

Biotech Daily

Tuesday August 23, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: IMPEDIMED UP 8%; ANTISENSE DOWN 13%
- * NANOSONICS REVENUE UP 17% TO \$120m, PROFIT DOWN 56% TO \$3.7m
- * SOMNOMED REVENUE UP 15.7% TO \$72.6m, LOSS UP 272% TO \$4.4m
- * VISIONEERING H1 REVENUE UP 19.5% TO \$5.4m, LOSS UP 112% TO \$4.6m
- * CLARITY: 175MBq/kg CU-67 SARTATE TAKES TRIAL TO 3rd COHORT
- * LUMOS: \$390k ORDERS FOR RAPID HORMONE TEST CARTRIDGE
- * BIOTRON RECRUITS THAI BIT225 PHASE II HIV TRIAL
- * ATOMO TO DISTRIBUTE HANGZHOU ALLTEST COVID RAPID TESTS
- * OSTEOPORE APPOINTS KONTOUR CHINA DISTRIBUTOR
- * TOTAL BRAIN FAILS \$4.4m ADDITIONAL PAYMENT CONDITION
- * RADIOPHARM TO RELEASE 11m ASX ESCROW SHARES
- * LUMOS TO RELEASE 8m VOLUNTARY SHARES
- * ALLIANZ TAKES 6% OF PARADIGM
- * PROTEOMICS M-D DR RICHARD LIPSCOMBE DILUTED TO 16.6%
- * EBOS DILUTED TO 5% IN MEDADVISOR

MARKET REPORT

The Australian stock market fell 1.21 percent on Tuesday August 23, 2022, with the ASX200 down 85.1 points to 6,961.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 fell and six traded unchanged. All three Big Caps were down.

Impedimed was the best, up 0.6 cents or 8.2 percent to 7.9 cents, with 326,656 shares traded. Nova Eye and Uscom climbed more than six percent; Neuren improved 4.7 percent; Dimerix was up 3.3 percent; Actinogen rose 2.6 percent; Cyclopharm, Immutep, Medical Developments and Proteomics were up more than one percent; with Paradigm and Starpharma up by less than one percent.

Antisense led the falls for the second day in a row, down 1.3 cents or 13.0 percent to 8.7 cents, with two million shares traded. Micro-X lost 10 percent; Kazia, Telix and Universal Biosensors were down six percent or more; Clinuvel fell 5.3 percent; Imugene, Opthea and Polynovo were down more than three percent; Atomo, Cochlear, CSL, Genetic Signatures, Mesoblast, Pharmaxis, Prescient and Resmed shed two percent or more; Avita, Compumedics, Emvision, Nanosonics, Pro Medicus, Resonance and Volpara were down one percent or more; with Next Science down by 0.5 percent.

NANOSONICS

Nanosonics says revenue for the year to June 30, 2022 was up 16.7 percent to \$120,320,000 with net profit after tax down 56.4 percent to \$3,742,000.

Nanosonics said the increase in revenue and fall in profit reflected "the increased investment in the company's strategic growth agenda as well as the foreshadowed one-off impact in [the six months to June 30] on revenue in North America associated with the move to a largely direct sales model".

The company said it was "now managing all Trophon customers directly for the ongoing provision of consumables".

"This largely direct sales model aims to capture the full market opportunity for Trophon in North America as well as prepare for future product expansion plans," Nanosonics said. The company said research and development spending was up 30.0 percent to \$22,358,000, or 18.6 percent of revenue.

Nanosonics said sales of its Trophon ultrasound probe cleaning systems in North America were up 19.8 percent to \$106,900,000, up 4.2 percent to \$7,500,000 in Europe and the Middle East, and down 11.9 percent to \$5,900,000 in the Asia Pacific.

Nanosonics chief executive officer Michael Kavanagh said it "was an important year in the ongoing growth of the organization through the successful implementation of a number of key strategic priorities ... [including the] evolution of [its] sales model in North America to an expanded and largely direct model".

"With the total installed base continuing to grow and market fundamentals continuing to strengthen, we expect these investments to be further leveraged in [the year to June 30, 2023] with improved market access conditions after prolonged periods of Covid-19 related disruption," Mr Kavanagh said.

"Total revenue for the year grew 17 percent to \$120.3 million resulting from continued growth in new installed base, upgrades and consumables/service," Mr Kavanagh said. "Pleasingly, profit before tax for the year was \$1.6 million, which was ahead of recent expectations, despite the complex operating environment experienced during the year and the foreshadowed one-off impact in [the six months to June 30, 2022] on revenue in North America associated with the move to a largely direct sales model," Mr Kavanagh said. Nanosonics said net tangible asset backing per share was down 0.2 percent to 41.54 cents, with diluted earnings per share down 56.6 percent to 1.22 cents.

Nanosonics said it had cash and cash equivalents of \$94,512,000 at June 30, 2022, compared to \$96,027,000 at June 30, 2021.

Nanosonics fell eight cents or 1.7 percent to \$4.68 with 1.9 million shares traded.

<u>SOMNOMED</u>

Somnomed says revenue for the year to June 30, 2021 was up 9.4 percent to \$72,580,403 with net loss after tax up 271.9 percent to \$4,436,967.

Somnomed said revenue was from sales of its Somnodent product range for obstructive sleep apnoea.

The company said that sales were up 9.4 percent in Europe to \$42.5 million, North America was up 33.4 percent to \$24.7 million and sales in the Asia Pacific region were up 1.2 percent to \$5.4 million.

The company said that net tangible asset backing per share fell 68.4 percent to 5.7 cents, with diluted loss per share up 272.7 percent to 5.65 cents

Somnomed said it had cash and cash equivalents of \$15,644,331 at June 30, 2022 compared to \$21,109,841 at June 30, 2021.

Somnomed fell one cent or 0.8 percent to \$1.30.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the six months to June 30, 2022 was up 19.5 percent to \$US3,719,000 (\$A5,392,659) with net loss after tax up 112.2 percent to \$US3,154,000 (\$A4,573,392).

Visioneering said revenue from sales of its multifocal contact lenses was up 18.9 percent to \$US3,471,000 in North America, and up 29.2 percent to \$US248,000 in Europe and the Asia Pacific.

Visioneering said net tangible asset backing per share fell from 44 US cents to 28 US cents, diluted loss per share rose 62.5 percent to 13 US cents, and cash and equivalents of \$US6,856,000 at June 30, 2022 compared to \$US15,078,000 at June 30, 2021. Visioneering was untraded at 31 cents.

CLARITY PHARMACEUTICALS

Clarity says it completed dosing in the second cohort of its up-to 34-paediatric-patient trial of copper-67 for the diagnosis and treatment of high-risk neuroblastoma.

Clarity said that the 'CL04' study was a phase I/IIa, multi-centre, dose-escalation, openlabel, non-randomized, diagnostic and therapeutic trial in up-to 34 paediatric patients with high-risk neuroblastoma using Cu-64/Cu-67 Sartate.

In February, the company said it had dosed the first patient with Cu-67 Sartate at a dose of 175 mega becquerel (MBq) per kilogram of copper-67 in the second, higher-dose cohort in its trial for high-risk neuroblastoma (BD: Feb 25, 2022).

Today, Clarity said that the independent safety review committee assessed the safety data from the second cohort in all three participants confirming no dose limiting toxicities. Clarity said it had recommendation to progress the trial to the third cohort, with an increased dose of 275MBq/kg body weight.

The company said it would also conduct additional therapy cycles of Cu-67 Sartate for participants in the first and second cohort.

Clarity executive chair Dr Alan Taylor said "the further increase in dose between cohorts 2 and 3 is significant, and we look forward to analyzing the safety and efficacy data in these higher-level cohorts in neuroblastoma, a radiation sensitive disease".

"We are also pleased with the speed of recruitment in cohort 2 and have been able to close this cohort in six months," Dr Taylor said. "The increased pace of recruitment is due to the subsided effects of the global pandemic."

Clarity was up 2.5 cents or 3.6 percent to 72.5 cents.

LUMOS DIAGNOSTICS

Lumos says it has \$US270,000 (\$A391,458) in orders for the manufacture of its multiassay rapid diagnostic cartridge for use with a hormone monitoring platform.

Lumos said the start of pilot manufacturing at its Carlsbad, California facility followed a \$US320,000 manufacturing validation program and receiving Conformité Européenne (CE) mark certification.

The company said that its hormone monitoring platform would be used by in-vitro fertilization patients at-home and in clinical studies in the Asia Pacific region, Europe and the US, prior to a potential market launch by the end of 2023.

Lumos chief executive officer Doug Ward said "the receipt of this initial purchase order to manufacture and supply product is the culmination of years of development work and validates our recent site rationalization efforts in the US".

Lumos was up 0.3 cents or 5.1 percent to 6.2 cents.

BIOTRON

Biotron says it has recruited its 27-patient, Thailand-based, phase II trial of its BIT225 antiviral drug for human immunodeficiency virus-1 (HIV-1).

Biotron said the study was a multi-centre, randomized, placebo-controlled, double-blind study determining the safety and efficacy of BIT225 in HIV-1 infected, treatment-naïve patients commencing standard anti-retroviral treatment.

The company said the study would administer 200mg BIT225 daily for 24 consecutive weeks, with final dosing expected by February 2023, and preliminary results anticipated in "mid-2023".

Biotron fell 0.1 cents or 1.7 percent to 5.7 cents.

ATOMO DIAGNOSTICS

Atomo says China's Hangzhou Alltest Biotech will supply it with Covid-19 rapid antigen self-tests to be Atomo-branded for Australia and New Zealand.

Atomo did not disclose the commercial terms of the supply agreement.

The company said it intended to withdraw its existing Australian Therapeutic Goods Administration submission relating to its branded version of the Access Bio Covid-19 rapid antigen test to focus on the Alltest product.

In 2020, Atomo said that pending approvals it would sell up to 2 million of the Somerset, New Jersey-based Access Bio's severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) tests in Australia, New Zealand and India (BD: Jul 28, Sep 29, 2020).

Today, the company said that it would seek to register as a product sponsor in Australia and New Zealand of a branded version of Alltest's existing Therapeutic Goods Administration approved rapid antigen test.

Atomo said it had ordered an initial quantity of current Juschek branded product due in Australia late August to enable a commercial launch in parallel with activities to register an Atomo branded version of the product, with registration expected by January 2023. Atomo chief executive officer John Kelly said that "with some resurgence in Covid-19 infections in Australia and continued uncertainty related to future variants of concern, we are very pleased to be able to secure access to a well proven and low-cost rapid antigen self-test that will enable us to remain competitive in the local Covid self-test market". "We have identified a number of test applications commercialized by Alltest that we feel are suited to home test products on an Atomo device, and are working with Alltest to assess opportunities in the US market where the Covid-19 pandemic has transformed the home test landscape," Mr Kelly said.

Atomo fell 0.2 cents or 2.7 percent to 7.1 cents.

OSTEOPORE

Osteopore says it has an exclusive four-year distribution agreement with Kontour Xi'an Medical Technology to market and sell its products in China.

Osteopore said that with the Shanghai-based Kontour it would conduct trials for China National Medical Products Administration approval, which would take about 24 months. The company said that on approval, Kontour would buy a minimum of \$US500,000 (\$A725,037) of its products in the first year, and \$US1 million in the second year. Osteopore chair Mark Leong said "we are laying the necessary groundwork to enter the Chinese market and working with the right partner is essential".

Osteopore was up three cents or 13.6 percent to 25 cents.

TOTAL BRAIN

Total Brain says it was unable to satisfy a condition to earn an additional \$US3 million (\$A4.4 million) in its pending sale to the Denver, Colorado-based Sondermind. Earlier this month, Total Brain said telehealth company Sondermind would buy it for \$US10 million (\$A14.4 million), pending shareholder approval (BD: Aug 5, 2022). Today, the company said it had not implemented a clinical services agreement with a key customer by August 22, 2022, that would have triggered the payment. Total Brain fell 0.2 cents or 4.2 percent to 4.6 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it will release 11,111,018 shares from ASX escrow on September 1, 2022.

According to its most recent filing, Radiopharm would have a total of 129,704,179 shares on issue after the release, with a further 125,555,555 shares in ASX escrow. Radiopharm fell half a cent or 2.5 percent to 19.5 cents.

LUMOS DIAGNOSTICS

Lumos says it will release 7,823,594 shares from voluntary escrow on August 31, 2022. Lumos said that the shares were already quoted on the ASX, and according to its most recent filing it had 209,906,446 shares on issue.

PARADIGM BIOPHARMACEUTICALS

The Munich, Germany-based Allianz SE says it has become substantial in Paradigm with 16,378,604 shares or 6.08 percent.

Last week, Paradigm said it expected to raise \$45.7 million in an institutional placement, and \$20.3 million in a one-for-15 rights offer at \$1.30 a share (BD: Aug 15, 2022). Today, Allianz said that on August 19, 2022 it bought 5,916,154 shares at \$1.30 a share. Paradigm was up one cent or 0.8 percent to \$1.285 with 803,941 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics managing-director Dr Richard Lipscombe says his 19,048,704-share substantial holding has been diluted from 18.16 percent to 16.58 percent. Last week, Proteomics said it had raised \$8 million in a "heavily oversubscribed" placement at 85 cents a share (BD: Aug 15, 2022). Proteomics was up one cent or 1.1 percent to 92 cents.

MEDADVISOR

The Melbourne-based EBOS Group says its 26,459,627-share substantial shareholding in Medadvisor has been diluted from 6.04 percent to 5.01 percent. Last week, Medadvisor said its rights offer raised \$14.6 million (BD: Aug 18, 2022). Medadvisor was unchanged at 14.5 cents with one million shares traded.