

Biotech Daily

Monday January 18, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: PATRYS UP 16%; ALTERITY DOWN 10.5%
- * CHIMERIC IPO OPENS UP 60% FOR CLTX-CAR-T FOR GLIOBLASTOMA
- * CYNATA RIGHTS RAISE \$2.5m; SHORTFALL; TOTAL \$18.3m
- * PRESCIENT NAMES OMNICAR CAR-T CANCER PROGRAMS
- * AZURE NE1-ELITE, NE1-HEART ON ARTG
- * ASX POLYNOVO QUERY: DIRECTOR SALES, REVENUE, PRICE FALL
- * BOD: Q2 \$3m MARIJUANA SALES
- * FACTOR: LONGMILE TALKS TERMINATE ON ASX DELAY
- * M&G REDUCES TO 7.85% OR 6.78% OF STARPHARMA
- * HONSUE CHO REDUCES TO 21% OF INVION
- * SHENGLI WANG, NGPDT GREATER CHINA TAKE 12% OF INVION
- * AROA RELEASES 46m VOLUNTARY ESCROW SHARES
- * SUDA: G-M TONY MACINTYRE, CEO DR MICHAEL BAKER ASSUME CTO

MARKET REPORT

The Australian stock market fell 0.78 percent on Monday January 18, 2021, with the ASX200 down 52.4 points to 6,663.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 22 fell and four traded unchanged. All three Big Caps were up.

Patrys was the best, up 0.4 cents or 16 percent to 2.9 cents, with 49.7 million shares traded. Dimerix and Osprey climbed more than 14 percent; Amplia and Pro Medicus improved more than 11 percent; Optiscan rose 8.3 percent; Antisense was up 4.8 percent; Uscom climbed 3.1 percent; Nanosonics and Resmed rose more than two percent; Neuren and Volpara were up more than one percent; with Avita, Cochlear, CSL, Mesoblast and Next Science up by less than one percent.

Alterity led the falls, down 0.4 cents or 10.5 percent to 3.4 cents, with 25.7 million shares traded. LBT lost 8.3 percent; Impedimed, Orthocell and Resonance fell seven percent or more; Pharmaxis and Universal Biosensors were down more than five percent; Actinogen, Imugene, Starpharma and Telix fell four percent or more; Kazia and Proteomics were down more than three percent; Clinuvel, Cynata, Genetic Signatures, Medical Developments and Polynovo shed more than two percent; Paradigm and Prescient lost more than one percent; with Cyclopharm and Opthea down by less than one percent.

CHIMERIC THERAPEUTICS

Chimeric opened at 32 cents on the ASX, up 60 percent on its 20 cents initial public offer price, having raised \$35 million for its chimeric antigen receptor t-cells for cancer. In December, Chimeric executive chair Paul Hopper said the company's chlorotoxin chimeric antigen receptor (CLTX-Car) T-cell therapy, licenced from the Duarte, California-based City of Hope, was "an extremely promising technology" with an 18-patient, phase I trial underway (BD: Dec 11, 2020)

Today, the company said CLTX-Car-T used a peptide derived from scorpion toxin to direct T-cells to target the brain cancer glioblastoma and along with the phase I trial the funds would be used to develop "an oncology-focused pipeline of novel cell therapies". Chimeric said that joint lead managers to the offer were Bell Potter and Baker Young. Chimeric (CHM) climbed as much as 87.5 percent to 37.5 cents before closing up 9.5 cents or 47.5 percent at 29.5 cents with 42.5 million shares traded.

CYNATA THERAPEUTICS

Cynata says its one-for-15 rights offer at 70 cents a share has raised \$2.5 million of a hoped-for \$5.5 million, with an \$800,000 shortfall taking the total to \$18.3 million. Last month, Cynata said it raised \$15 million in a placement at 70 cents a share and hoped to raise a further \$5.5 million in the rights offer (BD: Dec 11, 2020). Today, the company said it had placed about \$800,000 of the shortfall. Cynata fell 1.5 cents or 2.1 percent to 69.5 cents.

PRESCIENT THERAPEUTICS

Prescient says it has developed three internal programs for its Omnicar chimeric antigen receptor T-cell (Car-T) platform.

Prescient said the development programs Omnicar CD33 and CLL-1 would be for acute myeloid leukaemia, Ominicar Her2 for HER2 positive solid tumors including breast, ovarian and gastric cancers, and Omnicar Her2 and EGFRviii for glioblastoma multiforme. The company said Omnicar was "a universal immune receptor technology platform that offers a number of potential benefits over existing Car-T therapies, including control, safety, flexibility and efficacy".

Prescient fell 0.1 cents or 1.25 percent to 7.9 cents with 34.8 million shares traded.

AZURE HEALTH TECHNOLOGY

Azure says two of its food additives NE1-Elite and NE1-Heart have been listed on the Australian Register of Therapeutic Goods as complementary medicines.

Azure said that the delta tocotrienol-based NE1-Elite and NE1-Heart were delivered by its MELT3 platform, with NE1-Elite "clinically proven to reduce muscle soreness, assist in post-exercise recovery and improve muscle recovery time [while] NE1-Heart reduces free radicals formed in the body and maintains a healthy heart function".

Azure US subsidiary Invictus chief executive officer Richard Estalella said the initial focus was launching the products in the US, but "the overwhelmingly positive response" from Australian consumers made a compelling case to provide Australian access.

The company said that the two products would be available outside the US through an online platform and it expected the products to be available online and through retail outlets in Australia by the end of 2021.

Azure is a public unlisted company.

POLYNOVO

Polynovo has responded to a series of ASX "aware" questions relating to revenue data, director share sales and a falling share price.

The ASX noted that Polynovo told the market on January 12, 2021 that while it had strong sales of its Novosorb wound treatment in the three months to September 30, 2020, up 75 percent compared to the previous corresponding period, with the half year to December 31, 2020 up 31 percent on the previous corresponding period, it had "slower than expected sales in October and November".

The ASX said the announcement included US Biomedical Advanced Research and Development Authority (BARDA) revenue "lower than anticipated [due] to the delay in obtaining our US [Food and Drug Administration investigational device exemption] approval".

The ASX said that on December 1, 2020, director Bruce Rathie via Katrat Investment sold 355,555 shares at \$3.3594 a share and managing director Paul Brennan sold 200,000 shares at \$3.39 a share, with director Leon Hoare's spouse Helen Charles-Hoare selling 100,000 shares at \$3.454 a share on December 2, 2020.

The ASX noted a fall in the Polynovo share price following the January 12 announcement, from \$3.39 on January 11 to \$2.68 on January 13, 2021, and asked "when did [Polynovo] first become aware of the information", whether it was material, and whether the trading was in compliance with the company's trading policy.

The ASX further asked that rather than describing the periods as being up 31 percent or 75 percent and trading being "slower than expected" that it provide "clearer information as required by Guidance Note 8" namely the specific amounts.

Polynovo responded that sales were "highly variable month on month", it was entering new markets and adding staff "further diminishing the materiality of prior month sales results".

The company said it approached the question of disclosure "on the assumption that the totality of the information, not necessarily each individual component of the information, is material" for the purposes of Section 677 of the Corporations Act 2001.

Polynovo said the question of when it first became aware of the information was "not necessarily a simple question to answer" saying that under Australian Accounting Standards Board accounting standards a sale could "only be recognized once the product is in the customer's possession ... [requiring] proof of delivery from [its] logistics partners globally for each sale to each customer".

The company said that its "approach to disclosure is consistent with ASX's own guidance". Polynovo said it did not have sales data for the six months to December 31, 2020 "until sales information for December 2020 had been finalized and verified in accordance with the AASB accounting standards ... on Wednesday, January 6, 2021", with other data received earlier.

The company said it had reported delays with the FDA investigational device exemption and approval in November for a trial to start recruitment early this year.

Polynovo said the share sales complied with Section 7 of the trading policy.

The company said that product sales for the six months to December 31, 2020 was \$11.25 million compared to \$8.57 million for the prior corresponding period, with the sales for the three months to September 30, 2020 \$6.13 million compared to \$3.49 million for the prior corresponding period.

Polynovo said that sales in October 2020 were \$1.43 million and lower than budget while November had sales of \$1.40 million and lower than budget.

The company it was "complying with the Listing Rules".

Polynovo fell seven cents or 2.8 percent to \$2.47 with 5.9 million shares traded.

BOD AUSTRALIA

Bod says it has made \$3.33 million in sales from its marijuana products in the three months to December 31, 2020.

Bod said the sales were 144 percent more than the previous corresponding period and 52 percent more than the three months to September 30, 2020.

Bod was up two cents or 4.3 percent to 49 cents.

FACTOR THERAPEUTICS

Factor says it has ceased negotiations with Longmile Veterinary (positron emission tomography) PET Imaging, citing delays in ASX advice.

Last July, Factor said it had a term sheet to acquire the Rockville, Maryland-based Longmile Veterinary, a subsidiary of Brain Bioscience (BD: Jul 24, Nov 16, 2020).

Today, Factor said that with Longmile it had agreed to two extensions "while the company awaited ASX feedback on the in-principle advice application [but] to date ... [it had] not received any definitive in-principle advice regarding the transaction".

The company said that due to prolongation of the transaction and changes in business circumstances, the companies were not "able to finalize acceptable commercial terms". Factor said the parties mutually agreed "to cease negotiation, with no further penalty". The company said trading remained suspended until an approved transaction was concluded and it satisfied all ASX requirements necessary to resume trading. In 2018, Factor fell as much as 97.3 percent to 0.2 cents on news that its 157-patient trial of VF001 for venous leg ulcers "failed to meet all endpoints" (BD: Nov 14, 2018). Factor was in a suspension and last traded at 0.5 cents.

STARPHARMA HOLDINGS

In overlapping notices, M&G Investment says it has reduced its substantial holdings in Starpharma to 7.85 percent and 6.78 percent.

In a notice filed by M&G Plc, the group said it reduced its holdings from 37,891,465 shares (9.33%) to 31,889,780 shares (7.85%).

In a separate filing lodged at the same time, 8.20am today, M&G Investment Funds said it had reduced its holdings from 33,225,473 shares (8.18%) to 27,552,109 shares (6.78%). In both announcements, M&G said that the single largest sale was 2,020,000 shares for \$3,038,650 or \$1.50 a share.

M&G Plc said the holders of the shares were HSBC Custody Nominees, and Hongkong and Shanghai Banking Corp.

M&G Investment Funds said its shares were held by HSBC Custody Nominees. Starpharma fell six cents or four percent to \$1.44.

INVION

Honsue Cho and Unlimited Innovation Group say they have reduced their holding in Invion from 3,739,652,180 shares (67.99%) to 1,146,031,359 shares (20.70%).

Last month, Invion said that the Hong Kong-based Unlimited Innovation Group had conducted an in-specie distribution of 220,682,156 shares to 49 group members, who had agreed to voluntary escrow periods from three to 12 months (BD: Dec 4, 2020).

Today, Unlimited Innovation Group said it had conducted an in-specie distribution of 2,814,302,977 shares.

Invion was unchanged at one cent with 2.1 million shares traded.

INVION

Shengli Wang and NGPDT Greater China say they have become substantial shareholders in Invion with 681,440,371 shares or 12.31 percent of the company.

The Hong Kong-based Mr Wang said he became substantial following the in-specie distribution of shares by Unlimited Innovation (see above).

AROA BIOSURGERY

Aroa Biosurgery says that 46,215,450 shares will be released from voluntary escrow on January 25, 2021.

According to the most recent Appendix 2A Aroa has 300,726,414 shares available for trading.

Aroa was up half a cent or 0.45 percent to \$1.12.

SUDA PHARMACEUTICALS

Suda says following a review, the role of chief technical officer will be conducted by general manager Tony Macintyre and chief executive officer Dr Michael Baker. Dr Baker told Biotech Daily that the previous chief technical officer was Dr Carol Worth. "We are committed to ensuring that Suda has the most efficient team in place to deliver on the projects we believe are likely to return value to shareholders," Dr Baker said. Suda fell 0.1 cents or 2.4 percent to four cents with 4.4 million shares traded.