



Biotech Daily

Thursday May 5, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMMUTEP UP 8%; ACTINOGEN DOWN 11%**
- * **IMMUTEP: 'IMP321 ENHANCES IMMUNE RESPONSE'**
- * **ARGENICA COMPLETES TOXICOLOGY STUDIES**
- * **MICROBA IDENTIFIES 3 DRUG CANDIDATES AHEAD OF SCHEDULE**
- * **BTC: FEDERAL REIMBURSEMENT 'UNCHANGED'**
- * **ANALYTICA RECEIVES \$269k FEDERAL R&D TAX INCENTIVE**
- * **AUDEARA PARTNERS WITH HEALTHIA, NEXTSENSE**
- * **UNIVERSAL BIOSENSORS: VIBURNUM FUNDS OPTIONS EGM**
- * **RICHMOND HILL TAKES 5% OF UNIVERSAL BIOSENSORS**
- * **ANATARA TO LOSE CEO STEVEN LYDEAMORE**
- * **POLYNOVO CEO SEARCH CONTINUES**
- * **ANITA JAMES REPLACES MEDICAL DEV CFO, CO SEC MARK EDWARDS**

MARKET REPORT

The Australian stock market was up 0.82 percent on Thursday May 5, 2022, with the ASX200 up 60.0 points to 7,364.7 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell and eight traded unchanged. All three Big Caps were up.

Immutep was the best, up 2.5 cents or 7.6 percent to 35.5 cents, with 1.6 million shares traded. Atomo, Imugene, Micro-X and Telix climbed five percent or more; Antisense, Impedimed, Patrys and Prescient improved more than four percent; Clinuvel, Genetic Signatures, Oncosil and Resmed were up more than three percent; Neuren and Proteomics rose more than two percent; Mesoblast, Pharmaxis and Pro Medicus were up one percent or more; with Avita, CSL, Cochlear, Paradigm and Starpharma up by less than one percent.

Actinogen led the falls, down 0.9 cents or 11.25 percent to 7.1 cents, with 4.8 million shares traded. Medical Developments and Resonance fell more than four percent; Universal Biosensors lost 3.4 percent; Alcidion, Emvision and Volpara shed more than two percent; Kazia, Nanosonics, Opthea and Polynovo were down one percent or more; with Cyclopharm down by 0.3 percent.

IMMUTEP

Immutep says data from its phase II trial of IMP321 and paclitaxel for metastatic breast cancer shows “statistically significant” biomarker responses linked to overall survival. Immutep said the data, presented at the European Society for Medical Oncology’s Breast Cancer Congress, showed that the IMP321, or eftilagimod alpha, or efiti, group saw statistically significant increases in innate and adaptive immune responses, including in monocyte ($p = 0.025$), activated CD8 T-cells ($p = 0.027$), and absolute lymphocyte counts. The company said the increase seen in the IMP321 group’s absolute lymphocyte count was significantly linked to improved overall survivability.

Last year, Immutep said that its 227-patient, randomized, blinded, phase II active immunotherapy paclitaxel with IMP321, or ‘Aipac’, trial for metastatic breast cancer showed a “non-significant survival benefit trend” (BD: Nov 10, 2021).

The company said at that time that 114 women with human epidermal receptor 2 (HER2) negative and hormone receptor (HR) positive metastatic breast cancer received IMP321, in combination with paclitaxel, while 113 women received placebo and paclitaxel.

Immutep said that at the May 14, 2021 data cut-off date, patients receiving IMP321 with paclitaxel had a median overall survival of 20.4 months compared to 17.5 months for control group patients, a benefit of 2.9 months ($p = 0.197$) and better quality of life.

Today, Immutep chief scientific officer Dr Frederic Triebel said “the biomarker analysis is highly valuable for two key reasons”.

“Firstly, the statistically significant difference in the immune response between the efiti and placebo patients confirms efiti is activating the immune system and helping patients live longer,” Dr Triebel said. “This is demonstrated by the increase in circulating monocytes, CD8 T-cells and a serum Th1 marker, CXCL10, plus the absolute lymphocyte count, and correlation of these improved immune parameters with overall survival.”

“Secondly, the early rise in [absolute lymphocyte count] in patients treated with efiti provides clinicians with a potential predictor of improved survival, helping them to determine early on if continued treatment with efiti is potentially beneficial,” Dr Triebel said.

“The exploratory analysis showing statistically significant improvements in [overall survival] in different patient subgroups is also very important as we work towards the optimal design of the planned registrational trial in breast cancer,” Dr Triebel said.

Dr Triebel said the data was consistent with the belief that efiti should be able to help of patients “including those who fail to respond to current immunotherapy options”.

Immutep was up 2.5 cents or 7.6 percent to 35.5 cents with 1.6 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has completed good laboratory practice (GLP) safety studies of ARG-007 for brain tissue death reduction, with no abnormal symptoms observed.

Argenica said the studies were a requirement for ethics permission for its proposed phase I trial of ARG-007, expected to begin later this year.

The company said the studies assessed the effects of ARG-007 on the central nervous and respiratory systems in rats, the cardiovascular system in non-human primates, and included doses within the therapeutic range and up to the maximum tolerated dose.

Argenica chief executive officer Dr Liz Dallimore said the company was “extremely encouraged by the results of these GLP safety pharmacology studies, which show that even at high doses of ARG-007, there were no abnormal effects seen”.

“This gives us great confidence as we prepare our ethics submission to gain approval for our upcoming phase I clinical trial,” Dr Dallimore said.

Argenica was up 2.5 cents or 5.7 percent to 46.5 cents.

MICROBA LIFE SCIENCES

Microba says it has identified three candidates for its immune-oncology program, and intends to begin pre-clinical animal studies by this year, 12 months ahead of schedule. Microba said it was targeting the discovery and development of a microbiome therapy to improve response rates in cancer patients receiving immune checkpoint inhibitor therapy, with a specific focus on melanoma and lung cancer patients.

Microba chief executive officer Dr Luke Reid the acceleration of the program was “really pleasing” because developing an effective adjuvant therapy for cancer patients receiving immune checkpoint inhibitors had the potential to affect outcomes for millions of patients. The company said its partnership with Sydney’s Garvan Institute of Medical Research, would collect data on “thousands of cancer patients over the coming years to establish a leading cancer microbiome dataset”, which was expected to broaden the number of cancers for which it could identify a clear microbiome signature.

Microba said the combination of the new leads and the partnership with Garvan would save more than \$US1 million on discovery activities which were scheduled to take place over the next 18 months.

Microba chief scientific officer Prof Lutz Krause said the company’s technology had uncovered therapeutic leads sooner than expected.

“We are excited to progress these into pre-clinical models and ultimately into human clinical trials pending the results,” Prof Krause said.

“This exemplifies the power of Microba’s data-driven therapeutic platform, which enables the rapid discovery and development of these novel monoclonal microbial therapies,” Prof Krause said.

Microba fell 2.5 cents or 6.7 percent to 35 cents.

BTC HEALTH

BTC Health says that current reimbursement levels applicable to the company’s Ambit infusion pumps will remain unchanged.

Last month, BTC said the Federal Department of Health’s reduction in Prosthesis List benefits was “potentially inconsistent with the agreed methodology” (BD: Apr 19, 2022).

Today, the company said the Federal Department of Health had confirmed that the proposed Protheses List benefit reductions scheduled from July 1, 2022 would not apply to its single use ambulatory drug delivery infusion devices and accessories.

BTC said that given the current reimbursement would remain unchanged, it expected no commercial impact.

BTC chair Dr Richard Treagus said the company was “very pleased that the [Department of Health] has agreed with our position and clarified this issue in our favor”.

“We are fully committed to working with the [Department of Health], hospital groups and healthcare providers to ensure that Australian patients continue to have ready access to these important medical products,” Dr Treagus said.

BTC was up 1.2 cents or 27.3 percent to 5.6 cents.

ANALYTICA

Analytica says it has received \$269,106 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Analytica said the rebate related to expenditure for the year to June 30, 2021.

Analytica was unchanged at 0.1 cents.

AUDEARA

Audeara says it has an indefinite seller agreement with Brisbane's Healthia Group and a partnership with the Sydney-based Nextsense.

Audeara said Healthia had stocked its products at five locations with the expectation that products would be available in more locations as audiology services were incorporated.

The company said that through Nextsense, its products would be available nationally and it would support Nextsense's initiatives to raise awareness of hearing health.

Audeara was up 2.5 cents or 7.6 percent to 35.5 cents with 1.6 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says shareholders will vote to issue 3,840,000 options to underwriter Viburnum Funds and one or more adjournments to pass the resolution.

In April, Universal Biosensors said it raised \$6 million in a placement at 77 cents a share and expected to raise \$20 million in an underwritten rights offer (BD: April 21, 2022).

Today, the company said it would seek shareholder approval to issue the underwriters, Viburnum Funds, 3,840,000 unquoted options, valued at \$680,000, with half exercisable at 92 cents and the remainder at \$1.00, within three years of issue.

Universal Biosensors said it would ask shareholders to approve "one or more adjournments of the meeting, if necessary, even if a quorum is present, to solicit additional [proxy votes] if there are not sufficient votes in favor of proposal 1".

The virtual meeting will be held on May 23, 2022, at 10am (AEST), available at:

<https://web.lumiagm.com/343806865>.

Universal Biosensors fell two cents or 3.4 percent to 57.5 cents with 1.2 million shares traded.

UNIVERSAL BIOSENSORS

Melbourne's Richmond Hill Capital says it has become a substantial shareholder in Universal Biosensors with 9,379,478 shares or 5.05 percent of the company.

Richmond Hill said that between January 4 and May 4, 2022, it bought 2,607,980 Chess depository instruments (CDIs) for \$1,684,427, or 64.6 cents a share.

ANATARA LIFESCIENCES

Anatara says chief executive officer Steven Lydeamore will resign, effective from June 26, 2022, with chair Dr David Brookes to be the interim executive chair.

Anatara said Mr Lydeamore was leaving to pursue "other business interests".

Dr Brookes said the company had "several important inflection points looming" ... [and it was] prudent to delay the recruitment process".

Dr Brookes thanked Mr Lydeamore "for his leadership and significant contribution to the company over the last three and a half years".

"During this time Anatara has faced major headwinds with the return of global rights to Detach followed by the Covid-19 pandemic," Dr Brookes said. "With limited resources, the Anatara team developed new formulations for piglets and poultry, both of which have been successful in proof-of-concept challenge studies."

Dr Brookes said that the company had changed its strategic focus to human health and completed development of the pineapple stem bromelain-based gastro-intestinal re-programming, or Garp technology, for irritable bowel syndrome.

Anatara was unchanged at 9.9 cents.

POLYNOVO

Polynovo says it has been unable to find a suitable replacement chief executive officer by March 31, 2021, as expected.

Polynovo said it was confident “that the appointment of an outstanding candidate can be made before the end of the current financial year”.

The company said it was considering several candidates for the role.

Polynovo fell one cent or 1.1 percent to 86.5 cents with 3.9 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Anita James will replace eight year chief financial officer and company secretary Mark Edwards effective from May 27, 2022.

Medical Developments said Ms James had been appointed effective from May 16, 2022.

The company said that Ms James was most recently Pact group’s general manager of finance and investor relations and previously worked for Orica (formerly Imperial Chemical Industries, Australia) for 15 years.

Medical Developments said Mr Edwards had been “a critical contributor to the development of the business”.

Medical Developments chief executive officer Brent MacGregor said that Mr Edwards “was hugely important as I took up my role”.

“The company appreciates his contribution ... and we wish him well for his future endeavors,” Mr MacGregor said.

Medical Developments fell 14 cents or 4.1 percent to \$3.31.