

Biotech Daily

Thursday March 22, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: TELIX UP 15%; ONCOSIL DOWN 7%
- * IMMUTEP STARTS 4th IMP321 TACTIMEL MELANOMA TRIAL COHORT
- * SIENNA ADJUNCT URINARY CANCER TEST 'INCREASES SENSITIVITY'
- * ONCOSIL PLACEMENT RAISES \$12.7m, PLAN FOR \$4m MORE
- * BARD1 RAISES \$1.3m
- * APPLICATIONS OPEN FOR GSK \$75k DISCOVERY FAST TRACK
- * PRO MEDICUS ANNOUNCES BUY-BACK OF 10m SHARES
- * ADHERIUM TELLS ASX AWARE QUERY: 'NEWS NOT MATERIAL'
- * VOLPARA APPOINTS PAUL REID DIRECTOR
- * PSIVIDA LOSES DEB JORN
- * ESENSE STARTS LEGAL ACTION AGAINST DR BRENDAN DE KAUWE

MARKET REPORT

The Australian stock market fell 0.22 percent on Thursday March 22, 2018, with the ASX200 down 13.1 points to 5,937.2 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Telix was the best on no news, up 7.5 cents or 14.6 percent to 59 cents with 515,474 shares traded. Volpara climbed 7.9 percent; Starpharma rose 5.3 percent; Dimerix was up four percent; Universal Biosensors improved 3.8 percent; Medical Developments rose 2.3 percent; Mesoblast and Optiscan were up more than one percent; with Viralytics up 0.3 percent.

Oncosil led the falls, down one cent or 7.1 percent to 13 cents with 2.4 million shares traded. Pharmaxis fell 4.7 percent; Admedus, LBT, Osprey, Pro Medicus and Reva lost more than three percent; Benitec, Bionomics, Clinuvel, Ellex, Neuren and Opthea shed more than two percent; Avita, Compumedics, Genetic Signatures, Nanosonics, Polynovo, Prana and Resmed were down one percent or more; with Cochlear, CSL and Cyclopharm down by less than one percent.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says it has dosed the first of six patients in a fourth cohort of its phase I trial of IMP321 combined with Keytruda for unresectable or metastatic melanoma. Immutep said that patients enrolled in the fourth cohort of its two active immune-therapeutics for melanoma (Tactimel) trial would receive 30mg of IMP321, or eftilagimod alpha, in combination with Keytruda, or pembrolizumab, for up to 12 months. Immutep chief operating officer, general counsel and company secretary Deanne Miller told Biotech Daily that the new cohort would be dosed with IMP321 from day-1 with Keytruda.

"Previously we waited for non and suboptimal responders and only dosed those patients after waiting to see their 'failed' response to Keytruda after five cycles of just Keytruda before injecting them with IMP321," Ms Miller said.

Last year, the then Prima said it had completed dosing third cohort patients at the 30mg IMP321 level bringing the total number dosed to 18 patients (BD: Dec 13, 2017). The company said that safety was the main objective of the study and previously said that interim data from the first two cohorts in the Tactimel study indicated that IMP321 was safe and well-tolerated at 1mg and 6mg doses (BD: Dec 22, 2016; Apr 19, 2017). Immutep chief scientific and medical officer Dr Frédéric Triebel said the additional cohort was "very important to the clinical development of [IMP321], especially in the light of our new collaboration study announced on March 12, 2018, as we are now dosing [IMP321] at cycle one in combination with Keytruda with the highest dose and for a 12-month duration".

Immutep was unchanged at 2.4 cents with 2.1 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says a 500-patient study shows its adjunct test for bladder cancer increases sensitivity from 29.2 percent to 50.8 percent, while maintaining 89.2 percent specificity. Sensitivity measures true positives, while specificity measures true negatives. Sienna said that the Baltimore, Maryland-based Johns Hopkins Hospital study investigated the presence of human telomerase reverse transcriptase (hTERT) a cancer-related biomarker in urothelial cells, using its telomerase-based in-vitro adjunct diagnostic for bladder cancer.

The company said that the prospective study began in July 2016 and investigated 500 patients undergoing investigation for bladder cancer by urine cytology and/or cystoscopy, with a six-month follow-up to confirm the test results.

Sienna said that the results were presented at the US and Canadian Academy of Pathology meeting in Vancouver, Canada, March 17 to 23, 2018.

The company said the study concluded that hTERT testing might help identify patients with increased likelihood of high grade urothelial carcinoma (HGUC), who might otherwise by missed by standard screening alone.

"Additionally, negative hTERT staining was shown to be associated with a decreased risk of HGUC compared to cytology alone," Sienna said.

Sienna chief executive officer Matthew Hoskin said the company was "delighted with the results of the study, demonstrating that our hTERT test provides valuable additional information to physicians".

"Having the results presented at such a prestigious gathering of pathologists will provide the hTERT test great exposure to laboratories who may ultimately offer it as part of their testing menu" Mr Hoskin said.

Sienna was untraded at 9.9 cents.

ONCOSIL MEDICAL

Oncosil says it has closed its "oversubscribed" two-tranche institutional placement to raise \$12.7 million at 12 cents a share (BD: Mar 21, 2018).

Oncosil said that first tranche of \$8.7 million was expected to be allotted on March 28, with the second tranche of \$4.0 million pending shareholder approval at an extraordinary general meeting expected to take place on May 4, 2018 "or as soon as practicable".

The company said that the share plan to raise a further \$4.0 million would have the record date of March 20, 2018.

Oncosil fell one cent or 7.1 percent to 13 cents with 2.4 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it has commitments to raise \$1,300,000 in a placement of 86,666,666 shares at 1.5 cents a share to sophisticated and professional investors.

Bard1 said that the funds would be used to fund ongoing research and development programs, commercial initiatives and for general working capital purposes.

The company said the placement was made to high net worth and institutional clients of the Perth, Western Australia-based Taurus Capital Group.

Bard1 fell 0.4 cents or 17.4 percent to 1.9 cents with 64.6 million shares traded.

GLAXOSMITHKLINE

Glaxosmithkline says applications have opened for its \$75,000 'Discovery Fast Track Australian Challenge' search for early drug-discovery partnerships.

Glaxosmithkline said that the program was "designed to accelerate the translation of earlystage research into game-changing new medicines ... [and] rapidly uncover the best opportunities for discovery research".

The company said that academic scientists were encouraged to participate in the Challenge by submitting details about the biological targets or pathways they research, along with the scientific rationale detailing how the early-stage research could direct future drug development.

Glaxosmithkline the shortlist would be "based on the strength of the ... hypotheses, originality, initial progress and the ability to deliver on an unmet medical need".

The company said that winners would have access to its screening technologies and library of compounds to test their hypotheses in the hope of finding compounds with the potential to develop into the medicines of the future.

Glaxosmithkline said that up to \$75,000 would be provided to enable winners to conduct supportive research for the collaboration.

The company said that since its launch in 2013, the annual Discovery Fast Track Challenge attracted more than 1,100 proposals from more than 300 universities, academic research institutions and hospitals in 28 counties.

Glaxosmithkline said that submissions close on April 27, 2018, with details available at: www.gsk.com/discoveryfasttrack.

PRO MEDICUS

Pro Medicus has announced an on-market share buy-back of up to 10 percent of shares on issue, or 10,336,904 shares, beginning April 1, 2018.

Pro Medicus said that the buy-back would end on March 31, 2019.

Pro Medicus fell 26 cents or 3.1 percent to \$8.19.

ADHERIUM

Adherium has told an ASX 'aware query' that news of its asthma trial results was not material and that director purchases caused increased share prices.

The ASX said that on March 5, 2018 identical media releases describing results of Adherium's Smartinhaler device trial for asthma were published in the NASDAQ newsletter Globe Newswire and on the Adherium website, but an ASX announcement marked as market sensitive with the same media release was not lodged until March 7, 2018 (BD: Mar 7, 2018).

The ASX asked Adherium to clarify when it first became aware of the information contained in the announcement, if it believed the information had had a material impact on the share price and if the director share purchases were in accordance with the Adherium trading charter.

Adherium said that "as the company's commercial focus is increasingly on the United States, it prepared a US press release in conjunction with the conference presentation and circulated this at 11.16 am, March 5, 2018 US Eastern Time (3.16am, March 6 2018 AEST [sic]) to increase its US profile".

"The press release was not made in any investment context," Adherium said.

"While the information was not considered to be material by the company, Adherium believed the results presented would also be of interest to shareholders (but not material to share price) and announced the results via [the] ASX announcements platform on March 7, 2018," Adherium said.

Adherium said that "the information contained in the presentation had been made publicly available on March 1, 2018, when the authors published the results of their study in the February 2018 edition of the Journal of Allergy and Clinical Immunology".

The company said that increases in the share price were "not correlated to the release of the study results on March 7, 2018, but largely due to the market reaction to the directors' own share purchases" which was announced on March 12, 2018, and that "the announcement of similar previous studies' results has not historically had a material effect on the price of Adherium's shares".

Adherium said its directors had received approval by email on February 27, 2018 to buy shares on-market from March 5 to 8, 2018.

According to ASX data provided by Commsec Adherium's share prices increased on March 5 from 8.9 cents to a high of 9.2 cents, closing at 8.9 cents and that after the Nasdaq announcement the share price opened at 9.2 cents and closed at 9.6 cents. The ASX data shows that after the announcement in Australia the Adherium share price opened and closed at 10 cents.

On March 12, after the announcement of the director share purchases, that trading volumes increased significantly and the share price rose from 10.5 cents to close at 15 cents on March 12, before retreating to 13 cents on March 13.

Adherium fell half a cent or 4.2 percent to 11.5 cents.

VOLPARA

Volpara says it has appointed the Wellington, New Zealand-based Paul Reid as a director. Volpara said Mr Reid had previously held positions as chief executive officer of software company Figured, chairman at Netlogix Holdings and Pukeko Pictures, as well as a director of Comvita and held executive roles at the New Zealand Meteorological Service, Carter Holt Harvey and Air New Zealand.

Volpara was up five cents or 7.9 percent to 68 cents.

PSIVIDA CORP

Psivida says that its head of corporate and commercial development Deb Jorn, who was appointed in November 2016, resigned on March 16, 2018 (BD: Nov 8, 2016). Psivida was untraded at \$1.625.

ESENSE-LAB

Esense says it has begun legal action against director Dr Brendan de Kauwe in the central district court in Lod, Israel.

Esense has a board spill extraordinary general meeting and a separate annual general meeting scheduled for March 29, 2018 (BD: Jan 29, 2018).

Last month, Esense announced that legal proceedings brought against it in Israel by directors Dr de Kauwe and Quentin Megson had been dismissed (BD: Feb 13, 2018). Today, Esense said that it requested the Court instruct Dr de Kauwe to comply with the resolution of the board of directors of January 19, 2018 regarding the change in the company's signature rights regarding its National Australia Bank account, which prevented funding ongoing operations.

The company said it requested that the Court instruct Dr de Kauwe comply with the board's resolutions regarding the approval of its budget for the 2018 fiscal year by signing the documents required by the NAB, so it could transfer funds from its Australian bank account for the period until the delivery of the Court's ruling.

Esense said that on March 21, 2018, the Court ruled that Dr de Kauwe's response to the company's request for temporary remedies should be filed with the Court by March 28, 2018, at 13:00 Israel time.

In January, Esense said it had a request under Israeli Companies Law from shareholders Romfal Sifat, Buzz Capital and Attollo Investments for a meeting to remove directors Haim Cohen, Eran Gilboa and Ilan Saad; and appoint as directors the then chairman Dr de Kauwe, if he was not re-elected at the annual general meeting, as well as MMJ Phytotech chief executive officer Andreas Gedeon and Faldi Ismail (BD: Jan 29, 2018). Esense fell half a cent or 2.9 percent to 16.5 cents.