



Biotech Daily

Wednesday August 17, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: CYCLOPHARM UP 9%; PARADIGM DOWN 8%**
- * **CSL REVENUE UP 2% TO \$15b; PROFIT DOWN 5% TO \$3b**
- * **CYCLOPHARM H1 REVENUE UP 35% TO \$11.4m, LOSS DOWN 35% TO \$2.6m**
- * **BTC REVENUE UP 9% TO \$7.7m, LOSS UP 60% TO \$758k**
- * **MEMPHASYS \$1.6m PLACEMENT; RIGHTS OFFER for \$1.76m MORE**
- * **NUHEARA WELCOMES US FDA O-T-C HEARING AID APPROVAL**
- * **BRISBANE EDA: MEDTECH PARTNER INITIATIVE**
- * **RHINOMED RECEIVES 1st SURESCREEN RHINOSWAB JUNIORS ORDER**
- * **NEUROSCIENTIFIC RECEIVES \$1.1m FEDERAL R&D TAX INCENTIVE**
- * **RESAPP 20.8c IS PFIZER'S 'BEST AND FINAL OFFER'**
- * **BTC TO DISTRIBUTE ALTECO LPS ADSORBER FOR SEPSIS**
- * **PHARMAUST TO BEGIN US MONEPANTEL DOG CANCER TRIAL**
- * **TRAJAN TO RELEASE 19m VOLUNTARY ESCROW SHARES**
- * **DR PAUL KASIAN REPLACES ZUCERO CHAIR DR STEFFEN NOCK; US PATENT**
- * **ANTISENSE TAKES 'LONG-COVID' TRADING HALT TO SUSPENSION**
- * **FIL (FIDELITY) TAKES 8.7% OF MEDICAL DEVELOPMENTS**
- * **LINDMARK, LINDA KERR, MARK KERR TAKE 5% OF CRYOSITE**
- * **THORNEY, TIGA BELOW 5% OF MESOBLAST**

MARKET REPORT

The Australian stock market was up 0.31 percent on Wednesday August 17, 2022, with the ASX200 up 22.3 points to 7,127.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and two were untraded.

Cyclopharm was the best, up 13 cents or 9.0 percent to \$1.58, with 31,452 shares traded. Alcidion and Polynovo climbed more than three percent; Compumedics, Next Science, Nova Eye and Opthea rose two percent or more; Amplia, Clinuvel, Impedimed and Pro Medicus were up more than one percent; with Emvision and Resmed up by less than one percent.

Paradigm led the falls, down 11.5 cents or 7.8 percent to \$1.355, with 1.8 million shares traded. Dimerix lost 6.25 percent. Resonance fell 4.1 percent; Actinogen, Genetic Signatures, Kazia, Imugene, Oncosil and Telix were down three percent or more; Neuren, Prescient and Starpharma shed two percent or more; Atomo, Cochlear, CSL, Immutep, Medical Developments, Mesoblast, Micro-X, Proteomics and Volpara were down one percent or more; with Avita and Nanosonics down by less than one percent.

[CSL](#)

CSL says revenue for the year to June 30, 2022 was up 2.4 percent to \$US10,562 million (\$A15,056 million) with net profit after tax down 5.1 percent to \$US2,255 million (\$A3,214 million).

CSL chief executive officer Paul Perreault said the company had “delivered a good result at the top end of our guidance, demonstrating our resilient performance against the ongoing challenges presented by the global Covid pandemic”.

“Despite the uncertain environment, we have carefully managed our costs and significantly boosted our investment in research and development, supporting our commitment to providing innovative medicine to patients.” Mr Perreault said.

CSL said that plasma collections were “impacted by the pandemic, constraining subsequent sales of core plasma therapies in [the year to June 30, 2022], given the long-term nature of our manufacturing cycle.”

The company said sales of Idelvion rose 20 percent, Kcentra sales were up 18 percent, with human papillomavirus royalties up 55 percent, and Seqirus seasonal influenza vaccine sales increasing 13 percent.

CSL said that the Behring division improved two percent to \$US8.6 billion, with North America up one percent, the Asia-Pacific up 21 percent, the European Union down five percent and the rest of the world down 18 percent.

The company said Seqirus revenue rose 13 percent to \$US1.96 billion, up seven percent in North America, 42 percent in the European Union and four percent in the Asia Pacific. The company said that a partly-franked dividend of \$US1.18 (\$A1.68) per share, constant from the previous year, would be paid on October 5 to shareholders at the record date of September 7, 2022, following the unfranked interim dividend of \$1.04 US cents (\$A1.48) per share paid on April 6, 2022.

The company said that with the acquisition of Switzerland’s Vifor Pharma its net tangible asset backing per share was up 97.5 percent from \$US12.55 to \$US24.79.

CSL said that diluted earnings per share down 7.9 percent to \$US4.80.

CSL said research and development spending increased 15.4 percent to \$US1,156 million compared to the previous year and was 10.9 percent of the total revenue, compared to \$US1,001.4 million in the previous year which was 9.7 percent of the total revenue.

The company said it had US\$10,436.4 million in cash and cash equivalents at June 30, 2022 compared to the previous corresponding period’s \$US1,808.8 million.

“While we are not immune to the macroeconomic environment, I can assure you we will continue to operate with resilience, integrity and agility, and deliver sustainable growth,” Mr Perreault said.

Mr Perreault said that following last year’s decrease in plasma collections, the company “grew plasma collections significantly, albeit at a higher cost”.

“Collections were up 24 percent, which we expect will underpin strong sales growth in our core plasma products, [immunoglobulin] and albumin, going forward,” Mr Perreault said.

“Having said that, the pandemic has put us two years behind projected growth in plasma collections – which is suboptimal for patient care,” Mr Perreault said.

“Our influenza vaccines business, CSL Seqirus, delivered an exceptional performance with revenue up 13 percent, achieved by growth in seasonal influenza vaccines driven by their differentiated and high value product portfolio,” Mr Perreault said.

Mr Perreault said that 2022-’23 would see “a return to strong sustainable growth” with net profit after tax for 2022-’23 expected to be in the range of \$US2,400 million to \$US2,500 million “returning to strong sustainable growth”.

“This excludes CSL Vifor earnings and costs associated with the acquisition,” he said.

CSL fell \$3.90 or 1.3 percent to \$292.50 with 1.4 million shares traded.

CYCLOPHARM

Cyclopharm says total revenue for the six months to June 30, 2021 was up 34.7 percent to \$11,427,483 with net loss after tax down 34.7 percent to \$2,564,256. Cyclopharm said sales of Technegas for lung imaging were at record levels, with Europe accounting for 51 percent of sales of the product.

The company said it would pay an unfranked interim dividend of 0.5 cents, for a record date of September 5 and payable on September 12, 2022.

Cyclopharm said net tangible asset backing per share was down 9.5 percent to 38 cents.

The company said that its diluted loss per share was down 37.7 percent to 2.78 cents.

Cyclopharm said that it had cash and cash equivalents of \$26,517,893 on June 30, 2022 compared to \$31,648,411 in June 30, 2021.

Cyclopharm was up 13 cents or 9.0 percent to \$1.58.

BTC HEALTH

BTC says its subsidiaries' unaudited revenue for the year to June 30, 2022 was up 8.75 percent to \$7,737,581 with net loss before tax up 60.4 percent to \$757,527.

BTC said that it was an "investment entity and therefore does not consolidate the operating results of its investment ... [but] with a view to providing shareholders with a greater insight into the operating results of [its] underlying investments, a pro-forma consolidated, unaudited, financial view of BTC and its wholly owned subsidiaries is provided".

Separately, BTC said the audited results for the ASX-listed investment vehicle showed revenue for the 12 months to June 30, 2022 up 395.1 percent from \$19,190 last year to \$95,004 for the year to June 30, 2022.

In the shareholder update including the non-ASX-listed entities, BTC said that sales to hospitals from its distributor Sigma Healthcare totalled \$8.2 million up 12 percent for the year; specialty pharmaceuticals including Pharmaxis' Bronchitol and Aridol contributed a maiden \$1.3 million of sales to hospitals; and the remaining medical devices and medical consumables fell five percent to \$6.9 million.

The company said that "the ongoing impact of elective surgery cancellation associated with hospital staff shortages reduced the expected volume of elective surgeries".

"Elective surgery waitlists have increased and private health insurers, clinicians and hospitals are expected to increase elective surgeries to pre-Covid-19 rates," BTC said.

The company said that June quarter sales were strong, with medical devices and medical consumables "closely aligned to 2021 demand".

BTC said that it had won new accounts for its Ambit infusion pumps and general surgery medical devices.

"We anticipate sales of this product range will rebound and grow over the prior year's run rate," BTC said.

BTC said the ASX-listed entity had a net loss after tax up 47.1 percent to \$576,076.

BTC said its net tangible assets per security was up 3.6 percent to 4.56 cents.

The company said that it had cash and equivalents of \$2,170,473 compared to \$2,368,975 the previous year.

BTC said its unaudited consolidated entities had cash of \$2,351,284 at June 30, 2022 compared to \$2,386,854 the previous year.

BTC was unchanged at 6.2 cents.

MEMPHASYS

Memphasys says it has commitments to raise \$1.6 million in a placement at two cents a share, and has an underwritten one-for-nine rights offer to raise a further \$1.76 million. Memphasys said it would use the funds to commercialize its Felix sperm selection device in low regulatory markets, undertake further Felix regulatory work, continue its pipeline development with the University of Newcastle, commence development of a next-generation Felix system, and pay down existing debts.

The company said the rights offer had a record date of August 23, would open August 26, and close September 6, 2022.

Memphasys said that the rights offer was fully underwritten by Canaccord Genuity (Australia) which would act as lead manager to both the placement and the rights offer. Memphasys fell 1.5 cents or 33.3 percent to three cents with 1.2 million shares traded.

NUHEARA

Nuheara says it welcomes the US Food and Drug Administration's decision to allow over-the-counter (OTC) hearing aids.

In a statement from the US White House, US President Joe Biden said that "for millions of Americans, hearing aids and the doctor's visit to get them prescribed are too expensive".

"In the executive order I issued last year to increase competition in key industries and lower costs, I called on the FDA to finally make hearing aids available over the counter," Mr Biden said. "Today, the FDA is doing just that."

"As early as mid-October, Americans will be able to purchase more affordable hearing aids over the counter at pharmacies and stores across the country," Mr Biden said.

"This action makes good on my commitment to lower costs for American families, delivering nearly \$US3,000 in savings to American families for a pair of hearing aids and giving people more choices to improve their health and wellbeing," Mr Biden said.

Nuheara managing-director Justin Miller told Biotech Daily: "Our proposed hearing aid model is under \$US1,000 for a pair, as compared to an average price in the US of \$US4,756 per pair and up-to \$US10,000 a pair".

Nuheara said the ruling would allow hearing aids in the over-the-counter category to be sold directly to consumers in shops or online without a medical examination or fitting by an audiologist.

Mr Miller said that "in one sweep, the FDA has revolutionized the way people can access hearing aids in the US".

"The FDA hasn't just created an extra [over-the-counter] category, it has completely overhauled the categorization of all hearing aids into two categories: [over-the-counter] and prescription," Mr Miller said.

"We have been patiently waiting for, and anticipating, these guidelines for five years," Mr Miller said.

"Changing the hearing landscape through accessibility and affordability is why we set out on this journey eight years ago," Mr Miller said.

"Nuheara's five years of direct-to-consumer and traditional retail sales experience places us at the forefront to lead the way with OTC offerings," Mr Miller said.

"This new OTC ruling, along with our experience, our technology, and our clinical trial, have placed us in the prime position of being able to deliver more accessible and affordable hearing devices to those in the US that need it most."

Nuheara was up 9.5 cents or 51.35 percent to 28 cents with 2.1 million shares traded.

BRISBANE ECONOMIC DEVELOPMENT AGENCY

The Brisbane Economic Development Agency says it is searching for 10 Brisbane-based medical technology companies to partner with investors.

A subsidiary of the Brisbane City Council, the Brisbane Economic Development Agency said that the 'Medtech Initiative' was accepting applications until September 7, 2022 and would culminate "with the opportunity to pitch to international investors in San Francisco next January" with mentorship from US companies such as Stryker.

Brisbane Lord Mayor Councillor Adrian Schrinner said the initiative would "further the city's global reputation for innovation in world-class healthcare technology".

"By facilitating global connections, these companies could secure funding that would usually take years in just a matter of months, fast-tracking better resources and new jobs for Brisbane," Cr Schrinner said.

Life Sciences Queensland chair Dr Christine Williams said the local industry had "remarkable growth" thanks to companies including Microba, Vaxxas and Ellume.

Translation Research Institute chief executive officer Prof Scott Bell said that Brisbane medical technology was entering a "crucial stage for growth".

"Rather than licencing [intellectual property] offshore where much of the potential revenue is lost, universities and research institutes are spinning out companies for local commercialization," Prof Bell said. "As a next step we need to be able to take those early-stage companies into scale-up."

US-based Life Science Nation chief executive officer Dennis Ford said the program was his company's first collaboration with an Australian agency.

"Tentativeness can make or break early-stage ventures, and this program will help promising businesses build the tools and confidence to approach some of the most active early-stage life science investors in the world and stand out in this competitive environment," Mr Ford said.

The Brisbane Economic Development Agency said that for further information, go to:

<https://businessinbrisbane.com.au/medtech/medtech-accelerator-program/>.

To apply, go to: <https://form.jotform.com/222050636344852>.

RHINOMED

Rhinomed says it has received its first purchase order, for 250,000 Rhinoswab Junior Covid-19 swabs, from the Sydney-based Surescreen Australia.

In July, Rhinomed said it would supply more than 10 million Rhinoswabs to Surescreen Australia for its respiratory tests in Australia, New Zealand, Singapore and the South Pacific (BD: Jul 18, 2022).

Today, the company said the swabs would be included in the Surescreen Sars-Cov-2 (severe acute respiratory syndrome coronavirus-2) test for children.

The company said the Surescreen test was currently the only one designed for children available on the Australian market.

Rhinomed was up half a cent or 2.9 percent to 17.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has received \$1,134,710 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Neuroscientific said the rebate related to research and development expenditure for the year to June 30, 2021.

Neuroscientific was up 1.5 cents or six percent to 26.5 cents.

RESAPP HEALTH

Resapp says Pfizer Australia has declared that the 20.8 cents a share offer “is its best and final offer, and it will not increase its offer”.

In April, Resapp said Pfizer would offer 11.5 cents a share to buy the company, valuing it at \$100 million (BD: April 11, 2022).

Today, the company said Pfizer had agreed to provide Resapp a \$680,000 loan at six percent interest to provide Resapp working capital during the scheme period.

Resapp said its scheme meeting had been adjourned to allow shareholders to consider the new information, and would take place on September 2, 2022.

Resapp was up one cent or 5.6 percent to 19 cents with 20.35 million shares traded.

BTC HEALTH

BTC says it has exclusive Australia and New Zealand distribution rights to the Lund, Sweden-based Alteco Medical AB’s Alteco LPS Adsorber for sepsis.

BTC said that the distribution rights were through investee company that through Bioimpact Pty Ltd and the Alteco LPS Adsorber was a “safe, single-use medical product, used to treat sepsis or septic shock in patients with suspected or confirmed septicaemia caused by gram-negative bacteria”.

The company said the Adsorber was used as an extra-corporeal filter, typically in intensive care units where patients were on haemoperfusion, and could “actively bind circulating endotoxins, removing them from the patient’s bloodstream”.

BTC said the Adsorber was a class IIa medical device with Conformité Européenne (CE) mark approval and had been available since 2007 and it intended to apply to the Australian Therapeutic Goods Administration for product registration to have the Adsorber available to hospitals in early 2023.

PHARMAUST

Pharmaust says a US trial assessing the anti-cancer potential of monepantel will treat up to 10 dogs following US Food and Drug Administration guidelines.

Pharmaust said Monepantel was “approved for veterinary use for a different indication in food-chain animals” namely round worm in sheep and goats.

The company said that of 27 treated dogs, 16 had “optimum blood levels”; of the 16, one dog had a partial response, 13 dogs had “stable target lesions” and nine “stable disease”.

Pharmaust said it required 18 or more of 46 dogs to show a clinical benefit to meet its statistical endpoint.

Pharmaust principal investigator Dr Kim Agnew said Monepantel showed “effective anti-cancer activity and minimal side effects” supporting development to registration trials.

Dr Agnew said the aim was to develop and partner a product better than the standard-of-care, prednisolone, and provide a dog lymphoma treatment that could be administered daily by the owner “and enabling excellent quality of life for the dog during treatment”.

Pharmaust fell half a cent or 5.8 percent to 8.1 cents.

TRAJAN GROUP

Trajan says it will release 19,117,617 shares following the release of its preliminary final report for the year ending at June 30, 2022.

According to its most recent filing, Trajan had 152,051,483 shares on issue.

Trajan fell three cents or 1.4 percent to \$2.18.

ZUCERO THERAPEUTICS

Zucero says Dr Paul Kasian has replaced chair Dr Steffen Nock who will continue as an independent director, and it has been granted a US patent.

Zucero said that Dr Kasian would be its executive chair and previously worked for investment groups HSBC Asset Management and HSBC Global Financial Team and was the founding director of Accordius and Wallara Asset Management, and a project leader at ICI Australia.

The company said that Dr Kasian was previously the chair of Genetic Technologies.

Zucero said that Dr Kasian was currently a director of Atomo and the chair of accounting software company IODM

The company said that Dr Kasian held a Bachelor of Science, a Master of Business Administration and a Doctor of Philosophy from the University of Melbourne.

Zucero said Dr Kasian would assist “drive corporate outcomes while providing support to chief executive officer Dr Keith Dredge who will focus on business operations and oversight of its drug development program”.

The company said the US Patent and Trademark Office had granted a patent relating to its lead clinical candidate pixatimod in combination with programmed death-1 (PD-1) and programmed death-ligand-1 (PD-L1) drugs.

Zucero said that the patent, titled ‘Composition and Uses Thereof’ would protect its intellectual property until December 15, 2037.

Dr Dredge, the sole inventor on the patent, said it was “a very significant step in Zucero’s intellectual property strategy aligned with its drug development plan and provides patent protection for the use of such combinations involving pixatimod”.

“Pixatimod, in combination with PD-1 drug Opdivo is currently in phase II trials for advanced cancers at the University of Pittsburgh Medical Center,” Dr Dredge said.

Zucero is a public unlisted company

ANTISENSE THERAPEUTICS

Antisense has requested a suspension to follow Monday’s trading halt pending “reporting outcomes of the long Covid-19 strategic collaboration” (BD: Aug 15, 2022).

Antisense last traded at 11 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

The Sydney and Hong Kong-based FIL says it has increased its substantial holding in Medical Developments from 4,091,641 shares (5.74%) to 7,069,520 shares (8.71%). FIL, also known as Fidelity Investments Limited, said that between March 2 and August 15, 2022 it bought 3,524,197 shares and sold 546,318 shares, at prices ranging from \$1.61 and \$4.44 a share.

Medical Developments fell two cents or one percent to \$1.96.

CRYOSITE

Lindmark Investments Staff Superannuation Fund says it has become substantial in Cryosite, with 2,519,413 shares or 5.16 percent of the company.

The Melbourne-based Lindmark said the holder of the shares were Linda and Mark Kerr and that between April 12 and August 12, 2022, it bought shares in Cryosite, with the largest single purchase 361,474 shares for \$251,065, or 69.5 cents a share.

Cryosite was unchanged at 68 cents.

MESOBLAST

Thorney Developments, Thorney Technologies and Tiga Trading say they have ceased to be substantial in Mesoblast following a recent placement.

In three separate filings, Thorney Developments, Thorney Technologies, and Tiga Trading said that between March 28, 2017 and August 12, 2022, they bought and sold shares in company.

Earlier this month, Mesoblast said it had raised \$US45 million (\$A65.5 million) in a placement at 75 cents a share, a five percent discount to the 30-day volume-weighted average price (BD: Aug 9, 2022).

Tiga Trading said it bought 2,600,000 shares in the placement.

Mesoblast fell one cent or 1.1 percent to 89.5 cents.