Biotech Daily

Thursday March 10, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PARADIGM UP 14%; NOVA EYE DOWN 8%**

*** VOLPARA: EURO SOCIETY BACKS BREAST DENSITY AWARENESS**

*** RACE: ZANTRENE KILLS KIDNEY CANCER, IN-VITRO**

*** INCANNEX: MARIJUANA IHL-42X 'REDUCES SLEEP APNOEA 44%'**

*** IMMUTEP: IMP321 BREAST CANCER TRIAL FDA TALKS 'CONSTRUCTIVE'**

*** BIO-MELBOURNE OPTIMIZES MEDTECH SUCCESS**

*** CHAIR PAUL RENNIE INCREASES, DILUTED TO 8.7% OF PARADIGM**

*** SANDON TAKES 12.2% OF IDT**

*** GEOFFREY O'BRIEN 'INCREASES, DILUTED' TO 9% OF HEXIMA**

*** STEVEN WALLER REPLACES CRYOSITE CHAIR BRYAN DULHUNTY**

MARKET REPORT

The Australian stock market was up 1.1 percent on Thursday March 10, 2022, with the ASX200 up 77.8 points to 7,130.8 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 12 fell, three traded unchanged and two were untraded. All three Big Caps rose.

Paradigm was the best, up 14.5 cents or 13.9 percent to $1.185, with 802,401 million shares traded. Amplia climbed 11.1 percent; Medical Developments improved 7.3 percent; Proteomics was up 5.8 percent; Imugene and Volpara were up more than four percent; Actinogen, Neuren, Pharmaxis, Polynovo, Prescient and Resonance rose more than three percent; Alcidion, Clinuvel, CSL, Immutep, Mesoblast and Oncosil climbed more than two percent; Cochlear, Emvision, Orthocell, Pro Medicus, Resmed and Starpharma were up more than one percent; with Nanosonics and Next Science up by less than one percent.

Nova Eye led the falls, down two cents or 8.3 percent to 22 cents, with 77,844 shares traded. Cynata and Universal Biosensors fell more than four percent; Antisense, Impedimed and Patrys were down more than three percent; Avita, Dimerix and Opthea shed more than two percent; Kazia and Telix were down more than one percent; with Compumedics down by 0.8 percent.

VOLPARA HEALTH

Volpara says that as a result of its 10-year Density study, the European Society of Breast Imaging recommends women be informed of breast density.

Last year, Volpara said its 10-year, 3,000-patient, randomized, controlled Dense trial assessing the cost-effectiveness of magnetic resonance imaging said it reduced the false-positive cancer rate in women with dense breasts (BD: Mar 18, 2021).

Today, the company said the European Society of Breast Imaging "recommends that all European mammography providers offer breast MRI to women with extremely dense breasts".

Volpara said the recommendation urged European mammography providers to notify women of their breast density at screening, and along with greater awareness of the risks of extremely dense breast tissue, "presents a significant opportunity for Volpara to expand its European footprint to capitalize on the potential increased use of breast density screening software".

The company said 17.9 million women a year were screened for breast cancer in Europe.

Volpara chief executive officer Dr Ralph Highnam said the Society's recommendations were "a major step toward wide-scale European implementation of personalized breast care for women with extremely dense breasts".

"Volpara has long advocated the informing of women about their dense breast tissue and offering them additional imaging as needed," Dr Highnam said.

"It's gratifying to see a major group of breast imaging experts base its new guidance on the results generated by our automated density assessment software in the ground-breaking Dense trial," Dr Highnam said. "I'm hopeful that other public health bodies will now follow the [Society's] lead."

The recommendations, in an article titled 'Breast cancer screening in women with extremely dense breasts recommendations of the European Society of Breast Imaging' were published in Nature European Radiology and are available at: https://link.springer.com/article/10.1007/s00330-022-08617-6.

Volpara was up three cents or 4.5 percent to 69.5 cents.

RACE ONCOLOGY

Race says a University of Newcastle study has shown Zantrene kills kidney cancer as a single agent and in combination with other chemotherapy treatments, in-vitro.

Race said the study, led by the New South Wales University of Newcastle and Hunter Medical Research Institute Prof Nikki Verrills showed that when used in combination with Zantrene, the kidney cancer drugs lenvatinib, cabozantinib and pazopanib showed "greatly improved cell killing" of clear cell renal cell carcinoma, and that these synergistic combinations would increase the potential for rapid clinical translation.

The company said that at sub-cytotoxic concentrations, Zantrene effectively slowed the growth of kidney cancer cells.

Race said that it would pursue discussions with key opinion leaders in renal cancer regarding the possibility of using Zantrene in a phase I/II combination treatment, starting as early as the end of the year.

Race chief executive officer Phillip Lynch said the company was "pleased to note Zantrene's effectiveness both in isolation and in combination with other known kidney cancer treatments".

"This result encourages clinical translation, and we look forward to determining an optimal approach for progressing clinical study," Mr Lynch said.

Race was up nine cents or 3.4 percent to $2.72.

INCANNEX HEALTHCARE

Incannex says its 11-person, phase II trial of IHL-42X, for obstructive sleep apnoea showed IHL-42X reduces patient apnoea-hypopnoea indices and is well-tolerated.
Incannex said the 11-person study evaluated its marijuana-based IHL-42X for sleep apnoea with an average 44.4 percent reduction ($p = 0.0067$) across low, mid, and high doses compared to patient baselines.
The company said the trial was conducted at the University of Western Australia Centre for Sleep Science and Melbourne's Alfred Hospital, which dosed participants with three doses of IHL-42X or placebo in seven-day treatment periods, with one week washout periods between dosing.
The company said that 60 percent of participants had a reduction in their apnoea-hypopnoea index (AHI) of more than 50 percent during at least one treatment compared to baseline.
Incannex said that 20 percent of participants had a reduction in their AHI of more than 80 percent during at least one treatment compared to baseline.
Incannex chief scientific officer Dr Mark Bleackley said the company was "delighted that IHL42X has demonstrated efficacy and good safety characteristics in our preliminary assessment of data from the proof-of-concept trial".
"The average reduction in AHI calculated across low, mid, and high-dose IHL-42X has met our expectations for what would constitute a valuable product for the treatment of obstructive sleep apnoea," Dr Bleackley said.
"IHL-42X has the potential to reduce disease severity, resulting in improved sleep quality, multiple major health benefits and increased quality of life," Dr Bleackley said.
"We look forward to the further analysis of the study data by Novotech, which will include identification of which dose strength performed best," Dr Bleackley said.
The company said it has been granted a pre-investigative new drug meeting with the US Food and Drug Administration on May 11, 2022, and that it was planning pivotal trials.
Incannex fell four cents or 7.1 percent to 52.5 cents with 24.7 million shares traded.

IMMUTEP

Immutep says it has received "constructive feedback" from the US Food and Drug Administration on its phase III trial of IMP321 for metastatic breast cancer.
Last year, Immutep said its 227-patient, phase II 'Aipac' trial of IMP321, or eftilagimod alpha, with paclitaxel for metastatic breast cancer showed a "non-significant survival benefit trend" (BD: Nov 10, 2021).
Today, the company said that based on overall survival data from its phase IIb trial of IMP321 for metastatic breast cancer, the FDA "supported [its] view to continue exploring the development of [IMP321 in metastatic breast cancer] in a new registrational trial".
Immutep said the proposed phase III trial would be based on the phase II trial, but with an optimized design and directed to patients most likely to benefit from the treatment.
The company said the trial was intended to take place in multiple countries with regulatory interactions ongoing, including with the FDA and the European Medicines Agency.
Immutep chief executive officer Marc Voigt said the company was "pleased to receive constructive feedback from the US FDA regarding … Efti in metastatic breast cancer".
"The FDA's advice builds on the feedback we received from the EMA in October 2021 and will help solidify the optimal trial design," Mr Voigt said. "Interactions with the FDA and other regulatory agencies will continue and we will keep the market informed of our progress as we plan for our registrational trial for Efti."
Immutep was up one cent or 2.6 percent to 40 cents with 3.2 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its April Biosymposium will address 'Optimizing the Victorian Medtech Ecosystem: Origins of Demand & Successful Translation'.
The Network said the event would examine "the key drivers behind successful innovation, translation and commercialization of medical devices and diagnostics in Victoria and take a deep dive into the environment and the approach being taken to further develop the ecosystem".
The Network said that guest speakers would include Prime Accounting & Business Advisory partner Brendan Brown, Bio-Melbourne Network deputy chair Dr Elane Zelcer, Commonwealth Scientific and Industrial Research Organisation biomedical manufacturing research director Dr Susie Nilsson and Medtechvic director Prof Sally McArthur.
The Bio-Melbourne Network said that the State Government of Victoria, CSIRO, Prime Accounting, Seerpharma Pty Ltd and Fundsquire were sponsoring the symposium.
The industry organization said the virtual event would be held on April 5, 2022 from 8:45am to 5:15pm (AEDT).
For details and registration, go to: https://bit.ly/3vPBf05.

PARADIGM BIOPHARMACEUTICALS

Paradigm chair Paul Rennie says he has increased his substantial holding in Paradigm but been diluted from 20,109,222 shares (8.77%) to 20,157,389 shares (8.66%).
The Adelaide-based Mr Rennie said that on March 8, 2022 he bought 48,167 shares on-market for $50,634, or $1.05 a share.
Paradigm has had multiple issues of restricted shares since Mr Rennie's last substantial shareholder notice.
Paradigm was up 14.5 cents or 13.9 percent to $1.185.

IDT AUSTRALIA

Sandon Capital says it has increased its substantial holding in IDT from 26,769,292 shares (11.2%) to 29,219,212 shares (12.2%).
The Sydney and Cayman Islands-based Sandon said that between February 17 and March 7, 2022 it bought 2,450,000 shares for $470,923, or 19.2 cents a share.
IDT was up one cent or 5.6 percent to 19 cents.

HEXIMA

Geoffrey O'Brien and related entities say they have increased their holding in Hexima but been diluted from 14,659,353 shares (11.20%) to 15,126,853 shares (9.06%).
The South Yarra-based Mr O'Brien said that between January 13 and December 9, 2021 he acquired 467,500 shares, through Woobinda Nominees Pty Ltd and Caroline House Superannuation Fund Pty Ltd, saying the shares were acquired for both shares and "cash purchases via SPP" but did not state the consideration as required by the Corporations Act 2001.
Last year, Hexima said it raised $10 million in a placement and $1 million in a share plan at 32 cents a share (BD: Nov 1, 26, 2021).
Hexima was up one cent or 2.9 percent to 36 cents.

CRYOSITE

Cryosite says it has appointed Steven Waller as its chair, replacing Bryan Dulhunty, effective from today.

Cryosite said Mr Dulhunty was appointed chair in March 2018 would continue as a non-executive director.

The company said Mr Waller was appointed a director in November 2021.

Cryosite was untraded at 45 cents.