Biotech Daily

Wednesday June 15, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 15%;**
- MEDICAL DEVELOPMENTS DOWN 11%

*** RESMED TO PAY HG $1.2b FOR GERMANY'S MEDIFOX DAN**

*** MIPS LICENCES GLYPH TO PURETECH TO MAKE IV DRUGS ORAL**

*** NEUROSCIENTIFIC EMTINB 'REDUCES MS, BIOMARKERS', IN MICE**

*** ISLAND: SOFGEN REPLACES CURIA FOR ISLA-101 MANUFACTURE**

*** ALLAN GRAY BELOW 5% IN IMPEDIMED**

*** DR PAUL COZZI TAKES 9.6% OF VISIONEERING**

*** PLANET INNOVATION TAKES 29% OF LUMOS**

*** PERENNIAL VALUE TAKES 14.6% OF LUMOS**

*** ACORN DILUTED BELOW 5% IN LUMOS**

MARKET REPORT

The Australian stock market fell 1.27 percent on Wednesday June 15, 2022, with the ASX200 down 85.0 points to 6,601.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 23 fell and five traded unchanged. All three Big Caps fell.

Patrys was the best, up 0.3 cents or 15.0 percent to 2.3 cents, with 2.7 million shares traded. Proteomics climbed 12.2 percent; Universal Biosensors was up 7.35 percent; Opthea rose 6.1 percent; Alcidion and Polynovo improved more than four percent; Genetic Signatures and Prescient were up more than three percent; Impedimed rose 2.9 percent; Cynata and Next Science were up more than one percent; with Pro Medicus up by 0.8 percent.

Medical Developments led the falls, down 21.5 cents or 10.9 percent to $1.755, with 169,170 shares traded; followed by Actinogen down 10.2 percent to 5.3 cents, with 1.8 million shares traded. Amplia and Resonance lost nine percent or more; Antisense and Starpharma fell more than seven percent; Mesoblast and Micro-X were down more than six percent; Paradigm shed 5.9 percent; Immutep and Oncosil fell more than four percent; Atomo, Avita, Cochlear, Emvision, Nanosonics and Orthocell were down more than three percent; Resmed, Telix and Uscom shed more than two percent; CSL, Cyclopharm, Pharmaxis and Volpara were down more than one percent; with Clinuvel and Neuren down by less than one percent.

RESMED

Resmed says it will pay London's HG Capital EUR 810,000,000 ($A1,224,000,000) to acquire the Hildesheim, Germany-based Medifox Dan.

Resmed said Medifox Dan was a developer of out-of-hospital patient care platforms employing more than 600 people, and that the acquisition would further its software as a service strategy by extending its position in care settings in Germany.

The company said that under the agreement, it would retain Medifox Dan's employees, management structure, locations, business processes and brand.

Resmed said Medifox Dan co-managing-directors Dr Thorsten Schliebe and Christian Städtler would continue in their current roles, reporting to Resmed head of software as a service Bobby Ghoshal.

The company said Medifox Dan's net revenue for 2021 was about $US83 million, with an adjusted earnings before interest, taxation, depreciation and amortization (Ebitda) of about $US35 million, and an enterprise value of EUR950,000,000.

Resmed said that the acquisition was "expected to be accretive to Resmed's non-GAAP diluted earnings per share".

The company said it would fund the transactions with cash and borrowings under an existing credit facility, as well as an inter-company loan from Resmed to Resmed Germany SaaS to allow the German subsidiary to fund its portion of the purchase price.

Resmed said that Medifox Dan would integrate into Resmed's Germany's out-of-hospital software as a service business segment, with Medifox Dan offering a similar service for out-of-hospital care providers in Germany to the offerings of Resmed's brands in the US.

Resmed chief executive officer Mick Farrell said the "with the acquisition of Medifox Dan, a fast-growing and innovative German healthcare software leader, we will expand Resmed's [software as a service] business portfolio outside our current base in the US market and strengthen our position as the global leader in healthcare software solutions for lower-cost and lower-acuity care".

Mr Farrell said the company was "excited to welcome the Medifox Dan team to our global Resmed family".

"Our management cultures are highly aligned with a laser-focus on lowering costs, improving outcomes, and changing the course of chronic disease management," Mr Farrell said. "Medifox Dan has a strong track record of innovation, fully aligned with our teams at Brightree, Matrixcare and beyond."

"Medifox Dan's customer centricity has built strong and ongoing, growing demand for its software solutions across Germany, and we expect that momentum to continue and strengthen as we become one global team," Mr Farrell said.

"Our Medifox Dan and Resmed teams are united with the same global mission: to help many hundreds of millions of people live healthier lives outside the hospital, and preferably in their own home," he said.

Resmed head of software as a service Bobby Ghoshal said: "We're seeing greater adoption of digital solutions across Germany as its population continues to age and severe staffing shortages continue to challenge German care providers."

"Medifox Dan and Resmed are well positioned to help providers across major out-of-hospital care settings meet rising demands and ultimately help improve patient outcomes," Mr Goshal said.

Resmed said the transaction was expected to close by December 31, 2022, subject to regulatory clearances, and if the deal was not completed by March 31, 2023 the seller could terminate the agreement and if not completed by June 30, 2023 Resmed would pay the seller EUR10,000,000.

Resmed fell 74 cents or 2.5 percent to $29.01 with two million shares traded.

MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Monash Institute of Pharmaceutical Sciences says it has licenced its Glyph drug delivery platform to Boston's Puretech Health Plc to make intravenous drugs orally available.

Monash Institute of Pharmaceutical Sciences (MIPS) did not disclose the licence value.

The University said that Glyph had "reached a significant milestone, showing for the first time, in humans, that a drug that currently must be injected due to breakdown in the liver after oral administration, may be administered as a simple oral capsule".

The University said that data was generated with LYT-300 an oral form of allopregnanolone, which was the only US Food and Drug Administration-approved medication for the treatment of postpartum depression.

Monash University said that allopregnanolone needed to be administered as a 60-hour intravenous infusion.

The University said that postpartum depression affects up to one in five new mothers, but readily accessible medications were limited.

Monash said that an ongoing phase I study of LYT-300 showed that when orally administered, systemic blood levels were approximately nine-fold greater than that of orally administered allopregnanolone, based on previously published data, holding the potential to dramatically increase practicality and usability.

The University said that the platform was developed by a team from the Monash Institute of Pharmaceutical Sciences led by Prof Chris Porter and the study was "the first clinical validation of the Glyph technology in humans".

Monash said that the Glyph platform "piggybacks onto lipid absorption pathways, targeting drug absorption to the lymphatic system and away from the liver … [providing] patients an opportunity to switch from invasive intravenous administration to a simple oral capsule".

"These data show that allopregnanolone can be successfully administered orally, which is very encouraging not only for women with [postpartum depression], but also for those with other neurological and neuropsychiatric conditions, including other forms of depression, anxiety and sleep disorders, who could benefit from an oral form of allopregnanolone," Prof Porter said.

"Because Glyph re-routes drug transport via the lymphatic system, it has the potential to enhance the bioavailability of orally administered drugs like allopregnanolone," he said.

"In addition, since it selectively traffics therapeutics into the lymphatic system, it has the potential to target therapies to the immune system," Prof Porter said.

Puretech chief medical officer Dr Julie Krop said that the company was "hopeful that LYT-300 will be the first of many applications for Glyph".

"Natural allopregnanolone has demonstrated efficacy for the treatment of [postpartum depression] and other neuropsychological conditions, but up to now has required [intra-venous] delivery due to high first pass liver metabolism," Dr Krop said.

"LYT-300 is designed to unlock the validated pharmacology of natural allopregnanolone with a potential oral treatment option for [postpartum depression], and a range of other neurological and neuropsychological conditions," Dr Krop said.

Monash University said that the LYT-300, multi-part, phase I program had three primary objectives: to demonstrate oral bioavailability; evaluate safety and tolerability across a range of doses; and to identify a dose to take forward.

The University said that the first objective had been achieved, additional dose exploration and the effect of food on oral absorption of the pro-drug were progressing and assessments of safety, tolerability, pharmaco-kinetics and pharmaco-dynamics would be measured.

Monash said that dose escalation continued with no dose-limiting toxicities observed to date.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says that it observed strong positive results across all endpoints in a study of Emtinb for multiple sclerosis, in mice.

Neuroscientific said the study was a myelin oligodendrocyte glycoprotein-induced experimental autoimmune encephalomyelitis mouse model "the gold-standard animal model for replicating the inflammatory mechanisms of human [multiple sclerosis]".

The company said the study evaluated Emtinb across four dose groups: 5mg/kg, 10mg/kg, 20mg/kg, and 40mg/kg, with the drug administered daily for 30-days, following the onset of initial symptoms in the mice.

Neuroscientific said that mice treated with 10mg/kg and 20mg/kg Emtinb "consistently achieved lower clinical scores, indicating reduced disease severity from the onset of symptoms and through to the peak of the disease in comparison to untreated controls".

The company said that treated mice had lower levels of the neuro-filament light chain biomarker associated with nerve damage in their cerebral spinal fluid and plasma samples than the control group.

Neuroscientific said mice treated with 10mg/kg and 20mg/kg Emtinb had higher levels of myelin, important for the efficient function of nerve cells, than those in the control group.

The company said treatment reduced chronic inflammatory immune responses typical of multiple sclerosis, including T-cell penetration of the blood brain barrier and activation of microglia and macrophages, which in turn reduced central nervous system inflammatory responses.

Neuroscientific managing-director Matt Liddelow said the preliminary results were "highly encouraging for the development of Emtinb as a treatment for [multiple sclerosis], in particular the relapse-remitting type … in which inflammation is a key driver of symptoms".

Neuroscientific was up 1.5 cents or 8.6 percent to 19 cents.

ISLAND PHARMACEUTICALS

Island says it has a proposal with Sofgen for the manufacture of ISLA-101 clinical material for its planned phase IIa 'Peach' trial for dengue fever.

Island said it had been "investigating alternative manufacturers as the prior manufacturer was unable to provide the certainty required to plan effectively".

The company said the prior manufacturer updated advice suggesting additional delays and it turned to Sofgen, a softgel manufacturer in Florida, owned by Procaps Group SA, a manufacturer with a significant presence in Latin America.

Last year, Island said Curia Inc would produce two 2.5-kilogram batches of its ISLA-101 dengue fever drug for its phase IIa trial, previously expected from the Lubbock, Texas-based Cerrx (BD: Jul 22, Sep 20, 2021)

In September, the company said that "in view of an inventory error at a third-party storage facility … there is less [active pharmaceutical ingredient] available to purchase than originally expected" and cancelled the Cerrx agreement at no cost, engaging Curia to produce the material for $US431,300 ($A595,776) with the original delivery of late 2021 pushed back to early 2022.

Today, Island said the new proposal would cost $US134,000 ($A194,200) and contained a schedule that had ISLA-101 clinical material being manufactured in mid-August 2022, a six-week delay from most recent estimates.

The company said it expected the investigational new drug application would be filed in October with the trial commencing in November 2022.

Island fell two cents or 12.5 percent to 14 cents.

IMPEDIMED

Allan Gray and its associates say they have reduced their substantial holding in Impedimed by 7,118,510 shares, falling below five percent of the company.
Last year, Allan Gray said it had reduced its substantial holding in Impedimed from 97,306,655 shares (6.50%) to 95,388,768 shares (5.37%) (BD: Nov 23, 2021).
Today, the Sydney-based company said that between November 19, 2021, and June 9, 2022, it sold 7,118,510 shares for $935,360, or 13.14 cents a share.
Impedimed was up 0.2 cents or 2.9 percent to seven cents with 2.8 million shares traded.

VISIONEERING TECHNOLOGIES

Dr Paul Cozzi says he has increased his substantial holding in Visioneering from 1,591,815 shares (6.74%) to 2,298,789 shares (9.57%).
The Sydney-based Dr Cozzi said that between November 17, 2021 and June 14, 2022, he bought and sold shares at prices ranging from 30 cents to 97 cents a share.
Visioneering was up half a cent or 1.7 percent to 30 cents.

LUMOS DIAGNOSTICS

Planet Innovation says it has increased its substantial holding in Lumos from 40,124,914 shares (26.72%) to 55,860,176 shares (28.99%).
The Melbourne-based Planet Innovation said that on June 14, it bought 15,735,261 shares in Lumos for nil consideration, in an entitlement offer.
Last week, Lumos said the institutional component of its fully-underwritten, one-for-2.55 pro-rata $11.2 million rights offer at 19 cents a share had raised $8 million with the retail component to raise a further $3.2 million (BD: Jun 8, 2022).
Lumos fell half a cent or 3.7 percent to 13 cents with 1.3 million shares traded.

LUMOS DIAGNOSTICS

Perennial Value Management says it has increased its substantial holding in Lumos from 19,060,257 shares (12.64%) to 28,055,261 shares (14.56%).
Sydney's Perennial Value said that between March 21 and June 14, 2022 it bought and sold shares with the single largest purchase on June 14 on-market of 3,635,742 shares for $563,540 or 15.5 cents a share (see above).

LUMOS DIAGNOSTICS

Acorn says it has been diluted below five percent in Lumos, following the company's recent capital raising (see above).
In 2021, Acorn said it had become a substantial shareholder in Lumos with 8,973,877 shares or 5.98 percent of the company (BD: Jul 6, 2021)