# Biotech Daily

Tuesday July 26, 2022

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: NEXT SCIENCE UP 24%; IMPEDIMED DOWN 12%**

*** SOMNOMED RECEIPTS UP 20% TO $71m**

*** NEXT SCIENCE H1 RECEIPTS DOWN 10% TO $6m**

*** MAYNE, MITHRA NEXTSTELLIS CONTRACEPTIVE IN AUSTRALIA**

*** PAINCHEK BEGINS PILOT PAIN PROGRAM IN WALES**

*** IMMURON: US FDA WANTS 'MORE TRAVELAN TRIAL INFORMATION'**

*** GENETIC SIGNATURES ENTERIC PROTOZOAN TRIAL RECRUITED**

*** INOVIQ: SUB-B2M '91% SENSITIVE' FOR CANCER, IN VITRO**

*** KORDA MENTHA: PALLA PHARMA TO DELIST ON AUGUST 2**

*** IMPEDIMED LOSES M-D RICHARD CARREON; DAVID ANDERSON INTERIM**

*** HERAMED APPOINTS ANOUSHKA GUNGADIN PARTNERSHIPS DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.26 percent on Tuesday July 26, 2022, with the ASX200 up 17.4 points to 6,807.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 19 fell, three traded unchanged and three were untraded.

Next Science was the best, up 19 cents or 23.75 percent to 99 cents, with 256,668 shares traded. Nanosonics climbed 6.6 percent; Telix was up 5.8 percent; Imugene and Patrys improved more than four percent; Dimerix, Neuren and Pharmaxis were up more than three percent; Antisense and Paradigm rose more than two percent; Clinuvel, Cochlear, Cyclopharm, Proteomics and Resmed were up one percent or more; with Emvision and Opthea up by less than one percent.

Impedimed led the falls, down 0.7 cents or 12.3 percent to five cents, with 31.2 million shares traded. Universal Biosensors lost 9.9 percent; Volpara shed 6.15 percent; Actinogen fell five percent; Avita, Cynata and Medical Developments fell more than four percent; Alcidion, Atomo, Mesoblast, Micro-X and Oncosil lost three percent or more; Compumedics, Genetic Signatures and Polynovo shed more than two percent; CSL, Immutep, Kazia and Starpharma were down one percent or more; with Pro Medicus down by 0.3 percent.

## SOMNOMED

Somnomed says receipts from customers for the year to June 30, 2022 was up 19.7 percent to $71,470,000 compared to the previous corresponding period.
Somnomed said that receipts from customers for its treatments for sleep-related breathing disorders and obstructive sleep apnoea for the three months to June 30, 2021 was up 27.8 percent to $19,831,000.
The company said it was $3,316,000 cashflow positive for the three months to June 30, with cash equivalents of $15,664,000 at June 30, 2022.
Somnomed was up 15 cents or 12.5 percent to $1.35.

## NEXT SCIENCE

Next Science says customer receipts for the six months to June 30, 2022 fell 9.8 percent to $US4,186,000 ($A6,007,000) compared to the prior corresponding period.
Next Science said that receipts from customers from the sales of its wound care products Xperience, Bactisure, Surgx, Blastx and for the three months to June 30, 2022 were up 72.2 percent to $US2,220,000 compared to the previous corresponding period.
The company said it had cash burn of $US3,516,000 for the three months to June 30, 2022, with cash and equivalents of $11,063,000, and 3.1 quarters of funding.
Next Science was up 19 cents or 23.75 percent to 99 cents.

## MAYNE PHARMA

Mayne Pharma says its Nextstellis oral contraceptive, developed in partnership with the Liege, Belgium-based Mithra, is available in Australia.
In November, Mayne said the Australian Therapeutic Goods Administration had approved Mithra Pharmaceuticals' Nextstellis combination oral contraceptive (BD: Nov 29, 2021).
Mayne said Nextstellis was the first contraceptive pill containing the "low impact" oestrogen, oestetrol, and a progestin, drospirenone.
Mayne Pharma fell 0.5 cents or 1.45 percent to 34 cents with 3.7 million shares traded.

## PAINCHEK

Painchek says the Gwent Regional Partnership Board will fund a 12-month pilot program of its pain assessment system in residential, nursing and palliative care homes.
Painchek did not disclose the amount of funding but said it was not material.
In a November 2021 presentation, the company quoted prices of $38 and $50 per bed for its pain assessment system.
The company said that phase one of the pilot program would involve an initial deployment of the Painchek facial recognition pain assessment software in the Pontypool-based Gwent Region of South East Wales, and encompass 1,000 beds in the residential aged care sector.
Painchek said the second phase would see the pain assessment system expanded to hospices, hospitals and palliative care facilities.
Painchek chief executive officer Philip Daffas told Biotech Daily that if the successful, the pilot program could lead to gaining a share of the 30,000 aged care beds and 20,000 hospital beds throughout the Principality of Wales.
Painchek senior business development manager Sandeep Gill said the agreement to fund the pilot was "the first step in rolling-out Painchek across Wales".
Painchek was up 0.8 cents or 28.6 percent to 3.6 cents with 2.1 million shares traded.

## IMMURON

Immuron says the US Food and Drug Administration says its investigational new drug application for a Travelan trial “does not contain sufficient information”.
In May, Immuron said that the US Naval Medical Research Centre (NMRC) had applied for two 30-volunteer trials of Travelan for campylobacteriosis and enterotoxigenic Escherichia coli-induced diarrhoea (BD: May 11, 2022).
Today, the company said the NMRC had “received feedback” from the FDA that the investigational new drug application did “not contain sufficient information … to assess the risk to subjects in the proposed clinical studies”.
Immuron said the FDA had placed the application on clinical hold until it had received and reviewed a response “justifying dosing, safety monitoring and a risk mitigation plan”.
The company said that the NMRC previously filed and had applications approved by the FDA on similar colostrum-based products without being requested for supporting pharmacology-toxicology data.
Immuron said the Centre was addressing the clinical hold comments and would seek a meeting with the FDA, expected 30 days from receipt of the NMRC meeting request.
Immuron fell 0.4 cents or 4.35 percent to 8.8 cents.

## GENETIC SIGNATURES

Genetic Signatures says it has completed recruitment for its 1,500-sample, three-site trial of its 3-Base Easyscreen enteric protozoan diagnostic kit.
Genetic Signatures said the trial was “an essential step to support an application to the US Food and Drug Administration with a 510(k)-application planned [by the end of] 2022” with the FDA expected to review the submission within 90 days.
Genetic Signatures chief executive Dr John Melki said “after facing considerable recruitment delays due to the Covid-19 pandemic, we are very pleased to have achieved this significant milestone”.
“The US is a significant opportunity for our enteric protozoan kit with an estimated total addressable market of 5.5 million tests per annum,” Dr Melki said. “We are targeting to gain 40 percent of the market within five years while also providing the introduction for utilization of our other 3-Base Easyscreen molecular diagnostic kits.”
Genetic Signatures fell three cents or 2.65 percent to $1.10.

## INOVIQ

Inoviq says its Sub-B2M antibodies detected melanoma with 91 percent sensitivity and discriminated between malignant melanoma and benign skin lesions, in vitro.
Inoviq said that in a study of 144 tissue samples, of which 13 were normal, 17 benign, 92 malignant and 22 metastatic, Sub-B2M staining scores were significantly greater in malignant ($p < 0.003$) and metastatic ($p < 0.03$) samples, compared to benign skin lesions.
The company said that cells staining positive for Sub-B2M approached 100 percent in malignant and metastatic tissues.
Inoviq said the study confirmed the presence of Sub-B2M’s binding target, Neu5Gc, in tissue sections including breast, prostate, cervical, ovarian, colorectal and skin, which it said supported its program to develop tests to monitor breast, ovarian, and other cancers.
Inoviq chief executive officer Dr Leearne Hinch said that completing the Sub-B2M immune-histo-chemistry feasibility study, the company would seek interest from diagnostic companies and pathology laboratories to sublicense Sub-B2M for tissue-based tests.
Inoviq was up one cent or 1.5 percent to 67 cents.

## PALLA PHARMA

Korda Mentha as liquidators of the Palla Pharma says the company will be removed for the ASX Official List at the close of trading on August 2, 2022.
In March, Korda Mentha said the second meeting of creditors resolved to wind-up Palla Pharma and the administrators "do not anticipate a return to shareholders" following the liquidation of the company (BD: Mar 9, 2022).
Today, the company formally applied to the ASX requesting the removal from the ASX official list and received in-principle advice from the ASX that it "proposes to remove the company from the official list at the close of trading on August 2, 2022".
Palla Pharma was in a suspension and last traded at 29.5 cents.

## IMPEDIMED

Impedimed says 10-year chief executive officer and managing-director Richard Carreon has resigned, effective from July 26, 2022.
Impedimed said that director David Anderson would be interim chief executive officer until a replacement was found.
The company said that most recently, Mr Anderson served for nine years as chief executive officer of Healthnow New York.
Mr Carreon was appointed Impedimed chief executive officer in 2012, and managing-director in 2015 (BD: Jun 12, 2012; May 11, 2015)
Impedimed chair Donald Williams said "Mr Carreon led the company through a very transformative time over the past 10 years, achieving tremendous success in gaining regulatory clearance for Sozo, initiating commercialization of Impedimed's technology and setting the company on a path for future success."
"The entire Impedimed team thanks him for his contributions and wishes him the best," Mr Anderson said.
Biotech Daily also wishes Mr Carreon all the best after a decade in a most challenging job.
Impedimed fell 0.7 cents or 12.3 percent to five cents with 31.2 million shares traded.

## HERAMED

Heramed has appointed Anoushka Gungadin as its director of strategic partnerships for Australian and New Zealand.
Heramed said that Ms Gungadin was currently on the Deakin University Council and the boards of Imageryworks, Anglo African Investment and Getmee.ai, and previously was the founding chief executive officer of the Australia-India Chamber of Commerce.
Heramed said Ms Gungadin held a Bachelor of Science from the University of Mauritius and a Master of Business Administration from Melbourne Business School.
Heramed was unchanged at 13.5 cents.