



# Biotech Daily

Tuesday February 28, 2023

*Daily news on ASX-listed biotechnology companies*

- \* ASX, BIOTECH UP: AVITA UP 9.5%; ACTINOGEN DOWN 8%
- \* MAYNE PHARMA H1 REVENUE DOWN 33% TO \$101m, \$290m PROFIT
- \* TELIX REVENUE UP TO \$160m, LOSS UP 29% TO \$104m
- \* MEDADVISOR H1 REVENUE UP 66% TO \$64m, LOSS TO \$4.6m PROFIT
- \* SDI H1 REVENUE UP 9% TO \$50.5m; PROFIT UP 1% TO \$2.7m
- \* COGSTATE H1 REVENUE DOWN 15% TO \$29m; PROFIT DOWN 99% TO \$90k
- \* MACH 7 H1 REVENUE UP 15% TO \$16.4m, LOSS DOWN 69% TO \$130k
- \* NEXT SCIENCE REVENUE UP 31% TO \$17m; LOSS UP 36% TO \$19m
- \* IMEX REVENUE UP 28% TO \$17m, LOSS DOWN 35% TO \$3m
- \* HYDRIX H1 REVENUE UP 40% TO \$7.2m, LOSS DOWN 18% TO \$2m
- \* VISIONEERING REVENUE UP 2% TO \$10.8m, LOSS UP 151% TO \$8.7m
- \* MESOBLAST H1 REVENUE DOWN 39% TO \$5m, LOSS DOWN 15% TO \$61m
- \* RHINOMED H1 REVENUE DOWN 10% TO \$3.4m, LOSS UP 43% TO \$4.7m
- \* ANTERIS REVENUE DOWN 41% TO \$5m, LOSS UP 94% TO \$44m
- \* KAZIA SHARE PLAN RAISES \$2.6m; TOTAL \$7.1m
- \* HYDRIX \$1.5m CYBAN BRAIN OXYGEN MONITOR CONTRACT
- \* ATOMO WINS \$900k HIV SELF-TEST EURO ORDER
- \* MAYNE PHARMA CANCELS \$113m CAPITAL RETURN
- \* REGENEUS TO SETTLE \$2m PADDINGTON ST LOAN; RUNWAY
- \* NUHEARA: TARGET.COM US DISTRIBUTOR; SHIPS HP HEARING PRO
- \* HYDRIX WITHDRAWS GUARDIAN ANGELMED TGA APPLICATION
- \* AMPLIA COMPLETES 2<sup>nd</sup> AMP945 PANCREATIC CANCER COHORT
- \* PHARMAUST MONEPANTEL FOR CANCER EURO PATENT
- \* INCANNEX MARIJUANA, HCQ IHL-675A RHEUMATOID ARTHRITIS TRAL
- \* PERENNIAL TAKES 9% OF LUMOS
- \* MEMPHASYS APPOINTS DR DAVID ALI BUSINESS DEVELOPMENT DIRECTOR

## MARKET REPORT

The Australian stock market was up 0.47 percent on Tuesday February 28, 2023, with the ASX200 up 33.6 points to 7,258.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and four were untraded. All three Big Caps fell.

Avita was the best, for the third trading day in a row, up a further 35 cents or 9.5 percent to \$4.04, with 1.3 million shares traded. Uscom climbed seven percent; Polynovo and Telix were up more than six percent, Universal Biosensors was up 5.3 percent; Mesoblast and Volpara were up four percent or more; Next Science was up 3.55 percent; Compumedics and Kazia rose more than two percent; Nanosonics, Neuren and Pro Medicus were up one percent or more.

Actinogen led the falls, down 0.7 cents or 7.8 percent to 8.3 cents, with 495,249 shares traded. Prescient lost 5.6 percent; Clinuvel and Emvision fell more than four percent; Alcidion, Patrys and Resonance were down more than three percent; Cochlear, Proteomics and Starpharma shed two percent or more; with Antisense, CSL, Opthea and Resmed down by less than one percent.

## MAYNE PHARMA GROUP

Mayne says revenue for the six months to December 31, 2022 was down 32.7 percent to \$101,165,000 with last year's loss turned to a profit after tax of \$289,927,000.

Mayne said revenue included the \$US475 million (\$A704 million) sale of its Metrics Contract Services development and manufacturing company to the Somerset, New Jersey-based Catalent Pharma Solutions (BD: Aug 10, 2022).

The company said that increased competition in the generic drug market accounted for lower revenues.

Mayne said that last year's diluted loss per share of 3.1 cents was turned to earnings of 17.6 cents, with net tangible asset per share down 63.6 percent to four cents.

Mayne said it had cash and cash equivalents of \$175,541,000 at December 31, 2022 compared to \$114,733,000 at December 31, 2021.

Mayne was up 17 cents or 5.4 percent to \$3.32 with 1.1 million shares traded.

## TELIX PHARMACEUTICALS

Telix says revenue for the year to December 31, 2022 was up from \$7,596,000 in the previous year to \$160,096,000 with net loss after tax up 29.3 percent to \$104,079,000.

Telix said that \$149,700,000 of its revenue came from sales and licencing of its first commercial product Illuccix, a prostate specific membrane antigen positron emission tomography (PSMA PET) cancer diagnostic imaging kit.

The company's chief executive officer Dr Christian Behrenbruch said Telix had "punched above its weight as the second commercial entrant to PSMA-PET imaging in the US market, generating \$US100.4 million (\$A149.7 million) in revenue from US sales of Illuccix in the first nine months since launch".

The company said that diluted loss per share was up 17.5 percent to 33.5 cents with net tangible assets per share up from negative 19.8 cents to 3.3 cents.

Telix said it had cash and cash equivalents of \$116,329,000 at December 31, 2022 compared to \$22,037,000 at December 31, 2021.

Telix was up 41 cents or 6.2 percent to \$6.98 with 3.25 million shares traded.

## MEDADVISOR

Medadvisor says revenue for the six months to December 31, 2022 rose 65.8 percent to \$64,081,197 with last year's net loss after tax turned to a profit of \$4,596,285.

Medadvisor said that revenues for its medication and vaccine adherence programs, and digital pharmacy platform network in the US and Australia were "seasonal as expected and supported by increased pharmaceutical spend to drive vaccine awareness entering the winter months".

The company said diluted earnings per share was 0.9 cents compared to a loss of 2.0 cents in the previous corresponding period, with negative net tangible assets per share down 82.3 percent to negative 0.65 cents.

Medadvisor said it had cash and cash equivalents of \$32,662,647 at December 31, 2022 compared to \$5,336,890 at December 31, 2021.

Medadvisor was up two cents or eight percent to 27 cents.

## SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the six months to December 31, 2022 was up 9.0 percent to \$50,491,000 with net profit after tax up 0.9 percent to \$2,713,000.

SDI said that the revenue came from its dental products, with aesthetics products revenue up 8.4 percent to \$47.4 million, whitening products revenue down by 18.7 percent to \$28.9 million, amalgam sales up 17.8 percent to \$17.4 million and equipment sales down to \$6.3 million.

SDI said that an unchanged interim fully-franked dividend of 1.5 cents a share for holders at the record date of April 14 would be paid on April 28, 2023.

SDI said diluted earnings per share were up 0.9 percent to 2.28 cents, with net tangible assets per ordinary security up 4.8 percent to 49.22 cents.

SDI said it had cash and cash equivalents of \$6,003,000 at December 31, 2022 compared to \$6,523,000 at December 31, 2021.

SDI fell eight cents or 8.4 percent to 87 cents.

## COGSTATE

Cogstate says revenue for the six months to December 31, 2022 was down 15.3 percent to \$US19,544,710 (\$A29,070,000) with net profit after tax down 98.5 percent to \$US60,861 (\$A90,270).

Cogstate said revenue came primarily from its cognitive tests for clinical trials and the healthcare market, but said revenue was negatively impacted by a slower than expected enrolment of patients into clinical trials by pharmaceutical companies.

Cogstate said diluted earnings per share were down 98.6 percent to 0.03 US cents, with net tangible asset backing per share up 25.6 percent to 10.8 cents.

Cogstate said it had cash and equivalents of \$US28,929,880 at December 31, 2022 compared to \$US25,336,663 at December 31, 2021.

In a separate announcement, Cogstate announced it would buy back up to \$13 million of its 173,459,998 shares, between March 20, 2023 and March 19, 2024.

Cogstate was up 15 cents or 10.6 percent to \$1.56 with 826,616 shares traded.

## MACH 7 TECHNOLOGIES

Mach 7 says revenue for the six months to December 31, 2022 was up 14.5 percent to \$16,412,740 with net loss after tax down 68.9 percent to \$130,371.

Mach 7 said \$8.16 million in revenue was recurring subscription, support and maintenance payments from customers for its diagnostics and imaging consolidation platform, with \$7.15 million in revenue came from software licenses.

The company said diluted loss per share was down 50 percent to 0.1 cents, net tangible assets per ordinary share fell 16.1 percent to 8.22 cents and it had cash and equivalents of \$20,604,764 at December 31, 2022 compared to \$20,255,338 at December 31, 2021. Mach7 fell two cents or three percent to 64 cents.

## NEXT SCIENCE

Next Science says revenue for the year to December 31, 2022 was up 30.9 percent to \$US11,712,722 (\$A17,354,000) with net loss after tax up 35.7 percent to \$US12,683,312 (\$A18,792,000).

Next Science said its revenue mainly came from its Xperience, Bactisure, Blastx and Surgx products to counter biofilms in chronic wound care and post-operative surgical complications, as well as product sales through its durable medical equipment business in October, 2022.

The company said diluted loss per share rose 26.9 percent to 6.03 US cents, net tangible assets per share fell 37.0 percent to 2.62 US cents and it had cash and equivalents of \$US5,073,625 at December 31, 2022 compared to \$US7,000,869 at December 31, 2021. Next Science was up 2.5 cents or 3.55 percent to 73 cents.

## IMEX HEALTH SERVICES

Imex says revenue for the year to December 31, 2022 was up 28.0 percent to \$17,117,357 with net loss after tax up 35.3 percent to \$3,038,653.

Imex said revenue came from sales, licensing and leasing of its internet cloud-based Aquila radiology data platform and its Hiruko medical imaging software platform.

The company said diluted loss per share fell 43.9 percent to 8.54 cents, net tangible assets per share shed 25.5 percent to 18.86 cents, and it had cash and equivalents of \$1,911,910 at December 31, 2022 compared to \$4,186,428 at December 31, 2021.

Imex was unchanged at 40 cents.

## HYDRIX

Hydrix says revenue for the six months to December 31, 2022 was up 39.9 percent to \$7,234,691 with net loss after tax down 18.3 percent to \$1,966,863.

Hydrix said revenue came from sales of its cardiac monitoring and diagnostic technologies, including the Angel Medical Guardian System implantable heart-attack warning device, as well as contracts developing medical products including Memphis's Felix sperm separation system and the Australian Nuclear Science and Technology Organisation's Coris360 radiation imaging solution.

The company said diluted loss per share was down 35.4 percent to 0.95 cents, with net tangible assets per share up from negative 0.81 cents to 0.39 cents.

Hydrix said it had cash and cash equivalents of \$3,193,437 at December 31, 2022 compared to \$2,733,919 at December 31, 2021.

Hydrix was up 0.3 cents or seven percent to 4.6 cents.

## VISIONEERING TECHNOLOGIES

Visioneering says revenue for the year to December 31, 2022 was up 1.8 percent to \$US7,285,000 (\$A10,797,000) with net loss after tax up 150.8 percent to \$US5,854,000 (\$A8,676,000).

Visioneering said revenue was from sales of its Naturalvue multifocal one-day contact lenses, with net loss after tax up due to an increase in clinical expenses associated with its progressive myopia treatment evaluation for the Naturalvue trial.

The company said diluted loss per share rose 109.1 percent to 23.0 US cents, net tangible asset backing per chess depository interest (CDI) fell 53.8 percent to 19.0 US cents, with cash and equivalents of \$US3,117,000 at December 31, 2022 compared to \$US10,985,000 at December 31, 2021.

Visioneering fell five cents or 14.3 percent to 30 cents.

## MESOBLAST

Mesoblast says revenue for the six months to December 31, 2022 was down 39.2 percent to \$US3,636,000 (\$A5,387,000), with net loss after tax down 14.9 percent to \$US41,370,000 (\$A61,300,000).

Mesoblast said \$US3,422,000 in revenue came from royalty income on sales of its Temcell product for graft-versus-host disease in Japan.

The company said its losses after tax fell due to a \$US6.1 million reduction in research and development costs in the six months to December 31, 2022.

The company said diluted loss per share fell 22.9 percent to 5.78 US cents, negative net tangible asset backing per share was up 98.9 percent to negative 8.75 US cents, and it had cash and equivalents of \$US67,619,000 at December 31, 2022, compared to \$US94,849,000 at December 31, 2021.

Mesoblast was up 4.5 cents or 4.8 percent to 97.5 cents with 3.5 million shares traded.

## RHINOMED

Rhinomed says revenue for the six months to December 31, 2022 was down 9.7 percent to \$3,383,772, with net loss after tax up 43.2 percent to \$4,654,391.

Rhinomed said revenue came from sales of its wearable nasal and respiratory medical products, including its Rhinoswab and Rhinoswab Junior with \$1.6 million of total revenue from sales on Amazon US.

The company said diluted loss per share rose 27.3 percent to 1.63 cents, net tangible assets per share fell to negative 0.50 cents, and it had cash and equivalents of \$3,630,646 at December 31, 2022 compared to \$1,599,811 at December 31, 2021.

Rhinomed was up 0.2 cents or 2.2 percent to 9.2 cents.

## ANTERIS TECHNOLOGIES

Anteris says revenue for the year to December 31, 2022 fell 41.1 percent to \$4,590,000 with net loss after tax up 93.6 percent to \$44,340,000.

Anteris said revenue came from sales of its transcatheter heart valve system and that the loss was from increased research and development expenditure.

The company said diluted loss per share was up 7.4 percent to \$3.32, net tangible asset backing per share fell 25.2 percent to 89.0 cents, and it had cash and cash equivalents of \$13,805,328 at December 31, 2022 compared to \$21,299,864 at December 31, 2021.

Anteris was up 65 cents or three percent to \$22.35.

## KAZIA THERAPEUTICS

Kazia says its share plan at 11 cents a share has raised \$2,606,000, taking the total raised with its \$4.5 million placement to \$7,106,000.

In January, Kazia said it had raised \$4.5 million in a placement at 11 cents a share and would offer an uncapped share plan at the same price (BD: Jan 22, 2023).

Today, the company said the funds would support its research and development pipeline, comprising two assets in nine clinical trials.

Kazia said the funds provided a “runway” to the end of 2023, on current cashflow forecast.

Kazia was up 0.25 cents or two percent to 12.5 cents.

## HYDRIX

Hydrix says it has a \$1.48 million contract to develop Cyban’s non-invasive, red and infrared, brain oxygen patient monitoring unit.

Hydrix said it was contracted to deliver “detailed design, construction and testing of engineering prototypes ... [and to] support a streamlined path for this product to achieve class II medical device US Food and Drug Administration regulatory submission”.

Hydrix general manager Michael Trieu said the two companies were “working very collaboratively to accelerate completion of the first generation of the product, which can potentially establish a new gold standard of care in brain trauma injury management”.

Hydrix said it expected the development program to be completed and recognized in revenue during the next six months.

## ATOMO DIAGNOSTICS

Atomo says it has a \$900,000 order for its HIV Self-Tests from London’s Newfoundland Diagnostics.

Atomo said that the order was for the immediate supply of the tests to Newfoundland, subject to updating Atomo’s existing HIV Self-Test Conformité Européenne (CE) mark certificate to include the relevant distributor information and branding.

The company said that Newfoundland was “an emerging leader in the growing European diagnostic self-test market that has arisen out of the Covid pandemic and has established extensive distribution networks in Europe across public health, pharmacy and retail”.

Atomo said it expected the Newfoundland order for HIV Self-Tests to be “the first of many”.

Atomo chief executive officer John Kelly said the company was “delighted to have received this initial order from Newfoundland”.

“We believe they are an ideal commercial partner for our HIV products as well as potentially a range of other at-home tests that we are looking to commercialize,” Mr Kelly said.

“We are seeing an increase in HIV sales volume globally and now expect to see a significant growth in the European market with this new commercial relationship,” Mr Kelly said.

Atomo said it had “terminated the HIV distribution agreement covering the UK and other European markets previously entered into with Owen Mumford” and the appointment of an alternative distributor would be disclosed in due course.

Atomo was unchanged at 4.7 cents with 2.8 million shares traded.



## MAYNE PHARMA

Mayne says it has cancelled its \$113 million capital return to shareholders to build on its US women's health product and pre-natal vitamin business.

In October, Mayne said it intended to return the funds through a fully franked dividend of 2.72 cents a share and a pro-rata return of 3.8 cents a share (BD: Oct 28, 2022).

In January, the company said it would defer the capital return until at least March 2023 in order to maintain "funding flexibility" (BD: Jan 22, 2023).

Today, the company said that following its decision to build on its US women's health portfolio, the board believed it "prudent to retain an appropriate balance sheet to support the business while it [continued] to assess the appropriate capital structure".

Mayne chair Frank Condella said the company was a "significantly different business today with a clear strategy to drive accretive growth, and a more simplified structure once the US retail generics business exit is closed."

## REGENEUS

Regeneus says it will settle a \$2.0 million outstanding loan and interest payable to Paddington St Finance with 700,000 Sangui Bio Pty Ltd shares and \$400,000 in cash.

Regeneus said that Paddington St Finance was a related entity, controlled by Regeneus chair Barry Sechos.

The company said that the Sangui Bio shares were a "substantial asset" worth more than five percent of its equity, with finalization of the Sangui Bio shares to Paddington St Finance subject to shareholder approval.

Regeneus said the \$400,000 cash payment would occur "immediately".

The company said that the Sangui Bio shares were valued at \$2.50 each.

Regeneus said it continued to explore opportunities to dispose of other non-core assets to improve liquidity including donor material, including stromal vascular fraction or isolated mesenchymal stem cells, in excess of its current and expected future needs.

The company said that after the loan settlement it would have \$411,192 in cash, was expecting a Federal Research and Development Tax Incentive after June 30, 2023 and was "not considering any equity capital raise".

Regeneus said discussions were continuing with Kyocera Corp regarding the termination of the licence and collaboration agreement, and was searching for additional partners for the commercialization of its fat-based Progenza for knee osteoarthritis.

The company said it was "in merger discussions with US and Japanese biotechnology companies".

Regeneus was unchanged at 1.2 cents.

## NUHEARA

Nuheara says it has appointed Target.com as a US distributor and shipped its first batch of US Food and Drug Administration cleared self-fitting HP Hearing PRO.

Nuheara US-based chief executive officer John Luna said that Target.com was "another significant point of distribution that builds greater access for Americans to the HP Hearing PRO".

The company said that Target.com online reached "millions of consumers across the US". Nuheara was up half a cent or 2.5 percent to 20.5 cents.

## HYDRIX

Hydrix says it has withdrawn its application to the Australian Therapeutic Goods Administration for its Guardian cardiac arrest warning device.

Earlier this month, Hydrix said the TGA told it that its application for its Angel Medical Systems Guardian was “not going to be accepted” (BD: Feb 15, 2023).

Today, the company said the TGA was “not yet convinced that the patient benefits sufficiently outweigh potential risks”.

Hydrix executive chairman Gavin Coote said it was “particularly disappointing for Australian patients, noting it is a US FDA-approved device and is being prescribed to patients in the US”.

“The FDA concluded that the Guardian is more effective at diagnosing life-threatening situations than relying on patient symptoms alone; with benefits outweighing the risks. This was affirmed by regulatory authorities in Singapore and Malaysia when they granted their approvals in 2022,” Mr Coote said.

“For all the reasons we have advocated for the Guardian, we remain confident in the positive benefits the device could offer to high-risk Australian ACS patients,” Mr Coote said.

## AMPLIA THERAPEUTICS

Amplia says it has completed enrolment of the second cohort of patients in its phase Ib/IIa trial of AMP945 for frontline patients with pancreatic cancer.

Amplia said that the first stage of the trial would test ascending doses of AMP945 in combination with standard gemcitabine/nab-paclitaxel chemotherapy in patients with advanced pancreatic cancer.

The company said that after one month of treatment, the Safety Committee would review the data and decide whether to proceed to the next dose cohort.

Amplia managing-director Dr Chris Burns said the company was making “good progress ... having recruited the three patients for cohort 2 within one month of opening enrolment”.

The company said that the phase Ib trial, was a single-arm, open-label study to select an optimal dose of AMP945 by assessing the safety, tolerability, pharmaco-kinetics, pharmaco-dynamics and preliminary efficacy of AMP945 in combination with gemcitabine and nab-paclitaxel (Abraxane) in first-line patients with advanced pancreatic cancer.

Amplia said the phase IIa trial was also a single-arm, open-label study designed to perform an assessment of the optimal dose of AMP945 in combination with gemcitabine and nabpaclitaxel.

The company said that the primary endpoint of the phase IIa trial was the objective response rate of patients to treatment, with further endpoints to assess efficacy by other means as well as safety and tolerability.

Amplia was untraded at 8.5 cents.

## PHARMAUST

Pharmaust says that the European Patent Office has issued a notice to grant a patent relating to the use of monepantel combinations in cancer.

Pharmaust said that, when granted, the patent, titled ‘Pharmaceutical combinations for the treatment of cancer’ would protect its intellectual property until October 31, 2034.

The company said that the grant would extend its patent coverage, including granted patents in Australia, the US, China, Japan, Korea, Canada and New Zealand.

Pharmaust fell 0.05 cents or 0.6 percent to eight cents.



## [INCANNEX HEALTHCARE](#)

Incannex says it begun a 120-patient, phase II, blinded, placebo-controlled trial of its marijuana and hydroxychloroquine (HCQ) IHL-675A for rheumatoid arthritis.

Incannex said the trial aimed “to determine the safety and effect on pain and function of IHL-675A in patients with rheumatoid arthritis”.

The company said the trial followed the phase I trial, “where IHL-675A was observed to be well tolerated and animal studies whereby IHL-675A was observed to reduce inflammatory disease scores to a greater extent than hydroxychloroquine, a common long standing prescription drug for rheumatoid arthritis” (BD: Mar 16, 2021; Oct 13, 2022).

Today, Incannex said the trial would be managed by Avance Clinical at eight to 10 trial sites in Australia and New Zealand.

The company said the trial would assess the effect of IHL-675A on pain and function using patient reported outcomes, disease scores and inflammatory biomarker analysis over 24 weeks.

Incannex said trial participants would have the option to join an extension study following the trial and patients, who met the criteria for joint damage, might be included in a magnetic resonance imaging assessment sub-study.

Incannex chief scientific officer Dr Mark Bleackley said the trial was “a key milestone in the IHL-675A development program”.

Incannex was up half a cent or 3.6 percent to 14.5 cents with 2.3 million shares traded.

## [LUMOS DIAGNOSTICS](#)

Perennial Value Management says it has increased its substantial holding in Lumos from 18,181,615 shares (8.19%) to 21,997,010 shares (9.19%).

The Sydney-based Perennial said that between February 10 and 27, 2023, it bought 3,815,395 shares for \$149,694.09 or an average of 3.92 cents a share.

Lumos fell 0.3 cents or 5.8 percent to 4.9 cents.

## [MEMPHASYS](#)

Memphasys says it has appointed Dr David Ali as its director of business development, effective from March 27, 2023.

Memphasys said that Dr Ali would lead business development, sales and marketing activities for all products in development, with initial focus on the Felix sperm separation device.

The company said that Dr Ali had more than 40 years' experience in medical management, business development, sales and marketing for pharmaceutical, medical device and diagnostic companies in human and animal reproduction.

Memphasys said that Dr Ali previously worked for the Commonwealth Scientific and Industrial Research Organisation, Bayer, Astrazeneca, Novo Nordisk and Biogen.

The company said that Dr Ali held a Bachelor of Science Degree and a Doctor of Philosophy from Macquarie University.

Memphasys was unchanged at 1.5 cents.