Biotech Daily

Thursday December 3, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 18%; IMPEDIMED DOWN 6%**

*** NOXOPHARM PLACEMENT RAISES $23m**

*** FDA WANTS MORE DATA FOR TELIX TLX591 PROSTATE CANCER TRIAL**

*** UK WANTS MORE PALLA DATA FOR NORWEGIAN CODEINE PLANT**

*** IMEX: AQUILA IN-THE-CLOUD $675k REVENUE IN 6 MONTHS**

*** TELIX APPOINTS DUCHEMBIO SOUTH KOREA TLX591-CDx DISTRIBUTOR**

*** GOODBYE AVITA THERAPEUTICS, HELLO AVITA MEDICAL**

*** UN NARCOTIC DRUGS COMMISSION DOWNGRADES MARIJUANA**

*** BOD: H&H $200k HEMP OIL ORDER FOR EUROPE**

*** LEON SERRY, CITY CASTLE BELOW 5% IN ANTISENSE**

*** MEDICAL DEVELOPMENTS GORDON NAYLOR CHAIR; DAVID WILLIAMS**

MARKET REPORT

The Australian stock market was up 0.4 percent on Thursday December 3, 2020, with the ASX200 up 25.1 points to 6,615.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Proteomics was the best on no news, up 10 cents or 18.0 percent to 65.5 cents, with 839,612 shares traded. Osprey climbed 15 percent; Cynata and Universal Biosensors improved eight percent or more; Clinuvel and Cyclopharm were up more than five percent; Telix was up 3.75 percent; Paradigm rose 2.7 percent; Immutep, Neuren, Nova Eye and Orthocell were up more than one percent; with Pro Medicus up 0.6 percent.

Impedimed led the falls, down one cent or 6.45 percent to 14.5 cents, with 3.5 million shares traded. Patrys lost five percent; Antisense, Next Science and Optiscan fell more than four percent; Mesoblast and Pharmaxis were down more than three percent; Compumedics, Nanosonics and Polynovo shed more than two percent; Cochlear, Genetic Signatures, Kazia and Medical Developments were down one percent or more; with Avita, CSL, Opthea, Resmed and Starpharma down by less than one percent.

NOXOPHARM

Noxopharm says it has raised $23 million in a placement at 54 cents a share, a 15.6 percent discount to the five-day volume weighted average price.
Noxopharm said the placement was supported by cornerstone investors from Australia, Hong Kong and the US, with Canaccord Genuity as the lead manager and bookrunner.
The company said the funds raised would be used to begin and complete clinical trials of Veyonda, or NOX66, for cancer and Covid-19-related lung dysfunction.
Noxopharm said its objective was to establish Veyonda "as the standard of care cancer co-treatment, enabling immuno-oncology therapy, radiotherapy, and chemotherapy to reach their full potential".
Noxopharm fell 6.5 cents or 10.2 percent to 57.5 cents with 1.9 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration wants "additional supportive data" for its up-to 390 patient, randomized, controlled, phase III trial of TLX591 for prostate cancer.
Telix said that following a pre-investigational new drug application meeting, the FDA suggested it obtain data on dosimetry and dosing regimen in the intended patient population, as well as a confirmatory comparison between its prostate cancer imaging technology, TLX591-CDx, and the cancer-targeting behavior of TLX591 to support the analysis behind Telix's intended patient selection strategy.
The company said it intended to begin the 'Prostact' trial of TLX591, next year, in patients with prostate-specific membrane antigen (PSMA)-expressing, metastatic, castration-resistant prostate cancer who had disease progression following prior treatment.
Telix said the primary endpoint would be progression-free survival, with secondary outcomes including overall survival, quality-of-life and safety.
The company said it would assess the study population using its prostate cancer imaging TLX591-CDx, or 68-gallium-PSMA-11, to identify patients with PSMA-avid disease, in which the antigen was displayed on the surface of the cells.
The company said it planned to begin the trial in Australia, pending approval, adding sites across Europe and Australia by April 2021, and enrol US patients in "mid-2021" subject to FDA approval, and assess the feasibility of enrolling Chinese patients.
Telix chief medical officer, Dr Colin Hayward said that the feedback from the FDA meeting helped finalize the clinical development plan for TLX591.
"We expect the study will require a significantly reduced recruitment time, due to both the reduced sample size and the patient-centric randomization scheme," Dr Hayward said.
Telix was up 15 cents or 3.75 percent to $4.15 with two million shares traded.

PALLA PHARMA

Palla says the UK Medicines and Healthcare Products Regulatory Agency wants more information to approved its Norwegian codeine manufacturing site.
In May, Palla said it would target the codeine market in the UK and Europe, and hoped to sell Co-Codamol, codeine combined with paracetamol in caplet and tablet form, with first sales expected by January 2021 (BD: May 28, 2020).
Today, the company said it had submitted the information requested by UK Agency and pending a successful review expected to start manufacturing and selling codeine products under its own marketing authorizations by April 2021, with its Norwegian facility ready to begin manufacturing Co-Codamol for the Norwegian and UK markets.
Palla fell one cent or 1.2 percent to 82 cents.

IMEX HEALTH SERVICES

Imex says it has signed 28 deals worth $675,000 for its Aquila “in-the-cloud” standardized radiology platform product in the six months since the May 2020 launch.

Imex said Aquila was a low-cost, internet cloud-based data platform which provided access to the company’s Hiruko medical imaging software platform.

Imex co-founder and chief executive officer Dr German Arango said Aquila was “designed to provide small and medium-sized customers with an affordable, comprehensive and flexible [radiology information system and picture archive and communication system]”.

“Since it was launched, I have been astonished by the number of clinics and medical imaging centres that have been completely overlooked by the large on-premise providers”, Dr Arango said.

“Hiruko’s multi-tenancy capabilities mean that we can deploy our [Aquila] offering in around 13 days compared to over 60 days for customized projects, and our sales cycle is also significantly shorter”, Dr Arango said.

“To date, our results have been very positive, and we are determined to democratize access to cutting-edge technologies that will address the complex medical imaging needs of communities across the globe,” Dr Arango said.

Imex said that since Aquila was launched in May, the company had signed 28 deals worth about $675,000 in annual recurring revenue and generated 175 new pipeline opportunities across 13 countries, including its first US customer, which would conduct a 30-day trial in Miama, Florida.

The company said the US was “a significant opportunity” because the high cost of on-premise products limited access to medical imaging for about 80 percent of the country.

Imex was unchanged at $1.68.

TELIX PHARMACEUTICALS

Telix says it has appointed the Seoul-based Duchembio Co to commercialize its TLX591-CDx for prostate cancer imaging in South Korea.

Telix said TLX591-CDx, or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11) used positron emission tomography for the imaging of prostate cancer.

The company said that with Dechembio it would apply for marketing authorization from the Korea Ministry of Food and Drug Safety, but did not disclose the financial details of the partnership.

Telix chief executive officer Dr Christian Behrenbruch said Duchembio had “a well-deserved reputation as the number one radiopharmaceutical company in [South] Korea and we look forward to exploring future commercial and clinical opportunities through the experience of this initial partnership”.

AVITA MEDICAL (FORMERLY AVITA THERAPEUTICS)

Avita says it has changed its name from Avita Therapeutics to Avita Medical, effective from today.

Avita said the name change intended to re-align the company with its former parent company, Avita Medical Pty Ltd

The company said its ASX and Nasdaq tickers codes, AVH and RCEL respectively, would remain unchanged.

Avita fell five cents or 0.9 percent to $5.78 with 653,572 shares traded.

UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

The United Nations Commission on Narcotic Drugs has removed cannabis, or marijuana from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

A media release from the Commission said that a vote in Vienna yesterday removed marijuana from the Schedule "where it was listed alongside deadly, addictive opioids, including heroin".

The Commission said it took "a number of decisions … leading to changes in the way cannabis is internationally regulated, including its reclassification out of the most dangerous category of drugs".

The UN body said it reviewed World Health Organization recommendations on marijuana and its derivatives and the 53 member states voted to removed cannabis, where it had been for 59 years, from the strictest control schedules, that even discouraged its use for medical purposes.

The Commissions said the vote was "historic" with 27 countries in favor, 25 against, and one abstention, and "opened the door to recognizing the medicinal and therapeutic potential of the commonly-used but still largely illegal recreational drug".

The media release said that the decision "could also drive additional scientific research into the plant's long-heralded medicinal properties and act as catalyst for countries to legalize the drug for medicinal use, and reconsider laws on its recreational use".

The commission said that the WHO "clarified that cannabidiol (CBD) - a non-intoxicating compound - is not subject to international controls … [and] has taken on a prominent role in wellness therapies in recent years, and sparked a billion-dollar industry".

The media release said that more than 50 countries had medicinal cannabis programs, while Canada, Uruguay and 15 US states had legalized its recreational use, with Mexico and Luxembourg close to becoming the third and fourth countries to do so.

The Commission said that Ecuador supported all of the WHOs recommendations and urged that cannabis production, sale and use, have "a regulatory framework that guarantees good practices, quality, innovation and research development".

The Commission said the US voted to remove cannabis from Schedule IV of the Single Convention while retaining them in Schedule I, saying it was "consistent with the science demonstrating that while a safe and effective cannabis-derived therapeutic has been developed, cannabis itself continues to pose significant risks to public health".

The media release said Chile voted against, arguing that there was "a direct relationship between the use of cannabis and increased chances of suffering from depression, cognitive deficit, anxiety, psychotic symptoms, among others" while Japan believed the non-medical use of the plant "might give rise to negative health and social impacts".

Biotech Daily asked the Australian Department of Foreign Affairs how Australia voted, but the Department said the matter was the responsibility of the Department of Health.

Responses to queries to the Department of Health and the Vienna-based United Nations Commission on Narcotic Drugs but had not been received at the time of publication.

BOD AUSTRALIA

Bod says its distributor Health & Happiness Group has purchased $200,000 of its Swisse Wellness branded soft-gel hemp seed oil capsules.

Bod said the Hong Kong-based Health & Happiness would distribute the capsules through electronic commerce channels in France, the Netherlands, and the UK.

The company said the capsules improved "sleep, energy levels, stress and general wellness".

Bod was up one cent or 1.7 percent to 61 cents.

ANTISENSE THERAPEUTICS

Citycastle and Leon Serry say they have ceased their substantial shareholding in Antisense.

The substantial shareholder notice, signed by Circadian (now Opthea) founder and Citycastle director Mr Serry, said that between December 9, 2019 and November 23, 2020 Citycastle sold 3,000,000 shares for $316,003 or 10.5 cents a share, and acquired 3,120,472 shares for $255,050 or 8.2 cents a share, through the exercise of options and participation in the November entitlement offer.

Last month, Antisense said it had raised a total of $8.5 million through its over-subscribed share plan and its placement at 10 cents a share (BD: Nov 11, 30, 2020).

Citycastle said that related holders included Sked Pty Ltd Super Fund and Traders Macquarie Pty Ltd.

Biotech Daily calculates that Citycastle and Mr Serry retain 25,936,901 shares or 4.52 percent of the company.

Antisense fell half a cent or 4.8 percent to 10 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Gordon Naylor will replace David Williams as non-executive chair, effective from December 18, 2020.

Medical Developments said that Mr Williams had been chair since the company listed in December 2003 and would continue as a non-executive director.

Mr Williams said that Mr Naylor and recently appointed chief executive officer Brent MacGregor had “a vision to build on the significant base … and to take the company to a new level”.

“In a sense they have done this before at CSL and I am convinced they can do the same at [Medical Developments],” Mr Williams said.

“Since joining the board in October, Gordon has provided invaluable commercial and strategic insight and [Medical Developments] could not have found a better or more suitably qualified professional to assume the role of chairman,” Mr Williams said.

Medical Developments fell seven cents or one percent to $6.92 with 152,599 shares traded.