Biotech Daily

Tuesday May 10, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: POLYNOVO UP 16%; PRESCIENT DOWN 9%**

*** REDHILL TO RAISE $21.5m, WARRANTS**

*** PACIFIC EDGE CXBLADDER MONITOR VALIDATION STUDY**

*** IMUGENE AUSTRALIAN HER-VAXX GASTRIC CANCER TRIAL APPROVED**

*** CLINUVEL READY FOR PHASE II SCENESSE VITILIGO TRIAL**

*** TOTAL BRAIN: AARP $3.8m BRAIN HEALTH EXTENSION**

*** MEDICAL DEVELOPMENTS: ENDO CANADA PENTHROX DISTRIBUTOR**

*** OSTEOPORE, MAXONIQ TO SELL OSTEOMESH PRODUCTS**

*** CLARITY 'UNAFFECTED BY NOVARTIS DRUG, TRIAL HALT'**

*** PYC VP-001 PK RESULTS SUPPORT HUMAN TRIAL**

*** BOD STARTS MARIJUANA TRIAL FOR INSOMNIA**

*** INCANNEX IHL-216A 'RESTORES MEMORY' IN CONCUSSED RATS**

*** EMYRIA EXPANDS MDMA ANALOGUES**

*** CRESO: HEALTH CANADA APPROVES PSILOCYBIN IMPORT**

*** BIO-MELBOURNE CONNECTING WOMEN LUNCH 'SOLD-OUT'**

*** ARTRYA APPOINTS DR JACK LEWIN ADVISER**

*** OSPREY EXTENDS VOLUNTARY SUSPENSION**

*** PERENNIAL REDUCES TO 14% OF MICROBA**

MARKET REPORT

The Australian stock market fell 0.98 percent on Tuesday May 10, 2022, with the ASX200 down 69.5 points to 7,051.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded.

Polynovo was the best, up 14.5 cents or 15.6 percent to $1.075, with seven million shares traded. Impedimed improved 10.5 percent; Resonance climbed 6.1 percent; Universal Biosensors was up four percent; Actinogen, Clinuvel, Imugene and Nanosonics were up more than three percent; Compumedics, Neuren, Pro Medicus and Starpharma rose two percent or more; with Opthea and Paradigm up by more than one percent.

Prescient led the falls, down 1.5 cents or 9.4 percent to 14.5 cents, with 6.9 million shares traded. Orthocell fell 8.45 percent; Avita was down seven percent; Amplia, Antisense, Atomo and Volpara fell more than four percent; Alcidion, Genetic Signatures and Medical Developments were down more than three percent; Cochlear, Mesoblast, Micro-X, Nova Eye and Telix shed two percent or more; Emvision and Resmed were down more than one percent; with Cyclopharm and Next Science down by less than one percent.

REDHILL BIOPHARMA

Redhill says it has “a definitive agreement with [an unnamed] single leading healthcare investor” to raise $US15 million ($A21.5 million) at $1.42 ($A2.04) a share.

Redhill said it had agreed to issue the investor unregistered private warrants to acquire up to 13,204,225 shares exercisable at $US1.48 per share from six months from issue to five and a half year from issue, in a concurrent private placement.

The company said the closing was expected by May 11, 2022, subject to conditions.

Redhill said that Cantor Fitzgerald & Co was the exclusive placement agent for the offer, and the proceeds would be used for working capital, acquisitions and corporate purposes.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

In March, the company said that Talicia, formerly RHB-105, for Helicobacter pylori was “the most prescribed branded [Helicobacter] pylori therapy in the US achieving record quarterly prescriptions” with revenue up 78.4 percent compared to the prior corresponding period, but did not disclose the amount of revenue.

On the Nasdaq, Redhill fell 40 US cents or 27.03 percent to $US1.08 ($A1.55) with 1.2 million shares traded.

PACIFIC EDGE

Pacific Edge says it will conduct an up to 426-patient study to evaluate its Cxbladder Monitor for surveillance of recurrent urothelial cancer against existing guidelines.

Pacific Edge said the multi-centre, observational study, titled the ‘Longitudinal Bladder Cancer Stud for Tumor Recurrence’, would recruit patients with previously diagnosed urothelial cancer categorized as intermediate or high-risk for urothelial cancer recurrence.

The company said its Cxbladder Monitor was a urine-based gene expression biomarker test for the surveillance of recurrent disease in bladder cancer patients, and would be tested against the American Urological Association standard-of-care.

Pacific Edge said patients would provide urine samples over four visits during a 12-months to 24-months, for Cxbladder testing and central urine cytology.

The company said the study would collect tumor tissue from the first tumor and the most recent recurrence to genotype each tumor using DNA markers indicative of an elevated risk of urothelial cancer.

Pacific Edge said that patient records would be reviewed up-to four years after the final urine sample to check clinical outcome when Cxbladder indicated high probability of bladder cancer when cystoscopy was negative.

The company said the study would recruit patients from the US Veterans Administration, US academic centres and from research collaboration sites in Australia and would begin recruitment by June 2022, with first results expected in 2024.

Pacific Edge chief executive officer Dr Peter Meintijes said the study would build on previous studies showing that Cxbladder could be incorporated into a surveillance strategy to safely reduce the frequency of cystoscopy for intermediate and high-risk patients.

“[The study] is an important component of Pacific Edge’s ongoing commitment to demonstrating the clinical utility of Cxbladder in pursuit of further inclusion into global standards of urothelial cancer diagnosis and management,” Dr Meintjes said.

“Our urine based Cxbladder tests are non-invasive and allow for sample collection in the privacy of a patient’s home with our patient in-home sampling system and therefore can help to overcome entrenched patient non-compliance with management and surveillance regimes,” Dr Meintjes said.

Pacific Edge fell 2.5 cents or 3.2 percent to 75 cents.

IMUGENE

Imugene says it has ethics approval for its up-to 30 patient, phase II 'Nextherizon' trial of HER-Vaxx with chemotherapy or pembrolizumab for gastric cancer.

Imugene said that the trial was an open-label, multi-centre, signal-generating phase II study assessing the safety and efficacy of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic human epidermal growth factor 2 (HER-2)/neu over-expressing gastric or gastroesophageal junction adenocarcinomas who have previously progressed on trastuzumab.

In March, the company said it would conduct a phase II trial to evaluate HER-Vaxx using Merck &Co Inc's prembrolizumab or Keytruda (BD: Mar 15, 2022).

Last week, Imugene said its agreement with Merck had been terminated, but that the "trial continues unchanged" (BD: May 2, 2022).

Imugene said the primary endpoints were safety and response rate, with secondary endpoints duration of response, progression-free survival, overall survival and biomarkers.

The company said Adelaide's Queen Elizabeth Hospital was the first approved, with principal investigator Dr Tim Price and additional sites to open in Australia and the US.

Imugene managing-director Leslie Chong said the start of the Australian study was "a significant milestone for Imugene and clinicians treating Australians faced with the challenge of HER-2+ gastric cancer and we look forward to further evaluating HER-Vaxx in combination with pembrolizumab in a relapsed/refractory metastatic setting".

Imugene was up half a cent or 3.1 percent to 16.5 cents with 47.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has approval for and up-to six-patient study of afamelanotide, or Scenesse, as a monotherapy in darker-skin vitiligo patients.

Clinuvel said that the CUV104 study was an open-label phase II trial assessing the safety and changes in pigmentation in generalized vitiligo following sub-cutaneous administration of 16mg afamelanotide as a monotherapy.

In January, the company said that the US Food and Drug Administration had approved the study (BD: Jan 16, 2022).

Today, Clinuvel said that the trial's primary objective was to evaluate afamelanotide's ability to repigment facial lesions or patches.

Clinuvel North American operations director Dr Linda Teng said that "visible and beneficial effects from the drug as a single therapy would be a leap forward for these patients, as our hormonal solution would be the most biological answer to a stigmatizing disorder".

"We have fundamentally supported the concept of providing an effective therapy acting through the bloodstream reaching all melanocytes, as opposed to a localized or topical therapy that requires frequent applications for patients," Dr Teng said.

"We have received positive encouragement both from expert physicians and regulatory authorities to use our lead hormone analogue in vitiligo," Dr Teng said.

Clinuvel was up 50 cents or 3.3 percent to $15.63 with 169,285 shares traded.

TOTAL BRAIN

Total Brain says it has a $3.8 million, five-year extension of its agreement with the American Association of Retired Persons for cognitive brain health support services.

Total Brain said that the extended agreement supported a 2.5 percent recurring year-on-year price increase, subsequent to the $725,000 first year payment.

Total Brain was unchanged at 9.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Endo Ventures will distribute its Penthrox inhaled methoxyflurane analgesic in Canada.

Medical Developments said that Endo Ventures was a subsidiary of the Dublin, Ireland and Malvern, Pennsylvania-based Endo International PLC and had designated its Saint Laurent, Quebec subsidiary Paladin Labs Inc to assume the rights to Penthrox and would begin commercial activities in 2022, once the required drug licence transfer processes were completed with Health Canada.

Medical Developments chief executive officer Brent MacGregor said the company was "excited to embark on this renewed journey for Penthrox in Canada with such a reputable partner as Paladin Labs".

Medical Developments fell 10 cents or 3.2 percent to $3.01.

OSTEOPORE

Osteopore says it has appointed Melbourne's Maxoniq as the exclusive distributor for its oral and maxilla-facial reconstruction products in Australia and New Zealand.

Osteopore said the three-year agreement meant Maxoniq would market and sell its Australian Therapeutic Goods Administration-listed Osteomesh products for use in orbital floor reconstruction surgery.

The company did not disclose the commercial terms of the agreement but said that it did not contain binding minimum sales thresholds and that each party would bear their own costs in relation to the collaboration.

Osteopore executive chair Mark Leong said that the partnership would "help strengthen our reach beyond the cranial space into the [oral and maxilla-facial] area where our [products] have been successfully adopted in Asia".

Osteopore was up half a cent or 2.8 percent to 18.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it is unaffected by the Novartis suspension of production and a temporary hold on clinical trials of Lutathera and Pluvicto 177-lututium-PSMA-617.

Clarity said that its clinical development programs were not impacted by the Basel, Switzerland-based Novartis production disruptions as its copper isotypes for cancer diagnostics and therapy were "wholly independent of the Lutathera and Pluvicto supply chains and other first-generation radiopharmaceuticals".

In February, the company said that the outage at the High Flux Reactor in Petten, Belgium did not affect its copper isotopes in any way (BD: Feb 3, 2022).

Clarity fell one cent or 2.2 percent to 44 cents.

PYC THERAPEUTICS

PYC says non-human primate pharmaco-kinetic studies of VP-001 for the eye disease retinitis pigmentosa type 11 (RP11) support a human clinical trial.

PYC said that VP-001 showed distribution of the drug to the target cells in the eye, extended residence time of the drug in target cells and minimal off-target distribution of the drug.

The company said that it was "on track" to submit an investigational new drug application to the US Food and Drug Administration for VP-001 in the second half of this year.

PYC fell 0.3 cents or 3.6 percent to 8.1 cents.

BOD AUSTRALIA

Bod says it has enrolled the first of more than 200 patients in a phase IIb trial investigating the efficacy of its cannabidiol formulation on symptoms associated with insomnia.
Bod said the double-blind, randomized, placebo-controlled trial would investigate the schedule 3, over-the-counter, 50mg and 100mg oral cannabidiol product per day, versus placebo, over eight weeks at Sydney's Woolcock Institute of Medical Research.
The company said that schedule 3 products could be sold over-the-counter by a pharmacist without a prescription and that after the study, it was "confident" that it would have enough data to progress product registration for schedule 3 low-dose cannabidiol product with the Australian Therapeutics Goods Administration.
Bod said that it "expected to be one of the first companies in Australia" to have its cannabidiol product added to the Australia Register of Therapeutic Goods.
Bod fell half a cent or 3.3 percent to 14.5 cents.

INCANNEX HEALTHCARE

Incannex says its marijuana and anaesthetic combination IHL-216A restores spatial memory following a sports concussion model in rats.
Incannex said that the study of 24 rats compared IHL-216A to its component parts of cannabidiol and the anaesthetic isoflurane.
The company said that 24-hours after injury, rats treated with IHL-216A were found to have "no difference" in discrimination index compared to uninjured animals ($p = 0.5855$), missing statistical significance.
Incannex said t injured animals treated with either vehicle or isoflurane alone after injury had a discrimination index "significantly reduced" compared to uninjured animals ($p = 0.0498$; $p = 0.0245$ respectively), and the group treated with cannabidiol alone had intermediate performance between uninjured and vehicle treated animals ($p = 0.2933$).
The company said the findings indicated that "the defect in spatial memory observed at one day post-injury is restored in animals treated with IHL-216A".
Incannex chief scientific officer Dr Mark Bleackley said that "combining the results from our two animal studies indicates that IHL-216A has the potential to be effective at reducing the effects of traumatic brain injuries across the spectrum of injury severity".
Incannex fell one cent or 2.6 percent to 37 cents with 10.9 million shares traded.

EMYRIA

Emyria with the University of Western Australia says 16 of its 17 3,4 methylene-dioxy-meth-amphetamine (MDMA) analogues passed screening at test concentrations.
Emyria said the analogues of MDMA or 'ecstasy' showed "no evidence of interactions with one or more of the enzymes or cell receptors that can be associated with unwanted clinical side effects" and the additional analogues brought its total to 83 analogues.
Emyria managing-director Dr Michael Winlo said that with the University of Western Australia, the company had "a set of over 80 MDMA-like compounds with strong [intellectual property] and therapeutic potential".
"We are now planning pivotal preclinical studies to help identify which of these compounds may have the potency of common MDMA but with enhanced safety and shorter acting times and half-lives," Dr Winlo said.
"We anticipate this screening program will help identify compounds with the potential to become registered treatments for other neuro-psychiatric conditions," Dr Winlo said.
Emyria was up two cents or eight percent to 27 cents.

CRESO PHARMA

Creso says Health Canada has approved its subsidiary Halucenex Life Sciences importing one kilogram of psilocybe cubensis, equating to 20 grams of psilocybin.
Creso said that Halucenex would import the dried Jamaican grown psilocybe cubensis from Grogenex JA, with the shipment expected by the end of the month.
The company said that it had paid $C22,750 ($A25,149) to Grogenex and would pay an additional $C22,750 when the material had been shipped.
Creso said that the psilocybe cubensis would be used for research and development purposes.
Creso fell 0.3 cents or 5.6 percent to 5.1 cents with 9.7 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its sold-out Connecting Women Lunch this Friday May 13 will “connect more than 500 women and men” from all parts of the industry.
Bio-Melbourne Network chief executive officer Jeff Malone said the Network was “delighted” that the event could go ahead after a two-year absence “and continues to see such great sector engagement”.
Mr Malone said the keynote speaker was oncologist Dr Ranjana Srivastava, with a special interest in the holistic care of elderly cancer patients.
The Network said that CSL was the premier sponsor of the lunch, along with major sponsors Avatar Brokers Pty Ltd, Almac Group, Radium Capital and Syneos Health.

ARTRYA

Artrya says it has appointed the former chief executive officer of the American College of Cardiology Dr John (Jack) Lewin to its clinical advisory board.
Artrya said that Dr Lewin was currently the founder and chair of Lewin and Associates, and previously was the Cardiovascular Research Foundation’s chief executive officer.
The company said that Dr Lewin was chief executive officer of the American College of Cardiology from 2006 to 2012, and previously the California Medical Association chief executive officer for eight years, Hawaii’s Director of Health from 1986 to 1994, and working for the US Public Health Service, he was the founder and first director of the Navajo Nation Department of Health.
Artrya said that Dr Lewin held a Bachelor of arts in biological sciences from the University of California, Irvine and a Doctor of Medicine from the University of Southern California.
Artrya was up 20 cents or 28.6 percent to 90 cents.

OSPREY MEDICAL

Osprey has requested an extension to its voluntary suspension “as it considers its strategic and funding options”.
Last week, Osprey requested a suspension to follow the trading halt requested on April 29 to consider its strategic and funding options” (BD: Apr 29, May 3, 2022).
Today, the company said that the suspension would continue for up to 16 trading days to June 1, or on release of an announcement.
Osprey last traded at 20 cents.

MICROBA LIFE SCIENCES

Perennial Value Management says it has reduced its substantial holding in Microba from 40,651,376 shares (14.82%) to 37,651,376 shares (13.72%).
The Sydney-based Perennial said that on May 6, 2022 it sold 3,000,000 shares for $1,017,756 or an average of 33.925 cents a share.
Microba fell 1.5 cents or 4.4 percent to 32.5 cents with 47.9 million shares traded.