

Biotech Daily

Thursday December 1, 2016

Daily news on ASX-listed biotechnology companies

- * NOVEMBER BDI-40 DOWN 5%, ASX200 UP 2%, BIG CAPS DOWN 2% NEUREN UP 51%; ACTINOGEN 30%; IMPEDIMED DOWN 25%
- * TODAY: ASX UP, BIOTECH DOWN: ACTINOGEN UP 12%, IDT DOWN 5%
- * CSL TAKES 3 MABS TO PHASE I, R&D SPEND CONSTANT AT \$810m
- * ELLEX PLACEMENT RAISES \$10m
- * DORSAVI LAUNCHES MYVISAFE MANUAL HANDLING ANALYSIS TOOL
- * CHAIR DAVID BREEZE REPLACES DEBORAH AMBROSINI AS BPH CO SEC

MARKET REPORT

The Australian stock market was up 1.1 percent on Thursday December 1, 2016 with the ASX200 up 59.7 points to 5,500.2 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and one was untraded.

Actinogen was the best for the second day in a row, following yesterday's resignation of chairman Martin Rogers, up 0.6 cents or 12.2 percent to 5.5 cents with 1.8 million shares traded (BD: Nov 30, 2016).

Universal Biosensors climbed 8.5 percent; Prana was up 7.4 percent; Genetic Signatures improved 6.5 percent; Compumedics and Cyclopharm rose five percent or more; Polynovo and Starpharma were up more than three percent; Admedus, Anteo and Uscom rose more than two percent; CSL and Osprey were up more than one percent; with Pro Medicus, Resmed, Sirtex and Viralytics up by less than one percent.

IDT led the falls, down one cent or 5.3 percent to 18 cents with 480,687 shares traded.

Living Cell fell 4.3 percent; Atcor, Avita, Cellmid, Factor Therapeutics and Orthocell lost more than three percent; Ellex, Impedimed, Medical Developments and Opthea shed more than two percent; Benitec, Bionomics, Clinuvel, Mesoblast, Oncosil, Pharmaxis and Reva were down one percent or more; with Airxpanders, Cochlear and Nanosonics down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) fell 4.6 percent in November on a plethora of mainly small falls, countered by a few small rises.

The ASX200 recovered 2.3 percent, while the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) slipped a collective 1.6 percent, while the Nasdaq Biotechnology Index climbed 6.8 percent.

Resmed's 6.0 percent rise to \$11,694 million was insufficient to counter the Cochlear 7.2 percent fall to \$6,817 million and CSL's 2.5 percent, \$1,141 million slip to \$44,684 million.

Despite the November BDI-40 falls, for the year to November 30, 2016, the BDI-40 climbed 13.3 percent, compared to the ASX200 up 5.3 percent, the Big Caps falling 0.6 percent and the NBI losing 18.1 percent (see chart below).

Just 10 of the BDI-40 companies were up in November, with only five up by more than 10 percent, while 26 fell, with 16 down by more than 10 percent and four were unchanged.

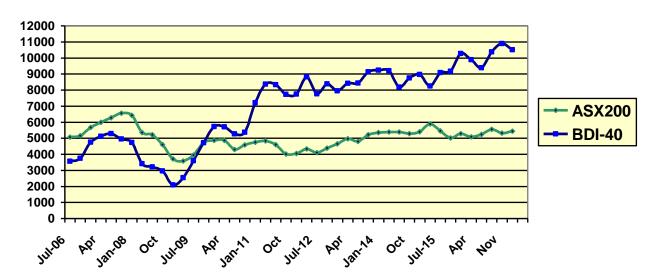
Neuren was the best of November's few, up 50.6 percent to \$116 million, followed by Actinogen (30.4%), Ellex (26.6%), Factor Therapeutics (20.8%) and Living Cell (15.0%).

Impedimed led the falls, down 25.1 percent to \$457 million, followed by Cyclopharm (22.9%), Atcor (21.1%), Dimerix (20.0%), IDT (19.0%), Medical Developments (17.0%), Prana (16.2%), Uscom (14.8%), Psivida (14.1%), Compumedics and Reva (13.8%).

Outside the BDI-40, Noxopharm jumped 81.8 percent from a low base to \$20 million with Medlab Clinical up 46.6 percent, Genetic Technologies up 40.9 percent and Optiscan up 35.7 percent, while Innate continued upwards to \$169 million, a 312.2 percent gain on its market capitalization 12 months ago.

On the Nasdaq, Aviragen (Biota) recovered 14.1 percent to \$73 million, Sunshine Heart was flat at \$6 million and Israel's Redhill shed 5.5 percent to \$188 million.

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



CSL

CSL says its research and development spending is expected to remain constant at about \$US600 million, despite an increase in programs.

In a media release associated with the annual investor research and development briefing, CSL said it had "progressed three new therapies into first-in-human studies in Australia" based on targeted monoclonal antibody technologies.

The company said that CSL324, CSL312 and CSL346 were phase I monoclonal antibodies with novel mechanisms of action addressing important areas of unmet medical need, with the potential for multiple indications.

CSL said CSL324 was an anti-granulocyte colony-stimulating factor receptor (G-CSF-R) monoclonal antibody for "rare inflammatory diseases caused by overactive neutrophil [or white blood cell] activity" to prevent over-active neutrophils from destroying healthy tissue and it might be a new treatment for inflammatory diseases involving skin, joints and lungs. The company said that CSL312 was an anti-factor XIIa monoclonal antibody being studied for multiple indications, including hereditary angioedema, a disorder causings episodic, sometimes life-threatening attacks of swelling that could affect the face, extremities, gastrointestinal tract and upper airways.

CSL said that CSL312 could reduce dosing frequency from biweekly to subcutaneous administration once every two to three weeks, with the potential for the prevention of thrombosis, particularly on artificial surfaces such as cardiac implants.

CSL said that CSL346 was an anti-vascular endothelial growth factor B (VEGF-B) monoclonal antibody that could be used to control glucose absorption in insulin-resistant patients with type 2 diabetes, by targeting fatty acid metabolism and might be beneficial for diabetic nephropathy, a common kidney complication of type 2 diabetes.

In the media release, chief scientific officer Dr Andrew Cuthbertson said that "CSL has worked hard to build appropriate [research and development] skills and capacity to support what has now become a \$45.1 billion global biotech company".

Dr Cuthbertson said that for the year to June 30, 2017, CSL would spend "more than \$US600 million [\$A810 million] ... on research and development, backed by a ... workforce of approximately 1,400 people worldwide".

In August, CSL said that research and development spending increased 32.7 percent to \$US613.8 million compared to the previous year (BD: Aug 17, 2016).

In last year's briefing Dr Cuthbertson said the research and development budget fell from \$US466 million in the year to June 30, 2014 to \$US463 million in the year to June 30, 2015, but much of the work had been performed in Australia and the falling Australian dollar meant that work was effectively cheaper (BD: Dec 10, 2015).

CSL confirmed it would "double its tenancy at Bio21 [in Parkville] over the next three years" to about 150 researchers and expanded its Australian early -development capabilities to both produce clinical trial materials and provide the regulatory and quality resources to support clinical trial development in Australia.

"We anticipate that our investment in translational research, taking drug targets from bench-top to bedside, will contribute to Australia's capacity to develop early research into commercial medicines for global markets," Dr Cuthbertson said.

"Translating basic medical research to a therapy ready for the marketplace can be a real challenge for our scientific community," Dr Cuthbertson said

"To move one product from the early concept stage into a phase I clinical trial is an important milestone," Dr Cuthbertson said.

"We are very pleased to move three projects into clinical trials over a 12 month period, all of which will be conducted in Australia," Dr Cuthbertson said.

CSL was up \$1.22 or 1.2 percent to \$99.22 with 1.2 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has raised \$10.3 million in a placement at \$1.47 a shares with Australia and New Zealand investors.

Ellex said the funds would be used to accelerate sales of its Itrack with its US-based minimally invasive glaucoma surgery business focussed on growth the US and China. The company said that it would build a US sales force of at least 15 people over the next six to nine months.

Ellex said that the funds would also be used to further the pipeline of Itrack products and increase surgeon engagement, through training and key opinion leader development. Ellex chief executive officer Tom Spurling said that the Itrack was "a leading product in the minimally invasive glaucoma surgery market and this capital raising puts Ellex in a position to capitalize on opportunities for growth in the US and Chinese markets". The company said that the placement was jointly managed by Petra Capital and Taylor Collison.

Ellex fell four cents or 2.5 percent to \$1.55.

DORSAVI

Dorsavi says it has launched its Myvisafe manual handling movement analysis product for the workplace.

Dorsavi said that Myvisafe training and education product was developed with gambling and casino operator Crown Resorts and comprised an application for use on a mobile telephone or tablet computer, four mini-movement sensors and a desktop dashboard. The company said that the sensors could be worn on the back or shoulders to measure movement in the workplace, so that employees could see their own movement profile and understand how safely they were moving.

Dorsavi said that Crown had been a development partner for Mivisafe over two years and Crown would be the first company to adopt the Myvisafe product, which would be used across all Crown casino business areas in Melbourne and Perth.

The company said that the project would involve more than 13,500 employees who would be regularly assessed based on the level of manual handling risk within their jobs. Dorsavi said that Crown expected Myvisafe to deliver "a significant reduction in manual handling workplace incidents which account for more than 80 percent of all workplace injuries".

Dorsavi chief executive officer Dr Andrew Ronchi said that "Crown's vision for its workplace safety and its adoption of Myvisafe shows Crown's willingness to pioneer new solutions and think creatively to bring about real change".

The company said that in addition to Crown, two other unnamed organizations in Australia and the US had purchased Myvisafe ahead of the commercial release.

"The interest in Myvisafe prior to launch has been strong and we know that we're filling a very real gap in the market with this interactive, personalized approach to manual handling training," Dr Ronchi said.

Dorsavi was up 1.5 cents or 3.2 percent to 49 cents.

BPH ENERGY

BPH says that executive chairman David Breeze has replaced Deborah Ambrosini as company secretary, effective from November 29, 2016.

BPH has investment interests in Cortical Dynamics and Molecular Discovery Systems. BPH was unchanged at 0.6 cents with 4.6 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT OCT 31, 2016

Company \$Am	Dec-15	Nov-16	Dec-16
Cochlear	5,396	7,347	6,817
CSL	46,537	45,825	44,684
Resmed	11,624	11,028	11,694
BDI-20			
Admedus	138	91	91
Airxpanders	165	284	268
Bionomics	216	183	176
Clinuvel	125	403	384
Compumedics	86	152	131
Ellex	59	143	181
Impedimed	286	610	457
Medical Developments	227	311	258
Mesoblast	667	468	462
Nanosonics	441	1,033	1,000
Neuren	169	77	116
Opthea	47	113	112
Pharmaxis	70	86	88
Polynovo	67	174	155
Prima	107	75	77
Pro Medicus	342	510	553
Psivida	157	99	85
Reva	316	551	475
Sirtex	2,307	1,610	1,594
Viralytics	125	269	274
Second 20			
Acrux	120	57	52
Actinogen	30	23	30
Anteo	67	61	53
Atcor	33	19	15
Avita	52	86	86
Benitec	48	19	17
Cellmid	24	31	31
Cyclopharm	33	70	54
Dimerix	8	15	12
Factor Therapeutics	12	48	58
Genetic Signatures	42	54	47
IDT	78	58	47
Living Cell	21	40	46
Oncosil	61	49	45
Orthocell	26	29	29
Osprey	35	108	111
Prana	72	37	29
Starpharma	256	269	243
Universal Biosensors	82	58	52
Uscom	18	27	23

^{*} 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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