



Biotech Daily

Wednesday June 14, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: MICRO-X UP 9.5%; PHARMAXIS DOWN 11%**
- * **FIVEPHUSION PLANS Ib/IIa DEFLEXIFOL FOR CNS TUMOR TRIAL**
- * **CSL \$368m PROFIT WARNING**
- * **ATOMO \$2.1m EU HIV SELF-TEST SUPPLY AGREEMENT**
- * **STARPHARMA, ASTRAZENECA PHASE I/II AZD0466 'WELL-TOLERATED'**
- * **MICROBA \$526k OVERSEAS FEDERAL R&D TAX INCENTIVE FINDINGS**
- * **CLARITY: PETNET CU-64 SAR-BIS-PSMA SUPPLY FOR PHASE III TRIAL**
- * **FIL (FIDELITY) TAKES 10% OF IMMUTEP**
- * **EUROZ HARTLEYS TAKES 5.9% OF ARGENICA**
- * **JM FINANCIAL, NO PLAN B TAKE 11.4% OF IMEX**
- * **BIO-MELBOURNE 2nd MEDTECH SEMINAR: HEALTH PROCUREMENT**

MARKET REPORT

The Australian stock market was up 0.32 percent on Wednesday June 14, 2023, with the ASX200 up 22.8 points to 7,161.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 17 fell and six traded unchanged. All three Big Caps fell.

Micro-X was the best, up one cent or 9.5 percent to 11.5 cents, with 578,405 shares traded. Cyclopharm climbed 8.1 percent; Genetic Signatures was up 5.7 percent; Actinogen improved 4.35 percent; Atomo, Nova Eye and Telix were up more than three percent; Amplia, Compumedics, Dimerix and Medical Developments rose two percent or more; Immutep, Mesoblast, Neuren, Next Science and Proteomics were up one percent or more; with Paradigm up by 0.6 percent.

Pharmaxis led the falls, down 0.6 cents or 11.3 percent to 4.7 cents, with 144,534 shares traded. Universal Biosensors lost 10 percent; CSL fell 6.9 percent; Antisense and Emvision were down more than five percent; Clinuvel and Prescient fell more than four percent; Cynata was down 3.45 percent; Kazia, Opthea, Polynovo, Resonance, Starpharma and Volpara shed more than two percent; 4D Medical, Avita, Cochlear and Nanosonics were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

[FIVEPHUSION PTY LTD](#)

Fivephusion says it will conduct an up-to 34-patient dose-ranging, safety and efficacy phase Ib/IIa trial of its Deflexifol combination for gliomas and ependymoma.

Fivephusion executive director and former Pfizer and Actinogen executive Dr Bill Ketelbey told Biotech Daily that Deflexifol was a combination of the chemotherapy drugs 5-fluorouracil and its bi-modulator leucovorin, a drug that potentiates 5-fluorouracil anti-tumor activity, for the treatment of solid tumors.

“Deflexifol is a novel reformulation of 5-fluorouracil and leucovorin, with cyclodextrin, which for the first time, allows for the concurrent co-administration of these two pharmacologically incompatible anticancer drugs,” Dr Ketelbey said.

“This co-administration of 5-fluorouracil and leucovorin presents the real potential for significantly enhancing the anti-tumor effect of 5-fluorouracil, across a range of different cancers,” Dr Ketelbey said.

In a media release, the Sydney based Fivephusion said that ependymoma was “the third most common brain tumor in children” with no drugs approved for its treatment.

The company said that pre-clinical and clinical data showed “promising [5-fluorouracil] activity against ependymoma ... [but] until the development of Deflexifol, it has not been possible to co-administer therapeutically effective doses of [5-fluorouracil and leucovorin] in a safe and tolerable manner”.

Fivephusion said the up-to 24-patient part A study would determine the safety, tolerability, maximum tolerated dose and recommended dose in children with refractory or recurrent central nervous system tumors, or newly diagnosed diffuse intrinsic pontine glioma or diffuse midline glioma who had completed radiotherapy.

The company said up-to 10 patients in the part B study with refractory or recurrent ependymoma would be assessed for response rate, progression-free and overall survival. Fivephusion said the study was led by the Kids Cancer Centre and coordinated by the Sydney Children’s Hospital in Randwick, with support from the Cancer Institute New South Wales and run at paediatric oncology centres in Australia.

Fivephusion managing-director Dr Christian Toouli said the company was “very grateful of the generous charity funding support enabling the investigation of Deflexifol as a promising new treatment for paediatric brain cancer patients”.

The company said that it had completed a 19-patient, phase Ib/IIa, Deflexifol dose-ranging study “confirming the superior attributes of Deflexifol over standard-of-care chemotherapy formulations” in end-stage solid tumor patients.

Fivephusion said the study was designed to confirm the pharmaco-kinetics, safety, tolerability and maximum tolerated dose of Deflexifol as a monotherapy, administered as a bolus followed by 46-hour infusion, mimicking the standard-of-care regimen.

The company said the data confirmed the bioequivalence of 5-fluorouracil and leucovorin co-formulated in Deflexifol to standard-of-care individual formulations of the drugs, “positioning Deflexifol for expedited regulatory routes in major markets”.

Fivephusion said Deflexifol had a 69 percent disease control rate, and “stable disease in the majority of evaluable patients, with one patient achieving a partial response”.

The company said that prior to recruitment into the trial, patients had typically received and failed multiple rounds of prior chemotherapy, including 5-fluorouracil and leucovorin”.

Fivephusion said it had a collaboration with New York’s Treehill Partners advisory firm, and the Morrisville, North Carolina bio-pharmaceutical company Syneos Health.

“By collaborating with Treehill Partners and Syneos Health, we believe we are positioned to successfully bring our development work on Deflexifol to global markets, including in the US, Europe and Asia,” Dr Toouli said.

Fivephusion is a private company.

CSL

CSL says that due to foreign exchange rates it expects net profit after tax and amortization to be down \$US250 million (\$A368 million).

Last year, CSL said revenue for the year to June 30, 2022 was \$US10,562 million (\$A15,056 million) with net profit after tax of \$US2,255 million (\$A3,214 million).

Today, the company said it now expected a “foreign currency headwind” between \$US230 million and \$US250 compared to \$US175 million as anticipated in its half yearly results in February.

CSL said it expected net profit after tax and amortization for the year to June 30, 2024 to increase by 13-to-18 percent to \$US2.9 billion to \$US3 billion at constant currency.

CSL said net profit after tax and amortization for the year to June 30, 2023, was expected to decrease from the \$US2.7 billion to \$US2.8 billion range to between \$US2.55 billion and \$US2.8 billion.

CSL fell \$21.27 or 6.9 percent to \$287.25 with 2.3 million shares traded.

ATOMO DIAGNOSTICS

Atomo says it has a one-year, at-least \$2.1 million exclusive supply agreement with London’s Newfoundland Diagnostics for its HIV rapid self-test in Europe.

Atomo said the agreement followed a \$900,000 initial purchase order from Newfoundland in February this year, with a commitment for a follow-on order of about \$1.2 million by the end of 2023 (BD: Feb 28, 2023).

The company said the two purchases secured Newfoundland the exclusive agreement for next year, which could be extended for a further three years with “increasing indicative annual volumes already agreed ... for 2024 and 2025”.

Atomo chief executive officer John Kelly said the company expected “delivery of the first batch of Newfoundland branded HIV Self-Tests to Europe shortly”.

Atomo was up 0.1 cents or 3.7 percent to 2.8 cents.

STARPHARMA HOLDINGS

Starpharma says Astrazeneca presented data from its 26-patient phase I/II clinical trial of AZD0466 for acute myeloid leukaemia showing the treatment was “well-tolerated”.

In 2021, Starpharma said Astrazeneca intended to expand its AZD0466 program to a phase I trial for patients with acute leukaemia (BD: Feb 9, 2021).

Last year, the company said Astrazeneca data showed that AZD0466, “a highly optimised dendrimer nanoparticle formulation of an Astrazeneca drug” had no dose-limiting toxicities and was safe and well-tolerated (BD: Dec 13, 2022).

Today, Starpharma said a poster titled ‘Safety and Tolerability of AZD0466 as Monotherapy for Patients with Advanced Hematological Malignancies - Preliminary Results from an Ongoing Phase I/II Trial’ was presented at the European Hematology Association 2023 meeting June 8 to 11, 2023.

The poster concluded that AZD0466 was “well-tolerated in patients with [relapsed and/or refractory] acute leukaemia, with [adverse events] matching expected toxicity based on data from pre-clinical studies”, with modelling suggesting further dose escalation was warranted to explore clinical activity, as well as the safety and tolerability of AZD0466.

Starpharma said the study of AZD0466 for acute leukaemia was ongoing and continued to enrol patients, and that another parallel study of the drug for advanced non-Hodgkin lymphoma continued to recruit patients as well.

Starpharma fell one cents or 2.6 percent to 37 cents.

MICROBA LIFE SCIENCES

Microba says it expects to receive \$526,000 from offshore expenditure approved under the Federal Government Research and Development Tax Incentive program.

Microba said these two incentives from \$1,210,000 of eligible expenditure were in addition to findings approving up-to \$13,400,000 for last year.

The company said the rebate related to two overseas finding claims for research and development associated with its inflammatory bowel disease and immune-oncology programs for the financial years of 2023, 2024 and 2025.

Microba was up 0.5 cents or 1.8 percent to 28 cents.

CLARITY PHARMACEUTICALS

Clarity says Siemens Healthineers subsidiary Petnet Solutions will supply 64-copper SAR-bis-PSMA (prostate-specific membrane antigen) for prostate cancer imaging.

The company said Petnet would manufacture ready-to-use 64-copper SAR-bis-PSMA for its phase III trial, expected to begin in the US by the end of 2023.

Clarity executive chairman Dr Alan Taylor said previous trials of the 64-copper PSMA agent had “already shown increased uptake of the product into lesions compared to first-generation PSMA agents, as well as having more robust retention ... over time”.

“We are looking forward to commencing our registrational phase III trials with Petnet Solutions and elucidating the many benefits of 64-copper SAR-bis-PSMA to bring this next generation PSMA-PET [positron emission tomography] diagnostic to prostate cancer patients around the world,” Dr Taylor said.

Clarity was up four cents or 5.1 percent to 82 cents.

IMMUTEP

FIL Investment Management Ltd says it has increased its substantial shareholding in Immutep from 63,312,462 shares (7.14%) to 114,582,698 shares (10.05%).

The Sydney and Hong Kong-based FIL (Fidelity) said that between November 15, 2021 and June 8, 2023 it bought, sold and transitioned shares in more than 100 transactions at prices from 62.25 cents a share on November 15, 2021 to 24.42 cents a share on March 3, 2023.

FIL said that on June 8, 2023 it bought 43,801,675 shares at 26 cents a share.

Earlier this month, Immutep said its placement and rights offer at 26 cents a share raised \$50 million and \$17.9 million, respectively (BD: Jun 2, 2023).

Immutep was up 0.5 cents or 1.7 percent to 30 cents with 1.6 million shares traded.

ARGENICA THERAPEUTICS

Euroz Hartleys Ltd says it has become a substantial shareholder in Argenica with 5,814,891 shares, or 5.91 percent.

The Perth-based Euroz said that between March 23 and June 9, 2023 it bought 2,766,391 shares in seven transactions, with the single largest purchase 2,685,715 shares on June 9 for \$940,000, or 35 cents a share.

Argenica was up 0.5 cents or 1.35 percent to 37.5 cents.

IMEX HEALTH SYSTEMS

JM Financial Group Ltd and No Plan B Pty Ltd say they have increased their holding in Imex from 4,283,658 shares (10.37%) to 4,737,032 shares (11.43%).

The Melbourne-based JM and No Plan B said that between April 3, 2023 and May 26, 2023 they bought 479,130 shares in 12 transactions, with the single largest purchase 150,739 shares on April 28, 2023 for \$97,400, or 64.62 cents a share.

Imex was untraded at 50 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the second of four medical technology seminars is titled 'Supplying to Health: The Changing Nature of Health Procurement in Victoria'.

In March, the Bio-Melbourne Network said that with the Australian Medtech Manufacturing Centre it would host four seminars supporting the Victorian medical technology manufacturing sector (BD: Mar 14, 2023).

Today, the Network said that the Australian Medtech Manufacturing Centre was an initiative of the Victoria Government and the second of the four seminars on health procurement would discuss "the key drivers and barriers to increased local procurement".

The Bio-Melbourne Network said the seminar would include speakers from the Australian Medtech Manufacturing Centre, Healthshare Victoria, the Victorian Institute of Forensic Medicine, the Clayton-based orthotics and prosthetics provider OPC Health and August Consulting, who would discuss opportunities for local suppliers in the health system, sustainability and supply chain resilience.

The Network said the event would be at the Australian Centre for the Moving Image in Flinders Street, Melbourne, and online on June 21, 2023 from 4pm to 6:30pm, followed by networking.

For details and registration, go to: www.bit.ly/43DYqbQ.