



Biotech Daily

Monday December 5, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 4%; GENETIC SIGS DOWN 11%**
- * **MAYNE PAYS THERAPEUTICS MD \$205m FOR WOMEN'S HEALTH PRODUCTS**
- * **INCANNEX 'COMMITMENTS' FOR \$13m PLACEMENT**
- * **CANN GROUP SHARE PLAN RAISES \$8.2m**
- * **IMUGENE CLAIMS MORE 'SIGNIFICANT' HER-VAXX SURVIVAL BENEFIT**
- * **S&P DEMOTES 4D, ALCIDION, COGSTATE FROM TECH INDEX**
- * **CYNATA RECEIVES \$1.65m FEDERAL R&D TAX INCENTIVE**
- * **IMUGENE STARTS 2nd I-V VAXINIA SOLID TUMOR COHORT**
- * **MERCHANT CALLS TO SPILL HEXIMA DIRECTORS, APPOINT CHRIS MEWS**
- * **CRONOS 'MILLIONTH MARIJUANA UNIT, RECORD \$10.7m MONTH REVENUE'**
- * **IMMURON FILES US FDA TRAVELAN E COLI TRIAL APPLICATION**
- * **NEUROSCIENTIFIC FILES EMTINB COMBINATION MS AUSTRALIAN PATENT**
- * **RACE APPOINTS EX-CANNACORD DANNY SHARP DIRECTOR**
- * **TELEX: GENEVIEVE RYAN CO SEC; RICHARD VALEIX, RAPHAEL ORTIZ**
- * **BOYSENHOLTZ, GENENIKA, MACROGEN, SA MICROBA DILUTED IN MICROBA**
- * **REGAL FUNDS BELOW 5% OF PHARMAXIS**
- * **BIO-MELBOURNE MEETING ON 'GOING GREEN'**

MARKET REPORT

The Australian stock market was up 0.33 percent on Monday December 5, 2022, with the ASX200 up 24.1 points to 7,325.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and five were untraded. All three Big Caps fell.

Universal Biosensors was the best, up one cent or 4.35 percent to 24 cents, with 144,708 shares traded. Alcidion, Mesoblast, Pharmaxis and Starpharma climbed more than three percent; Immutep rose 2.8 percent; Clinuvel and Opthea were up one percent or more; with Nanosonics, Paradigm and Pro Medicus up by less than one percent.

Genetic Signatures led the falls, down 10 cents or 11.2 percent to 79 cents, with 99,611 shares traded. Cynata lost 7.1 percent; Amplia fell 5.3 percent; Actinogen and Patrys shed more than four percent; Micro-X and Next Science were down more than three percent; Dimerix, Imugene, Neuren, Oncosil and Polynovo shed two percent or more; Atomo, Avita, Cochlear, Impedimed, Orthocell, Proteomics and Resmed were down more than one percent; with CSL, Medical Developments and Volpara down less than one percent.

MAYNE PHARMA

Mayne says it will pay the Boca Raton, Florida-based Therapeutics MD \$US140 million (\$A205 million) for three women's health products and a portfolio of pre-natal vitamins. Mayne said it would licence the health products Anovera, Imvexxy, Bijuva and the Bocagreenmd and Vitamedmd lines of prenatal vitamins, "including inventory and regulatory filings to support the operation and commercialization of the portfolio".

The company said that it would pay \$US140 million in cash, as well as potential sales-based milestone royalties and payments, including \$US5 million on reaching \$US100 million in net revenue, \$US10 million on reaching \$US200 million in net revenue and \$US15 million on reaching \$US300 million in net revenue, and a 20-year royalty term at eight percent of net revenue.

Mayne said that it would pay about \$US13.1 million for the "acquisition of net working capital, in exchange for inventory, accounts receivables and related liabilities, subject to certain adjustments".

Mayne said Anovera was a ring for birth control, Imvexxy were vaginal inserts for vaginal pain and Bijuva was a hormone therapy for menopause symptoms.

The company said it would fund the payment through existing cash and debt facilities and through a "binding commitment from Rubric Capital Management LP" for about \$US27.95 million in "an unsecured senior convertible note at a price equal to 90 percent of the face value".

Mayne chief executive officer Shawn O'Brien said the company was "pleased to add these highly complementary and patent protected women's health products to our portfolio".

"The products will be supported by our existing commercial capability across sales and marketing, customer service and medical affairs," Mr O'Brien said.

"Women's health is a core therapeutic area for the company and this deal enables Mayne Pharma to accelerate and extend its position in this specialty," Mr O'Brien said.

"We are very attracted by the underlying fundamentals of the contraceptive and menopause market and these products provide a solid foundation to creating a market leadership position in the US women's health market," Mr O'Brien said.

Mayne fell three cents or 12.5 percent to 21 cents with 28.7 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has "firm commitments" to raise \$13 million in a placement at 20.5 cents a share, a 10.9 percent discount to the last closing price of 23 cents.

Incannex said that for every share bought, it would issue one option, exercisable at 28.5 cents, by December 31, 2025, and, if fully exercised, the options would raise a further \$18.1 million.

The company said the placement was "undertaken by a small consortium of US and international investors with significant healthcare experience" and the funds would be used for research and development and general working capital.

Incannex managing-director Joel Latham said "we are delighted to welcome new institutional shareholders onto our share register after an approach to me directly from the consortium's cornerstone investor in September".

"The consortium has a long history of providing expertise and support to emerging healthcare companies focused on changing gears from research and development to drug registration and commercialization," Mr Latham said.

Incannex fell 2.5 cents or 10.9 percent to 20.5 cents with 20.5 million shares traded.

CANN GROUP

Cann Group says it has raised \$8.18 million in its share plan purchase plan at 22 cents a share, to expand its Mildura manufacturing capabilities.

In October, Cann Group said it hoped to raise \$8 million to \$10 million in a share purchase plan at 22 cents, an 18.8 percent discount to the five-day volume-weighted average price of its shares to October 24, 2022 (BD: Oct 25, 2022).

Today, the company said it had received applications from 1,254 shareholders, totaling \$8.18 million.

Cann Group chief executive officer Peter Crock said the funds would allow the company “to execute on important commercial projects and accelerate our path towards a positive cashflow position”.

“We are encouraged by the strong support of our shareholders,” Mr Crock said.

Cann Group was unchanged at 23.5 cents.

IMUGENE

Imugene says HER-Vaxx combined with chemotherapy shows “a statistically significant 42 percent overall survival benefit compared to chemotherapy alone”.

Imugene said that new interim data from 36 patients in its planned 68-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer showed that the median overall survival was a “statistically significant” showing 13.9 months for the combination group compared to 8.3 months for chemotherapy alone with a “one-sided p-value of 0.066”.

Biotech Daily understands that a one-sided p-value of 0.066 is equivalent to a two-sided p-value of 0.132.

The company said that the duration of response was longer in the HER-Vaxx and chemotherapy arm over chemotherapy alone of 30 weeks compared to 19 weeks, and that “vaccination with HER-Vaxx induced persistent HER-2 specific antibodies which correlated with clinical response as proof of concept for a first-in-class B-cell immunotherapy based on HER-2 peptides”.

Imugene said the research, titled ‘Herizon: A Phase 2 Study of HER-Vaxx (IMU-131), a HER2-targeting Peptide Vaccine, Plus Standard of Care Chemotherapy in Patients with HER2-Overexpressing Metastatic or Advanced Gastric/GEJ Adenocarcinoma - Overall Survival Analysis,’ was presented at the European Society for Medical Oncology conference in Singapore.

In November 2020, Imugene said an interim analysis of 27 patients in its 68-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer showed a “statistically significant” benefit (BD: Nov 23, 24, 2020).

Imugene said at that time, that in the trial being conducted in Eastern Europe and India, of the 13 patients in the chemotherapy-alone arm, eight had died, with four dead in the 14-patient arm receiving HER-Vaxx and chemotherapy

The company said that the independent data monitoring committee established a “hazard ratio” of 0.418 meaning that HER-Vaxx reduced the risk of death by 58.2 percent.

Imugene said that it specified a one-sided false positive probability of 0.10, and the interim analysis resulted in “a statistically significant one-sided p-value of 0.083”.

Imugene said the primary endpoint was overall survival, and the secondary endpoint was progression-free survival, with safety, tolerability and immune response to be measured.

The company said in 2020 that the median overall survival for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months for chemotherapy alone.

Imugene fell half a cent or 2.7 percent to 18 cents with 26.3 million shares traded.

STANDARD & POOR'S DOW JONES INDICES, 4D MEDICAL ALCIDION, COGSTATE

Standard & Poor's says Alcidion, Cogstate and 4D Medical will be removed from its ASX All Technology Index, effective from December 19, 2022.

Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

4D Medical was up 1.5 cents or 3.3 percent to 46.5 cents.

Alcidion was up half a cent or 3.1 percent to 16.5 cents with 1.5 million shares traded.

Cogstate fell three cents or 1.6 percent to \$1.815.

CYNATA THERAPEUTICS

Cynata says it has received \$1,654,310 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cynata said the rebate related to research and development expenditure for the year to June 30, 2022.

Cynata fell 2.5 cents or 7.1 percent to 32.5 cents.

IMUGENE

Imugene says it has dosed the first of up-to six patients in the second intra-venous cohort of its phase I trial of CF33-hNIS, or Vaxinia, for advanced solid tumors.

In May, Imugene said it dosed the first of up-to 100 patients, in its phase I trial of intra-tumoral and intra-venous Vaxinia and pembrolizumab for metastatic or advanced solid tumors (BD: May 18, 2022).

In October, the company said it had dosed the first patient in the second cohort of intra-tumoral dosing in the trial (BD: Oct 31, 2022).

In November, Imugene said the first cohort of intra-venous delivery had cleared, meaning that cohort two was open for administration (BD: Nov 11, 2022).

Today, Imugene said that the intra-tumoral arm continued to progress.

HEXIMA

Perth's Merchant Group has called for a meeting to remove Hexima directors Michael Aldrige, Jake Nunn and Scott Robertson and replace them with Chris Mews.

Hexima said that it had received a notice under Section 203D(2), 249D and 249P of the Corporations Act 2001 from investors holding more than five percent of the company and requesting the meeting to remove and appoint directors, but did not disclose from whom the notice was received.

Merchant Group managing-director Andrew Chapman told Biotech Daily that his company had filed the notices.

Mr Chapman said that Mr Mews was Merchant Group's chief financial officer and company secretary.

Last week, Merchant said it increased its Hexima holding to 18,000,000 shares (10.78%).

In June and July, Hexima fell on news that its phase II study of pezadeftide (HXP124) for onychomycosis was "inconclusive ... [and did] not support moving directly into a phase III program" and that it had begun the process of winding-up (BD: Jun 24; Jul 11, 2022).

According to Commsec, Hexima currently has six directors and one alternate director.

Hexima was unchanged at 1.6 cents.

CRONOS AUSTRALIA

Cronos says it has sold its one millionth unit of medical marijuana through the Canview platform, with November a \$10.7 million “record month” of unaudited revenue.

Cronos said the Canview marketplace platform was launched in June 2020 and had sold increasing numbers of units with “nearly 215,000 units” sold in the three months to September 30, 2022.

The company said it stocked “almost 200 product lines on the Canview platform from nearly 30 leading suppliers ... the majority of the medicinal cannabis products currently available in Australia”.

The company said it had \$10.7 million in unaudited revenue in November, with 86,190 products sold, and forecast that the three months to December 31, 2022 would be another “record quarter”.

Cronos chief executive officer Rodney Cocks said “with today’s sale of our one millionth unit of a medicinal cannabis product through our market leading Canview platform, Cronos Australia is very proud to recognize such a significant milestone in the company’s history”. “Importantly, given the continued growth of unit sales, we anticipate that the second million units should be sold through the platform before the end of 2023,” Mr Cocks said. “Based on the revenues generated in November, we remain confident of our earlier forecast that our total revenues for 2022-’23 will exceed \$100 million, up from \$67 million in 2021-’22,” Mr Cocks said. “Based on the unaudited November numbers, total revenues now annualize at nearly \$130 million and unit sales at more than one million.”

Cronos fell 1.5 cents or 2.2 percent to 66.5 cents.

IMMURON

Immuron says it has submitted an investigational new drug application to the US Food and Drug Administration for its Travelan for Escherichia coli, or E coli.

In October, Immuron said it had appointed the Baltimore, Maryland-based Pharmaron CPC Inc for a 60-patient, phase II trial of Travelan for diarrhoea (BD: Oct 4, 2022).

The company said the trial would be funded in part by the \$6.2 million award from the US Department of Defense for the development of a military dosing regimen of Travelan for diarrhoea (BD: Jan 16, 2022).

At that time, Immuron said the study would enrol up to 60 volunteers who would be randomly assigned to receive either a once-daily dose of 1,200mg of Travelan or placebo to evaluate the efficacy of a single dose regimen of Travelan in a controlled human infection model using the enterotoxigenic Escherichia coli strain H10407.

Today, Immuron said that it expected to begin the trial by July 2023, subject to FDA approval, with initial results expected by the end of 2023.

Immuron was up 0.6 cents or 7.5 percent to 8.6 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has filed a patent application to IP (intellectual property) Australia, for its combination of Emtinb and Copaxone for multiple sclerosis.

Neuroscientific said the patent, titled ‘Neuroprotective compositions and methods,’ would provide protection until November 24, 2042, if granted.

The company said the patent was based on an in-vitro study showing that co-treatment of Emtinb and Copaxone produced “all the inflammatory related in-vitro signals necessary to treat the disease of multiple sclerosis in a more effective way than Copaxone alone”.

Neuroscientific was up half a cent or 3.3 percent to 15.5 cents.

RACE ONCOLOGY

Race says it has appointed former Cannacord Genuity director Daniel Sharp as an independent non-executive director.

Race said Mr Sharp had more than 25 years of investment experience and had “a deep understanding of capital markets with an extensive network of institutional and private wealth investors”.

The company said Mr Sharp was most recently Canaccord Genuity corporate finance executive director, previously was an executive at Shaw and Partners and Lodge Partners and was currently a director of Alcidion and Botanix.

The company said that Mr Sharp held a Bachelor of Economics and a Bachelor Laws from Melbourne’s Monash University.

Race said that it would issue Mr Sharp 110,392 options, exercisable at \$3.32 each, within five years, subject to shareholder approval.

Race said it would issue director Mary Harney 110,392 options under the same terms, subject to shareholder approval.

Race fell one cent or 0.4 percent to \$2.33.

TELIX PHARMACEUTICALS

Telix says it has appointed Genevieve Ryan company secretary, with Richard Valeix chief commercial officer and Raphael Ortiz head of Europe, Middle East and Africa.

Telix said Mr Valeix had been its Europe, Middle East and Africa (EMEA) chief executive officer since May 2021 and had been appointed to the new position of chief commercial officer.

The company said that Mr Ortiz joined the company in January 2022 as EMEA chief operating officer had been promoted to EMEA chief executive officer.

Telix said Ms Ryan had been appointed company secretary, replacing Melanie Farris.

The company said that Ms Ryan had 17 years’ experience in legal and governance roles, most recently at Orora as general counsel and Australian Pharmaceutical Industries as senior legal counsel.

Telix said Ms Ryan held a Bachelor of Science and a Bachelor of Laws from Melbourne’s Monash University.

Telix was unchanged at \$7.40 with 760,506 shares traded.

MICROBA LIFE SCIENCES

In separate notices, Boysenholtz, Genenika, Macrogen and SA Microba say they have been diluted in Microba due to the issue of shares on December 1, 2022.

In November, Microba said Sydney’s Sonic Healthcare would pay \$17.8 million for a 19.99 percent holding, with a further five percent in options, worth \$7.5 million, subject to shareholder approval (BD: Nov 29, 2022).

The Brisbane-based Boysenholtz Pty Ltd, Philip Hugenhotlz and Penelope Boys said their 17,178,431 Microba shares had been diluted from 6.26 percent to 5.01 percent.

Brisbane’s Genenika Pty Ltd as trustee for the Tyson Trust, with Gene Tyson and Mikita Boase, said it had been diluted below five percent of Microba.

The Seoul, South Korea-based Macrogen Inc said its 17,828,431 Microba shares had been diluted from 6.50 percent to 5.20 percent.

The Adelaide-based SA Microba, with Richard Bund and Nicolaos Perdelis said its 31,524,277 Microba shares had been diluted from 11.49 percent to 9.19 percent.

Microba fell one cent or 3.3 percent to 29 cents.

PHARMAXIS

The Sydney-based Regal Funds Management says it has ceased its substantial holding in Pharmaxis.

Regal said that between October 27 and November 30, 2022 it sold shares, with the single largest sale on October 28 of 806,392 shares for \$50,641 or 6.3 cents a share. Pharmaxis was up 0.2 cents or 3.2 percent to 6.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says a meeting on Thursday will discuss why organizations are adopting environmentally responsible and sustainable practices.

The Network said that its 'Going Green: Environment and Sustainability in Life Sciences' event would be an opportunity to explore the drivers behind these changes and hear how the life sciences sector is "going green".

The Bio-Melbourne Network said that guest speakers included Deakin Research Innovations executive director Ross Mahon, Leica Biosystems marketing director for Asia Pacific Dr Ewa Douroux, Bio-Strategy executive Rick Filonzi and CSL executive Michael Starkey.

The Network said the event would be at Citadines on Bourke, 131-135 Bourke Street, Melbourne, and online on December 8, 2022 from 4pm to 5:30pm, followed by networking. For details and registration, go to: <https://bit.ly/3VyNyru>.