



Biotech Daily

Tuesday August 29, 2023

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: ANTISENSE UP 29%; PATRYS DOWN 11%
- * CLINUVEL REVENUE UP 24% TO \$83m; PROFIT DOWN 47% TO \$31m
- * HYDRIX REVENUE UP 27% TO \$13m; LOSS DOWN 93% TO \$397k
- * PHARMAXIS REVENUE UP 32% TO \$13m; LOSS UP 487% TO \$11m
- * IDT REVENUE DOWN 42% TO \$7m; LOSS UP 633% TO \$8.5m
- * FISHER & PAYKEL GUIDANCE: H1 REVENUE \$726m; PROFIT \$87m to \$96m
- * ALLEGRA COMPLETES \$4.3m ORTHOPAEDIC SALE TO ROBINWOOD
- * CHIMERIC DOSES FINAL PHASE Ia CHM1101 GLIOBLASTOMA COHORT
- * PHARMAXIS: PXS-5505 UPS PANCREATIC CANCER SURVIVAL 35%, IN MICE
- * NUHEARA: '5k US SHOPS TO SELL HP HEARING PRO THIS YEAR'
- * ECHO IQ: ADVARA HEARTCARE TO TRIAL ECHOSOLV IN WA
- * RESPIRI: ACCESS US CONTRACTS FOR \$900k
- * GOODBYE ANALYTICA
- * NEXT SCIENCE REQUESTS 'CAPITAL RAISING' TRADING HALT
- * GREGORY GEORGE, G TO THE FOURTH TAKE 8% OF MESOBLAST
- * SELECTOR FUNDS BELOW 5% IN MEDICAL DEVELOPMENTS
- * PINNACLE TAKES 7.8% OF CURVEBEAM
- * HR GLOBAL TAKES 6% OF IMRICOR
- * VISIONEERING APPOINTS DR JUAN CARLOS ARAGÓN CEO ON \$623k PA
- * BIO-MELBOURNE PRECISION HEALTHCARE SYMPOSIUM

MARKET REPORT

The Australian stock market was up 0.70 percent on Tuesday August 29, 2023, with the ASX200 up 50.7 points to 7,210.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Antisense was the best on no news, up 1.5 cents or 28.85 percent to 6.7 cents, with 3.7 million shares traded.

Amplia was up 10 percent; Cyclopharm climbed 8.1 percent; Orthocell was up 6.8 percent; 4D Medical and Proteomics were up five percent or more; Alcidion and Prescient improved more than four percent; Mesoblast and Starpharma were up more than three percent; Avita rose 2.65 percent; Neuren, Pro Medicus and Telix were up more than one percent; with Nanosonics up by 0.2 percent.

Patrys led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 1.85 million shares traded.

Nova Eye lost 9.3 percent; Cynata, Dimerix, Medical Developments and Volpara were down more than seven percent; Genetic Signatures and Imugene lost six percent or more; Clinuvel and Emvision fell more than five percent; Atomo and Paradigm were down more than three percent; Compumedics, Impedimed and Polynovo shed two percent or more; Immutep, Opthea and SDI were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the year to June 30, 2023 was up 23.9 percent to \$82,990,256 with net profit after tax up 46.6 percent to \$30,604,566.

Clinuvel said revenue was driven by increased demand for its Scenesse, or erythropoietic protoporphyria (EPP) in the US and Europe, a treatment for the prevention of anaphylactoid reactions and burns, with sales increasing 24 percent to \$83 million.

The company said despite increasing expenditures to expand its product development and clinical pipeline it had higher profitability due to return on sales improving to 58 percent in 2022-'23 compared to 52 percent in the previous period.

Clinuvel said it would pay a fully franked dividend of 5.0 cents a share to holders on the record date of September 6 to be paid on September 20, 2023, up 1.0 cent on 2022.

Clinuvel chief financial officer Darren Keamy said "since the launch of Scenesse in 2016, we have pursued clear and ambitious objectives for Clinuvel, with a strong financial foundation and consistent performance being central".

Clinuvel managing-director Dr Philippe Wolgen said "clinical expansion and increased demand led to a better than anticipated result of [a] 24 percent increase in global revenues".

"As the group increases in size and functions, the aim is to make each of the new divisions profitable on their own merits, as products and services are added," Dr Wolgen said.

The company said diluted earnings per share for the year to June 30, 2023 was up 46.7 percent to 59.1 cents, with net tangible assets up 31.4 percent to \$3.290.

Clinuvel said it had cash and cash equivalents of \$156,813,537 at June 30, 2023 compared to \$121,509,282 at June 30, 2022.

Clinuvel fell \$1.12 or 5.3 percent to \$20.02 with 99,951 shares traded.

HYDRIX

Hydrix says revenue for the year to June 30, 2023 was up 27.4 percent to \$13,156,572 with net loss after tax down 92.8 percent to \$396,926.

Hydrix said revenue was primarily from its three subsidiaries Hydrix Services, Hydrix Medical and Hydrix Ventures for their medical technology consulting services, product distribution and investment portfolio, respectively.

The company said that revenue was up in Australia, Europe and North America but fell in Singapore and other countries.

Hydrix said its reduced loss related to the release of \$800,000 from expiring consulting services and the release of \$2.9 million non-cash consideration relating to the acquisition of the distribution rights to Angel Medical's Guardian heart attack alert.

Hydrix said that diluted loss per share fell 94.7 percent to 0.17 cents, net tangible assets per share turned from negative 0.65 cents to a positive 1.14 cents and it had cash and equivalents of \$1,153,080 at June 30, 2023, compared to \$1,940,411 at June 30, 2022. Hydrix fell 0.2 cents or 6.25 percent to three cents.

PHARMAXIS

Pharmaxis says revenue for the year to June 30, 2023 was up 31.8 percent to \$13,074,000 with loss up 486.8 percent to \$11,360,000.

Pharmaxis said revenue included milestone payments and option fees of \$7,192,000 from Aptar Pharma's purchase of its Orbital inhaler technology for \$US5 million (\$A7.79 million) last year (BD: Aug 16, 2022).

The company said that sales of its Bronchitol, or mannitol, inhaler for cystic fibrosis were down 26.1 percent to \$4,295,000, with Aridol lung function test sales down 8.75 percent to \$1,470,000.

Pharmaxis said diluted loss per share for the year to June 30, 2023 fell 33.3 percent to 0.02 cents with net tangible assets per share down 50.0 percent to one cent.

Pharmaxis said it had cash and equivalents of \$9,230,000 at June 30, 2023, compared to \$8,937,000 at June 30, 2022.

Pharmaxis was unchanged at four cents.

IDT AUSTRALIA

IDT says revenue for the year to June 30, 2023 was down 42.0 percent to \$7,032,000 with net loss after tax up 632.6 percent to \$8,498,000.

IDT said revenue came from sales of its specialty oral products including medical marijuana and psychedelics, active pharmaceutical ingredients and advanced therapies.

The company said the previous year's results were "skewed by government payments related to Covid-19 worth ... [about] \$6 million, which makes comparing the two years' results less than straight forward".

IDT said that the establishment of its specialty orals and advanced therapies businesses had "breathed new life" into its active pharmaceutical ingredients business and that the investments it had made in the year enabled it to "grow the pipeline of potential sales leads across [these businesses]".

The company said diluted loss per share for the year to June 30, 2023 was up 600 percent to 3.5 cents a share, net tangible assets per share fell 28.2 percent to 7.93 cents, and it had cash and cash equivalents of \$4,433,000 at June 30, 2023 compared to \$9,214,000 at June 30, 2022.

IDT was unchanged at 6.5 cents.

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel Healthcare says it expects revenue for the six months to September 30, 2023 to be about \$NZ790 million (\$A725.5 million), with net profit after tax between \$NZ95 million and \$NZ105 million (\$A87.2 million to \$A96.4 million).

Fisher & Paykel said the forecast revenue was an increase of about 14 percent on the previous corresponding period.

Fisher & Paykel chief executive officer Lewis Gradon said that “for the first four months of the 2024 financial year, revenue from [obstructive sleep apnea] masks was stronger, and revenue from hospital hardware was marginally lower, than assumed”.

“Constant currency group revenue and operating expense results to date remain consistent with the full year guidance we provided in May, with gross margin improvement approaching 200 basis points in constant currency for the full year,” Mr Gradon said.

The company said that in the last year it had reached significant milestones, acquiring land in Karaka for a second New Zealand campus, opened a third building in Tijuana, Mexico and began fitting-out a new manufacturing facility in China.

Fisher & Paykel fell 32 cents or 1.6 percent to \$20.23 with 787,487 shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has sold its orthopaedic division to substantial shareholder Robinwood Investments Pty Ltd, for about \$4.3 million, following approval at its general meeting.

Allegra said Robinwood was an entity associated with director Dr Nicholas Hartnell and that the sale allowed it to focus solely on its medical innovations division while maintaining a close connection to its orthopaedics business.

In July, Allegra said it would sell its orthopaedics division for a \$1 million initial fee as well as the value of the inventory, in excess of \$3.3 million (BD: Jul 19, 25 2023).

Allegra was unchanged at six cents.

CHIMERIC THERAPEUTICS

Chimeric says it has completed its phase Ia clinical trial of CHM1101 chlorotoxin chimeric-antigen-receptor T-cell (CLTX-Car-T) treatment for glioblastoma.

Chimeric said participants in the final dose escalation cohort received a dose of 440 million CHM1101 cells through both intra-tumoral and intra-ventricular administration, with safety and efficacy to be assessed “prior to the end of 2023”.

The company said it had begun enrolment for a phase Ib trial of CHM1101 at the Austin, Texas-based St David’s South Austin Medical Center.

Chimeric said the phase Ib trial was being conducted under a US investigational new drug application and was a two-part trial designed to determine a recommended phase II trial dose and administration schedule.

Chimeric said the first part of the trial was to enrol between three to six participants at the highest phase Ia dose, and based on a favorable review of results in late 2023, it would begin the second part of the phase Ib trial, in which it would enroll a further 12 to 26 patients for a dose expansion cohort.

Chimeric said it intended to design and open a registrational trial for CHM1101 on successful completion of the phase Ib dose expansion cohort.

Chimeric managing director and chief executive officer Jennifer Chow said the company was “very pleased that the phase Ia City of Hope clinical trial has completed dose escalation at all four planned dose levels”.

Chimeric was up 0.2 cents or 5.7 percent to 3.7 cents.

PHARMAXIS

Pharmaxis says its pan-lysyl oxidase inhibitor (pan-LOX) PXS-5505 with chemotherapy increases pancreatic cancer survival rates by 35 percent, in mice.

Pharmaxis said the study compared PXS-5505 in combination with chemotherapy to chemotherapy alone, and showed the combination treatment resulted in a 45 percent reduction in the spread of the cancer to other organs.

The company said the study, at Sydney's Garvan Institute of Medical Research, titled 'A first-in-class pan-lysyl oxidase inhibitor impairs stromal remodeling and enhances gemcitabine response and survival in pancreatic cancer' was published in Nature Cancer and was available at <https://www.nature.com/articles/s43018-023-00614-y>.

Pharmaxis said the study focused on pancreatic ductal adenocarcinoma, "one of the most aggressive forms of pancreatic cancer".

Pharmaxis said PXS-5505 was an anti-fibrotic pan-lysyl oxidase inhibitor that had passed toxicity studies and phase Ia and Ib trials, inhibiting fibrosis.

Study author Prof Thomas Cox said "the pre-clinical validation of this first-in-class anti-fibrotic drug marks a major milestone in the quest to overcome the significant challenges in treating pancreatic cancer and brings hope to patients and their families".

Pharmaxis chief executive officer Gary Phillips said the company had "already seen very promising early results in a phase II trial with patients that have the bone marrow cancer myelofibrosis".

Mr Phillips said the research provided evidence that PXS-5505 might "improve the effect of current chemotherapy drugs in solid tumors like pancreatic cancer".

NUHEARA

Nuheara says it expects that more than 5,000 US outlets will be selling its Hewlett Packard (HP) Hearing Pro over-the-counter hearing aids by the end of 2023.

Nuheara said it had expanded its sales in the US, with the HP Hearing Pro to be sold at more than 4,000 Walmart shops and 600 Best Buys outlets, along with other retailers.

The company said it reduced HP Hearing Pro's consumer retail price to \$US499 (\$A774).

Nuheara said that, in light of its "direct relationship" with Walmart, it had terminated its agreement with the Sacramento, California-based Interscope (BD: Dec 12, 2022).

The company said that with Realtek, it had "invested heavily to design and implement a single chip solution, creating a lighter and more functional hearing aid" at a lower cost.

Nuheara said that the single chip feature was expected to be launched as its generation 4 product at the US Consumer Electronics Show in January 2024.

Nuheara fell half a cent or 2.9 percent to 17 cents.

ECHO IQ

Echo IQ says Advara Heartcare WA will conduct a pilot program of its Echosolv aortic decision-support platform for stenosis technology in Western Australia.

Echo IQ said that Advara was "Australia's largest cardiology provider" and should the program be successful, it would consider rolling out Echosolv at multiple sites in Australia.

The company said the trial program would "assess echo-cardio-graphic (ECG) measurement data, retrospectively" ... [and aim] to demonstrate the effectiveness of Echosolv as a tool to support enhanced clinical practice for the timely identification of severe aortic stenosis".

Echo IQ said the deal included an implementation fee and variable "outcome-driven" fees.

Echo IQ was up half a cent or 3.45 percent to 15 cents.

RESPIRI

Respiri says its subsidiary Access has remote patient and therapeutic monitoring contracts worth about \$900,000 in annualized revenue.

Respiri said that remote patient monitoring contracts with VDO Cardiology and Angelic Health Partners would generate about \$US450,000 (\$A675,000), with the Minnesota Lung Center pilot study of its remote therapeutic monitoring for obstructive sleep apnoea generating about \$US150,000 (\$225,000).

Respiri said the remote patient monitoring contracts were at \$US85 per patient per month, with New York's VDO Cardiology targeting an initial 300 patients and the New Jersey-based palliative care provider Angelica Health aiming for an initial 150 patients.

Respiri chief executive officer Marjan Mikel said the "new contracts and initiatives continue to underpin the importance of Respiri's strategic acquisition of Access to pursue our remote patient monitoring strategy in the US".

"I am excited that other significant contracts for the combined Access and Respiri team are being negotiated and close to finalizing and confident that our goal of monthly cash breakeven in 2024 is on track," Mr Mikel said.

Respiri was up half a cent or 18.5 percent to 3.2 cents with 3.6 million shares traded.

ANALYTICA

The ASX says it has removed Analytica from the official list for failing to pay its annual listing fees, effective from August 28, 2023.

Analytica last traded at 0.1 cents.

NEXT SCIENCE

Next Science has requested a trading halt pending an announcement "in relation to a capital raising by way of a placement and a share purchase plan".

Trading will resume on August 31, 2023, or on an earlier announcement.

Next Science last traded at 65 cents.

MESOBLAST

Gregory George and G to the Fourth Investments say they have increased their holding in Mesoblast from 53,920,195 shares (6.62%) to 66,366,800 shares (8.15%).

The Tampa, Florida-based Mr George said the shareholders included Grant George and James George and the single-largest purchase was 721,640 Australian shares for \$234,275, or 32.5 cents a share.

Mesoblast was up 1.5 cents or 3.4 percent to 45.5 cents with six million shares traded.

MEDICAL DEVELOPMENTS

Selector Funds says it has ceased its substantial holding in Medical Developments, selling 16,038 shares, transferring 791,210 shares and buying 334,152 shares.

Sydney's Selector Funds did not disclose the prices paid and received for the shares as required under the Corporations Act 2001.

The company previously filed a becoming substantial shareholder notice on August 15, 2022, saying it held 4,690,446 shares (5.78%).

Biotech Daily calculates that Selector Funds retains 4,217,350 shares or 4.9 percent.

Medical Developments fell 7.5 cents or 7.1 percent to 97.5 cents.

[CURVEBEAM AI \(ARTIFICIAL INTELLIGENCE\)](#)

Pinnacle Investment Management Group says it has become substantial in Curvebeam, with 24,960,025 shares or 7.80 percent of the company.

Pinnacle says it bought shares on August 22 and 23, 2023, with the single largest purchase 14,349,791 shares for \$4,821,529.75 or 33.6 cents a share.

Curvebeam was up 4.5 cents or 9.9 percent to 50 cents with one million shares traded.

[IMRICOR MEDICAL SYSTEMS](#)

HR Global Investments LLC says it has become a substantial shareholder in Imricor, with 9,746,663 shares or 6.11 percent of the company.

In July, Imricor said it had raised \$US1 million (\$A1.56 million) through a placement to the Delaware-based HR Global Investments at 35 US cents (55.0 Australian cents) a share.

Imricor was up 8.5 cents or 17 percent to 58.5 cents.

[VISIONEERING TECHNOLOGIES](#)

Visioneering says it has appointed Dr Juan Carlos Aragón as its chief executive officer and executive director on \$US400,000 (\$A620,84) a year, effective from October 1, 2023.

Visioneering said Dr Aragón had been the head of Cooper Vision Speciality Eyecare and worked for the company for 23 years, previously worked for CIBA Vision and Bausch and Lomb and held a Doctor of Optometry from Mexico City's National Polytechnic Institute.

Visioneering said that, subject to shareholder approval, Dr Aragón's would earn a long-term performance grant of 850,000 restricted stock units, short-term incentives worth 50 percent of his base salary and long-term incentives worth 40 percent of base salary.

Visioneering was untraded at 22 cents.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says it will host a symposium on precision healthcare to improve outcomes for people living with or at risk of cancer and rare diseases.

The Bio-Melbourne Network said the October 'Bio-Symposium', titled 'Precision Healthcare: The New Normal' would discuss "the developing role of precision healthcare to improve health outcomes for people living with cancer and rare diseases, or at risk of developing cancer".

The Network said that the event would cover "the latest collaborations and approaches, how organizations, systems and bio-informatics can help healthcare professionals match patients to the right therapies and clinical trials, and how these developments are ushering in a new era of personalized treatment strategies.

Bio-Melbourne said the event would be held at Monash College, Level 2 Auditorium, 750 Collins Street, Docklands, Melbourne, on October 4, 2023 from 8:45am to 6:30pm, including networking.

The organization said the event sponsors included the Victoria Department of Jobs, Skills, Industry and Regions; the Commonwealth Scientific and Industrial Research Organisation; Seerpharma, Radium Capital, Prime Financial Group, Monash Talent and World Courier.

For details and registration, go to: www.bit.ly/3YRaa96.