

# **Biotech** Daily

## Monday October 11, 2021

## Daily news on ASX-listed biotechnology companies

\* ASX, BIOTECH DOWN: COMPUMEDICS UP 5%; IMUGENE DOWN 6%

- \* ACRUX TERMINATES HARRIS EMLA LICENCE ON BANKRUPTCY
- \* AUDEARA, AMPLIFON SIGN HEADPHONE SUPPLY AGREEMENT
- \* RESAPP FILES SLEEPCHECKRX FDA 510(k) APPLICATION
- \* UNIVERSAL BIOSENSORS RECEIVES \$2.8m FEDERAL R&D TAX INCENTIVE
- \* CRESO: 'MERNOVA HIGHEST LEGAL THC IN CANADA'
- \* USPTO ALLOWS NEUREN NNZ-2591 FOR AUTISM PATENT
- \* MEDLAB US NRGBIOTIC DEPRESSION PATENT
- \* NEUROSCIENTIFIC 8m DIRECTORS OPTIONS AGM
- \* CMO DR SUD AGARWAL, CANNVALATE TAKE 8.9% OF INCANNEX

#### MARKET REPORT

The Australian stock market fell 0.28 percent on Monday October 11, 2021, with the ASX200 down 20.3 points to 7,299.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 24 fell and four traded unchanged. All three Big Caps fell.

Compumedics was the best, up two cents or 5.1 percent to 41.5 cents, with 2,500 shares traded. Actinogen, LBT, Neuren and Pharmaxis climbed four percent or more; Genetic Signatures and Impedimed were up more than three percent; Antisense and Prescient rose more than two percent; Volpara was up 1.2 percent; with Kazia and Polynovo up by less than one percent.

Imugene led the falls, down 2.5 cents or 5.6 percent to 42 cents, with 16.6 million shares traded. Medical Developments and Starpharma fell more than four percent; Alterity, Clinuvel, Nova Eye, Osprey and Pro Medicus were down three percent or more; Amplia, Cochlear, Oncosil, Optiscan and Patrys shed more than two percent; Avita, CSL, Cynata, Dimerix, Mesoblast, Nanosonics, Next Science, Opthea, Resmed and Resonance were down one percent or more; with Immutep, Paradigm, Proteomics and Telix down by less than one percent.

## <u>ACRUX</u>

Acrux says it has terminated its licence for generic pain creams with the Fort Myers, Florida-based Harris Pharmaceutical after Harris filed for bankruptcy.

Last year, Acrux said it had a five-year sales, marketing, and distribution agreement with Harris for its generic Emla topical anaesthetic cream, a combination of lidocaine and prilocaine (BD: Aug 11, 2020).

Today, Acrux said Harris had filed for chapter 11 bankruptcy in the United States Bankruptcy Court, Middle District Florida.

The company said it was currently negotiating a replacement agreement with another US specialist generic company.

Acrux fell half a cent or 3.85 percent to 12.5 cents.

## <u>AUDEARA</u>

Audeara says Amplifon will sell its specialist personalized sound headphones at its 300 Australian clinics.

Audeara said the agreement followed the success of a trial of its headphones at Amplifon clinics, and Audeara headphones were the only headphones stocked by Amplifon. The company said its headphones used an algorithm to personalize sound for each listener's "unique hearing profile".

Audeara was unchanged at 12 cents.

#### RESAPP HEALTH

Resapp says it has filed a 510(k) pre-market application to the US Food and Drug Administration for its Sleepcheckrx obstructive sleep apnoea smartphone product. Resapp said the FDA had a 90-day targeted timeline for review for the application. The company said the Sleepcheckrx was a smartphone application that used algorithms to screen for obstructive sleep apnoea by analyzing breathing and snoring sounds during sleep and would be made available to patients by a medical prescription.

Resapp managing-director Dr Tony Keating said the filing was "another important milestone for our sleep apnoea product line".

"Last year, we obtained [Australian Therapeutic Goods Administration] approval and [Conformité Européenne] mark certification for our direct-to-consumer Sleepcheck app which is now available in over 36 countries," Dr Keating said.

"Sleep apnoea is a serious sleep disorder and research tells us that most people in the US with sleep apnoea don't know they have it," Dr Keating said.

"With Sleepcheckrx, physicians will have the opportunity to screen their patients conveniently and quickly for sleep apnoea, helping their patients take the first step in getting treatment," Dr Keating said/

Resapp was up 0.2 cents or 2.9 percent to seven cents.

## UNIVERSAL BIOSENSORS

Universal Biosensors says it has received \$2,826,244 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Universal Biosensors said the rebate related to research and development expenditure for the year to December 31, 2020.

Universal Biosensors was unchanged at 76 cents.

#### CRESO PHARMA

Creso says Mernova's new marijuana strains have "some of the highest [tetrahydrocannabinol] content ... to be sold in Canada's legal market". Creso said that the Bible Hill Nova Scotia-based Bloom Labs completed tetrahydrocannabinol (THC) content testing on four new strains of marijuana, Miracle Alien Cookies, Grape Cream Cake, Monkey Berries and Vineyard Select which had THC content of 30.1 percent, 26 percent, 23.6 percent and 19.6 percent, respectively. The company said the results provided Mernova with "another key competitive advantage", because the THC content of most commercially available marijuana was between 15.0 and 20.0 percent.

Creso fell half a cent or 4.35 percent to 11 cents with 4.3 million shares traded.

## NEUREN PHARMACEUTICALS

Neuren says the US Patent and Trademark Office has allowed a patent for NNZ-2591 as a treatment for autism.

Neuren said the patent, titled 'Bicyclic compounds and methods for their use in treating autism' would provide intellectual property protection until July 2034.

The company said that it was developing NNZ-2591 for Phelan-McDermid, Angelman, Pitt Hopkins and Prader-Willi Syndromes.

Neuren chief executive officer John Pilcher said that "the mechanism of action of NNZ-2591 appears to have broad utility in neuro-developmental disorders".

"Given that autism is estimated to affect one in 160 children, the grant of this important US patent could potentially enable a very large future opportunity as more becomes known about the causes of autism," Mr Pilcher said.

The company said similar claims had been granted in the European Union and Japan. Neuren was up nine cents or 4.5 percent to \$2.10.

#### MEDLAB CLINICAL

Medlab says the US Patent and Trademarks Office has granted "the Orotate patent" covering its NRGBiotic treatment for depression.

Medlab said that the patent, titled 'Treatment of depression and depressive disorders' would provide intellectual property protection until May 28, 2037.

In July, the company said that a 120-patient, randomized, controlled trial at the Queensland University of Technology showed that NRGBiotic significantly boosts the activity of anti-depressants (BD: Jul 5, 2021).

Medlab chief executive officer Dr Sean Hall said the patent was "specific for treating depression or a depressive disorder that are not responding to anti-depressant medications".

"So, what we now have is a patent covering 16 years for a commercially available substance to be used in one of the largest global health concerns of our time," Dr Hall said.

The company said that the patent also covered depression and Orotate in Canada, the European Union, Singapore, Hong Kong, Australia and New Zealand. Medlab was unchanged at 15.5 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says that its annual general meeting will vote to grant five directors a total of 8,000,000 options.

Neuroscientific said that it proposed to issue chair Paul Rennie 5,000,000 appointment options, vesting in three tranches over two years, and exercisable at 40 cents each within five years of the grant.

The company said it proposed to issue executive director Dr Anton Uvarov and managingdirector Matthew Liddelow 900,000 options each, with Mr Rennie and director Stephen Quantrill to be issued 600,000 options each, exercisable at 50 cents each within three years of being granted.

Neuroscientific said the annual general meeting would vote on the remuneration report, the election of directors Mr Rennie and Mr Quantrill, approval of the 10 percent placement capacity and the replacement of the company's constitution.

The meeting will be held virtually on November 11, 2021 at 10am (AWST). Neuroscientific fell 1.5 cents or 3.6 percent to 40 cents.

#### **INCANNEX HEALTHCARE**

Incannex director and chief medical officer Dr Sudhanshu Agarwal and Cannvalate say they have become substantial holders with 107,303,093 shares or 8.88 percent. Dr Agarwal said he were acquired 40,999,500 shares on September 8 and October 6, 2021 for \$8,199,500 or 20 cents a share.

Earlier this month Incannex said it had raised \$17.66 million from the exercise of options, including by Dr Agarwal.

Incannex was up one cent or 2.9 percent to 35 cents with 1.2 million shares traded.