

# Biotech Daily

Thursday February 10, 2022

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: KAZIA UP 13%; RESONANCE DOWN 6%
- \* FEDERAL 'PATENT BOX' TO CUT TAX TO 17%; FEDERAL OPPOSITION
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- \* FIREBRICK: NASODINE TRIALS REDUCE SARS-COV-2 VIRAL SHEDDING
- \* ANTEO: NEW EUGENI READER, SARS-COV-2 TEST TRIALS FOR TGA
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- \* USCOM UNMARKETABLE PARCEL FACILITY
- \* LITTLE GREEN TO RELEASE 55.5m ASX ESCROW SHARES

#### MARKET REPORT

The Australian stock market was up 0.28 percent on Thursday February 10, 2022, with the ASX200 up 20.2 points to 7,288.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 16 fell and six traded unchanged.

Kazia was the best, up 13 cents or 13.1 percent to \$1.12, with 109,504 shares traded. Uscom was up 10 percent; Universal Biosensors improved 7.3 percent; Cyclopharm climbed 6.7 percent; Pharmaxis and Prescient were up five percent or more; Actinogen and Nanosonics improved more than four percent; Compumedics, Dimerix and Polynovo rose more than two percent; Immutep, Next Science, Nova Eye and Volpara were up more than one percent; with Avita, Paradigm, Resmed and Starpharma up by less than one percent.

Resonance led the falls, down one cent or 6.1 percent to 15.5 cents, with 379,076 shares traded. Atomo fell 4.9 percent; Medical Developments and Patrys lost more than three percent; Impedimed, Micro-X and Orthocell shed more than two percent; Clinuvel, Cochlear, Emvision, Mesoblast, Neuren and Telix were down more than one percent; with CSL, Genetic Signatures, Opthea, Pro Medicus and Proteomics down by less than one percent.

# FEDERAL GOVERNMENT

Australia at 17 percent (BD: May 11, 12, 2021).

The Federal Government has introduced the so-called 'patent box' legislation providing a tax concession form profits derived from Australian intellectual property.

A spokesperson for Federal Assistant Treasurer Michael Sukkar told Biotech Daily that Mr Sukkar introduced the 'Treasury Laws Amendment (Tax Concession for Australian Medical Innovations) Bill 2022' to the House of Representatives, this morning. In his 2021-'22 Budget, Federal Treasurer Joshua Frydenberg said that a new 'patent box' system would start on July 1, 2022, and tax profits derived from patents developed in

The Bill said the change in taxation law "applies to [research and development] entities that make an election under this division, and to certain patents linked to therapeutic goods included in the Australian Register of Therapeutic Goods".

"It defines certain income streams in respect of such patents to be patent box income streams," the Bill said.

"Assessable income of an [research and development] entity that arises from a patent box income stream can be, to an extent, non-assessable non-exempt income," the Bill said The legislation said it covered patents issued in the US, Europe or Australia and defined therapeutic good as one "included in a part of the Australian Register of Therapeutic Goods", and included a formula for the amount of income from the patent subject to the tax concession.

# FEDERAL OPPOSITION

The Federal Shadow Treasurer Dr Jim Chalmers told Biotech Daily that the legislation required further consideration.

"After so much hype - and on the eve of an election - like everyone else, we've only just seen this legislation," Dr Chalmers said.

"We will consider it through our usual processes to make sure that the Government's rhetoric matches the reality," Dr Chalmers said.

"Despite their spin, the Morrison Government doesn't have a good track record when it comes to innovation and technology," Dr Chalmers said.

#### **AUSBIOTECH**

Industry organization Ausbiotech says it "has welcomed the 'patent box' legislation ... to provide a tax incentive for Australian medical innovations".

Ausbiotech chief executive officer Lorraine Chiroiu said the progression of the patent box legislation was "a positive first step".

"Ausbiotech looks forward to the establishment of an expert working group, with industry representation, to support the implementation of the patent box scheme, in order for Australia to realize the benefits of this important incentive," Ms Chiroiu said.

"This tax concession ... aims to support Australian medical innovators to be globally competitive, retain value-creation from home-grown research and [intellectual property] and to support sovereign capability," Ms Chiroiu said.

"Its purpose is to make it more genuinely viable for businesses to retain this value creation and manufacturing in Australia, including providing an incentive to industry to locate the associated high-value jobs at home," Ms Chiroiu said.

"A well-designed patent box will support Australian manufacturers to remain competitive on an international scale by bridging the gap between [research and development] and commercialization," Ms Chiroiu said.

# BIOTECH DAILY EDITORIAL: THE IS NOT A PATENT BOX

In 2009, the Biotech and Related Industries Leadership Group proposed a patent box to Labor Industry Minister Kim Carr as part of a proposal for Commercialization Australia. All recommendations were duly ignored.

The patent box proposal, from GBS Ventures' Dr Joshua Funder, was an 'Australian Intellectual Property Clearing House' to fund the patent process, advertise and distribute their existence, and auction Australian inventions.

"Proceeds from the auction and future royalty streams would be shared between the inventor, originating institution and the Commonwealth Commercialization Institute, to become self-funding over the long term," the BRIL Group proposed.

A tax break on profits from Australian intellectual property from 30 percent to 17 percent is always welcome, but a 'patent box' could have been so much more than just a tax-break.

David Langsam Editor

#### FIREBRICK PHARMA

Firebrick says a pilot study shows Nasodine reduces or ceases severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) viral shedding one hour after application. Firebrick Pharma said the study, published in the Australian Journal of Otolaryngology, was titled 'In-vivo (human) and in-vitro inactivation of Sars-Cov-2 with 0.5% povidone-iodine nasal spray', available at <a href="https://www.theajo.com/article/view/4466/html">https://www.theajo.com/article/view/4466/html</a>. The study said that following a single Nasodine dose of four sprays in each nostril "only six of the 14 PCR-positive samples yielded culturable virus (the efficacy subset)". "Of the eight culture-negative samples, seven had Ct scores above 30, which corresponded with extremely low levels of viral RNA present, that is, 30 doubling cycles were needed to reach the positivity threshold," the study reported.

"Given the well documented difficulty of culturing virus at Ct values above 25, it is not surprising that culturable virus could not be isolated from these samples," the study said. "Even in the six cases where virus could be cultured, the Ct scores were still high and indicative of low baseline virus levels, which were confirmed by the observed viral titers, making demonstration of any material antiviral effect challenging," the study said. "Five minutes after the administration of Nasodine, the mean viral titer was reduced by 65 percent versus baseline, and this was reduced further (79% versus baseline) at 60 minutes post-dose," the study said.

"At five minutes post-dose, five of the six subjects (83%) were found to have either a reduction or cessation of viral shedding and at 60 minutes post-dose, virus titers were below the respective baseline values in all six subjects," the study report said. Firebrick said that the in-vitro experiments showed that a 15-second exposure to Nasodine "reduced infectivity of Sars-Cov-2 by 99.97 percent, while a 60-second exposure completely eliminated viral infectivity".

Firebrick chief medical officer and lead author Prof Peter Friedland said that the in-vitro and pilot study results were "encouraging" and the company expected to conduct a double-blind, randomized, phase II trial this year to assess whether repeated doses of Nasodine over several days could suppress or eliminate viral shedding.

Firebrick executive chair Dr Peter Molloy said that the company was focussed on the approval of Nasodine as a treatment for the common cold.

"However, in parallel, we will continue to research its potential future utility in other indications, including Covid-19," Dr Molloy said.

Firebrick was up three cents or 6.25 percent to 51 cents with 1.4 million shares traded.

## **ANTEOTECH**

Anteo says it will conduct new trials of its Eugeni reader and severe-acute-respiratory-syndrome (Sars-CoV-2) rapid test for its Therapeutic Goods Administration application. Anteo said it would collect further clinical data based on samples collected directly from patients and immediately analyzed on the Eugeni reader.

The company said that discussions with the TGA focused on "the reconciliation of [its] clinical data set, which includes stored and direct patient samples, and the TGA's requirements for additional clinical evidence".

Anteo said that "conducting new clinical trials represents the most expeditious pathway to meeting these data requirements".

The company said the data would "ensure that a new submission ... will meet the TGA's regulatory requirements, as well as providing the company with data for additional regulatory approval processes, including registration for the EU Common List".

Anteo chief executive officer, Derek Thomson said the company had "worked directly with the TGA to understand the most efficient method of supplying the data they now require and our highest priority is to generate this data as quickly as possible".

"These further trials will provide Anteo with the opportunity to gain additional clinical data which will enhance the growing body of evidence for performance of both the Eugeni Reader and the [rapid diagnostic test]," Mr Thomson said.

Anteo fell two cents or 8.5 percent to 21.5 cents with 30.9 million shares traded.

# **GI DYNAMICS**

GI Dynamics says it has approval for a 100-patient, clinical trial in India for its Endobarrier duodenal sleeve for type 2 diabetes and obesity.

In 2020, GI Dynamics said it would delist from the ASX but remain focused on attaining a Conformité Européenne (CE) mark for Endobarrier with clinical trials in India and the US (BD: Jul 20, Nov 6, 2020).

In 2015, the company closed its 500-patient Endobarrier trial due to bacterial liver infections in five of the 325 enrolled patients and a later analysis showed that it failed to meet safety and efficacy endpoints (BD: Mar 6, 2015, Mar 15, 2016).

Today, GI Dynamics said the 'I-Step' trial was a multi-centre, randomized, pivotal study evaluating the safety and efficacy of Endobarrier for glycaemic improvement in patients with inadequately controlled type 2 diabetes and obesity.

The company said that the study would be conducted with the Chennai, India-based Apollo Hospital System and Apollo Sugar Clinics and follow the 100 patients with a predetermined haemoglobin A1c range for up to 24 months.

The company said it would work with Apollo Sugar for a marketing, distribution and clinical support agreement for India and Southeast Asia.

GI Dynamic chief executive officer Joe Virgilio said the incidence and risks of type 2 diabetes and obesity continued to increase.

# USCOM

Uscom says it has established a share sale facility for holders of unmarketable parcels of shares, worth less than \$500, at the record date of February 8, 2022.

Uscom said that 206 of its 1,011 shareholders, holding a total of 432,840 shares, would be eligible for the facility which would allow them to sell shares without brokerage or handling costs and allow the company to reduce administrative costs.

Uscom was up one cent or 10 percent to 11 cents.

# LITTLE GREEN PHARMA

Little Green Pharma says that 55,534,703 shares will be released from ASX escrow on February 20, 2022.

Little Green said that 3,000,000 performance rights and 7,573,536 unlisted options would also be released at the same time.

According to its most recent filing, following the release of the shares from ASX escrow, it would have 237,711,216 shares available for trading.

Little Green fell two cents or 3.45 percent to 56 cents.