



Biotech Daily

Monday October 16, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PHARMAXIS UP 9%; ATOMO DOWN 11.5%**
- * **CSL 'CAPITAL MARKETS DAY' REPLACES R&D BRIEFING**
- * **BIONICS INSTITUTE: BIONIC HAND FUNCTIONAL AT 5 YEARS**
- * **VICTORIA \$1m FOR MCRI RAG1-SCID STEM CELL TRIAL**
- * **IMMUTEP: 3 ESMO PRESENTATIONS FROM 3 EFTI TRIALS**
- * **STARPHARMA AACR DATA ON DEP IRINOTECAN, DEP-HER2 ZIRCONIUM**
- * **FISHER & PAYKEL LAUNCH 'SOLO' MASK FOR SLEEP APNOEA**
- * **CORRECTION: DIMERIX, NOXOPHARM**
- * **CHIMERIC 4m M-D RIGHTS, 18m DIRECTOR OPTIONS AGM**
- * **ANATARA REQUESTS 'FURTHER TRIAL DATA' TRADING HALT**
- * **BLUECHIIP REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **PARADIGM REQUESTS 'MORE TRIAL DATA' TRADING HALT**
- * **PINNACLE TAKES 6.2% OF FISHER & PAYKEL**
- * **GZ FAMILY DILUTED TO 12.5% OF ATOMO**
- * **M&G INVESTMENT BELOW 5% OF STARPHARMA**

MARKET REPORT

The Australian stock market fell 0.35 percent on Monday October 16, 2023, with the ASX200 down 24.5 points to 7,026.5 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and one was untraded.

Pharmaxis was the best, up 0.3 cents or 8.6 percent to 3.8 cents, with 272,465 shares traded. Starpharma climbed six percent; Genetic Signatures and Micro-X improved four percent or more; Immutep was up 3.8 percent; Proteomics and Resmed rose more than two percent; Emvision and Nova Eye were up more than one percent; with Neuren up 0.3 percent.

Atomo led the falls, down 0.3 cents or 11.5 percent to 2.3 cents, with 58,179 shares traded. Alcidion lost 8.0 percent; Antisense and Prescient shed more than six percent; Cynata, Imugene, Polynovo, Telix and Volpara fell four percent or more; 4D Medical and Medical Developments were down more than three percent; Avita and Dimerix shed more than two percent; Amplia, Mesoblast, Nanosonics, Next Science, Pro Medicus, Resonance and SDI were down one percent or more; with Clinuvel, Cochlear and CSL down by less than one percent.

[CSL](#)

By JAMIE MILLER, DEPUTY EDITOR

CSL has replaced its annual research and development briefing with its first “capital markets day”, focusing on its businesses as well as its pipeline.

According to Commsec data, CSL’s all-time market capitalization high was \$144,793 million on May 31, 2023, with a closing share price of \$306.39, falling 22.3 percent from \$310.73 on June 5, 2023 to \$241.39 at the close on October 13, 2023.

Today, CSL chief executive officer Dr Paul McKenzie said despite increased competition in a changing health sector and the continued effect of the Covid-19 pandemic the company expected “to deliver annual double-digit earnings growth over the medium term”. Dr McKenzie told the online and in-person conference that the immunoglobulin business was lower but remained at CSL’s core and drove increased revenue, with its “secret sauce” its “ability to continue to innovate and meet patient demand”.

CSL Behring head Andy Schmeltz said the company was increasing plasma volume while reducing costs with donation levels up 22 percent in 2021-'22 and 31 percent in 2022-'23. Mr Schmeltz said plasma was a “critical raw ingredient of many of CSL’s products”, including the manufacturing of immunoglobulins, albumin and hyperimmunes.

Mr Schmeltz said sales of Privigen and Hizentra for immunodeficiency diseases were down due to the Covid-19 pandemic resulting in fewer disease infections, causing immunodeficiency diagnosis to be down 80 percent of pre-pandemic levels.

CSL said its Vifor business, which included its intravenous iron injections Ferinject and Injectafer for iron deficiencies, expected to lose exclusivity in Europe at the end of the year as another product reached regulatory approval.

CSL Vifor general manager Hervé Gisserot said that “by the end of the year, we will learn more on the competitive landscape ... by then there may be one or two more products on the market as they await approval”, but Ferinject “should remain the standard-of-care”.

Mr Gisserot said that as well as iron replacement therapy the business was developing its patient blood management pipeline, which focused on minimizing blood loss and preserving blood to ensure patients “have their own blood in their own circulatory system”. The company said renal disease portfolio revenue was expected to increase in the medium-term and would not be affected by GLP-1s, or glucagon-like peptide-1 receptor agonists, such as the recently approved anti-obesity drugs Ozempic and Wegovy.

“We do not see GLP-1s having a material impact on the business,” Dr McKenzie said.

CSL said that despite a decline in influenza cases due to Covid-19 it expected influenza vaccine rates to return to pre-pandemic levels as case levels began to reverse.

CSL chief strategy officer Ken Lim said recently increased vaccine sales were “underpinned by [the company’s] Fluad and Flucelvax” vaccines, with a phase III trial of its adjuvanted cell-based quadrivalent influenza vaccine expected to expand the vaccine’s indication to patients aged 50-years-old and above.

CSL head of research and development Dr William Mezzanotte said subcutaneous Haegarda for hereditary angioedema, Ferinject for iron deficiency anaemia and Hemgenix for haemophilia B had all received regulatory approval from at least one regulatory body. The company said it had halted development of CSL730 for immune complex-mediated autoimmune diseases and SNF4723 for calcific uremic arteriolopathy.

Dr Mezzanotte said that CSL’s Australian-developed subcutaneous, auto-injected Garadacimab for the potential treatment of hereditary angioedema had completed phase III trials and was expected to be commercialized in 2023-'24, and that top-line results from a study of CSL112 for myocardial infarction was expected by December 31, 2023.

CSL fell \$1.49 or 0.6 percent to \$239.90 with 670,514 shares traded.

BIONICS INSTITUTE

The Bionics Institute says it has developed a bionic hand merging with the user's nervous and skeletal systems that has remained functional "after years of daily use".

The Institute said the long-term integration of a bionic hand with the nervous and skeletal systems was "successful for the first time in a patient with a below-elbow amputation".

The Institute said that Swedish woman, Karin, lost her right hand in a farming accident and was implanted with a human-machine interface into her residual bone, nerves and muscles in December 2018, with the residual limb surgically modified to better integrate with a bionic hand using artificial intelligence to understand commands.

The Bionics Institute said the research was led by neural prosthetic research head Prof Max Ortiz Catalan, the founder of Sweden's Centre for Bionics and Pain Research.

The Institute said the research, titled 'A highly integrated bionic hand with neural control and feedback for use in daily life' was published in 'Science Robotics' with the full article available at: <https://www.science.org/doi/10.1126/scirobotics.adf7360>.

The Institute said the patient had "intractable pain ... [and] conventional prostheses were uncomfortable and unreliable, and thus of little help in daily life", but the technology allowed her "to wear a much more functional prosthesis comfortably all day" and the higher integration of the prosthetic hand and residual limb relieved pain.

"Karin was the first person with a below-elbow amputation to receive this new concept of a highly integrated bionic hand that can be used independently and reliably in daily life," Prof Ortiz Catalan said. "The fact that she has been able to use her prosthesis comfortably and effectively ... [shows] the potential life-changing capabilities of this novel technology".

"Our integrated surgical and engineering approach also explains the reduction in pain, as Karin is now using somewhat the same neural resources to control the prosthesis as she did for her missing biological hand," Prof Ortiz Catalan said.

Bionics Institute chief executive officer Robert Klupacs said the research paved the way for people with a below-elbow amputation to regain quality of life.

The Bionics Institute said that "a key feature of the new bionic technology is the skeletal attachment of the prosthesis via osseointegration, the process by which bone tissue embraces titanium creating a strong mechanical connection".

"The nerves and muscles in the patient's residual limb were re-arranged to provide more motor control information to the prosthesis," the Institute said.

VICTORIA GOVERNMENT, MURDOCH CHILDREN'S RESEARCH INSTITUTE

The Victoria Government says it has provided \$1 million to the Murdoch Children's Research Institute for a trial of stem cells for immune-deficiency.

A media release from the Victoria Minister for Medical Research Ben Carroll said the funds for the Institute at the Royal Children's Hospital would support the extension to a trial conducted by the Netherlands Leiden University Medical Centre for children with the rare disease RAG-1 deficient severe combined immune-deficiency or RAG-1 Scid.

The State Government said the trial was also supported by Novo Nordisk Foundation Centre for Stem Cell Medicine, in partnership with the Melbourne Children's Trials Centre.

The media release said that children born without infection-fighting immune cells caused by the genetic defect, RAG-1 Scid meant they were "extremely vulnerable to common illnesses" and most children born with the condition would die from infection early in life.

The Victoria Government said trial participants would have stem cells taken from their own bone marrow to be genetically modified with a healthy copy of the RAG-1 gene, before being injected back into the bloodstream where it would become "healthy white blood cells that will build a functional immune system".

IMMUTEP

Immutep says it will present abstracts with data from three trials of efti for non-small cell lung cancer and sarcomas at the European Society for Medical Oncology meeting. Immutep said the first abstract, titled 'Combining the antigen-presenting cell activator eftilagimod alpha (soluble LAG-3) and pembrolizumab: overall survival data from the 1st line non-small cell lung carcinoma (NSCLC) cohort of TACTI-002 (Phase II)' included data from its phase II trial of efti with anti-programmed death-1 therapy Keytruda.

The company said the abstract contained data based on a cut-off date of March 31 2023, and showed an initial survival benefit across the patient population in first-line non-small cell lung cancer, including a tumor proportion score of more than 50 percent after 38.8 months and between one-to-49 percent after 23.4 months.

Immutep said the second abstract titled 'INSIGHT 003 evaluating feasibility of eftilagimod alpha (soluble LAG-3) combined with 1st line chemo-immunotherapy in metastatic non-small cell lung cancer (NSCLC) adenocarcinomas' was from its phase I investigator-led trial of efti with Keytruda and doublet chemotherapy in non-squamous patients.

Immutep said the data had a cut-off date of April 18, 2023 and showed efti had a 67 percent overall response rate.

The company said the third abstract titled 'Pembrolizumab in combination with eftilagimod alpha and radiotherapy in neoadjuvant treatment of patients with soft tissue sarcomas - EFTISARC-NEO trial' had data from a trial in progress of efti with radiotherapy and Keytruda.

Immutep was up one cent or 3.8 percent to 27.5 cents with 2.3 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it presented data in three posters at the American Association of Cancer Research relating to its DEP-irinotecan and Herr2 studies for various cancers.

Starpharma said the posters were presented at the International Conference on Molecular Targets and Cancer Therapeutics, co-hosted by the American Association of Cancer Research, the National Cancer Institute and the European Organisation for Research and Treatment of Cancer (EORTC) between October 11 and 15, 2023.

Starpharma said the first poster was titled 'A Phase I/II Study of Dendrimer-Enhanced (DEP) SN38 (SN38-SPL9111/DEP Irinotecan) in Patients with Advanced Solid Tumours' and included interim data from its phase I/II clinical trial and showed DEP-irinotecan had durable anti-tumor responses in advanced colorectal cancer and ovarian cancer.

The company said the data showed the objective response rate of DEP-irinotecan dosed every two weeks had increased from the 29 percent to 43 percent.

Starpharma said a second poster titled 'An SN38 dendrimer nanoparticle, DEP irinotecan (SN38-SPL9111), demonstrates efficacy in mouse models of gastrointestinal cancer and augments anti-tumor effects of immune checkpoint blockade and PARP inhibition' included data from a study of irinotecan in combination with anti-cancer agents in colorectal cancer in mice, which showed DEP-irinotecan had "superior anti-tumor activity and significant survival benefit when compared to these agents delivered alone"

Starpharma said the third poster, 'A HER2 targeted polylysine dendrimer nanoparticle radiotheranostic demonstrates excellent tumor accumulation, rapid clearance from circulation, and promising performance in PET-CT imaging' had the results from a study of a dendrimer enhanced HER2-zirconium breast cancer diagnostic, which included a favorable biodistribution profile, imaging contrast between tumor and normal tissue as well as rapid uptake and high levels of tumor accumulation for HER2 breast cancer in mice.

Starpharma was up one cent or 7.1 percent to 15 cents.

[FISHER & PAYKEL HEALTHCARE](#)

Fisher & Paykel says sales of its Solo autofit nasal and pillows mask for obstructive sleep apnoea have begun in New Zealand will start in Australia this month.

Fisher & Paykel said the mask simplified the setup process, allowing users to stretch the mask onto the face and adjust it into place with one touch, which was “a significant step forward in mask innovation”.

The company said without the conventional straps to undo and pull, the mask reduced overtightening on the face, with an auto-lock technology holding “the mask in place with minimal force and dynamically [responding] to sleep movement and [continuous positive airway pressure]-therapy pressure”.

Fisher & Paykel head of products and technology Andrew Somervell said “patients can set themselves up without assistance and then easily finetune the mask during nightly use for an optimal fit.”

Fisher & Paykel was up 41 cents or 2.1 percent to \$19.76 with 286,675 shares traded.

[CORRECTION: DIMERIX, NOXOPHARM](#)

Friday’s article on Dimerix incorrectly said, in passing, that Noxopharm shares rose 61 percent on FDA approval for CRO-67 for pancreatic cancer.

In fact, the US Food and Drug Administration approved Noxopharm’s investigational new drug application (IND) for CRO-67 to begin trials for pancreatic cancer.

We apologise for the confusion, but the Friday sub-editor said he was distracted by recent events in the Middle East, and the then impending Voice to Parliament referendum as well as the New Zealand election.

Biotech Daily accepts his grovelling excuses and apologizes for the sub-editor’s error.

[CHIMERIC THERAPEUTICS](#)

Chimeric says investors will vote to issue managing-director Jennifer Chow 15,139,467 options and 4,062,997 performance rights and director Eric Sullivan 2,750,000 options. Chimeric said its annual general meeting would vote to issue Ms Chow 15,139,467 options exercisable at 3.8 cents each by July 1, 2028 and vesting in three equal tranches on July 1 2024, 2025 and 2026; and 4,062,997 performance rights expiring on September 30, 2026 and vesting at the same time as the options.

The company said that shareholders would vote to issue Mr Sullivan 2,750,000 options, exercisable at 3.7 cents each by August 30, 2027 and vesting in three equal tranches on August 30, 2024, 2025 and 2026.

Chimeric said investors would vote to ratify the issue of 79,333,333 shares to Lind Global Fund II LP, adopt the remuneration report, elect Phillip Hains and Mr Sullivan as directors, approve the 10 percent placement capacity and renew the omnibus incentive plan.

The meeting will be held virtually and at Level 3, 62 Lygon Street, Carlton, Victoria on November 14, 2023 at 11am (AEDT)

Chimeric was up 0.2 cents or 7.7 percent to 2.8 cents with 1.1 million shares traded.

[ANATARA LIFESCIENCES](#)

Anatara has requested a trading halt “in relation to ... the analysis of secondary endpoints from ... [ITS] irritable bowel syndrome trial stage 1 data”.

Trading will resume on October 18, 2023, or on an earlier announcement.

Anatara last traded at 2.9 cents.

[BLUECHIIP](#)

Bluechiip has requested a trading halt “pending an announcement to the market in connection with a capital raising program”.

Trading will resume on October 18, 2023, or on an earlier announcement.

Bluechiip last traded at 2.7 cents.

[PARADIGM BIOPHARMACEUTICALS](#)

Paradigm has requested a trading halt pending an analysis of magnetic resonance imaging data from its trial of pentosan polysulfate sodium for knee osteo-arthritis.

Trading will resume on October 18, 2023, or on an earlier announcement.

Paradigm last traded at 63 cents.

[FISHER & PAYKEL HEALTH](#)

Pinnacle Investment Management says it has increased its substantial shareholding in Fisher & Paykel from 29,363,690 shares (5.0865%) to 36,059,206 shares (6.1954%).

The Brisbane-based Pinnacle said that between May 13, 2022 and October 10, 2023, it bought, sold, reinvested and transferred shares with the single largest purchase 731,833 shares for \$15,033,484 or \$20.54 a share.

[ATOMO DIAGNOSTICS](#)

GZ Family Holdings Pty Ltd says its 79,787,536 substantial share-holding in Atomo from 13.98 percent to 12.48 percent.

The Sydney-based GZ said it was diluted in the recent Atomo capital raising.

In August, Atomo said that its share plan at 3.0 cents a share raised \$1,000,00 taking the total raised with its placement to \$2,250,000 (BD: Aug 8, 2023.)

Atomo fell 0.3 cents or 11.5 percent to 2.3 cents.

[STARPHARMA](#)

M&G Investment says it has reduced its shareholding in Starpharma below the five percent substantial level.

Last year, M&G Investment said it held 23,619,915 Starpharma shares or 5.78 percent (BD: Oct 21, 2022).

Today, the London-based M&G Investment said that February 8 and October 12, 2023, it sold 3,187,725 shares for \$1,440,503 or an average of 45.2 cents a share.

Biotech Daily calculates that M&G Investment retains 20,432,190 shares or 4.98 percent of the company.