



Biotech Daily

Thursday November 29, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ITL UP 20%; FACTOR DOWN 33%**
- * **VICTORIA APPOINTS MARTIN PAKULA MINISTER FOR BIOTECH**
- * **OSPREY RIGHTS RAISE \$4.3m OF HOPED FOR \$10.5m, TOTAL \$14.3m**
- * **TELIX, NIHON WORK ON ACTINIUM-225 FOR KIDNEY CANCER**
- * **NOXOPHARM NOX66 TOLERATED, 'SUSPENDS TUMOR GROWTH'**
- * **EUROPEAN PATENT FOR IMMUTEP IMP321**
- * **ITL DELISTING, BUY-BACK EGM**
- * **ELLEX'S 35% OPPOSE DIRECTOR ALEX SUNDICH**
- * **ADALTA 17% OPPOSE DR JOHN CHIPLIN'S SHARE PURCHASE**
- * **MMJ VOTES 22% AGAINST REMUNERATION REPORT**
- * **GENETIC TECHNOLOGIES FACES UP TO 23% DISSENT AT AGM**
- * **10.5% DISSENT FOR MAYNE PHARMA REMUNERATION REPORT**
- * **CORRECTION: GI DYNAMICS**
- * **ATO DELAYS INVION, CHRONIC AIRWAY DEMERGER**
- * **EMPERY REDUCES TO 7% IN IMMURON**
- * **RICHARD CASHIN INCREASES, DILUTED TO 21% IN GI DYNAMICS**
- * **WENTWORTH WILLIAMSON TAKES 6% OF TPI**

MARKET REPORT

The Australian stock market was up 0.58 percent on Thursday November 29, 2018 with the ASX200 up 33.3 points to 5,758.4 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and one was untraded. All three Big Caps were up.

ITL was the best, up 1.8 cents or 19.6 percent to 11 cents, with 518,576 shares traded. Genetic Signatures and Pro Medicus were up more than eight percent; Clinuvel, Cochlear, Immutep, Polynovo, Resmed and Starpharma rose more than two percent; with Dimerix and Nanosonics up one percent or more; with CSL and Telex up by less than one percent.

Factor led the falls, down 0.1 cents or 33.3 percent to 0.2 cents with 8.4 million shares traded. Reva lost 10.3 percent; Airxpanders fell 7.5 percent; Ellex shed 6.6 percent; LBT lost 5.3 percent; Osprey fell four percent; Admedus, Avita, Bionomics, Medical Developments and Optiscan were down more than three percent; Actinogen, Neuren, Orthocell, Prana, Prescient and Volpara shed more than two percent; with Impedimed and Pharmaxis down more than one percent.

VICTORIA GOVERNMENT

Victoria Premier Daniel Andrews has appointed Martin Pakula as Minister for Jobs, Innovation and Trade replacing Philip Dalidakis as responsible for the biotech sector. In a statement on his website Mr Andrews said Mr Pakula was also the Minister for Tourism, Sport, Major Events and Racing.

Mr Andrews said that former Health Minister Jill Hennessy had been appointed as Victoria's first woman Attorney-General and Jenny Mikakos had been appointed Minister for Health and Ambulance Services.

Mr Andrews said Frank McGuire would continue as the Parliamentary Secretary for Medical Research.

OSPREY MEDICAL

Osprey says its one-for-five rights offer at 15.5 cents a share has raised \$4,304,820 of a hoped for \$10.5 million taking the total raised so far to \$14.3 million.

In October, Osprey said Allan Gray had invested \$10.0 million in a 15.5 cents a share placement and it hoped to raise a further \$10.5 million in a rights offer (BD: Oct 30, 2018) Today, the company said that it had three months to place the shortfall.

Osprey said 26.9 percent shareholder Brandon Capital had taken up its entitlement and applied for shares in the top-up facility to maintain its percentage ownership.

Osprey fell half a cent or four percent to 12 cents with 2.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says it will collaborate with Nihon Medi-Physics Co to evaluate the feasibility of actinium-225-labeled antibodies for the treatment of clear-cell renal cell cancer.

Telix said that Tokyo-based Nihon was "a leading manufacturer and supplier of radiopharmaceuticals and related products in Japan" and Sumitomo Chemical Co and General Electric Healthcare joint venture.

The company said that Nihon was developing an alpha-emitting based therapeutic pipeline, following the decision to build a new research and development site to produce radionuclides including 225-actinium (225Ac).

Telix said that compared to other types of radionuclides, alpha-emitters had relatively higher energy to damage cancer cells and a shorter energy deposit range to minimize damage to peripheral normal cells.

Telix said the parties would collaborate to apply Nihon's novel linker chemistry to Telix's anti-carbonic anhydrase IX (CAIX) antibodies and jointly conduct proof-of-concept studies. The company said that carbonic anhydrase IX was a surface-expressed protein which was over-expressed in renal cell cancer.

Telix Japan president Dr Shintaro Nishimura said that his company's 89-zirconium-girentuximab (TLX250) positron emission tomography (PET) imaging tracer also targeted CAIX and could select patients for therapy.

The company said the combination of a diagnostic with a therapy was called a "theranostics".

Nihon president Hisashi Shimoda said that his company viewed "theranostic radiopharmaceuticals as a growth driver for our business".

"This collaboration with Telix, [which] is extensively developing products in the oncology field, is expected to impact positively on our business strategy," Mr Shimoda said.

Telix was up half a cent or 0.7 percent to 69.5 cents.

NOXOPHARM

Noxopharm says a 19-patient, phase I trial has found that NOX66 with carboplatin was tolerated and suspended tumor growth in nearly half of cancer patients.

Noxopharm said that all patients in the study had late-stage breast, ovarian, lung or prostate metastatic solid cancers, had stopped responding to chemotherapy, including carboplatin, and had no remaining standard treatment options.

The company said that for the first month of the study patients received only NOX66, or Veyonda and for the following six months received NOX66 in combination with three cycles of carboplatin at half the standard dose followed by three cycles of carboplatin at 75 percent of the standard dose.

Noxopharm said 14 patients completed three carboplatin cycles and were able to be assessed and eight patients completed all six carboplatin cycles for assessment.

The company said there was one "serious case" of anaemia during treatment with only NOX66, with 83 percent of patients having one or more adverse events during treatment with NOX66 and carboplatin "of which 80 percent were attributed to carboplatin".

Noxopharm said that treatment with NOX66 and low dose carboplatin "provided suspension of tumor growth, or better, for at least six months in solid tumors ... in nearly 50 percent of patients considered unlikely to respond to further chemotherapy".

The company said that at three months "10 of 14 patients had shown no tumor progression" and of the eight patients who completed six cycles of carboplatin six had "no disease progression at the end of the study, including one partial responder with an almost 100 percent reduction in tumor size".

The company said "the response rate and ongoing survival of patients post-study, suggests that a meaningful increase in survival is achievable and therefore worthy of consideration of an eventual marketing approval process".

Noxopharm was up two cents or 3.8 percent to 55 cents.

IMMUTEP

Immutep says the European Patent Office has allowed a patent covering the use of IMP321, or eftilagimod alpha, with a therapeutic antibody for cancer treatment.

Immutep said the patent, titled 'Compositions comprising LAG-3 and therapeutic antibodies and their uses in treating cancer' protected IMP321, in combination with a therapeutic antibody for cancer until October 3, 2028.

Immutep said IMP321 elicited a monocyte-mediated immune response which enhanced the ability of therapeutic antibodies like rituximab, cetuximab, or trastuzumab to kill tumor cells through antibody dependent cell-mediated cytotoxicity.

The company said the patent "points to the broad potential of [IMP321] as an immune stimulant and provides protection ... for an additional range of combination therapies".

Immutep was up 0.1 cents or 2.8 percent to 3.7 cents with 1.4 million shares traded.

ITL HEALTH

ITL says it will hold an extraordinary general meeting in January to vote on delisting from the ASX and buying-back up to 50 percent of its shares (BD: Nov 23, 2018).

ITL said the delisting resolution was for removal from the ASX no earlier than February 8, 2019 and the directors be authorized to do all things reasonably necessary to delist.

The company said it proposed to buy-back up to 50 percent of the shares on-market.

The meeting will be at 10 Moore Street, Canberra on January 8, 2019 at 10am (AEDT).

ITL was up 1.8 cents or 19.6 percent to 11 cents.

ELLEX MEDICAL LASERS

Ellex's annual general meeting passed all resolutions easily, except the re-election of Alex Sundich as director was opposed by 34.8 percent of votes.

Ellex said that the re-election of Mr Sundich was supported by 39,050,645 votes (65.2%) and opposed by 20,842,152 votes (34.8%).

The company said the remuneration report faced 9.1 percent opposition with the election of directors Michael Southard and Michael Mangano, the appointment of auditor and approval of the employee incentive plan, passed by a wider majority.

Ellex's most recent Appendix 3B new share issue announcement said it had 143,601,138 shares on issue, meaning that the opposition to Mr Sundich amounted to 14.5 percent of the company's shares on issue, sufficient to requisition extraordinary general meetings.

Ellex fell five cents or 6.6 percent to 71 cents.

ADALTA

Adalta's annual meeting passed all resolutions easily, except for the issue of 189,117 shares to director Dr John Chiplin which was opposed by 16.7 percent of votes.

Adalta said that the issue of shares, acquired by Dr Chiplin in the July placement which raised \$4.25 million, was supported by 60,133,118 votes (83.3%) and opposed by 12,071,554 votes (16.7%) (BD: Jul 13, 2018).

The company said that all the other resolutions including the remuneration report, the re-election of directors James Williams and Liddy McCall, the issue of shares to director Robert Peach, approval of prior issue of securities under the company's 15% placement capacity, the issue of 375,000 options to chief executive officer Samantha Cobb, and approval of the 10 percent placement capacity, were passed overwhelmingly.

Adalta's most recent Appendix 3B new share issue announcement said it had 117,016,112 shares on issue with 588,411 shares not quoted on ASX, for a total of 117,604,523 shares, meaning that the opposition to Dr Chiplin's shares amounted to 10.3 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Adalta was up 1.5 cents or 5.8 percent to 27.5 cents.

MMJ

MMJ says its annual general meeting avoided a remuneration report first strike with 2,450,645 votes (22.4%) opposing the report, with 8,469,146 votes (77.6%) 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 by more than 50 percent of votes the directors must stand for re-election.

The company said that all the other resolutions including the re-election of directors Winton Willessee and Douglas Halley, the approval of the 10 percent placement capacity, performance rights plan, replacement constitution, and ratification of prior issue of performance rights, were passed by wider margins.

The performance rights plan faced opposition from 2,585,098 votes (12.6%) with 17,948,430 votes (87.4%) in favor.

MMJ's most recent Appendix 3B said it had 230,148,985 shares on issue meaning that the opposition to the performance rights plan amounted to 1.1 percent of the total shares on issue, not sufficient to requisition extraordinary general meetings.

MMJ fell one cent with 3.7 percent to 26 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says its annual meeting passed all resolutions but with up to 23.3 percent dissent against the issue of 152,500,000 performance rights to five directors. Genetic Technologies said the greatest percentage dissent was against the issue of 6,250,000 rights to director Dr George Muchnicki, with 155,469,368 votes (74.6%) in favor, 48,559,893 votes (23.3%) against and 4,403,250 votes (2.1%) at proxies' discretion. The company said there was similar dissent against all directors rights including 57,250,000 rights for executive chairman Dr Paul Kasian, 3,750,000 rights to Dr Lindsay Wakefield, 5,000,000 rights to Peter Rubinstein and of 3,750,000 rights for Sam Lee. Genetic Technologies said that other resolutions passed by wider margins, including the remuneration report, the reelection of director Dr Wakefield, the adoption of an employee option plan, the issue of a maximum of \$20,000,000 worth of shares for its equity placement facility with Kentgrove Capital, the ratification of 108,833,100 shares and 12,500,000 options under its equity placement with Kentgrove Capital, the issue of up to 486,000,000 milestone shares to Blockchain Global, the approval of a \$15,000,000 placement to sophisticated investors and a 10 percent increase in placement capacity. The company said it had 2,644,115,824 shares on offer, meaning that the largest number of votes opposing Dr Wakefield and Mr Rubinstein rights, 48,560,643 votes, was 1.84 percent of the company, not sufficient to requisition an extraordinary general meeting. Genetic Technologies fell 0.1 cents or 10 percent to 0.9 cents with 1.8 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says its annual meeting faced 10.5 percent dissent against the remuneration report and loan shares for chief executive officer Scott Richards. Mayne said that a poll showed 77,853,583 votes (10.55%) against the remuneration report and 660,001,571 votes (89.45%) in favor. The company said the issue of a five-year, interest-free share purchase loan of \$6,040,000 for Mr Richards faced 92,256,793 votes (10.48%) against and 787,847,871 votes (89.52%) in favor. Mayne said all other resolutions passed with less than 2.1 percent dissent. According to its latest Appendix 3B new share announcement, Mayne had 1,576,073,148 shares on offer, meaning the votes against Mr Richards loan shares amounted to 5.85 percent of the company, sufficient to requisition extraordinary general meetings. Mayne Pharma fell 4.5 cents or 4.3 percent to 99.5 cents with 23.3 million shares traded.

CORRECTION: GI DYNAMICS

Last night's edition incorrectly reported that GI Dynamics Endobarrier trial with Apollo Sugar in India was expected to conclude by September 2019. The company said that enrolment was expected to begin by July 2019 and conclude by September 2019. A GI Dynamics spokesperson told Biotech Daily that each patient was expected to have the Endobarrier insert for 12 months, with the length of follow-up to be determined. GI Dynamics said the US trial would file data at 12 months with a two-year follow-up and the India trial protocols were being determined. Biotech Daily apologizes for misreading the media release. The Wednesday sub-editor has been terminated. GI Dynamics was untraded at 1.8 cents.

INVION

Invion says that due to an Australian Taxation Office decision it will require a new shareholder meeting for the demerger of its respiratory assets.

In September, Invion said that through an in-specie distribution, it would demerge its respiratory assets INV102, or nadolol, and INV104, or zafirlukast, into Chronic Airway Therapeutics with inventor Dr Mitchell Glass leaving Invion to be a Chronic Airway Therapeutics director (BD: Sep 5, 2018).

At that time, the company said that, pending approvals, the demerger would be through an equal capital reduction on one Chronic Airway share for each Invion share held.

Today, the company said that due to a ruling by the ATO on tax relief for Invion shareholders who are Australian residents it would need to go back to shareholders for approval at a general meeting intended for mid-January, 2019.

Invion fell 0.3 cents or 15 percent to 1.7 cents with 4.1 million shares traded.

IMMURON

Empery Asset Management says it has reduced its shareholding in Immuron from 11,717,666 shares (8.21%) to 10,271,535 shares (7.17%).

The New York-based Empery said it sold the shares on July 23, 2018 but did not disclose prices, as required by the Corporations Act 2001.

In July, Empery said it had reduced to 8.2 percent in Immuron and gave July 23, 2018 as the date of the sale of the shares (BD: Jul 30, 2018).

In the substantial shareholder notice, Empery managing member Ryan Lane said that the holders included himself, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Asset Laster, Empery Tax Efficient LP and Empery Tax Efficient II LP, with Citicorp the registered holder.

Immuron fell one cent or 3.8 percent to 25.5 cents.

GI DYNAMICS

Richard Cashin says he has increased his holding in GI Dynamics from 175,545, 263 shares to 199,364,713 shares and been diluted from 22.90 percent to 20.68 percent.

The New York-based Mr Cashin said that on November 16, 2018 he was issued 23,819,450 Chess depository instruments (CDIs) purchased for \$476,389 or 2.0 cents per CDI in the company's September placement.

Last month, Mr Cashin said he acquired 150,000,000 CDIs for \$3 million or two cents a share after in the issue of the first tranche of CDIs from the placement (BD: Oct 2, 2018).

In September, GI Dynamics said it had commitments for a \$6,944,445 placement at 2.0 cents per CDI (BD: Sep 20, 2018).

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

The Sydney-based Wentworth Williamson Management says it has increased its substantial holding in TPI from 4,057,618 shares (5.00%) to 4,872,614 shares (6.01%).

Wentworth Williamson said it acquired the shares between July 23 and November 29, 2018, but failed to state the price paid as required under the Corporations Act 2001.

TPI was up four cents or 3.3 percent to \$1.24.