Biotech Daily

Tuesday April 12, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 19%; IMUGENE DOWN 9%**

*** TELIX TLX591 FOR PROSTATE CANCER TRIAL APPROVED**

*** CHIMERIC: WUXI ATU TO MANUFACTURE CAR-T-CELL**

*** ANTISENSE 1-FOR-20 BONUS OPTIONS TO RAISE $36m FOR DMD TRIAL**

*** FDA FAST TRACKS PARADIGM ZILOSUL FOR OSTEOARTHRITIS**

*** NUHEARA FILES US FDA 510K FOR 'SELF-FITTING HEARING AID'**

*** RECCE: SAFE 1,000mg R327 TAKES TRIAL TO 2,000mg**

*** MEDLAB MARIJUANA NANOCBD AWAITS FINAL UK IMPORT OKAY**

*** ZELIRA 99.4% PASS 175-TO-1 CONSOLIDATION**

*** IMUGENE TO RELEASE 28.3m VOLUNTARY ESCROW SHARES**

*** PROTEOMICS APPOINTS PROMARKERD LAUNCH ADVISORY BOARD**

*** RACE CEO MR LYNCH, CSO DR TILLETT 50% PRO RATA PAY RISE**

MARKET REPORT

The Australian stock market fell 0.42 percent on Tuesday April 12, 2022, with the ASX200 down 31.2 points to 7,454.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 23 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Paradigm was the best, up 22 cents or 19.0 percent to $1.38, with three million shares traded. Nova Eye and Patrys climbed more than nine percent; Antisense was up 8.7 percent; Micro-X improved 4.3 percent; Compumedics, Cynata, Genetic Signatures, Kazia, Proteomics and Universal Biosensors rose more than one percent; with Mesoblast up 0.9 percent.

Imugene led the falls, down two cents or 8.7 percent to 21 cents, with 34.9 million shares traded. Resonance retreated eight percent; Avita and Starpharma lost more than five percent; Actinogen, Atomo, Opthea and Pharmaxis fell four percent or more; Amplia, Cyclopharm, Resmed, Telix and Volpara were down more than three percent; Alcidion, Immutep, Nanosonics, Orthocell and Pro Medicus shed more than two percent; Clinuvel, CSL, Medical Developments, Neuren, Oncosil and Polynovo were down one percent or more; with Cochlear and Emvision down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it has ethics approval for its 50-patient, single-arm, phase II Australian trial of its TLX591 antibody therapy for prostate cancer.

Telix said that patients with prostate-specific antigen recurrence, would be treated with TLX591, or 177-lutetium-DOTA-rosopatamab, in combination with external beam radiation therapy, with a primary endpoint of "biological progression-free survival" of patients after two doses of TLX591 two-weeks apart.

The company said that the study, in collaboration with Sydney's Genesiscare, had the clinical objective of "delaying disease recurrence and thus deferring the commencement of androgen-deprivation therapy".

In January, Telix said it had dosed the first of up to 50 patients in a phase I trial of TLX591 and was conducting the study as part of its TLX591 'Prostact' therapeutic program, in parallel with its phase II and phase III study (BD: Jan 27, 2022).

Telix managing-director Dr Christian Behrenbruch said that "we are delighted to have been granted approval to commence the phase II, Prostact Target study for TLX591, a key milestone in the Prostact family of trials".

"[This trial] is part of the company's long-term clinical and commercial strategy to develop TLX591 across multiple points from men with early, localized disease all the way through to advanced metastatic disease," Dr Behrenbruch said.

Telix fell 16 cents or 3.55 percent to $4.35 with 519,453 shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has partnered with the Philadelphia, Pennsylvania-based Wuxi ATU for the manufacture and testing of its chimeric antigen T-cell (Car-T) programs.

Chimeric said that the partnership would enable it to "accelerate clinical manufacturing readiness for new Car-T assets …[and] scale Car-T manufacturing to support multiple, simultaneous, multi-center Car-T clinical trials in the future".

The company said it would transfer manufacturing and analytical testing technologies to Wuxi ATU to support process and analytical development of its Car-T-cell programs.

Chimeric said the initial focus of the partnership would be on its two autologous Car-T-cell therapies for solid tumors, CHM2101 (CDH17 Car-T) and CHM1101 (CLTX-Car-T).

Chimeric chief executive officer Jennifer Chow said that Wuxi ATU would "support the acceleration and expansion of the CHM1101 and CHM2101 development programs".

Chimeric was up half a cent or 3.6 percent to 14.5 cents with one million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it will offer one-for-20 bonus options, exercisable at 48 cents each to raise funds for its ATL1102 phase IIb/III Duchenne muscular dystrophy trial.

Antisense said that if fully exercised, the 33,439,699 options, along with options issued last December, the options would raise about $36 million and approximated the shortfall of the options not allocated in November 2021.

Last year, Antisense said that following a $20 million placement, it raised $2,586,504 in a one-for 9.4 rights offer at 24 cents a share, with one attaching option for every two new shares acquired (BD: Nov 1, 2021; Jan 16, 2022).

The company said the unquoted options would expire on December 20, 2024 or 20 business days after "the acceleration trigger date", and the offer had a record date of April 20, would open on April 21 and close on April 27, 2022.

Antisense was up one cent or 8.7 percent to 12.5 cents with 1.7 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has US Food and Drug Administration fast track designation for its phase III program of pentosan polysulfate sodium for treatment of osteoarthritis.
Paradigm said the designation for pentosan polysulfate sodium, or Zilosul, would expedite development and new drug application review, and allow it to submit portions of an applications for rolling review by the Food and Drug Administration.
The company said the two-stage, adaptive, randomized, double-blind, placebo-controlled, phase II trial would measure the change in pain and function after subcutaneous injections of pentosan polysulfate sodium compared with subcutaneous injections of placebo in participants with knee osteoarthritis pain.
Paradigm said the primary endpoint was change from baseline at day-56 using the Western Ontario and McMaster Universities Arthritis Index (Womac) pain score and the secondary outcomes including change from baseline at multiple time points out to day-168 in pain and function, patient global impression of change and quality of life.
Paradigm chief medical officer Dr Donna Skerrett said that “This is welcome news from the US FDA as the company continues to gain momentum in site activation and participant screening across the 56 selected sites in the US”.
Paradigm climbed 22 cents or 19.0 percent to $1.38 with three million shares traded.

NUHEARA

Nuheara says it has filed a 510(k) pre-market notification submission to the US Food and Drug Administration for its self-fitting, director-to-consumer hearing aid.
Nuheara said that the submission followed a clinical trial by the National Acoustic Laboratories that validated the self-fitted hearing aids compared to unaided listening across a range of settings (BD: Feb 1, 2022).
The company said the submission was “the final step of [its] expansion plans into the regulatory-approved medical device market” and aligned with the US Over-The-Counter Hearing Aid final rule publication in the FDA Federal Register expected by mid-2022.
The company did not disclose when it the FDA would make its decision.
Nuheara managing-director Justin Miller said that “once FDA clears our submission, we will have overcome the three major barriers to entering the hearing aid market … [which are] world leading hearing product and technology, alternative non-traditional paths to distribution, and lastly meeting strict regulatory standards”.
Nuheara was up 0.2 cents or 15.4 percent to 1.5 cents with 8.8 million shares traded.

RECCE PHARMACEUTICALS

Recce says a review of 10 healthy subjects dosed with 1,000mg of R327 showed “good safety and tolerability” and it would proceed to intravenous 2,000mg.
Recce said that with the low-dose cohorts data review complete and endpoints achieved, it had a unanimous recommendation from the safety committee to start the high-dose cohort of R327 at 2,000mg intravenously.
The company said that the phase I trial was an ascending dose, randomized, placebo-controlled, parallel, double-blind, single-dose study conducted at Adelaide’s CMAX clinical trial facility, evaluating the safety and pharmacokinetics of R327 in seven to 10 healthy subjects per dose, across eight sequential dosing cohorts of 50mg to 16,000mg.
Recce said the study was on track to complete dosing by December 2022.
Recce fell one cent or 1.1 percent to 93 cents.

MEDLAB CLINICAL

Medlab says its marijuana Nanocbd is awaiting final importation approval from the UK Government.
Medlab said that pricing for Nanocbd was expected to be around GBP130.00 ($A227.56) per prescription and was the first of two cannabinoid programs to launch in the UK, closely followed by Nanabis.
Medlab chief executive officer Dr Sean Hall said that a prescription of the buccal spray Nanocbd was “about a one-month supply”.
In a media release to the ASX Dr Hall said that Nanocbd was the company’s first cannabinoid to enter the UK under an approved compassionate program.
“Our partners WEP Clinical in the UK have all licences in place to distribute and supply under the UK named patient program which in a number of ways is similar to the Australian special access scheme,” Dr Hall said.
Medlab was up 0.3 cents or 3.45 percent to nine cents.

ZELIRA THERAPEUTICS

Zelira says its extraordinary general meeting has voted 99.38 percent for its proposed 175-to-one stock consolidation.
According to its most recent filing, Zelira had 1,675,101,964 shares on issue, implying that following the consolidation it would have about 9,572,011 shares on issue.
Today, Biotech Daily calculates that today’s closing share price of 1.8 cents would be equivalent to $3.15 per consolidated share.
Zelira was unchanged at 1.8 cents.

IMUGENE

Imugene says it will release 28,328,452 shares from voluntary escrow on April 22, 2022.
According to its most recently filing, Imugene had 5,848,062,841 shares on issue with no shares in ASX escrow.
Imugene fell two cents or 8.7 percent to 21 cents with 34.9 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has established a clinical advisory board of seven experts to advise it on the launch of its Promarkerd test for diabetic kidney disease.
Proteomics said that the clinicians were “experts in diabetes technology and care, and influential key opinion leaders in their respective fields … [offering] expert opinion on the best strategies for the market rollout of Promarkerd”.
The company said the board included Western Australia’s Fremantle Hospital Prof Tim Davis, Italy’s University of Pisa’s Dr Ele Ferrannini, the Santa Barbara, California-based Sansum Diabetes Research Institute Dr David Kerr, the University of California San Francisco’s Prof David Klonoff, Endocrine Associates of Long Island New York’s Prof Michael Shanik, Monash University’s Prof Merlin Thomas, and the Boston-based Brigham and Women’s Hospital’s Dr Alexander Turchin.
Proteomics was up 1.5 cents or 1.35 percent to $1.13.

RACE ONCOLOGY

Race says it will raise the pay of chief executive officer Phillip Lynch and chief scientific officer Dr Daniel Tillett 50 percent to $300,000 each to reflect the time worked.
Race said that the pay rise was effective from April 1, 2022 and the original 0.5 full time equivalent agreements from September 2020 did not reflect the continued employee time contribution which were reassessed at a 0.75 full time equivalent level.
Race fell 12 cents or 4.65 percent to $2.46.