# Biotech Daily

Wednesday November 7, 2018

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: OPTISCAN UP 9%; BENITEC DOWN 9%**

*** RESMED PAYS $1b FOR MATRIXCARE SOFTWARE.**

*** FDA OKAY FOR OPTISCAN, CARL ZEISS CONVIVO MICROSCOPE**

*** BIOTECH DAILY 13th BIRTHDAY EDITORIAL**

*** SOUTH KOREA APPROVES NUHEARA IQBUDS, IQBUDS BOOST**

*** EUROPE ALLOWS CYNATA MSC PATENT**

*** US, EU PATENTS FOR CELLMID'S MIDKINE N-DOMAIN**

*** BOTANIX TREATS 1st BTX1308 PSORIASIS PATIENT.**

*** INVION IVX-P02 ANTI-CANCER GEL, PRE-CLINICAL STUDIES PARTNERS**

*** PARADIGM NEW 20-PATIENT DATA BACKS OSTEOARTHRITIS PAIN REDUCTION**

*** ZELDA TO RELEASE 224m SHARES, 40m OPTIONS FROM ASX ESCROW**

*** SUDA REQUESTS 'LICENCE AGREEMENT NEGOTIATIONS' TRADING HALT**

*** BARD1 REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** MGC EXTENDS 'CANNAGLOBAL, MGC DERMA SALE' SUSPENSION**

*** POLYNOVO TO LOSE CO SEC GREG LEWIS; CFO, CO SEC WANTED**

## MARKET REPORT

The Australian stock market was up 0.37 percent on Wednesday November 7, 2018 with the ASX200 up 21.7 points to 5,896.9 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and four were untraded.

Optiscan was the best, up half a cent or 9.1 percent to six cents, with 353,920 shares traded. Compumedics climbed 7.9 percent; Imugene and Oncosil improved five percent or more; Paradigm and Prana were up more than four percent; LBT, Mesoblast and Uscom were up more than three percent; Clinuvel, Cynata, Starpharma and Volpara rose more than two percent; Factor and Pro Medicus were up more than one percent; with CSL, Opthea and Polynovo up by less than one percent.

Benitec led the falls, down 1.5 cents or 8.8 percent to 15.5 cents, with 203,260 shares traded. Impedimed lost 8.3 percent; Airxpanders and Genetic Signatures fell more than four percent; Dimerix, Osprey and Osprey were down three percent or more; Immutep and Orthocell shed more than two percent; Avita and Pharmaxis were down more than one percent; with Cochlear and Resmed down by less than one percent.

## RESMED

Resmed says it will pay $US750 million ($A1,036.2 million) to acquire the Bloomington, Minnesota-based Matrixcare for its long-term, post-acute care software.
Resmed said the acquisition of the privately-owned Matrixcare would expand its out-of-hospital software portfolio into skilled nursing and senior living.
The company said that Matrixcare served “more than 15,000 providers across skilled nursing, life plan communities, senior living and private duty”.
Resmed said the acquisition was complementary to its software-as-a-service for home medical equipment, home health and hospice, delivered through Brightree and Healthcarefirst.
The company said that Matrixcare’s electronic health record system supported “a wide range of long-term care [alternatives], enabling providers to increase patient management efficiencies and deliver superior clinical care” with point of care, lead and referral management, claims processing, payroll and nutrition management, among others.
Resmed chief executive officer Mick Farrell said the acquisition was “an excellent addition to the out-of-hospital software portfolio that we can offer our healthcare provider customers”.
“Resmed is the world’s leading tech-driven medical device company and is well positioned to be the leading out-of-hospital software provider in the market,” Mr Farrell said.
The company said that for the year to date, Matrixcare had pro-forma net revenue of about $US122 million, with earnings before interest, taxation, depreciation and amortization (Ebitda) of about $US30 million, and the $US750 million purchase price was a valuation multiple of 25 times the expected 2018 Ebitda of $US30 million.
Resmed said the transaction was expected to close by the end of 2018, subject to customary closing conditions and any applicable regulatory approvals.
Resmed fell nine cents or 0.6 percent to $14.45 with 1.45 million shares traded.

## OPTISCAN IMAGING

Optiscan says that Carl Zeiss Meditec AG has achieved US Food and Drug Administration clearance for the co-developed Convivo confocal microscope.
Optiscan said that Carl Zeiss would progress “as planned with full commercialization of [the] Convivo” microscope.
Last year, the company said the Jena, Germany-based Carl Zeiss Meditec formally unveiled its in-vivo Convivo “digital biopsy” microscope in Boston (BD: Oct 10, 2017).
Optiscan said at that time that the Convivo unit was “a major medical breakthrough that will positively affect thousands of patients around the world”.
The company said that with US Food and Drug Administration approval expected in early 2018, Convivo was validation of years of Optiscan development.
Optiscan said that the Convivo system could allow neurosurgeons to perform a digital biopsy without the need for tissue extraction, with the microscope enabling real-time visualization of tissue microstructure, and allowing for checking a virtually unlimited number of samples throughout the operation.
The company said that the Convivo system could transfer and analyze digital images anytime and anywhere.
Optiscan was up half a cent or 9.1 percent to six cents.

## BIOTECH DAILY 13th BIRTHDAY EDITORIAL

Biotech Daily is 13 years old today.

We have never missed a single important news story in all this time and never missed an edition. That makes about 3,185 editions and about 30,000 articles.

In the Jewish tradition, 13 years is the bar-mitzvah, or coming of age, and in many ways this year feels like the we have grown up with the sector.

In 2005, there were very few biotechnology companies with technologies approved and product in the market. The Biotech Daily Top 40 Index (BDI-40) primarily comprised companies at a later stage of development: phase II, phase III or pivotal trials, with just six making their first early sales.

Today, all but four companies in the Biotech Daily Top 20 Index have product returning revenue and nine of the Second 20 do, as well. Some are even profitable.

And we have grown from just under 100 ASX-listed companies to more than 130, partly a mix of the ASX looking for off-shore business, as well as people jumping onto the medical marijuana bandwagon.

Biotech Daily has expanded, with Tim Boreham contributing the weekly Crucible and the employment of assistant editors to help with the workload (not to be confused with those pesky sub-editors, who really are only kept for sacking when errors occur).

As always, we are deeply indebted to our founding subscribers who took the gamble that we would deliver daily hard news on the sector, and very grateful to everyone who has come along for the ride since.

Without you, we would not be here.

**David Langsam**
**Editor**

## NUHEARA

Nuheara says it has product certifications for its Iqbuds and Iqbuds Boost sound filter and hearing devices to be sold in the Republic of Korea.
Nuheara said the products had certification for battery compliance from the Korea Testing and Research Institute, as well as the Certificate of Broadcasting and Communications Equipment from National Radio Research Agency.
The company said it had appointed Sam Audio as the first non-exclusive distributor in South Korea.
Nuheara chief executive officer Justin Miller said the company was “delighted that Nuheara has secured entry to the South Korean market”.
The company said that its primary Asian country focus included Japan, Singapore, Hong Kong, Vietnam and South Korea
Nuheara fell 0.1 cents or 1.6 percent to six cents with 1.1 million shares traded.

## CYNATA THERAPEUTICS

Cynata says it the European Patent Office has allowed a patent covering its Cymerus mesenchymal stem cell (MSC) technology.

Cynata said the patent application, titled 'Methods and materials for hematoendothelial differentiation of human pluripotent stem cells under defined conditions' and would provide coverage until March 12, 2034.

The company said the patent was owned by the University of Wisconsin Madison's Wisconsin Alumni Research Foundation and was among the intellectual property licenced exclusively to Cynata.

Cynata chief executive officer Dr Ross Macdonald said the Cymerus therapeutic stem cell platform technology "enables the economic production of commercial quantities of high-quality MSCs sourced from just one donor".

"The excellent efficacy and safety results of our phase I clinical trial using Cymerus MSCs for the treatment of patients with steroid-resistant acute graft-versus-host disease validate the therapeutic potential of our proprietary platform," Dr Macdonald said.

The company said that the inventors named on the patent were Dr Gene Uenishi and Prof Igor Slukvin and Prof Slukvin was a Cynata founder, advisor and shareholder.

Cynata said it expected the patent to be granted by late February 2019.

Cynata was up 2.5 cents or 2.2 percent to $1.165.

## CELLMID

Cellmid says the US has granted and Europe intends to grant a patent covering the composition of antibodies and use relating to its midkine protein technology.

Cellmid said the US Patent and Trademark Office had granted, and the European Patent Office intended to grant, its Lyramid wholly-owned subsidiary a patent, titled 'Antibody recognizing N-domain of midkine' both providing coverage until December 23, 2032.

The company said the patent family protected "the composition of antibodies that recognize regions within the N-domain of midkine protein, as well as their use in several disease settings including cancer, inflammatory and autoimmune conditions".

Cellmid said that the N-domain patent family complemented the granted Australian, US and European patents titled 'Antibody recognizing C-domain of midkine' covering the murine monoclonal antibody IP14 and with the patent application 'Improved midkine antibody' for CAB102, the humanized form of IP14, which was under examination, the patents provided "comprehensive protection for [its] antibody assets".

The company said the newly granted midkine antibody patents and allied patent families underpinned its "dominant intellectual property position over the use of therapeutic midkine antibodies for the treatment of diseases arising from cancer, chronic inflammation, surgical adhesions and functional disorders in T-regulatory cells associated with autoimmune diseases".

Cellmid said it had also filed two new provisional patent applications for Lyramid's N-domain antibodies, the first covering accelerated bone healing following fractures, and the second for the treatment of chronic inflammatory heart failure, or myocarditis.

The company said its patent portfolio comprised 60 patents and applications in 13 patent families, including patents covering the use of midkine and anti-midkine agents for therapeutic purposes in a number of diseases such as cancer, inflammatory conditions and autoimmune diseases, and it held patents covering the use of midkine as a diagnostic marker in cancer and other disorders, which could be leveraged as a companion diagnostic, potentially accelerating clinical development.

Cellmid was up 1.5 cents or 4.6 percent to 34 cents.

## BOTANIX PHARMACEUTICALS

Botanix says it has treated the first of 15 patients in its phase Ib trial of its synthetic cannabidiol BTX1308 for psoriasis.

Botanix said the study was being conducted with the Hamburg, Germany-based Bioskin GmbH and an Australian dermatology clinic.

The company said the study was designed to assess the safety and efficacy of BTX1308 on psoriasis plaques or lesions, with the ability to compare multiple formulations and test products at the same time, and on the same patient.

Botanix executive director Matt Callahan said the company was “pleased to have enrolled and treated our first patient in the BTX1308 psoriasis study”.

“The unique design of this patient study, which allows us to compare multiple drugs in the same patient at the same time, means that the treatment duration can be shortened, while the quality of data can also be enhanced,” Mr Callahan said.

Botanix said the study would test BTX1308 against a vehicle and an active comparator in 15 patients at a single study site in Australia, with data expected by April 2019.

Botanix was up 0.2 cents or 2.3 percent to 8.8 cents.

## INVION

Invion says it has partnered with two companies to formulate and test a gel version of its photo-sensitizer product IVX-P02 as a photodynamic therapy gel for skin cancers.

Invion said it had engaged Melbourne’s Formulytica Pty Ltd to develop a topical formulation of IVX-P02 gel.

The company said that an injectable IVX-P02 was planned for testing in solid cancers such as ovarian, prostate and lung cancer.

Invion said that Melbourne’s Vivopharm would undertake pre-clinical studies of the IVX-P02 gel and the pre-clinical trials would form a significant part of the data package for regulators.

The company said that IVX-P02 was an improved version of its Photosoft technology, being developed for cancer, with human clinical trials expected to begin in 2019

Invion said it expected IVX-P02 gel would be more powerful than currently available topical therapies used to treat skin cancer and could offer skin cancer patients a new treatment option.

The company said that IVX-P02 gel would be applied to a patient’s skin and a medical light source would deliver light to the target area and activate the photo-sensitizing agent.

Invion said that based on pre-clinical studies to date, it was expected that the reaction of visible light and oxygen with the IVX-P02 gel would kill the cancer cells on the patient, leaving surrounding normal cells unharmed and the company had begun the Australian approval process for the light source equipment.

Invion chief executive officer Dr Greg Collier said the collaborations would “enable the Photosoft technology to become a clinical reality and provide new treatments for patients”.

“We have assembled a team of highly regarded experts to advance the formulation development and move quickly into pre-clinical and subsequently human clinical trials in 2019,” Dr Collier said.

“Invion’s IVX-P02 gel has the potential to provide even greater efficacy than current treatments, based on the results recently seen in in-vitro testing of IVX-P02 in ovarian cancer,” Dr Collier said.

Invion was up 0.2 cents or 8.7 percent to 2.5 cents.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says data on a further 20 osteoarthritis patients treated with its injectable pentosan polysulfate sodium have further reduced average pain scores.
Paradigm said the patients, treated under the Australian Therapeutic Goods Administration special access scheme, supported the continued reduction in average knee pain with the total average reduction for the 145 patients down 51.2 percent.
The company has previously released data showing pain reductions of 50.3 percent in the first 75 patients, 52.9 percent in 100 patients and 51.5 percent in 125 patients.
Paradigm said that of the 145 patients that had treated there were no serious adverse events, further validating the well-established safety profile of injectable pentosan polysulfate sodium.
The company said that the patients were treated under a similar dosing regimen as its 110-patient phase IIb randomized, double-blind, placebo-controlled, clinical trial of injectable pentosan polysulfate sodium for osteoarthritis.
Paradigm said the results were expected by the end of 2018.
Paradigm was up 4.5 cents or 4.7 percent to $1.00.

## ZELDA THERAPEUTICS

Zelda says that 224,374,844 shares and 40,000,000 unlisted options will be released from ASX escrow on November 22, 2018.
According to Zelda's most recent Appendix 3B new issue announcement, the company would have 755,341,934 shares on issue and available for trading on the ASX, but the company said that founder chairman Harry Karelis and directors Dr Stewart Washer and Jason Peterson and Mara Gordon would not sell any securities they own or controlled, directly or indirectly, about to be released from escrow, for a further 12 months, unless to help facilitate a major investment by a key strategic investor.
The company said that the options were exercisable at 3.125 cents each by Nov 17, 2021.
Zelda said that Mr Peterson had advised that his indirect holding would be reduced by 3,157,920 shares following the release of escrow as a result of a distribution by CPS Capital Pty Ltd, but the shares had not been sold.
Zelda was up 0.1 cents or 1.6 percent to 6.3 cents.

## SUDA PHARMACEUTICALS

Suda has requested a trading halt "pending an announcement … in relation to an update on [its] licence agreement negotiations".
Trading will resume on November 9, 2018 or on an earlier announcement.
Suda last traded at 0.5 cents.

## BARD1 LIFE SCIENCES

Bard1 has requested a trading halt pending "an announcement … in connection with a capital raising".
Trading will resume on November 9, 2018 or on an earlier announcement.
Bard1 last traded down 0.2 cents or 5.7 percent to 3.3 cents with 39.2 million shares traded.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested an extension to its voluntary suspension following the trading halt requested on November 1, “pending the release of an announcement … regarding the MGC Derma sale transaction with Cannaglobal” (BD: Nov 1, 5, 2018).
MGC last traded at 5.1 cents.

## POLYNOVO

Polynovo says that Greg Lewis will resign as company secretary, effective from December 7, 2018.
Polynovo said that recruitment for a company secretary and chief financial officer had begun.
Polynovo was up half a cent or 0.8 percent to 60 cents.