



Biotech Daily

Wednesday November 9, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: AVITA UP 9%; KAZIA DOWN 16%**
- * **VAXXAS STARTS PHASE I NEEDLE-FREE SARS-COV-2 VACCINE TRIAL**
- * **FIREBRICK RECEIVES \$1.1m FEDERAL R&D TAX INCENTIVE**
- * **IMPEDIMED \$1m ASTRAZENECA SOZO EXTENSION**
- * **GENETIC TECHNOLOGIES GENETYPE FOR OVARIAN CANCER RISK**
- * **IMMUTEP WINS JAPAN, SOUTH KOREA PATENT**
- * **BOTANIX OPENS \$3m SHARE PLAN**
- * **CRESO, SIERRA SAGE 'GREEN GOO' COSMETICS FOR CANADA**

MARKET REPORT

The Australian stock market was up 0.58 percent on Wednesday November 9, with the ASX200 up 40.4 points to 6,999.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded.

Avita was the best, up 14 cents or 8.9 percent to \$1.71, with 432,074 shares traded.

Alcidion climbed 6.9 percent; Actinogen and Micro-X both improved four percent; Nanosonics and Opthea were up more than three percent; Proteomics and Volpara rose more than two percent; Cyclopharm, Pharmaxis and Starpharma were up one percent or more; with Cochlear, Medical Developments, Neuren and Resmed up by less than one percent.

Kazia led the falls, down two cents or 16 percent to 10.5 cents, with 1.3 million shares traded.

Emvision lost 12.7 percent; Universal Biosensors fell 7.7 percent; Patrys was down five percent; Antisense and Resonance fell more than four percent; Genetic Signatures, Immutep, Orthocell and Prescient were down more than three percent; Impedimed and Next Science shed more than two percent; Mesoblast, Polynovo and Telix were down one percent or more; with Clinuvel, CSL and Pro Medicus down by less than one percent.

[VAXXAS PTY LTD](#)

Vaxxas says it has begun a 44-adult, phase I safety and tolerability trial of needle-free delivery of a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccine. Vaxxas said the phase I trial of the vaccine patch at the University of the Sunshine Coast would “assess the safety, tolerability, and immunogenicity of the Covid-19 vaccine candidate in 44 healthy adults, aged 18 to 50 years inclusive who have had three doses of an authorized Covid-19 vaccine, with the last dose received at least four months prior to participating in the study.

The company that in addition to demonstrating the safety of the vaccine candidate, the trial would also gather signals related to antibody and T-cell responses to dosing with the patch-delivered vaccine candidate.

Vaxxas said the trial was “a milestone” in its process of seeking Australian Therapeutic Goods Administration and US Food and Drug Administration approval for a Covid-19 vaccine patch.

The company said the vaccine candidate was a modified second-generation version of the spike protein used in the major US-approved Covid-19 vaccines which had been developed by the University of Texas at Austin, and was being administered through the Vaxxas high-density microarray patch (HD-MAP).

Vaxxas chief executive officer David Hoey said “It is important to note that this is our first-in-human trial of the Covid-19 vaccine patch”.

“We are starting at a very low dose with no adjuvants which we know are used regularly with vaccines to stimulate a greater immune response,” Mr Hoey said.

“As such, the primary endpoint is safety,” Mr Hoey said.

“If the vaccine proves safe, we have a lot of flexibility to increase the dose or supplement the vaccine with an industry-standard adjuvant or even mRNA delivery on the patch in future trials if we need or wish to drive an even greater immune response than what we see in the phase I trial,” Mr Hoey said.

“Vaxxas’ HD-MAP technology can potentially enable cost-effective distribution without the need for extensive refrigeration and our vaccination patch offers the potential for self-administration,” Mr Hoey said.

“This may enable an accelerated response in a pandemic situation and broader population coverage,” Mr Hoey said.

In July, the University of Queensland said that a research study in mice tested the Hexapro Sars-Cov-2 spike vaccine using Vaxxas’ high-density microarray patch (HD-MAP) technology and found the patch was far more effective at neutralizing variants, such as Omicron and Delta (BD: Jul 29, 2022).

In 2020, Vaxxas said the US government would pay \$US22 million (\$A30.6 million) through the Biomedical Advanced Research and Development Authority (BARDA) to test its “needle-free” vaccine technology for pandemic influenza (BD: Oct 6, 2020).

Today, the company said it expected the results from the phase I, Sars-Cov-2 high-density microarray patch by May 2023.

Vaxxas is a private company

[FIREBRICK PHARMA](#)

Firebrick says it has received \$1,081,266 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

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

Firebrick was up two cents or 8.2 percent to 26.5 cents.

IMPEDIMED

Impedimed says Astrazeneca has extended by eight months its contract to use the Sozo bioimpedance fluid volume system in a phase IIb chronic kidney disease trial.

In March, Impedimed said Astrazeneca had extended the trial by a further three months (BD: Mar 18, 2022).

Today, Impedimed said it would earn a further \$1 million from the extended contract to use 210 Sozo machines, bringing the total revenue from Astrazeneca to more than \$6.7 million.

The company said that between the separate Astrazeneca heart failure and kidney disease trial and the second chronic kidney disease trial, a combined 434 Sozo devices had been leased across 28 countries by Astrazeneca.

Impedimed fell 0.2 cents or 2.2 percent to nine cents with 2.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says a 10-year, 190,000 subject study shows that its Genetype ovarian cancer test “significantly improves” disease risk identification.

In 2019, Genetic Technologies said it would supply Genetype for breast cancer testing, with sales to begin by April 2020, claiming Genetype was “the world first genomic test to accurately predict risk of disease by combining the information contained in your DNA with family history and mammography data” (Dec 10, 2019).

Today, the company said the ovarian cancer test “significantly improves the identification of 10-year and lifetime risk in the general population of women who would normally be considered ‘average risk’” and was able to identify women in the top 20 percent who fell into increased 10-year and full-lifetime risk categories.

Genetic Technologies said the test was similarly able to identify women at very low risk. The company said Genetype used a “combined polygenic and clinical risk score” to predict risk of ovarian cancer in women who would otherwise be considered as being at average risk.

Genetic Technologies said the research, titled ‘A combined clinical and genetic model for predicting risk of ovarian cancer’ was authored by its staff and was published in the European Journal of Cancer Prevention, with the full text at: <https://bit.ly/3DZv1NM>.

The article said that “women with a family history of ovarian cancer or a pathogenic or likely pathogenic gene variant are at high risk of the disease, but very few women have these risk factors”.

“We assessed whether a combined polygenic and clinical risk score could predict risk of ovarian cancer in population-based women who would otherwise be considered as being at average risk,” the research study said

The article concluded that “identification of women who are at high risk of ovarian cancer can allow healthcare providers and patients to engage in joint decision-making discussions around the risks and benefits of screening options or risk-reducing surgery”.

Genetic Technologies chief executive officer Simon Morriss said the validation study “underpins the importance of implementing Genetype ovarian cancer risk assessment test, enabling healthcare providers to early-identify high-risk women and engage them in joint decision-making discussions around the risks and benefits of screening options or risk-reducing surgery”.

Genetic Technologies was up 0.05 cents or 16.7 percent to 0.35 cents.

IMMUTEP

Immutep says the Japan Patent Office and South Korean Patent Office have granted patents relating to its immunotherapies for cancer and autoimmune disease.

Immutep said that the patents filed as divisional applications, were titled 'Combined Preparations for the Treatment of Cancer' and would protect its intellectual property until December 19, 2034.

The company said the divisional applications followed the grant of the Japan parent patent and corresponding patents in the US, Europe, China and Australia.

Immutep said that the patents protected its intellectual property relating to combination preparations comprising lead active immunotherapy candidate IMP321 or eftilagimod alpha (efti) and a chemotherapy agent which is oxaliplatin, carboplatin, or topotecan.

The company said that the combination type patent claims were written in multiple formats to maximize the scope of protection.

Immutep chief executive officer Marc Voigt said the patents were "notable because this family of patents protects a component of the triple combination therapy being evaluated in our INSIGHT-003 clinical trial" (BD: Aug 5, 2021).

Immutep fell one cent or 3.1 percent to 31 cents with 1.4 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says its share plan to raise up to \$3 million, at 6.3 cents a share, has opened.

In October, Botanix said Antares Capital had committed to a \$5 million placement and it would offer a non-underwritten share plan (BD: Oct 31, 2022).

Today, the company said the record date was October 28 and that the offer would close on November 23, 2022.

Botanix was unchanged at 6.2 cents.

CRESO PHARMA

Creso says its subsidiary Sierra Sage Herbs will sell its Green Goo plant-based cosmetic and skin-care product range on Amazon in Canada.

Creso said the announcement follows "an extensive product review and registration process with Health Canada".

Creso managing-director William Lay said "the introduction of the Green Goo range in Canada is a logical progression for Sierra Sage Herbs."

"The initial product launch is already yielding units experiencing pleasing revenue, with multiple stock keeping considerable demand," Mr Lay said.

"We anticipate that the pending launch on Amazon may underpin additional sales growth, while management continues to pursue ranging agreements with major retail groups across the country," Mr Lay said.

"The company looks forward to providing additional updates on sales growth and the introduction on its other ranges into the Canadian market," Mr Lay said.

Creso fell 0.1 cents or 3.7 percent to 2.6 cents with 13.6 million shares traded.