

Biotech Daily

Wednesday February 28, 2024

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH UP: DIMERIX UP 12%; NEUREN DOWN 11%
- * PROBIOTEC H1 REVENUE UP 7% TO \$114m, PROFIT DOWN 43% TO \$3m
- * SDI H1 REVENUE UP 3.5% TO \$52m, PROFIT UP 36% TO \$3.7m
- * SOMNOMED H1 REVENUE UP 13% TO \$45m, LOSS UP 70% TO \$6m
- * ALCIDION H1 REVENUE \$19m, LOSS UP 40% TO \$4m
- * NEXT SCIENCE REVENUE UP 89% TO \$34m, LOSS UP 28% TO \$25m
- * CYCLOPHARM REVENUE UP 37% TO \$32m, LOSS DOWN 29% TO \$4.7m
- * MICRO-X H1 REVENUE UP 2% TO \$8m, LOSS DOWN 55% TO \$4m
- * STARPHARMA H1 REVENUE \$7m ON MUNDIPHARMA PAYMENT
- * ACRUX H1 REVENUE UP 210% TO \$4m, LOSS DOWN 2% TO \$3m
- * LUMOS H1 REVENUE DOWN 46% to \$4m, LOSS DOWN 2% TO \$10m
- * MICROBA H1 REVENUE UP 52% TO \$3.3m, LOSS UP 102% TO \$11.5m
- * NEUREN: ACADIA 2023 DAYBUE SALES \$271m; ROYALTY \$27m
- * HERAMED RIGHTS RAISE \$225k OF \$1.25m; TOTAL \$1.5m
- * PYC DOSES 3rd VP-001 RETINITIS PIGMENTOSA TYPE 11 COHORT
- * RADIOPHARM: 'TB-161 PROMISING FOR TARGETING CANCERS'
- * HERAMED SIGNS BROWARD HEALTH FOR FOETAL HEART MONITORS
- * PHARMAUST: 'MONEPANTEL SAFE, TOLERABLE FOR MND'
- * NYRADA: 'NYR-BI03 NEURO-PROTECTIVE, IN MICE'
- * MEDADVISOR, BRAND ENGAGEMENT NETWORK DEVELOP A.I. PLATFORM
- * PROTEOMICS WINS EU OXIDX PATENT
- * TRIVARX: FDA 'CLEAR PATH' FOR MEB-001 DE NOVO APPROVAL
- * GENETIC TECHNOLOGIES TO ADVERTISE GENOMICS TEST IN US
- * LITTLE GREEN SHIPS 1st MARIJUANA TO POLAND
- * MERCHANT FUNDS REDUCES TO 6% OF BCAL
- * VISIONEERING TO LOSE CHAIR DR DAVID MAZZO; KATHLEEN MILER INTERIM

MARKET REPORT

The Australian stock market slipped 0.03 percent on Wednesday February 28, 2024, with the ASX200 down 2.6 points to 7,660.4 points. Twenty-four Biotech Daily Top 40 stocks rose, seven fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Dimerix was the best, up 2.5 cents or 11.9 percent to 23.5 cents, with 6.1 million shares traded. Percheron (Antisense) climbed 11 percent; Actinogen was up 9.4 percent; Atomo, Polynovo and SDI were up more than seven percent; 4D Medical and Clarity climbed more than six percent; Clinuvel, Impedimed and Resonance were up five percent or more; both Imugene and Prescient improved 4.35 percent; Genetic Signatures and Telix were up more than three percent; Immutep, Medical Developments, Opthea, Orthocell and Pro Medicus rose more than two percent; Avita, Mesoblast and Proteomics were up more than one percent; with Cochlear, CSL, Cyclopharm and Resmed up by less than one percent.

Neuren led the falls, down \$2.33 or 10.85 percent to \$19.15 with 2.8 million shares traded. Next Science lost 8.7 percent; Amplia was down 6.25 percent; Emvision fell 3.3 percent; Curvebeam shed 2.3 percent; with Nanosonics and Paradigm down by less than one percent.

PROBIOTEC

Probiotec says revenue for the six months to December 31, 2023 was up 6.7 percent to \$113,961,568, with net profit after tax down 42.7 percent to \$3,128,481.

Probiotec said revenue came from sales and contracts for its pharmaceutical manufacturing services and that its increased loss was a result of a 6.1 percent rise in payments to suppliers and employees to \$110,227,100.

The company said that a fully-franked interim dividend was up 16.7 percent to 3.5 cents a share for shareholders at the record date of March 5 to be paid on March 15, 2024. Probiotec said diluted earnings per share fell 43.7 percent to 3.73 cents, with last year's net tangible assets per share of negative 4.5 cents turned to a positive 5.6 cents. The company said it had cash and equivalents of \$12,838,321 at December 31, 2023 compared to \$22,768,835 a December 31, 2022.

Probiotec fell one cent or 0.4 percent to \$2.79.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the six months to December 31, 2023 was up 3.5 percent to \$52,244,000 with net profit after tax up 36.3 percent to \$3,697,000.

SDI said that the revenue came from sales of its dental products, with aesthetics products revenue up 10.0 percent to \$26.3 million, whitening products revenue up by 4.1 percent to \$15.2 million, amalgam sales down 12.9 percent to \$7.7 million and equipment sales down 2.9 percent to \$6.3 million.

The company said that an unchanged interim fully-franked dividend of 1.5 cents a share for holders at the record date of April 16 would be paid on April 30, 2024.

SDI said diluted earnings per share were up 36.4 percent to 3.11 cents, with net tangible assets per ordinary security up 2.8 percent to 50.60 cents.

The company said it had cash and cash equivalents of \$7,087,000 at December 31, 2023 compared to \$6,003,000 at December 31, 2022.

SDI was up six cents or 7.9 percent to 82 cents.

SOMNOMED

Somnomed says revenue for the six months to December 31, 2023 was up 12.9 percent to \$45,114,567, with net loss after tax up 69.5 percent to \$6,347,116.

Somnomed said revenue from its products for obstructive sleep apnoea increased but at a reduced rate due to "unplanned and unexpected milling machine downtime".

The company said it had announced a cost reduction program at its annual general meeting which would "eliminate significant costs in the second half to June 30, 2024, and improve profitability in 2024-'25".

Somnomed said that its diluted loss per share was up 41.6 percent to 6.79 cents.

The company said that its net tangible asset backing per share was up 55.1 percent to 8.84 cents.

Somnomed said it had cash and cash equivalents of \$12,837,537 at December 31, 2023 compared to \$16,874,597 at December 31, 2022.

Somnomed was up five cents or 14.3 percent to 40 cents.

ALCIDION GROUP

Alcidion says revenue for the six months to December 31, 2023 was up 0.4 percent to \$19,059,000, with net loss after tax up 39.9 percent to \$4,158,000.

Alcidion said revenue came from licencing fees of its Miya Precision task management and patient administration system healthcare software product.

The company said its increased loss was due to "continued procurement delays across both the Australia, New Zealand and UK markets and the need to appropriately balance future growth potential against the current cost base", saying it would implement annualized costs savings including a reduction in staff, of about \$6.4 million.

Alcidion said diluted loss per share was up 54.5 percent to 0.34 cents.

The company said that its negative net tangible assets per share was down 34.0 percent to negative 0.35 cents.

Alcidion said it had cash and cash equivalents of \$7,914,000 at December 31, 2023 compared to \$11,868,000 at December 31, 2022.

Alcidion was unchanged at 4.5 cents with 9.6 million shares traded.

NEXT SCIENCE

Next Science says revenue for the year to December 31, 2023 was up 89.4 percent to \$US22,179,327 (\$A33,937,000) with net loss after tax up 28.3 percent to \$US16,270,814 (\$A24,896,000).

Next Science said it had "significant growth in both the wound care and surgical businesses" including sales of Blastx and Xperience.

The company said that its increased loss was a result of increased selling and distribution expenses, up 95.6 percent to \$US20,165,335.

Next Science said diluted loss per share rose 15.3 percent to 6.95 US cents.

The company said that its net tangible assets per share was up 36.6 percent to 3.58 US cents.

Next Science said it had cash and equivalents of \$US9,238,697 at December 31, 2023 compared to \$US5,073,625 at December 31, 2022.

Next Science fell three cents or 8.7 percent to 31.5 cents.

CYCLOPHARM

Cyclopharm says revenue for the year to December 31, 2023 was up 36.6 percent to a record \$31,715,884, with net loss after tax down 28.9 percent to \$4,700,806.

Cyclopharm said revenue came primarily from \$26,339,389 in sales of its imaging products, including \$14.43 million from its Technegas lung imaging generators and patient administration sets, as well as \$5,376,495 from financing activities.

The company said that it had paid an unfranked interim dividend of 0.5 cents a share for the six months to June 30, 2023, but that it would not pay a final dividend for shareholders.

Cyclopharm said diluted loss per share was down 29.3 percent to 5.07 cents with net tangible assets per share down 15.2 percent to 28 cents.

The company said that it had cash and cash equivalents of \$11,726,424 at December 31, 2023 compared to \$20,296,176 at December 31, 2022.

Cyclopharm was up half a cent or 0.3 percent to \$1.805.

MICRO-X

Micro-X says revenue for the six months to December 31, 2022 was up 2.1 percent to \$8,196,000 with net loss after tax up 95.9 percent to \$7,663,000.

Micro-X said revenue came from sales of its mobile digital radiology products and x-ray cameras and that its increased loss was "primarily due to the company not recognizing as a receivable, the Research and Development Tax Incentive for the 2023-'24 financial year".

The company said that it was uncertain whether it would meet the "less than \$20 million" revenue threshold required to receive the Federal Government rebate in cash, and has therefore "taken the conservative position, that its eligible research and development incentive be disclosed as a tax loss offset rather than a cash receivable".

The company said diluted loss per share was up 80.5 percent to 1.48 cents, with net tangible assets per share down 56.85 percent to 1.92 cents.

Micro-X said it had cash and cash equivalents of \$5,307,000 at December 31, 2023 compared to \$11,420,000 at December 31, 2022.

Micro-X was unchanged at 11.5 cents.

STARPHARMA HOLDINGS

Starpharma says revenue for the six months to December 31, 2023 was \$7,197,000, with \$6,553,000 from the settlement of its Vivagel BV Mundipharma agreement.

Last year, Starpharma said Singapore's Mundipharma would pay \$6.54 million in cash after terminating its Vivagel bacterial vaginosis (BV) agreement (BD: Aug 14, 2023).

Today, the company said the remainder of its revenue included product sales, royalties and research revenue from other commercial partners.

Starpharma said its net loss after tax was down 87.5 percent to \$1,034,000, diluted loss per share was down 87.7 percent to 0.25 cents and net tangible asset backing per share down 20.0 percent to eight cents.

The company said it had cash and cash equivalents of \$32,131,000 at December 31, 2023 compared to \$44,038,000 at December 31, 2022.

Starpharma was unchanged at 13 cents.

ACRUX

Acrux says revenue for the six months to December 31, 2023 was up 210.3 percent to \$4,409,000, with net loss after tax down 1.7 percent to \$3,239,000.

Acrux said sales of its topically applied generic pharmaceutical products was up 741.1 percent to \$3,928,000, with licencing income down 49.6 percent to \$481,000.

The company said diluted loss per share fell 2.6 percent to 1.12 cents, with net tangible assets flat at two cents, and it had cash and equivalents of \$4,565,000 at December 31, 2023 compared to \$4,350,000 at December 31, 2022.

Acrux was up 0.1 cents or 1.75 percent to 5.8 cents.

LUMOS DIAGNOSTICS

Lumos says that revenue for the six months to December 31, 2023 fell 45.6 percent to \$US2,766,000 (\$A4,231,000) with net loss after tax down 2.3 percent to \$US6,413,000 (\$A9,810,000).

Lumos said that its revenue was from sales, contract development and manufacturing services of its Febridx for viral and bacterial infections and Viradx for severe acute respiratory syndrome point-of-care tests in the US.

The company said revenue fell due to "a number of services resources" being diverted to work on internal projects including the marketing and manufacturing of Viradx in time for the influenza season following the US Food and Drug Administration's approval. Lumos said diluted loss per share fell 54.0 percent to 1.44 US cents, negative net tangible assets per share shed 55.2 percent to 0.13 US cents, and it had cash and equivalents of \$US1,379,000 at December 31, 2023 compared to \$US783,000 at December 31, 2022. Lumos fell 0.3 cents or 3.95 percent to 7.3 cents with 12.5 million shares traded.

MICROBA LIFE SCIENCES

Microba says revenue for the six months to December 31, 2023 was up 52.1 percent to \$3,272,855, with net loss after tax up 102.3 percent to \$11,488,179.

Microba said increased revenue was from sales of its Metaxplore microbiome test in Australia and overseas and the increased loss was "largely attributed to the research and development investment in advancement of [its] therapeutic programs".

The company said diluted loss per share was up 56.1 percent to 3.09 cents, net tangible assets per share fell 36.3 percent to 6.64 cents, and it had cash and equivalents of \$27,846,261 at December 31, 2023 compared to \$41,953,961 at December 31, 2022. Microba was up half a cent or 2.8 percent to 18.5 cents.

NEUREN PHARMACEUTICALS

Neuren says partner Acadia Pharmaceuticals has announced Daybue (trofinetide) US sales for the three months to December 31, 2023 of \$US87.1 million (\$A133.3 million). Neuren said that net sales of Daybue for Rett syndrome since the April launch to December 31 amounted to \$US177.2 million and Acadia guidance for full-year net sales in 2024 was between \$US370 million and \$US420 million.

Earlier this month, Neuren rebutted a Culper Research claim estimating 2024 sales at \$US316 million compared to an analyst consensus of \$US369 million (BD: Feb 16, 2024). Today, the company said its expected royalties were \$26.8 million for year to December 31, 2023, and between \$61 million and \$70 million for the year to December 31, 2024. Neuren fell \$2.33 or 10.85 percent to \$19.15 with 2.8 million shares traded.

HERAMED

Heramed says its rights issue and shortfall applications at 2.0 cents a share has raised \$224,713 of a hoped-for \$1.25 million taking the total raised to \$1,474,713.

In December, Heramed said it had raised \$1,250,000 in a placement at 2.0 cents a share and hoped to raise a further \$1,250,000 in a rights issue (BD: Dec 15, 2023).

Today, the company said that the shortfall of \$1,060,344 might be issued in the coming three months, and it had "indicative offers for the balance of the shortfall from new investors and existing shareholders including ... executive chair, Dr Ron Weinberger, who has received shareholder approval to subscribe for up to \$500,000 in the placement of shortfall shares".

Heramed was up 0.1 cents or 5.3 percent to two cents with 2.2 million shares traded.

PYC THERAPEUTICS

PYC says it has dosed the third and final cohort of three patients in its phase I single dose escalating trial of VP-001 for the childhood disease retinitis pigmentosa type 11 (RP11). PYC said it administered single doses of 3.0µg of VP-001, 10µg and 30µg.

The company said it was preparing an open-label multiple ascending dose study and both studies would be used "to inform the design of a registrational trial intended to support a new drug application that is expected to begin next year".

PYC was up 0.3 cents or 3.75 percent to 8.3 cents.

RADIOPHARM THERANOSTICS

Radiopharm says that a six-patient study shows that its terbium-161 (Tb-161) is "a promising candidate for use in the radio-therapeutic targeting of advanced cancers". Radiopharm said that six metastatic castration-resistant prostate cancer (mCRPC) patients were treated with Tb-161 prostate specific membrane antigen-617 (PSMA-617) and compared to lutetium-161.

The company said the study showed that Tb-161-PSMA-617 "delivers markedly higher tumor-absorbed doses compared to 177Lu-PSMA-617, whereas the absorbed doses of the relevant organs at risk were only slightly higher".

Radiopharm said that Tb-161-PSMA-617 "delivered a radiation dose to tumor lesions that was on average 2.4 times higher than that of Lu-177-PSMA-617".

"This strongly supports terbium-161 as a promising candidate for use in the radiotherapeutic targeting of advanced cancers," the company said.

Radiopharm managing-director Riccardo Canevari said that Tb-161 "holds remarkable promise in nuclear medicine and oncology".

"It has the strong potential to advance anti-tumor efficacy for not only primary tumors, but also micro-metastatic disease," Mr Canevari said.

Radiopharm fell 0.1 cents or 1.75 percent to 5.6 cents.

HERAMED

Heramed says it has a two-year agreement with the Fort Lauderdale, Florida-based Broward Health for its Heracare platform and Herabeat foetal heart monitoring devices. Heramed said the agreement would begin immediately, would support 700 pregnancies and allowed for 200 Heracare kits to be deployed with each kit including a Herabeat device, software and other connected devices.

Heramed said that pregnancies would be monitored through telehealth appointments.

PHARMAUST

Pharmaust says its 12-patient, phase I trial of monepantel for motor neuron disease "met its primary safety and tolerability endpoints ... [and showed] potential efficacy".

Pharmaust said that disease progression slowed by 58 percent in the second cohort of six patients, compared to an external control cohort).

The company said that the first cohort was administered 2.0mg/kg/day and 6.0mg/kg/day, and the second cohort was administered 4.0mg/kg/day and 10mg/kg/day.

Pharmaust said that there were no treatment-related deaths, with all 12 patients successfully completing the study and no dose limiting toxicities.

The company said that of 56 treatment-emergent adverse events, three were graded mild and considered possibly related to the study drug.

Pharmaust said that patients were on daily treatment for 10 to 16 months, and after completing the study, all participants continued receiving monepantel through a special access scheme and opted to enrol on a 12-month open-label extension study.

Pharmaust fell 5.5 cents or 14.5 percent to 32.5 cents with 21 million shares traded.

NYRADA

Nyrada says its NYR-BI03 "showed a significant neuro-protective signal providing strong evidence of efficacy" in mice.

Nyrada was up eight cents or 421.05 percent to 9.9 cents with 126.9 million shares traded.

MEDADVISOR

Medadvisor says it has partnered with Brand Engagement Network to develop an artificial intelligence (A.I.) powered medication advisor platform.

Medadvisor said that the Jackson, Wyoming-based Brand Engagement Network would assist it "to bring conversational [artificial intelligence] to patients through pharmacies" through its medication advisor platform.

The company said that "traditional chatbots have limited conversational skills, base knowledge of pharmaceutical products and capacity".

Medadvisor said that Brand Engagement Network's artificial intelligence assistants, paired with its "insight into pharmacy-driven patient engagement [was] expected to offer a personalized, conversational experience for patients".

The company said that the platform was being designed to enable support 24 hours a day and seven days a week.

Medadvisor was up four cents or 13.8 percent to 33 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the European Patent Office has granted its subsidiary Oxidx a patent for its oxidative stress finger-prick blood test.

Proteomics said the patent, titled 'Methods for measuring relative oxidation levels of protein' would protect its intellectual property until March 2039 in 19 European countries. The company said the patents were "part of a family of patent applications in all major jurisdictions, which, if granted, will significantly extend the lifespan and regional coverage of Oxidx's existing intellectual property portfolio".

Proteomics managing-director Dr Richard Lipscombe said the patent was a significant milestone for commercialization of the technology.

Proteomics was up 1.5 cents or 1.6 percent to 97.5 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says the US Food and Drug Administration has confirmed the de novo pathway for approval of its MEB-001 sleep diagnostic for mood disorders.

Trivarx said it would continue progressing with its phase II sleep signal analysis for major depressive episode study to gain additional data for a regulatory submission.

Trivarx fell half a cent or 13.2 percent to 3.3 cents with 4.9 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it will begin a targeted digital advertising campaign in the US for the commercialization of its Genetype risk assessment tests in March, 2024.

Genetic Technologies said the campaign would be led by its California-based advisor Dr Malcolm Bohm and would scale up through the year.

Genetic Technologies was up 1.1 cents or 11.1 percent to 11 cents.

LITTLE GREEN PHARMA

Little Green Pharma says it has shipped its first batch of branded, high tetra-hydro-cannabidiol (THC) Desert Flame cannabis flower products to Poland.

Little Green said Poland had "a population of 38 million, an import only supply regime, general practitioner prescribing capability [and] no restrictions on the conditions treatable with cannabis".

The company said the products would be distributed by its Polish partner Medezin. Little Green fell 1.5 cents or 10.3 percent to 13 cents.

BCAL DIAGNOSTICS

Merchant Funds Management Pty Ltd says it has reduced its substantial shareholding in Bcal from 18,191,663 shares (7.23%) to 15,686,999 shares (6.23%).

The Perth-based Merchant Funds said that between November 2023 and February 2024 it sold 2,504,664 shares on market for \$246,651, or 9.8 cents a share. Bcal was untraded at nine cents.

VISIONEERING TECHNOLOGIES

Visioneering says that Dr David Mazzo will retire from the company, effective from February 29, 2024 "to focus on other commitments".

Visioneering said that Dr Mazzo had been its chair for four years.

Visioneering chief executive officer Dr Juan Carlos Aragón said he was "grateful for David's service to the company".

"While I am saddened by his departure, I understand and respect his decision," Dr Aragón said. "I wish him continued success."

Visioneering said that it had elected Kathleen Miller as interim chair while a process was conducted to appoint a new chair.

Visioneering fell 1.5 cents or 6.7 percent to 21 cents.

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