

Biotech Daily

Monday December 3, 2018

Daily news on ASX-listed biotechnology companies

- * NOVEMBER BDI-40 DOWN 5%, ASX200 3%, BIG CAPS 4%, NBI UP 5%
 - PARADIGM UP 42%; FACTOR DOWN 95%, ADMEDUS 65%
- * TODAY: ASX, BIOTECH UP: BENITEC UP 7%; ORTHOCELL DOWN 9.5%
- * RESONANCE UP 139% ON FDA FERRISMART CLEARANCE
- * OSPREY SIGNS PREMIER FOR DYEVERT
- * TPI BUYS MELBOURNE PROPERTY
- * CHINA PATENT FOR REGENEUS STEM CELL BIOMARKERS
- * PHARMAUST SCALABLE MONEPANTEL KILLS CANCER IN-VITRO
- * ITL OPENS UNMARKETABLE PARCEL FACILITY
- * MEDADVISOR, ZUELLIG J-V FOR PRESCRIPTION REMINDERS IN ASIA
- * NEUROTECH FACILITY FAIL, 23% OPPOSE REMUNERATION REPORT
- * PHOSPHAGENICS ENDS US OTCQX LISTING
- * CRESO TO LIST ON TORONTO'S TSX-V

MARKET REPORT

The Australian stock market was up 1.84 percent on Monday December 3, 2018 with the ASX200 up 104.0 points to 5,771.2 points. Twenty-two Biotech Daily Top 40 stocks were up, seven fell, seven traded unchanged and four were untraded. All three Big Caps rose.

Benitec was the best, up one cent or 7.4 percent to 14.5 cents, with 77,094 shares traded. Genetic Signatures, Immutep and Prana climbed more than five percent; Actinogen was up 4.55 percent; Clinuvel, CSL, Pro Medicus and Uscom improved more than three percent; Cochlear, Cynata, Oncosil, Paradigm, Resmed and Volpara rose two percent or more; Cyclopharm, Ellex, Impedimed, LBT, Nanosonics, Opthea and Starpharma were up one percent or more; with Medical Developments, Mesoblast and Telix up less than one percent.

Orthocell led the falls, down two cents or 9.5 percent to 19 cents, with 47,011 shares traded. Airxpanders lost 5.6 percent; Osprey fell four percent; Dimerix, Proteomics and Universal Biosensors shed two percent or more; with Neuren down 0.7 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

It's been all downhill since the end of winter.

The ASX200, the Collective three Big Caps (Cochlear, CSL and Resmed) and the Biotech Daily Top 40 Index (BDI-40) have all lost ground for three months in a row.

November started badly for Australian biotech with Cochlear ordered to pay \$372 million for a patent case it thought would cost no more than \$21 million.

Mesoblast's mesenchymal precursor stem cells missed a cardiac trial primary endpoint, Bionomics announced a review starting with chief executive officer Dr Deborah Rathjen, Phosphagenics won nothing in the \$415 million Mylan patent case and Factor's VF001 did not outperform placebo for venous leg ulcers.

We ended November with Admedus emerging from a four-month suspension with its third chief financial officer and fourth company secretary in a year, and a complicated and uncertain capital raising, with Prof Ian Frazer's blue sky Coridon becoming a private concern of Hong Kong Star Bright and chief executive officer Wayne Paterson to be its chairman for at least five years.

And then ITL Health said it would de-list.

Some could run parallels with the competence of the Federal Liberal-National Party Government.

But we won't. Unlike the bereft-of-talent Federal Government, the Australian biotechnology sector has many companies vying for promotion.

In rebalancing the BDI-40, we err on the side of caution. We are slow to demote (in case a company's pipeline has further promise) and slow to promote (in case the next trial falls over).

Most years there are a few that enter and leave the BDI-40 but this year has been unusual. Viralytics, Psivida and Sirtex have all departed for honorable reasons, but this month marks the first time that four companies will depart the index at the same time.

Factor Therapeutics ran a rigorous trial which showed its sole product VF001 was no better than placebo, and was straight in its announcement. With the failure of BNC210 to show the much-claimed superiority as an anti-anxiolytic, Bionomics has drug discovery platforms but not much of a pipeline, ITL expects to delist in February and we can't use the correct term for Admedus in an industry publication, but "cluster" is a core part.

The good news is that Antisense is showing promise for Duchenne's muscular dystrophy and returns to the index, along with Patrys, which is back from the lab with a new anticancer compound, Kazia (formerly Novogen) is moving forward with its glioblastoma trial and Proteomics, after a slow start, is commercializing its diabetic kidney disease test.

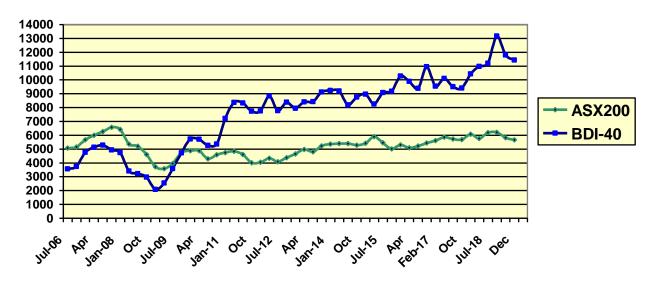
Seventeen of the BDI-40 companies were up (four by more than 10 percent) one was unchanged and 22 fell (18 by more than 10 percent).

Paradigm was November's best, up \$45 million or 42.1 percent to \$152 million, followed by Genetic Signatures (18.6%), Imugene (15.3%), Pro Medicus (10.6%), Neuren (9.5%), Ellex (8.6%), Cyclopharm (8.3%), Clinuvel (6.3%), Compumedics (6.25%) and Starpharma (6.1%).

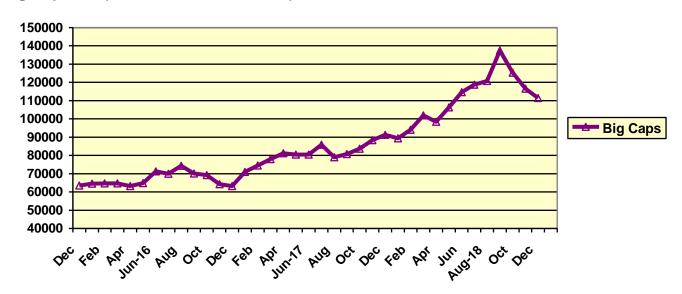
Factor Therapeutics led the falls, losing 95.0 percent of its value to \$3 million. Admedus fell 64.6 percent to \$17 million having been worth as much as \$223 million in September 2014, followed by Airxpanders down 45.9 percent, Impedimed (36.2%), ITL (35.7%), Mesoblast (33.4%), Reva (20.2%), Telix (16.9%), Benitec (16.7%) and Prana (16.7%).

The collective market capitalization of the 15 companies in Cannabis Corner edged up 1.5 percent, all due to Elixinol Global which was up \$57 million or 25.6 percent to \$280 million, with four others up, six companies down and four unchanged.

BDI-40 v ASX200 Jun 30, 2006 to Nov 30, 2018- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Nov 30, 2015 - Nov 30, 2018



RESONANCE HEALTH

Resonance shares climbed 138.5 percent to 6.2 cents on news that the US Food and Drug Administration had cleared its Ferrismart diagnostic for liver iron quantification. Resonance said Ferrismart analyzed magnetic resonance imaging "from most scanner makes and models and returned a liver iron quantification result within seconds". The company said the FDA 510(k) clearance followed Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approvals (BD: Jul 11, 2018). Resonance said that the FDA had cleared Ferrismart for the measurement of liver iron concentration in individuals with confirmed or suspected systemic iron overload, to monitor liver iron burden in transfusion-dependent thalassemia patients and patients with sickle cell disease receiving blood transfusions, as well as an aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox.

The company said this clearance would allow it to market Ferrismart for commercial distribution in the US.

Resonance said that it would sell Ferrismart through distributors such as the Blackford Platform allowing it "to integrate seamlessly into radiology workflows, delivering results efficiently to radiologists and clinicians".

Resonance closed up 2.6 cents or 100 percent to 5.2 cents with 190.4 million shares traded.

OSPREY MEDICAL

Osprey says US health care company Premier Inc has awarded a group purchase agreement for its Dyevert Plus cardiac contrast reduction system.

Osprey said that its dye reduction and monitoring system for patients having a coronary or peripheral angiogram reduced dye used in heart procedures by an average 40 percent and was part of a kidney care protocol "to improve quality and patient outcomes while lowering total cost of care in patients suffering from chronic kidney disease".

The company said that the Charlotte, North Carolina-based Premier had about 4,000 hospitals which could purchase the Dyevert Plus contrast reduction system. Osprey chief executive officer Mike McCormick said the company was "thrilled to be collaborating with Premier and making our Dyevert System available to all Premier members".

Osprey fell half a cent or four percent to 12 cents.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it has paid \$8.15 million for its Melbourne drug manufacturing facility.

TPI said it relocated its primary manufacturing operations from Tasmania to Melbourne in 2015 and the Melbourne property was subject to a deferred settlement contract of sale executed in 2014 and completing in November 2018.

The company said the Melbourne metropolitan industrial facility was on an 8.5 hectare (21.0 acre) property with an area under roof of 17,428 square metres (1.74ha, 4.3ac). TPI company said that the property was independently valued at \$10.9 million on an "as is" basis in October 2018.

The company said that to fund the acquisition it had extended its existing shareholder debt facility with Washington H Soul Pattinson and Co, providing a facility limit of \$25 million and maturity date of August 2020, with the facility to be secured over its assets. TPE fell four cents or 3.2 percent to \$1.20.

REGENEUS

Regeneus says that China has granted a patent for the use of biomarkers to monitor patients having mesenchymal cell therapy for inflammatory conditions.

Regeneus said that the State Intellectual Property Office of China had granted the patent, titled 'Biomarkers for cell therapy' which would provide commercial rights in China until 2033, including protection for licencing its Progenza allogeneic stem cell therapeutics in China.

The company said the patent covered use of a broad range of mesenchymal stem cell therapeutics for the treatment of inflammatory conditions in combination with the biomarkers.

Regeneus said that the therapeutics included allogeneic and autologous cells, the the stem cells sourced from any tissue type such as adipose (fat), bone marrow or placental tissue and included stem cells sourced from induced pluripotent stem cells and embryonic stem cells.

The company said that the patent covered the biomarkers macrophage migration inhibitory factor (MIF), cartilage oligomeric matrix protein (COMP) and crosslinked C-telopeptides of type II collagen (CTX II) in mesenchymal stem cell therapies.

Regeneus said that MIF was "a key modulator in promoting and modulating the magnitude of the inflammatory response, while COMP and CTX-II [were] degradation products of joint tissues, especially the cartilage extracellular matrix".

The company said it had more than 80 patents or patent applications across multiple patent families, providing its pipeline with a significant competitive advantage. Regeneus was unchanged at 19.5 cents.

PHARMAUST

Pharmaust says that Syngene's scalable production of its monepantel for cancer has shown anti-cancer activity in human cell lines in-vitro.

Pharmaust said that testing of the Bangalore, India-based Syngene International's good manufacturing practice monepantel was evaluated by Melbourne's Olivia Newton-John Cancer Research Institute on human cancer cell lines and non-cancer cell lines (BD: Oct 29, 2018).

The company said that cancer cell lines showed the expected sensitivity to treatment with monepantel, while non-cancer cells were relatively unaffected.

Pharmaust said that cancer cell lines tested included models of cancers it was studying for targeting in phase II human trials.

The company said it planned to use the monepantel in further pre-clinical work to understand "exactly how monepantel kills cancer cells".

Pharmaust chief scientific officer Dr Richard Mollard said that "recapitulating the anticancer effect of monepantel manufactured according to the Pharmaust method in-vitro is an important outcome".

"The selective targeting of the new drug to tumor cells and lack of toxicity to normal cells supports Pharmaust's product development strategy," Dr Mollard said.

"The Pharmaust method does not appear to change the properties of monepantel and therefore is not predicted to change the anti-cancer properties of Pharmaust's monepantel analogues, too," Dr Mollard said.

"Pharmaust is now in a strong position to advance its pre-clinical and drug development pipeline as needed," Dr Mollard said.

Pharmaust was up 0.1 cents or 2.6 percent to 3.9 cents.

ITL HEALTH GROUP

ITL says it has established a share sale facility for holders of unmarketable parcels of its shares, worth less than \$500.

ITL said that based on a 9.6 cents 5-day volume weighted average price to the market close on the record date of November 29, 2018 an unmarketable parcel was any holding of 5,208 shares or fewer.

The company said there were 214 holders of unmarketable parcels.

ITL said the facility would allow investors with small holdings the opportunity to sell their shares without brokerage costs.

The company said that the closing date for the facility was January 16, 2019.

ITL was unchanged at 11 cents.

MEDADVISOR

Medadvisor says it expects to form a joint venture with Zuellig Pharma Holdings Pte Ltd targeting more than 560 million potential customers for its prescription renewal service. Medadvisor said that the Singapore-based Zuellig Pharma was "one of the largest healthcare services groups in Asia" and the 50-50 joint venture heads of agreement would assist it to commercialize its medication management platform in Asia.

The company said it would licence its core prescription reminder service intellectual property to the joint venture on an exclusive, royalty-free basis and would develop localized versions of its platform for pharmacies and patients in the Philippine and South Korea.

Medadvisor said that with Zuellig it had assessed the technology which could be rolled out in these countries, which share a similar prescription model as Australia.

The company said that Zuellig would market the prescription reminder service to its network of pharmacies, medical clinics and pharmaceutical manufacturers, initially focussing on the Philippines and South Korea, followed by launches in additional Asian countries.

Medadvisor said it would retain ownership of all intellectual property in the platform, including any customizations for specific countries, and the joint venture would generate "multiple streams of revenue including software as a service, subscription fees from pharmacies, transaction-based revenue ... [through] reminders, in-application/online payment processing fees, [general practitioner] electronic script requests and program fees from pharmaceutical manufacturers for the delivery of digital patient engagement programs".

The company said it would invest working capital in the business in 2019-'20 which would be matched by Zuellig and it expected the initial investment would be sufficient to make the joint venture self-sustaining and was less than 10 percent of its current cost base. Medadvisor said that both parties would receive fees for assisting with sales and technical support once the joint venture was operational.

Medadvisor chief executive officer Robert Read said the agreement was "one of the most significant developments in our company's history".

"As one of the largest healthcare businesses in Asia, Zuellig Pharma is the perfect partner to take our offerings into the region," Mr Read said.

Zuellig chief executive officer John Davison said that the Medadvisor platform "has the potential to help millions of people manage their medications safely and effectively".

"This joint venture expands Zuellig Pharma's growing suite of digital solutions that address key pain points in delivering quality healthcare," Mr Davison said.

Medadvisor was up 0.6 cents or 18.2 percent to 3.9 cents with 1.8 million shares traded.

NEUROTECH

Neurotech says it has narrowly avoided a remuneration report first strike with up to 23 percent opposed, while the issue of director shares faced 45 percent opposition. The Malta-based Neurotech said that at the annual general meeting 5,650,179 votes (23.25%) opposed the remuneration report, with 18,647,067 votes (76.75%) in favor. Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election.

The company said that a special resolution requiring a 75 percent vote to pass, on the 10 percent placement capacity was defeated with 23,623,690 votes (42.9%) against and 31,399,436 votes (57.1%) in favor.

Neurotech said that the issue of 466,000 shares to former director Wolfgang Storf was opposed by 24,870,940 votes (45.2%) with 30,152,186 votes (54.8%) in favor.

The company said that the issue of 142,857 shares to director Dr David Cantor was passed with a similar margin, while the election of directors Dr Cantor and Dr Neale Fong were opposed by 34.7 percent of votes at the meeting.

Neurotech said that the resolution to re-elect Mr Storf was withdrawn prior to the meeting as he had been replaced as chief executive officer and managing director by Peter Griffiths (BD: Nov 26, 2018)

Neurotech's most recent Appendix 3B new share issue announcement said it had 109,012,046 shares on issue, meaning that the opposition to Mr Storf's shares, amounted to 22.1 percent, sufficient to requisition extraordinary general meetings.

Neurotech was unchanged at 5.4 cents.

PHOSPHAGENICS

Phosphagenics says it will withdraw from quotation on the US over-the-counter quality exchange (OTCQX) on December 4, 2018.

Phosphagenics said the Bank of New York Mellon had been instructed to terminate the depositary receipt facility.

Phosphagenics fell 0.05 cents or 16.7 percent to 0.25 cents with 3.8 million shares traded.

CRESO PHARMA

Creso says it has begun the process for listing on the Toronto Stock Exchange Venture Exchange (TSX-V), and will be a dual listed company.

Creso said it had appointed the Toronto-based law firm Aird and Brelis LLP and Toronto's Echelon Wealth Partners to advise on listing.

Creso chief executive officer Dr Miri Halperin Wernli said the potential dual listing was "an important milestone ... [and] we are pleased to offer Canadian and North American investors the opportunity to invest in a globally recognized cannabis company with a unique approach and high-quality, pharma-grade, innovative products".

"The Canadian market was always an ambition and given our operations in Canada, Colombia, Europe and Australia it not only makes sense but it is timely we begin this process to meet investor demand," Dr Halperin Wernli said.

"The recent landmark legislation for full, adult-use [recreational] legalization further demonstrates Canada's world-leading position in the cannabis industry and we look forward to reaping the benefits of this growing market," Dr Halperin Wernli said. Creso was up one cent or 2.4 percent to 42.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT NOVEMBER 30, 2018

Company \$Am	Dec-17	Nov-18	Dec-18
Cochlear	10,400	10,249	9,770
CSL	64,828	85,156	80,355
Resmed	15,976	21,089	21,360
BDI-20			
Avita	66	125	110
Clinuvel	384	766	814
Compumedics	75	64	68
Cyclopharm	64	72	78
Ellex	133	93	101
Impedimed	364	152	97
LBT Innovations	36	20	18
Medical Developments	372	316	279
Mesoblast	635	990	659
Nanosonics	760	899	939
Neuren	276	126	138
Opthea	146	134	119
Pharmaxis	82	108	112
Polynovo	248	388	395
Immutep	59	126	111
Pro Medicus	780	945	1,045
Reva	264	104	83
Starpharma	519	542	575
Telix	128	178	148
Volpara	61	245	222
Second 20			
Actinogen	28	52	49
Airxpanders	201	37	20
Antisense	5	15	12
Benitec	40	42	35
Cynata	57	107	101
Dimerix	14	17	15
Genetic Signatures	31	59	70
Imugene	47	72	83
Kazia	18	21	25
Oncosil	73	123	114
Optiscan	40	24	25
Orthocell	28	20	17
Osprey	144	54	54
Patrys	15	34	29
Paradigm	34	107	152
Prescient	15	19	17
Prana	37	24	20
Proteomics	11	19	39
Universal Biosensors	60	42	44
Uscom	17	19	20
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^{*} Biotech Daily editor, David Langsam, owns shares in Acrux, Amplia, Benitec, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Prana, Telix, 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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