



# Biotech Daily

Monday July 31, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: AVITA UP 12%; STARPHARMA DOWN 32%**
- \* **NEUREN (H1) MAIDEN \$60m CUSTOMER RECEIPTS**
- \* **MEDADVISOR RECEIPTS UP 37.6% TO \$104.5m**
- \* **MACH7 RECEIPTS DOWN 11.4% TO \$25m**
- \* **GENETIC SIGNATURES POST-COVID RECEIPTS DOWN 51.5% TO \$19m**
- \* **MESOBLAST RECEIPTS DOWN 25% TO \$11.2m**
- \* **RHINOMED RECEIPTS DOWN 5.3% TO \$8.3m**
- \* **PHARMAXIS RECEIPTS DOWN 51.1% TO \$5.8m**
- \* **ACTINOGEN REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **STARPHARMA: ASTRAZENECA ENDS AZD0466 ON ADVERSE EVENTS**
- \* **IMPEDIMED RECEIVES ACADIA PARK BOARD SPILL CALL**
- \* **IMPEDIMED: 5 ADDITIONAL MEDICAL POLICIES**
- \* **ANTERIS 1<sup>st</sup> VALVE-IN-VALVE DURAVR PROCEDURE**
- \* **BCAL RELEASES 74m ASX ESCROW SHARES, 9m OPTIONS**
- \* **NEXT SCIENCE LOSES DIRECTOR JUDITH MITCHELL**
- \* **RESONANCE HEALTH LOSES CFO, COO, CO-CO-SEC NICK ALLAN**
- \* **HERAMED APPOINTS RON BACSKAI, TIFFANY MCKEVER US CONSULTANTS**

## MARKET REPORT

The Australian stock market edged up 0.09 percent on Monday July 31, 2023, with the ASX200 up 6.8 points to 7,410.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Avita was the best, up 66 cents or 12.0 percent to \$6.14, with 1.5 million shares traded. Cynata and Emvision climbed more than 10 percent; Pharmaxis improved eight percent; Amplia, Genetic Signatures, Polynovo, Proteomics and Resonance rose two percent or more; SDI was up 1.7 percent; with Clinuvel, Cochlear, CSL, Neuren, Resmed and Telix up by less than one percent.

Starpharma led the falls, down 10.5 cents or 32.3 percent to 22 cents, with 6.5 million shares traded. Universal Biosensors lost 13.2 percent; Nova Eye fell 7.7 percent; 4D Medical was down 6.1 percent; Impedimed, Next Science and Impedimed fell more than four percent; Kazia and Medical Developments were down more than three percent; Prescient shed 2.7 percent; Antisense, Cyclopharm, Immunetep, Opthea, Orthocell and Volpara were down more than one percent; with Mesoblast, Nanosonics and Pro Medicus down by less than one percent.

## NEUREN PHARMACEUTICALS

Neuren says customer receipts for the six months to June 30, 2023 was \$59,810,000 following payment by Acadia for the approval of trofinetide, or Daybue, for Rett syndrome. In June, Neuren said it received the \$US40 million (\$A59.9 million) payment from Acadia Pharmaceuticals for the first commercial sale of Daybue (BD: Jun 7, 2023).

In March, Neuren said that US partner Acadia had US Food and Drug Administration approval for Daybue for Rett syndrome (BD: Mar 13, 2023).

Today, the company said that it was \$48,069,000 cashflow positive for the three months to June 30, with cash and cash equivalents of \$85,675,000 compared to \$31,088,000 at June 30, 2022.

Neuren was up seven cents or 0.5 percent to \$13.03 with 557,321 shares traded.

## MEDADVISOR

Medadvisor says receipts from customers for the year to June 30, 2023 were up 37.6 percent to \$104,508,000, compared to the previous corresponding period.

Medadvisor said that receipts from its patient medication management platform for the three months to June 30, 2023 were up 11.1 percent to \$17,123,000 compared to the prior corresponding period.

The company said the increased sales for the year were due to its digitization strategy and the expansion of its pharmacy network.

Medadvisor said it had a cash burn of \$5,695,000 for the three months to June 30, with cash and cash equivalents of \$14,199,000 compared to \$7,579,000 at June 30, 2022.

Medadvisor was up 1.5 cents or 6.8 percent to 23.5 cents.

## MACH7 TECHNOLOGIES

Mach7 says receipts from customers for the year to June 30, 2023 were down 11.4 percent to \$24,965,000, compared to the previous corresponding period.

Mach7 said sales of its medical imaging software for the three months to June 30, 2023 were up 8.2 percent to \$10,526,000, compared to the prior corresponding period.

The company said it was \$3,888,000 cash flow positive for the three months to June 30, with cash and cash equivalents of \$23,395,000 compared to \$25,748,000 at June 30, 2022.

Mach7 fell 13 cents or 13.6 percent to 82.5 cents.

## GENETIC SIGNATURES

Genetic Signatures says customer receipts for the year to June 30, 2023 fell 51.5 percent to \$19,098,000 compared to the prior corresponding period.

Genetic Signatures said that customer receipts for the three months to June 30 fell 32.7 percent to \$3,466,000, primarily from its Easyscreen diagnostics, reflected "the cessation of public health driven molecular testing for Covid-19 during the year" as compared to the previous year.

The company said that sales for the three months to June 30 were up 125 percent to \$4.5 million compared to the three months to March 31, 2023.

Genetic Signatures said that it had a cash burn of \$3,319,000 for the three months to June 30, with cash and equivalents of \$16,349,000 compared to \$36,897,000 at June 30, 2022.

Genetic Signatures was up 1.5 cents or 2.5 percent to 62.5 cents.

## MESOBLAST

Mesoblast says customer receipts for the year to June 30, 2023 fell 25.3 percent to \$US7,480,000 (\$A11,208,450) compared to the prior corresponding period.

Mesoblast said receipts, primarily from sales in Japan of Temcell for graft versus host disease, fell 8.8 percent to \$US1,834,000 for the three months to June 30, 2023 compared to the prior corresponding period.

The company said it had a cash burn of \$US16,278,000 for the three months to June 30, with cash and equivalents of \$US71,318,000 compared to \$US60,447,000 at June 30, 2022.

Mesoblast fell half a cent or 0.4 percent to \$1.145 with 4.8 million shares traded.

## RHINOMED

Rhinomed says receipts from customers for the year to June 30, 2023 were down 5.3 percent to \$8,317,000, compared to the previous corresponding period.

Rhinomed said sales of its Rhinoswab respiratory nasal swab self-test kits and Mute anti-snoring devices were up 31.6 percent to \$2,500,000 for the three months to June 30, 2023, compared to the prior corresponding period.

The company said it had a cash burn of \$1,190,000 for the three months to June 30, with cash and cash equivalents of \$226,000 compared to \$2,032,000 at June 30, 2022.

Rhinomed said it had 1.24 quarters of cash but had received initial orders for \$1.9 million of Rhinoswabs which had been delayed due to regulatory approvals but were expected to be received by October, 2023.

Rhinomed was untraded at 6.5 cents.

## PHARMAXIS

Pharmaxis says receipts from customers for the year to June 30, 2023 were down 51.1 percent to \$5,832,000, compared to the previous corresponding period.

Pharmaxis said while sales of its Aridol lung function test were up compared to 2022, sales of its Bronchitol inhaled dry powder for cystic fibrosis were down due to the quantity and timing of orders based on in-market sales and distributor inventory levels, and so were not indicative of underlying market trends.

The company said the sales of these products for the three months to June 30, 2023 were down 43.2 percent to \$1,913,000 compared to the prior period.

Pharmaxis said it had a cash burn of \$4,967,000 for the three months to June 30, with cash and cash equivalents of \$9,230,000 compared to \$8,937,000 at June 30, 2022.

Pharmaxis said although it had 1.85 quarters of cash it had no need to immediately raise further cash as it expected a Federal Research and Development Tax Incentive.

Pharmaxis was up 0.4 cents or eight percent to 5.4 cents.

## ACTINOGEN MEDICAL

Actinogen says it has requested a trading halt "pending an announcement regarding a capital raising".

Trading will resume August 2, 2023, or on an earlier announcement.

Actinogen last traded at 3.7 cents.

## STARPHARMA

Starpharma says Astrazeneca has discontinued development of dendrimer enhanced product (DEP) AZD0466 “prompted by a small number of asymptomatic adverse events”. Starpharma said that the adverse events “were unrelated to [its] dendrimer drug delivery technology” and the events were observed in two clinical trials evaluating AZD0466 for haematological malignancies and non-Hodgkin’s lymphoma (BD: Feb 9, 2021).

The company said Astrazeneca’s decision followed Astrazeneca’s voluntary partial clinical hold on the haematological malignancies trial (BD: Jun 27, 2023)

Starpharma said that the adverse events leading to the voluntary partial hold were asymptomatic and detected through routine laboratory testing.

The company said that the adverse events “do not adversely impact the therapeutic and commercial potential of DEP”.

Starpharma chief executive officer Dr Jackie Fairley said that while the decision was “clearly not what Starpharma would have hoped for, we note that it relates to haematological malignancies and at the highest three dose groups of AZD0466 and was not due to our dendrimer technology”.

“DEP has demonstrated multiple benefits in Starpharma’s clinical studies in patients with solid tissue tumors, including significant preferential accumulation in these tumors compared to blood levels,” Dr Fairley said.

Starpharma said the discontinued AZD0466 development did not impact its DEP platform, internal clinical and pre-clinical DEP programs, or DEP partnerships.

The company said the multi-product DEP licence with Astrazeneca “remains in effect”.

Starpharma fell 10.5 cents or 32.3 percent to 22 cents with 6.5 million shares traded.

## IMPEDIMED

Impedimed says it has received a notice from Acadia Park Pty Ltd calling for the removal of chair Donald Williams and directors Amit Patel, David Anderson and Daniel Sharp.

Impedimed said the notice “purports to be issued pursuant to section 203D of the Corporations Act 2001 ... on behalf of Acadia Park Pty Ltd regarding the intention of [Acadia Park] with the support of a small handful of private investors, to move resolutions for the removal of [the] four directors.

The company said that Acadia Park intended to provide a request to call an extraordinary general meeting under section 249D of the Corporations Act to appoint replacement directors, in addition to the removal of the four directors.

Impedimed said it had not had prior communication from Acadia Park, “nor has it been given any reason or context for the proposed moving of the resolutions”.

The company said it was “disappointed with the surprise and sudden actions of [Acadia Park] at a time when the company is making significant progress with private payor reimbursement and achieving market inroads ahead of stated timelines”.

Impedimed said its performance was “leading to consistent returns for investors ... [and the] share price has appreciated by 253 percent since March 8, 2023, when managing-director ... Rick Valencia updated shareholders on the focused direction of the company”.

The company said it had “widespread support from both institutional and retail shareholders in successfully raising new capital to accelerate its growth and has delivered in excess of 30 percent share price accretion from the date of the announcement of the capital raising in May”.

Biotech Daily was unable to find any reference to Acadia Park Pty Ltd other than business registration sites saying it was a Sydney company incorporated in 2018.

Impedimed fell one cent or 4.9 percent to 19.5 cents with 11.7 million shares traded.

## IMPEDIMED

Impedimed says it has five additional positive medical policy changes, bringing the total to 12 and including three additional Blue Cross Shield policies.

Earlier this year, Impedimed said the US National Comprehensive Cancer Network clinical practice guidelines included bioimpedance spectroscopy for the first time, which would help accelerate adoption by insurers (BD: Mar 27, 2023).

Today, the company said the policies were led by Cigna Healthcare and seven Blue Cross Blue Shield policies.

Impedimed said it had achieved critical mass, covering more than 80 percent of patients in Michigan and Alabama with the additional coverage from these policies bringing six additional states close to critical mass.

Impedimed chief executive officer and managing director Richard Valencia said the company was pleased with the continued domino effect that was occurring with private payor policies, which were happening well within its stated timelines.

## ANTERIS TECHNOLOGIES

Anteris says its Duravr transcatheter heart valve has been used for the first time in a valve-in-valve procedure as part of Health Canada's special access program.

Anteris said Dr Anita Asgar at the Institut de Cardiologie de Montreal made a request to use its biomimetic, balloon-expandable, single-piece transcatheter aortic valve to Health Canada and performed the procedure on male patient aged 84 years.

The company said a valve-in-valve procedure was required in patients whose bio-prosthetic aortic valves were failing due to calcification or structural deterioration and another prosthetic valve had to be implanted inside the failing valve.

Anteris said the procedure was successful, with haemodynamic performance "outstanding in such a complex patient" and that the patient had an 88 percent reduction in mean gradient, which brought him back to a near-normal physiological state.

Anteris was up 66 cents or 3.1 percent to \$21.66.

## BCAL DIAGNOSTICS

BCal says it released 74,349,071 shares and 9,246,318 options from ASX escrow on July 21, 2023.

BCal said that following the release from escrow it had 211,443,781 shares available for trading on the ASX.

BCal was up one cent or 14.3 percent to eight cents.

## NEXT SCIENCE

Next Science former chief executive officer Judith Mitchell says she has ceased to be a director of the company, effective from July 31, 2023.

In June, Next Science said that Harry Hall IV would replace managing-director Judith Mitchell, effective from July 10, with Ms Mitchell to remain with the company until July 31, 2023 (BD: Jun 16, 2023).

Next Science fell 2.5 cents or 4.55 percent to 52.5 cents.

## RESONANCE HEALTH

Resonance Health says chief operating officer, chief financial officer and joint company secretary Nick Allan has left the company, effective from today.

Resonance Health said Mr Allan joined the company in May 2021 and had made a “significant contribution” including improving and upgrading legacy systems and working closely with the scientific and product development teams.

Resonance was up 0.1 cents or two percent to 5.1 cents.

## HERAMED

Heramed says it has appointed Ron Bacskai and Tiffany McKeever as consultants to support its sales and marketing efforts in the US.

Heramed said Mr Bacskai had previously been president and chief executive officer of Nanosonics Inc and Ms McKeever was founder and chief executive officer of Consensus Healthcare Consultants Inc.

Heramed was up 0.1 cents or 1.3 percent to 7.6 cents.