

Biotech Daily

Monday December 2, 2019

Daily news on ASX-listed biotechnology companies

- * 12-MONTH BDI-40 UP 114%, ASX200 21%, BIG CAPS 56%, NBI 9.5%
- * TODAY: ASX UP, BIOTECH DOWN: OPTHEA UP 16%; IMUGENE DOWN 9%
- * OPTHEA PLACEMENT FOR \$50m
- * IMUGENE PLACEMENT FOR \$24.6m
- * PHYLOGICA DOUBLES EYE DRUG DELIVERY IN MICE
- * MEDLAB NANABIS 'OBSERVATIONAL' STUDY: PAIN REDUCTION
- * MGC 52% BLOCKS FOUNDER NATIV SEGEV RIGHTS, STRONG DISSENT
- * GI DYNAMICS 120k DIRECTOR OPTION, \$7m NOTES EGM
- * GOODBYE ZELDA, HELLO ZELIRA
- * NOXOPHARM DAART-1 STUDY: PARTIAL RESPONSE IN 1 OF 15 PATIENTS
- * ORTHOCELL REQUESTS CAPITAL RAISING TRADING HALT
- * THC REQUESTS MARIJUANA PRODUCTION TRADING HALT
- * BLACKROCK TAKES 6% OF CSL
- * PARKER FAMILY, XYLO DILUTED BELOW 5%
- * ANTHONY BARTON DILUTED BELOW 5% IN PHYLOGICA
- * SABBY REDUCES TO 5.6% IN BENITEC

MARKET REPORT

The Australian stock market was up 0.24 percent on Monday December 2, 2019, with the ASX200 up 16.3 points to 6,862.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded.

Opthea was the best, up 43 cents or 15.75 percent to \$3.16, with 1.5 million shares traded. Compumedics climbed 7.7 percent; Next Science was up 6.9 percent; Starpharma and Uscom improved four percent or more; Medical Developments was up 3.35 percent; Pharmaxis and Polynovo rose two percent or more; Avita, Cochlear, Kazia, Mesoblast and Nanosonics were up one percent or more; with CSL and Pro Medicus up by less than one percent.

Imugene led the falls, down 0.4 cents or 9.1 percent to four cents, with 126.4 million shares traded. Antisense lost 6.3 percent; Clinuvel, Prescient and Telix fell more than four percent; Amplia and Cynata were down more than three percent; Actinogen, Immutep, LBT, Neuren, Oncosil and Universal Biosensors shed two percent or more; with Paradigm and Volpara down by more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) continued into record territory in November edging up 0.2 percent in the month and 114.3 percent for the year to November 30.

The benchmark ASX200 rose 20.8 percent for the 12-months, with the collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up 55.9 percent to \$173,845 million.

The Nasdaq Biotechnology Index (NBI) continued its recovery, up 11.4 percent for the year to November 30 and 9.5 percent for the month of November.

For the month of November, the ASX200 was up 2.7 percent, the BDI-40 was up 0.2 percent; and the Big Caps improved 9.3 percent.

Both Cochlear and CSL improved 10.5 percent in November, to market capitalizations of \$13,517 million and \$128,440 million, respectively, with Resmed up 4.5 percent to a \$31,888 million, all in record territory.

Twenty-six of the BDI-40 stocks were up, with 17 up more than 10 percent and 11 up more than 20 percent. Thirteen companies fell, with six down by more than 10 percent.

The generally smaller capitalization Second 20 put on the best performances, led by Imugene up \$74 million or 87.1 percent to \$159 million, followed by Oncosil (77.3%), Kazia (70.4%), Prescient (54.5%), Resonance (52.8%), Actinogen (35.1%), Genetic Signatures (31.4%), Paradigm (30.6%), Dimerix (23.5%), Impedimed (22.5%), Pharmaxis (20.3%), Avita (18.8%), Medical Developments (17.2%), Universal Biosensors (16.1%), Proteomics (15.4%) and Starpharma (13.7%).

Opthea led the falls, ahead of today's discounted \$50 million capital raising, down \$115 million or 22.0 percent to \$683 million, followed by Antisense (21.4%), Polynovo (17.3%), Cynata (12.7%), Orthocell (12.0%), Immutep (9.2%), LBT (8.3%) and Pro Medicus (6.6%).

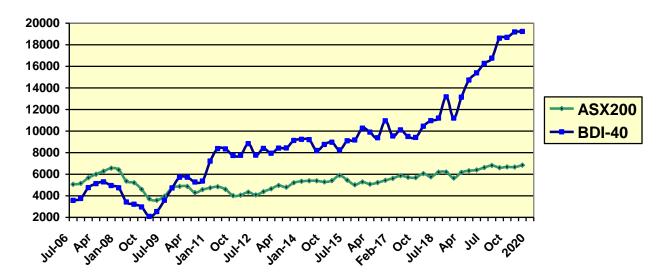
Outside the BDI-40, Bluechiip, Memphasys, Phylogica, Resapp and Somnomed were at 12-month highs, with Alcidion and Painchek down from their September 30 peaks. Mayne Pharma continued to ease, down 10.1 percent in November to \$738 million and down 52.2 for the year to November 30.

The 18 Cannabis Corner companies mislaid a further 16.2 percent in November, to a collective value of less than \$1 billion from the illusory high of \$1,913 million on July 31, 2019, to the lowest level since November 30, 2017. Four were up, 12 fell and two were unchanged.

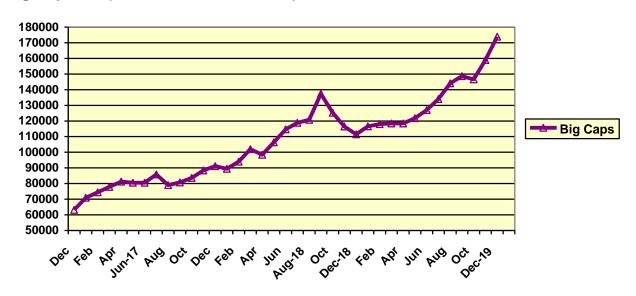
The only significant rise was Palla Pharma (formerly Tasmanian Poppy Industries Enterprises), up 28.6 percent to \$1.08 million, which markets opiates as well as marijuana.

In the US, Israel's Redhill with Australian assets was up 4.4 percent to \$358 million Eyepoint (Psivida) fell 29.0 percent to \$247 million, and Queensland's Protagonist lost 31.4 percent to \$351 million.

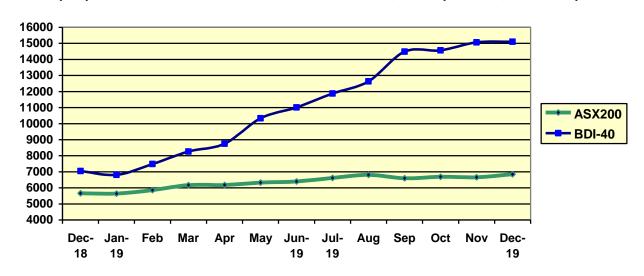
BDI-40 v ASX200 Jun 30, 2006 to Nov 30, 2019- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Nov 30, 2016 - Nov 30, 2019



BDI-40 (\$m) v S&P ASX 200 - Nov 30, 2018 - Nov 30, 2019 (current, raw data)



OPTHEA

Opthea says it has commitments to raise \$50 million in a placement at \$2.65 Aa share to sophisticated and institutional investors in Australia and the UK.

Opthea said the share price was a 3.0 percent discount to the closing price of \$2.73 on November 29, 2019.

The company said it would use the funds to support the late-stage clinical development of OPT-302 for wet age-related macular degeneration, including the manufacture of clinical grade OPT-302 for phase III clinical development, and begin two concurrent phase III pivotal registration trials.

Opthea climbed 43 cents or 15.75 percent to \$3.16 with 1.5 million shares traded.

IMUGENE

Imugene says it has "firm commitments" to raise \$24.6 million in an "oversubscribed" placement of shares at 3.6 cents each to sophisticated and professional investors. Imugene said it would issue one free attaching option for every three shares purchased, exercisable at 5.4 cents each, by November 30, 2022.

The company said the 3.6 cents placement price was a 19.8 percent discount to the 30-day volume-weighted average price to November 27, 2019.

Imugene said the funds would be used for its clinical programs, including two phase II oncolytic virus clinical candidates and to provide working capital.

Imugene managing-director and chief executive officer Leslie Chong said that "with our existing cash reserves of \$16 million, this placement allows Imugene to deliver on all clinical trials currently running and planned to commence in 2020".

Imugene said the placement would be managed by Bell Potter Securities, with Aurenda Partners as co-manager and Roth Capital Partners as the US placement agent. Imugene fell 0.4 cents or 9.1 percent to four cents with 126.4 million shares traded.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says an improvement to its method for isolating target cells has improved drug delivery more than 100 percent, in mice.

Phylogica said retinitis pigmentosa was the leading cause of childhood blindness and its drug delivery method was previously unable to differentiate between the two deepest cellular layers at the back of the eye, the retinal pigment epithelium and the choroid.

The company said the improved drug delivery technology would "separate the [retinal pigment epithelium] from the choroid in order to give a more accurate picture of the effectiveness of [the] delivery technology in the [retinitis pigmentosa] cells.

Phylogica said that the increased effectiveness of the delivery technology meant that it could deliver drugs to the target cells at lower concentrations.

The company said the lower drug concentration could have a "meaningful therapeutic effect" and achieve the lowest effective dosage.

Phylogica said that the improved cell isolation method of separating the retinal pigment epithelium had shown a 250 percent rise in the seven-days post-administration effectivity of a single dose of 1.6 micrograms of cell penetrating peptide in each eye, compared to the previously isolation protocol.

The company said that its lead drug program for retinitis pigmentosa would be defined by December 25, 2019, with read-outs regarding the drug's effectiveness in-vitro expected by April 1, 2020.

Phylogica was up 0.1 cents or 1.7 percent to six cents with two million shares traded.

MEDLAB CLINICAL

Medlab says preliminary results from 200 patients of its 2,000-patient, "observational" study of Nanabis for pain management showed an overall reduction in reported pain. Medlab said that "because of the sensitivity of the patient data" it has "soft launched the study" for 12-weeks to test and harden the process around data collection, transport and management, prior to the launch of the 12-month observational study.

The company said the dose guidelines of the marijuana-based Nanabis averaged to two sprays a day, which was "well below the dosage models used in the [Sydney-based Royal North Shore Hospital] Nanabis trial".

Medlab said that the 200 patients it had recruited had an average age of 56 years, with 50 percent of patients diagnosed with neuropathic pain and 66 percent of patients female. The company said it had 100 Australian doctors participating in the study so far. Medlab chief executive officer Dr Sean Hall said the study was critical for understanding real world use, dosing in relation to other prescribed drugs and any side-effects. Medlab said it expected to nationally launch the observational study in January 2020. Medlab was unchanged at 36.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its annual general meeting blocked performance rights to Nativ Segev, with heavy dissent against performance rights to Roby Zomer and Brett Mitchell. MGC said the issue of 10,000,000 free performance rights to company founder and director Mr Segev was opposed by 83,566,776 votes (52.1%) with the issue of 10,000,000 rights to executive chairman Mr Mitchell narrowly passed with 85,862,128 votes (53.5%) in favor and 10,000,000 rights for co-founder and managing-director Mr Zomer passed by a slightly larger majority, with 87,431,062 votes (54.4%) in favor.

The company said the adoption of the incentive performance rights plan was opposed by 70,358,177 votes (43.7%), with resolutions to ratify a prior share offer, shares for vendors of Panax Pharma SRO, options for Canaccord Genuity, Merchant Corporate Advisory and Chieftain Securities passed by wider margins, the remuneration report passed more easily with 20,210,432 votes (12.6%) opposing the report, while the election of directors Mr Segev, Dr Stephen Parker and Dr Ross Walker, the ratification of placement shares, the 10 percent placement capacity and the appointment of an auditor were passed easily. MGC's most recent Appendix 3B new issue announcement said it had 1,356,375,475 shares on issue, meaning that the votes against Mr Segev's performance rights amounted to 6.2 percent of the company, sufficient to requisition extraordinary general meetings. MGC fell 0.1 cents or 2.9 percent to 3.3 cents.

ZELDA THERAPEUTICS (TRADING AS ZELIRA THERAPEUTICS)

Zelda says it has merged with Ilera Therapeutics and appointed chair Osagie Imasogie and directors Lisa Gray and Dr Oludare Odumosu.

In October, Zelda said it would merge with Ilera Therapeutics to form Zelira Therapeutics, a "globally integrated company to develop clinically validated cannabis medical products". Today, the company said the merger was completed after it received "overwhelming support" from shareholders at the annual general meeting on November 28, 2019. Zelda said that Mara Gordon and Dr Stewart Washer had resigned as non-executive Directors, with Ms Gordon to join Zelira's medical advisory board.

The company said that former chair Harry Karelis had been appointed deputy chair. Zelda was unchanged at 6.7 cents.

NOXOPHARM

Noxopharm says in 10 of 15 patients with prostate cancer treated with NOX66 and radio therapy had "stable disease or better", with a partial response in one patient.

Noxopharm said that its six-month phase Ib direct and abscopal response to radiotherapy-1 (Daart-1) study treated 25 men with NOX66, or Veyonda, of which nine had withdrawn, died or been lost to follow-up, 16 completed the study and 15 were measurable radiographically.

The company said that five of 15 patients had progressive disease, nine had "stable disease" and one had a partial response, which Noxopharm said was "an overall tumor response rate of 66 percent".

Noxopharm executive chairman Dr Graham Kelly said that "a 66 percent response rate is a substantial response rate for such late-stage disease, putting NOX66 Darrt right at the top end of response rates in late-stage cancer".

The company said that five of 16 patients had a prostate-specific antigen (PSA) response of 50 percent below the baseline, with PSA reductions ranging from 61 to 98 percent. Noxopharm said that 10 of 16 patients had a pain response, or a 30 percent decrease from baseline, with falls ranging from 43 to 100 percent.

The company said the trial's primary end-point of safety was met with no significant or dose-limiting toxicities.

Noxopharm said the secondary end-point of efficacy "very clearly was achieved based on rates of PSA response, pain response and tumor response in a high proportion of men". The company said that the trial results triggered planning for double-blind, control-arm, multi-national phase II and III adaptive studies in 2020.

Noxopharm was up 4.5 cents or 13.85 percent to 37 cents with 1.5 million shares traded.

GI DYNAMICS

GI Dynamics says shareholders will vote to issue 120,000 options to directors and approve \$US4,596,893 (\$A6,786,092) in convertible notes to Crystal Amber Fund. GI Dynamics said it proposed to issue 30,000 options each to directors Timothy Barberich, Daniel Moore, Dr Oern Stuge and Juliet Thompson as "a significant portion of their annual compensation".

In August, the company said it had \$US10 million (\$A14,773,150) in convertible notes and warrants with Crystal Amber to fund trial enrolments and European approval and in October exercised \$US2 million (\$A2,962,200) in Chess depositary interests (CDIs) to Crystal Amber (BD: Aug 22, Oct 4, 2019).

GI Dynamics said it would seek approval for majority shareholder Crystal Amber to subscribe for 229,844,650 CDIs, representing 4,596,893 US shares and shareholders would vote to increase the number of authorized shares from 50,000,000 to 75,000,000. The meeting will be held at GI Dynamics, 320 Congress St, Floor 3, Boston, Massachusetts, on Monday December 16, 2019 at 5pm (US EST), which will be Tuesday December 17, 2019 at 9am (AEDT).

GI Dynamics was up 0.2 cents or 9.1 percent to 2.4 cents.

ORTHOCELL

Orthocell has requested a trading halt pending the release of "an announcement regarding a proposed capital raising".

Trading will resume on December 4, 2019 or on an earlier announcement.

Orthocell last traded at 56.5 cents.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS COMPANY)

THC has requested a trading halt "pending an announcement regarding "the completion of the first medicinal cannabis production at [its] Southport manufacturing facility". In August, THC said its Southport, Gold Coast, Queensland-based marijuana facility had been opened by the Federal Minister for Health Greg Hunt (BD: Aug 29, 2019). Trading will resume on December 4, 2019 or on an earlier announcement. THC last traded down 1.5 cents or 3.9 percent to 37 cents.

CSL

Blackrock Investment Management says it has increased in substantial holding in CSL from 22,884,245 shares (5.02%) to 27,353,205 shares (6.02%).

The New York-based Blackrock said that between March 6, 2017 and November 28, 2019 it bought, sold, borrowed, lent and transferred shares in more 13,000 transactions at prices ranging between \$120.23 and \$283.13 a share.

CSL was up \$2.62 or 0.9 percent to \$286.10 with 585,410 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Xylo Pty Ltd for the Parker Family says its substantial shareholding of 3,813,784 shares has been diluted to below five percent of the company.

Last year, the Perth-based Xylo said they held 5,027,594 shares (BD: Apr 16, 2018).

Today, Xylo said it had been diluted on November 25, following the issue of shares.

Last month Phylogica said it had raised \$3.0 million in a "heavily oversubscribed" placement at 28 cents a share (BD: Nov 15, 2019).

Biotech Daily calculated that Dr Parker held 4.71 percent of the company.

Proteomics was unchanged at 32.5 cents.

PHYLOGICA

The Perth-based Anthony Barton and associates say that their 145,141,814 shares in Phylogica have been diluted to 4.95 percent, following a recent share issue. Last month, Phylogica said it raised \$5,262,055 in a fully underwritten retail rights issue, with a \$7,270,134 shortfall, following a \$14.3 million institutional offer, for a total raised of \$26.8 million (BD: Nov 21, 2019).

BENITEC BIOPHARMA

Sabby Management and associated parties say they have reduced their substantial holding in Benitec from 28,000,000 shares (8.94%) to 17,591,600 shares (5.62%). The New Jersey and Cayman Islands-based Sabby said that between October 18 and November 20, 2019, it bought 700 American depository shares (ADSs) for \$US4,458 and sold 52,042 ADSs, equal to 10,408,000 shares, for \$US335,703 (\$A496,018) or \$US6.37 (\$A9.40) per ADS, equivalent to 4.7 cents per Australian share.

Benitec was up 0.1 cents or 2.6 percent to four cents with 2.6 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT NOVEMBER 30, 2019

Cochlear 9,770 12,231 13,517 CSL 80,355 116,204 128,440 Resmed 21,360 30,565 31,888 BDI-20 Avita 110 1,114 1,323 Clinuvel 814 1,496 1,416 Compumedics 68 127 138 Cyclopharm 78 80 79 Cynata 101 134 117 Ellex 101 82 88 Genetic Signatures 70 102 134 Immutep 111 109 99 Medical Developments 279 384 450 Mesoblast 659 958 974 Nanosonics 939 2,042 2,048 Neuren 138 229 252 Opthea 119 876 683 Paradigm 152 572 747 Pharmaxis 112 79 95	Company \$Am	Dec-18	Nov-19	Dec-19
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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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