



Biotech Daily

Thursday August 10, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: UNIVERSAL BIO UP 24%; IMPEDIMED DOWN 7%**
- * **ATMO STARTS 'PIVOTAL' GAS-SENSING CAPSULE TRIAL**
- * **CYNATA OPENS PHASE II CYP-001 GvHD TRIAL**
- * **CLARITY TAKES 67-CU SAR-BIS-PSMA TRIAL TO COHORT 3 DOSE**
- * **LBT: APAS PHARMA QC '100% SENSITIVITY FOR MICROBIAL GROWTH'**
- * **LUMOS RECEIVES \$705k FEDERAL R&D TAX INCENTIVE**
- * **INCANNEX HOLDS NASDAQ MOVE INVESTOR MEETINGS**
- * **M&G PLC REDUCES TO 5.9% OF MESOBLAST**
- * **M&G INVESTMENT FUNDS BELOW 5% OF MESOBLAST**
- * **CONTROL BIONICS LINDSAY PHILLIPS, NIGHTINGALE TAKE 19%**
- * **PYC TAKES 96% OF VISION PHARMA**
- * **MACH7 TO LOSE CHAIR DAVID CHAMBERS**

MARKET REPORT

The Australian stock market was up 0.26 percent on Thursday August 10, 2023, with the ASX200 up 19.4 points to 7,357.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and three were untraded.

Universal Biosensors was the best, on yesterday's news, up six cents or 24.0 percent to 31 cents, with 278,529 shares traded. 4D Medical climbed 15.25 percent; Resonance rose 14 percent; Dimerix was up 8.8 percent; Emvision, Medical Developments and Mesoblast were up more than five percent; Paradigm improved 4.65 percent; Avita, Nova Eye and Prescient rose two percent or more; Immutep and SDI were up more than one percent; with Clinuvel, Cochlear, CSL, Cyclopharm, Nanosonics, Neuren and Opthea up by less than one percent.

Impedimed led the falls, down 1.5 cents or 7.1 percent to 19.5 cents, with 1.3 million shares traded. Next Science fell 4.6 percent; Actinogen, Atomo, Cynata and Kazia were down more than three percent; Imugene and Pharmaxis shed more than two percent; Antisense, Genetic Signatures, Pro Medicus, Telix and Volpara were down more than one percent; with Resmed down by 0.4 percent.

ATMO BIOSCIENCES

Atmo says it expects to recruit about 100 patients with gastrointestinal symptoms and dysmotility for a “pivotal” trial of its gas-sensing capsule against Medtronic’s Smartpill. Melbourne’s Atmo said the trial, held at up-to 13 sites in the US and Australia, would test its gas-sensing capsule against the Smartpill to assess whole and regional gut transit, with clinicians to evaluate regional gut transit to diagnose motility disorders such as gastroparesis or delayed gastric emptying, and slow transit constipation.

The company said initial subjects had been recruited at the Fairfield, Connecticut-based Hartford Health Neurogastroenterology and Motility Centre, and the University of Western Sydney.

Atmo said the results would be used to submit a 510(k) application to the US Food and Drug Administration for market clearance for the device in the US.

The company said patients would ingest both the Atmo capsule and Medtronic Smartpill and let the capsules record measures as they travel through different regions of the gastro-intestinal tract.

Atmo said the Smartpill used pH, temperature and pressure to identify when the pill moved through different gut regions, while the Atmo capsule used measures including hydrogen and carbon dioxide concentration and temperature.

The company said the study followed pilot trials comparing transit measurements between the Atmo capsule and Smartpill, with one trial in healthy subjects and one in patients with symptoms of gastro-intestinal motility disorders, with the trials showing the Atmo capsule relative to the Smartpill for measuring transit time.

In March, Atmo said that it has raised \$8 million in a series B funding round at \$1.40 a share, for its ingestible gas-sensing capsule and the trial (BD: Mar 30, 2023).

Atmo Biosciences chief executive officer Malcolm Hebblewhite said the launch of the trial was “an important milestone”.

“This is a crucial step for the business, and will be used to support our submission for regulatory clearance with the FDA in 2024, paving the way for product launch in the important US market,” Mr Hebblewhite said.

Co-principal investigator and University of Michigan chief of gastro-enterology and hepatology Prof William Chey said that dysmotility disorders, such as gastroparesis and chronic constipation, affected many millions of people each year.

“Patients can experience chronic, debilitating symptoms such as nausea, vomiting, bloating, abdominal pain and abnormal bowel habits,” Prof Chey said.

Atmo is a public unlisted company.

CYNATA THERAPEUTICS

Cynata says it has opened recruitment for its up-to 60 patient, randomized phase II trial of its CYP-001 mesenchymal stem cells for high-risk acute graft versus host disease.

Cynata said the first recruitment centre open was Sydney’s Westmead Hospital.

Cynata chief executive officer Dr Kilian Kelly said that start of the randomized controlled trial was “a major milestone for Cynata”.

Dr Kelly said that the phase I trial of Cymerus induced pluripotent stem cell-derived mesenchymal stem cells for graft versus host disease results “were outstanding, with very encouraging response and survival rates, and no safety concerns identified”.

“As such, we are optimistic that this new trial will build on the substantial body of data we have generated so far, and ultimately make a difference to the lives of patients suffering from this terrible disease.” Dr Kelly said.

Cynata fell half a cent or 3.45 percent to 14 cents.

CLARITY PHARMACEUTICALS

Clarity says its 'Secure' 30 patient, phase I/II trial of 67-copper sarcophagine (Sar)-Bis-PSMA for prostate cancer will start its highest dose cohort three.

In October, Clarity said it had treated the first of up-to 30 patients in the 67-Cu Sar-Bis-prostate specific membrane antigen (PSMA) trial for prostate cancer (BD: Oct 7, 2022).

Today, the company said none of the three patients in cohort two had reported dose limiting toxicities, at 8.0 giga-Becquerel (GBq) with the safety review committee recommending that the trial continue to cohort three at 12.0GBq.

Clarity said that a patient from cohort one showed more than 50 percent reduction in prostate specific antigen levels after a 4.0GBq dose, and had completed a total of four doses with more than a 90 percent reduction in prostate specific antigen.

Clarity was up one cent or 1.1 percent to 89.5 cents.

LBT INNOVATIONS

LBT says data from an Astrazeneca study has shown its Apas Pharma QC has 100 percent sensitivity for detecting microbes from 1,515 monitoring plates.

In 2022, LBT said it was developing an automated plate assessment system (Apas) for pharmaceutical companies, Apas Pharma, for microbial quality control, along with other products (BD: Aug 10, 2022).

Today, the company said APAS Pharma QC was able to help remove 91.7 percent of plates from the manual workflow correctly, while giving a false positive result for 7.3 percent of plates it reported as positive.

LBT said the overall performance had "met the requirements for this stage of the project" and that next steps would include pilot validation testing and a formal validation program by LBT and Astrazeneca expected by December 31, 2023, with planned product launch by July 2024.

LBT research director Rhys Hill said the results were "hugely encouraging and give us confidence that we are on-track with our currently development objectives".

"Ensuring the system does not miss any potential growth on the plate is incredibly important for the application as any microbial growth within a sterile manufacturing facility can be a cause for investigation," Mr Hill said.

"We therefore tune the system to be conservative ensuring no positive plates are missed," Mr Hill said.

LBT was up 0.1 cents or 4.55 percent to 2.3 cents.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says it has received \$705,193 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive Program.

Lumos said the incentive related to expenditure for the year to June 30, 2023.

Lumos was up 0.6 cents or 11.1 percent to six cents with 11.9 million shares traded.

INCANNEX HEALTHCARE

Incannex says it will hold shareholder meetings in Sydney, Melbourne, Brisbane and Perth to discuss its move to the Nasdaq, from August 23 to September 5, 2023.

In July, Incannex said it intended to redomicile to the US and list its shares on the Nasdaq through the Delaware corporation Incannex Healthcare Inc (BD: Jul 10, 2023).

Incannex was up 0.3 cents or 3.4 percent to 9.2 cents with 2.5 million shares traded.

MESOBLAST

M&G Plc says it has reduced its substantial shareholding in Mesoblast from 58,312,858 shares (7.16%) to 48,079,421 shares (5.91%).

The London-based M&G Plc said it sold shares on August 7 and 8, 2023, with the single largest sale on August 7 of 2,789,741 shares for \$1,234,207 or 44.2 cents a share.

Mesoblast was up two cents or 5.7 percent to 37 cents with 30.7 million shares traded.

MESOBLAST

M&G Investment Funds says it has ceased its substantial shareholding in Mesoblast, selling 1,999,914 shares for \$793,872 or 39.7 cents a share.

The London-based M&G Investment said it sold the shares on August 8, 2023.

Yesterday, M&G Investment Funds said it held 41,562,523 Mesoblast shares (5.10%) and Biotech Daily calculates it retained 39,562,609 shares or 4.86 percent of the company.

CONTROL BIONICS

The Sydney-based Nightingale Partners says it has increased its shareholding in Control Bionics from 14,319,863 shares (15.83%) to 19,537,595 shares (19.07%).

In a substantial shareholder notice signed by former Control Bionics director Lindsay Phillips, Nightingale said it bought shares on July 13 and on August 1, 2023 acquired 4,773,288 shares for \$453,462 or 9.5 cents a share in a rights issue.

Last week, Control Bionics said its non-renounceable rights issue at 9.5 cents a share raised a total of \$1,133,341 of a hoped-for \$2,865,000 (BD: Aug 1, 2023).

Control Bionics was up 0.35 cents or 4.4 percent to 8.25 cents.

PYC THERAPEUTICS

PYC says it has increased its shareholding in Vision Pharma from 95.2 percent to 96.2 percent.

PYC said that Vision owned the VP-001 program for retinitis pigmentosa type 11 (RP11).

PYC fell 0.1 cents or 1.8 percent to 5.5 cents with two million shares traded.

MACH7 TECHNOLOGIES

Mach7 says its chair David Chambers will retire, effective from the close of its annual general meeting November 16, 2023.

Mach7 said Mr Chambers joined the board in August 2018 as an independent non-executive director and was appointed chair in June 2019.

Mach7 managing director Mike Lampron thanked Mr Chambers for his contribution and said a search was underway for a replacement.

Mach7 was up 2.5 cents or 3.2 percent to 81.5 cents.