



# Biotech Daily

Wednesday April 13, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: IDT UP 19%, UNIVERSAL BIOSENSORS DOWN 7%**
- \* **ITIF: 'AUSTRALIA 52<sup>nd</sup> FOR BIOPHARMA INNOVATION POLICIES'**
- \* **VICTORIA LEGALIZES MEDICINAL CANNABIS**
- \* **INNATE COMPLETES PHASE IIb MIS416 FOR MS ENROLMENT**
- \* **FDA APPROVES IDT GENERIC TEMOZOLOMIDE FOR BRAIN CANCER**
- \* **BIOTA 'TRANSFORMATION' NAME CHANGE TO AVIRAGEN**
- \* **ROTARY BOWEL CANCER PROGRAMS ADOPT CLINICAL GENOMICS TEST**
- \* **ANTEO FILES TWO MORE BATTERY PATENTS**
- \* **MGC SELLS FIRST CANNABIDIOL-BASED COSMETICS ON-LINE**
- \* **3D DIRECTOR FRANK PERTILE DILUTED TO 4.75% OF MACH7**
- \* **MICHAEL CATANZARITI, TY WEBB DILUTED TO 4.99% OF MACH7**
- \* **OPTISCAN LOSES 2<sup>nd</sup> CHAIRMAN PATRICK O'CONNOR**

## MARKET REPORT

The Australian stock market was up 1.59 percent on Wednesday April 13, 2016 with the ASX200 up 79.1 points to 5,054.7 points. Twenty-one of the Biotech Daily Top 40 were up, eight fell, eight traded unchanged and three were untraded. All three Big Caps rose.

IDT was the best, up 5.5 cents or 19.3 percent to 34 cents with 1.2 million shares traded, followed by Actinogen up 12.9 percent to 7.9 cents with three million shares traded. Cellmid climbed 9.5 percent; Impedimed, Mesoblast and Oncosil were up more than six percent; Living Cell and Pro Medicus were up more than five percent; Benitec climbed 4.55 percent; Avita was up 3.7 percent; Admedus, Medical Developments, Neuren, Opthea and Prima rose more than two percent; Airxpanders, Bionomics, Orthocell, Pharmaxis, Reva and Resmed were up more than one percent; with Cochlear, CSL and Sirtex up by less than one percent.

Universal Biosensors led the falls, down two cents or 6.8 percent to 27.5 cents with 59,000 shares traded. Tissue Therapies lost 5.3 percent; Compumedics and Starpharma fell more than three percent; Acrux and Clinuvel shed more than two percent; with Ellex and Prana down by less than one percent.

## ITIF, FEDERAL GOVERNMENT

The Information Technology and Innovation Foundation says that Australia ranks 52nd of 56 countries for Government support for biotechnology innovation.

The Washington, DC-based Information Technology and Innovation Foundation (ITIF) used the four parameters of Government research and development as a share of gross domestic product (GDP), percentage of research and development spent on health research and development, "extent of price controls" on drug prices and the period of biologics data exclusivity.

The Foundation said it was a non-profit, non-partisan research and educational institute. ITIF ranked the US overall first with 0.87 percent of GDP spent on research and development, with 23.0 percent of that figure spent on health research and development, with low drug price controls and 12 years of biologics data exclusivity.

Of the 56 countries, Austria, ranked seventh, had the highest R&D/GDP ratio at 1.10 percent, followed by Iceland, ranked 11<sup>th</sup> at 1.00 percent and South Korea, ranked 30<sup>th</sup> at 0.95 percent, compared to Australia's 0.26 percent, with 18.2 percent spent on health. Although Israel was ranked 26<sup>th</sup>, it had an R&D/GDP spend of 0.52 percent, but according to the ITIF only 1.1 percent was spent on health.

ITIF head of innovation policy Stephen Ezell said the report was "not evaluating which country does biopharmaceutical innovation best, but rather, which countries are creating an ecosystem that is conducive toward biopharmaceutical innovation, [that is] having mechanisms in place that encourage innovation rather than shun it".

"Life sciences innovation requires years of painstaking and expensive research," Mr Ezell said. "To ensure global health outcomes continue improving, more nations must do their share to support biopharmaceutical innovation and not free ride off the hard work and investment of the leaders."

Mr Ezell told Biotech Daily that of the four evaluation parameters the two relating to Government research and development spending accounted for 35 percent of the weighting, price controls were given an equal weight of 35 percent and data exclusivity accounted for 30 percent of the weighting.

An ITIF media release said that the three policy areas of research and development spending, price controls and data exclusivity "not only support life-sciences innovation domestically but also have positive spill-over effects globally".

ITIF said the analysis found that the US, Switzerland, Taiwan, Singapore and Sweden had policies that contributed the most to global life-sciences innovation, while India, South Africa, Thailand, the Philippines, and Australia had policies that contribute the least.

"Despite tremendous progress over the past half century, the world is still not producing as much life-sciences innovation as is needed or possible," said Mr Ezell. "Countries that fail to invest adequately in life-sciences research, pay less than their fair share for drugs, or put in place weak intellectual property protections for drugs hurt the entire global community by slowing down biopharmaceutical innovation that could cure or better manage diseases for future generations," Mr Ezell said.

ITIF said that the report found that countries with the strongest life-sciences policies also had some of the most competitive innovation ecosystems, meaning that doing well domestically could also mean doing well for the world.

Foundation president Robert Atkinson said that it was "understandable that policy-makers tend to focus first and foremost on the short-term interests of their own citizens, but too many ignore the fact that this comes at the expense of less innovation of new drugs".

"The bottom line is that all nations need to do their part to support robust global biopharma innovation," Mr Atkinson said.

The full report is available at: <http://bit.ly/1N7AVyP>.

## VICTORIA GOVERNMENT

The Victoria State Government says the Access to Medicinal Cannabis Bill 2015 passed both houses of the Victoria Parliament, last night.

Victoria said it was “the first state in Australia to make medicinal cannabis available to people in exceptional circumstances, safely, securely and lawfully”.

A media release from Victoria Premier Daniel Andrews said the Bill created “a legal framework to enable the manufacture, supply and access to safe and high quality medicinal cannabis products in Victoria” and children with severe epilepsy would be given first access to medicinal cannabis from early 2017.

The Government said it was establishing the Office of Medicinal Cannabis to oversee manufacturing and all clinical aspects of the medicinal cannabis framework.

The media release said the Office would work with clinicians, doctors and general practitioners to help them understand their role in prescribing medicinal cannabis and with patients and families to educate them about medicinal cannabis and eligibility for use.

The Government said it would establish an independent medical advisory committee to advise on the cannabis products that should be available under the access scheme, the possible expansion of patient eligibility and other clinical matters.

The State Government said that initially, “government production will supply products to the first patient group [and] a key step to providing on-going access to medicinal cannabis will be the establishment of cultivation and manufacturing industries in Victoria to support an on-going and reliable supply of products”.

The Government said it would undertake a small-scale, strictly-controlled cannabis cultivation trial at a Victorian research facility.

## INNATE IMMUNOTHERAPEUTICS

Innate says it has completed enrolment in its 93 patient phase IIb randomized, placebo controlled trial of MIS416 for secondary progressive multiple sclerosis.

In 2013, Innate raised \$10 million to list on the ASX, and following investigator and site delays, started the trial in November 2014 (BD: Dec 18, 2013; Nov 11, 2014).

Today, the company said it exceeded the original recruitment target of 90 subjects with the successful enrolment of the 93rd patient.

The Brisbane-based Wesley Hospital neurologist and co-principal investigator Prof Pamela McCombe said patients had been enthusiastic to be part of the study.

Prof McCombe said that drugs used in early stage multiple sclerosis were not effective in treating secondary progressive multiple sclerosis, “so finding a treatment for patients that slows the deterioration of their symptoms is very important”.

Innate said that as part of gaining ethical approval for the efficacy trial, the company had undertaken to make MIS416 available to patients completing the 12-month study.

The company said that to date nine of the 13 patients who completed the study had requested support from their physicians to enable access to MIS416 post-study.

Innate said that the study would be completed “this time next year” with a substantive initial report expected about four months later, about September 2017.

The company said it had “strong on-going interest in the study from several major pharmaceutical companies” with multiple meetings assisting in the study design”.

Innate chief executive officer Simon Wilkinson said that he was “confident that a successful trial result in the first half of next year will quickly translate into a major partnering transaction”.

Innate was up half a cent or three percent to 17 cents.

## IDT AUSTRALIA

IDT says it has US Food and Drug Administration approval for its generic oral brain cancer drug Temozolomide, paving the way for the launch of its first generic drug in the US. The company said the approval was its first under the FDA's abbreviated new drug application system and was granted more than six months earlier than expected.

IDT said the market for Temozolomide in the US was more than \$US200 million and it had appointed Mayne Pharma as its US distributor, with launch preparations underway.

IDT said that Temozolomide sales were expected to deliver revenues in 2016.

IDT chief executive officer Dr Paul MacLeman said that "securing FDA approval for the first of IDT's proprietary products is a major milestone ... and to have this ahead of schedule is a fantastic result".

IDT climbed 5.5 cents or 19.3 percent to 34 cents with 1.2 million shares traded.

## BIOTA PHARMACEUTICALS, AVIRAGEN THERAPEUTICS

Biota claims that following "a meaningful transformation" it has changed its name to Aviragen Therapeutics.

Biota said that it was "focused on the development of the next generation of direct-acting antivirals that address infections that have limited therapeutic options".

Biota chief executive officer Dr Joseph Patti claimed that "a meaningful transformation has taken place over the last two years as we transitioned from a drug discovery and early-stage licencing organization to one focused on drug development and progressing key late-stage product candidates in important viral diseases".

"Our name change reflects this transition and better defines our strategic initiatives moving forward," Dr Patti claimed.

Prior to Biota departing Australia in a failed attempt to acquire \$US54 million in cash held by Nabi Pharmaceuticals and settling for \$US27 million, the company had produced the Relenza anti-influenza drug marketed by Glaxosmithkline and was earning multi-million dollar sales royalties, as well as multi-million dollar royalties from Daiichi Sankyo sales of Inavir in Japan (BD: Feb 1, 2011; Apr 23, Oct 30, 2012).

Following its move to the US, Biota lost its \$US231 million contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to further develop its laninamivir anti-influenza drug with BARDA citing "concerns about the project with regard to the product manufacturing, clinical study enrolment pace, costs, and contractor performance" (BD: Apr 1, 2011; Apr 30, May 1, May 9, 2014).

Today, Dr Patti said that the start of a phase IIa study of the Melbourne-developed BTA585 for respiratory syncytial virus "highlights our focus on bringing new medicines to treat and prevent viral infections with limited therapeutics options".

Biota said that the name change was effective from Monday, April 11, 2016 in the US, and its Nasdaq code would change to AVIR on April 13, 2016 in the US.

Biotech Daily understands that about 10,000 Australian investors held shares in Biota when it moved from the ASX to the Nasdaq and few have sold their holdings.

In February Dr Patti told Biotech Daily that about 9,000 Biota shareholders held an average of less than 1,000 shares each (BD: Feb 18, 2016).

Prior to the eight-to-one consolidation and move to the US and subsequent share price fall, those shares were equivalent to 8,000 shares each, and worth about \$8,000 or a total of about \$72 million.

Last night on the Nasdaq, Biota fell a further four US cents or 2.52 percent to \$US1.55 (\$A2.02 equivalent to 25.2 cents, before the move to the Nasdaq when the company was trading around \$A1.00 a share) with 11,648 shares traded.

## CLINICAL GENOMICS

Clinical Genomics says its faecal immunochemical test (FIT) will be included in bowel cancer screening programs through Australia this year.

Clinical Genomics said that the Chicago, Illinois-based Rotary International not-profit community service organization operated two programs Bowelcare and Bowelscan which would see more than 120,000 Rotary-branded tests manufactured by Clinical Genomics distributed to participating pharmacies.

The company said that its test was “one of the most effective and easiest ways to screen for and reduce the risk of bowel cancer”.

Bowelscan coordinator Richmond Manyweathers said the adoption of Clinical Genomics test nationally would assist the program to save lives and alleviate suffering. “The Rotary-inspired programs encourage Australians pick up a bowel cancer test from their pharmacy,” Mr Manyweathers said.

“Last year over 4,000 people were referred for additional follow up after the test, which shows the impact of this program,” Mr Manyweathers said.

Bowelcare coordinator Rod Chippindale said that community pharmacies played a vital role in the success of the awareness initiative.

“Pharmacies do a great job of displaying the kits and promotional materials to encourage people to pick up a test,” Mr Chippindale said.

“This year all pharmacies will know they are providing the same top quality test and efficient follow up process to their customers,” Mr Chippindale said.

Clinical Genomics Asia Pacific head Warren Bingham said the partnership with Rotary was “a cause of great pride as it aims to reduce deaths from bowel cancer through early detection”.

“Since 2005, we have distributed more than 20 million tests globally,” Mr Bingham said. Clinical Genomics is a private company.

## ANTEO DIAGNOSTICS

Anteo says it has filed two patents related to battery technology.

Last year, Anteo created a third subsidiary company Anteo Energy and filed a patent to develop its nanometer thin coating technologies for batteries (BD: Apr 21, 2015).

Anteo said at that time that from its inception chief scientific officer Dr Joe Maeji saw potential for its molecular adhesive technology platform in diverse fields and the scientific team had worked on a research project led by battery technologies expert Dr Quansheng Song.

Toda, Dr Maeji told Biotech Daily that the battery technology had application in home power storage as well as electric vehicle, but also could be applied to medical devices.

Dr Maeji said that the patents were entitled ‘Composites’ and ‘Binding’ and would take about two years to grant, providing coverage until April 2036.

In a media release, Dr Maeji said that “early last year, we successfully concluded a body of work into coatings for new anode and cathode materials for lithium ion batteries as part of our long-term diversification strategy”.

“This culminated in the filing of a patent application in April, 2015 directed at new methods that significantly increase battery capacity, enable faster charging as well as improve cycle life,” Dr Maeji said.

“We are very confident that we have established a unique patent position in energy storage and conversion systems,” Dr Maeji said.

Anteo was unchanged at five cents with two million shares traded.



### MGC PHARMACEUTICALS

MGC says it has launched its online cosmetics shop with first retail sales of its Ananda line cannabidiol-based cosmetics products.

MGC (medical-grade cannabis) said that the [www.mgcderma.com](http://www.mgcderma.com) website would allow consumers to buy the cosmetics in the European Union and other countries where cannabidiol cosmetics were legal.

The company said that subsidiary MGC Derma's Ananda range of 15 cannabidiol-based cosmetics products would be available through the website, including a moisturising day cream, active firming anti-aging mask, active whitening facial cream, anti-puffiness and dark circles eye serum to sold for an average price of EUR60 or about \$A90.

The company said it expected to have about 50 products available on-line by early 2017. MGC managing director Nativ Segev said the launch was "a strong complement to the company's established wholesale product sales channel".

MGC was up 0.2 cents or 6.45 percent to 3.3 cents with 18.7 million shares traded.

### MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

Former 3D Medical director Frank Pertile says he has been diluted below the five percent substantial level through the issue of shares to Mach7 Technologies.

3D and Mach7 completed their merger last week (BD: Apr 8, 2016).

Mr Pertile said that his holding directly and through Perco Group remained at 42,472,075 shares, but with 894,500,997 shares of offer, of which 510,810,046 shares were held in escrow until February 18 and April 8, 2017, Mr Pertile was diluted to 4.75 of Mach7.

Mach7 was unchanged at 6.4 cents.

### MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

Michael Catanzariti says he has been diluted below five percent substantial level through the issue of shares to Mach7 Technologies.

Last year, Mr Catanzariti increased his holding in 3D to 44,612,035 shares (10.40%) with the shares held in his name as well as through Ty Webb Pty Ltd, Swooper Pty Ltd, Super Impose Investments and Clemenza.

The issue of merger shares to Mach7 diluted his holding to 4.99 percent.

### OPTISCAN IMAGING LIMITED

Optiscan says that chairman Patrick O'Connor has resigned from the board, effective immediately.

Last year, Mr O'Connor was appointed to the board, replacing the then chairman Angus Holt, following a detailed ASX query regarding Mr Holt's director's interest disclosures (BD: Jul 10, 21, 2015).

Today the company said that it had been "actively engaged in a process of strategic review and fundraising, including identifying new management and board composition" for some weeks and it expected to be in a position to announce new board appointments as part of that process.

Optiscan was in a voluntary suspension and last traded at two cents.