured by mean forced expiratory volume in one second.

The company said that University of Nottingham's Sam Howard presented a study entitled 'Exploring the attitudes of adolescents with asthma towards monitoring and sharing of data on their inhaler use' which showed that adolescents and parents were "significantly positive" about having inhaler use monitored and shared with family or healthcare providers and the adolescents were enthusiastic about using the device to prove their independence and demonstrate responsibility for their asthma.

The company said that Royal Brompton & Harefield National Health System Foundation Trust study, entitled 'Improvement in asthma control and airway inflammation during a period of electronic monitoring', compared self-assessment of adherence with electronic monitoring with the Smartinhaler in 50 children with difficult asthma, resulting in improved lung function, lung inflammation and quality of life.

Adherium fell one cent or 1.6 percent to 61 cents.

## PARANTA BIOSCIENCES

The Melbourne-based privately owned Paranta says it has raised \$7 million to develop recombinant human follistatin PB01 for cystic fibrosis.

Paranta chief executive officer Ross Barrow told Biotech Daily that a three-part, phase I trial of 80 healthy volunteers began last month for the first study of inhaled PB01.

The company said that the study was a randomized, double-blind, placebo controlled trial, with the first two stages to be conducted at CMax in Adelaide to evaluate the safety, tolerability and pharmacokinetics of single and multiple ascending doses, with the third stage expected to start in January 2016 in Manchester, UK to investigate the effects of a single dose of PB01 on lung inflammation.

Paranta said that its second program was focused on the development of intravenously administered PB01 as a chemotherapy-sensitizing agent for use in the treatment of cancer.

## REVA MEDICAL

Reva says it has enrolled the first cohort of 110 patients in the Fantom II clinical trial which will provide the data for its Conformité Européenne (CE) mark application.

Reva said that the enrolment was a "milestone" for the Fantom sirolimus-eluting bio-resorbable coronary stent.

The company said it expected to file the application in mid-2016 based on six-month follow-up data from the 110 patients.

Reva chief executive officer Reggie Groves said that enrolment of the 110 patients was "a significant accomplishment for the company".

"It moves us one step closer to our goal of commercializing Fantom, which we believe offers the performance and ease-of-use features that will enable physicians to provide the best possible care for their patients," Ms Groves said.

The Toulouse, France-based Central University Hospital Rangueil's Dr Didier Carrié said he was "very pleased with how easy Fantom is to implant".

"The delivery to the target lesion has been successful in our cases and the single-step inflation reduces the overall procedure time," Dr Carrié said.

Belgium's Cardiovascular Center Aalst's Dr Bernard De Bruyne said that "the ability to visualize the scaffold under x-ray sets Fantom apart from other bio-resorbable scaffolds".

"This unique feature will make it easier for physicians to incorporate bioresorbable scaffold use into their practice," Dr De Bruyne said.

In August, Reva said the second cohort of 110 patients would be enrolled sequentially following the first 110 patient cohort and would provide data on the longer term effects of the Fantom stent. (BD: Aug 13, 2015).

Reva fell two cents or 2.5 percent to 78 cents.

## PATRYS

Patrys says it will close its German facility and Melanie Leydin will replace chief operating officer and company secretary Roger McPherson as company secretary.

Patrys said that Ms Leydin would replace Mr McPherson effective from October 1 and the German facility would close at the end of 2015.

The company said it thanked the staff of the Germany subsidiary, particularly Dr Frank Hensel and Dr Stephanie Brändlein, for their efforts to discover and develop therapeutic immunoglobulin M assets, work originating at the University of Würzburg.

Patrys said it thanked Mr McPherson "for his valued contribution to the company since his commencement in October 2008, including his role as chief operating officer and as Interim chief executive officer last year, and wish him well for his future endeavours".

The company said that Ms Leydin held a Bachelor of Business from Swinburne University in 1997 and since February 2000 had been the principal of chartered accounting firm Leydin Freyer providing outsourced company secretarial and accounting services to public and private companies specialising in the resources, technology, bioscience and biotechnology sectors.

Patrys fell 0.2 cents or 16.7 percent to one cent with 13.3 million shares traded.

## GENETIC SIGNATURES

Genetic Signatures says Patrick Noland has resigned as a non-executive director to head US Operations, effective immediately (BD: Sep 22, 2015).

Genetic Signatures fell 1.5 cents or 3.4 percent to 42.5 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT SEP 30, 2015

Company \$Am	Oct-14	Sep-15	Oct-15
Cochlear	3,966	4,877	4,772
CSL	35,197	42,705	41,472
Resmed	7,969	10,269	10,213
<b>BDI-20</b>			
Acrux	256	105	95
Admedus	216	122	116
Benitec	116	82	64
Bionomics	261	167	199
Biotron	23	31	20
Circadian	9	30	29
Clinuvel	140	130	124
Impedimed	106	305	260
Medical Developments	61	138	190
Mesoblast	1,390	1,119	1,066
Nanosonics	262	379	374
Neuren	125	143	138
Osprey	71	113	106
Pharmaxis	16	65	73
Prima	47	99	115
Psivida	147	157	147
Reva	90	249	270
Sirtex	1,242	1,983	1,871
Universal Biosensors	26	63	61
Viralytics	59	115	109
<b>Second 20</b>			
Actinogen	10	32	36
Anteo	121	82	81
Antisense	17	14	15
Atcor	14	38	47
Avita	33	33	35
Cellmid	21	30	27
Compumedics	20	47	46
Ellex	36	41	43
Genetic Technologies	15	36	29
IDT	17	50	69
Living Cell	25	16	16
Oncosil	41	36	52
Optiscan	7	12	11
Orthocell	19	32	37
Polynovo	40	42	56
Prana	115	77	69
Pro Medicus	92	229	241
Starpharma	204	184	251
Tissue Therapies	79	17	13
Uscom	18	14	13

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