Biotech Daily

Monday November 21, 2022

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PARADIGM UP 10%; NANOSONICS DOWN 12%**

*** LUMOS TAKES $8m LIND, SBC DRAW-DOWN EQUITY FACILITY**

*** FDA APPROVES SDI STELA TOOTH-COLORED FILLING**

*** STARPHARMA LAUNCHES VIRALEZE IN HONG KONG & MACAU**

*** INVEX RANDOMIZES 1st PHASE III PRESENDIN IIH PATIENT**

*** CLARITY: FDA OKAYS SAR-BOMBESIN PROSTATE CANCER TRIAL**

*** CHIMERIC LICENCES CORE-NATURAL KILLER PLATFORM FOR CANCER**

*** CRESO TO TAKE HEALTH HOUSE FOR '$4.6m', REPAY ZELIRA LOAN**

*** CANN DOSES LAST PHASE III MARIJUANA SLEEP TRIAL PATIENT**

*** ZELIRA ZLD007 DIABETIC NERVE PAIN TRIAL 'ENROLLED'**

*** UNIVERSAL BIOSENSORS RECEIVES $3.9m FEDERAL R&D TAX INCENTIVE**

*** ARTRYA TO RELEASE 25.6m VOLUNTARY ESCROW SHARES**

*** HEXIMA TO RELEASE 7.3m ASX ESCROW SHARES**

*** AUDEARA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** VECTUS REQUESTS 'MATERIAL FUNDRAISING' TRADING HALT**

*** JASON CARROLL TAKES 13.5% OF ISLAND**

*** MERCHANT TAKES 9.8% OF HEXIMA**

MARKET REPORT

The Australian stock market fell 0.17 percent on Monday November 21, 2022, with the ASX200 down 12.5 points to 7,139.3 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and three were untraded.

Paradigm was the best, up 16 cents or 10.4 percent to $1.70, with one million shares traded. Prescient and Starpharma were up more than seven percent; Mesoblast climbed 6.45 percent; Impedimed and Universal Biosensors improved more than four percent; Medical Developments and Neuren were up three percent or more; Emvision, Next Science, Oncosil, Opthea and Patrys rose more than two percent; Avita, Genetic Signatures, Telix and Volpara were up one percent or more; with CSL and Resmed up by less than one percent.

Nanosonics led the falls, down 56 cents or 12.2 percent to $4.02, with 1.56 million shares traded. Antisense lost 8.1 percent; Compumedics and Nova Eye were down more than six percent; Cyclopharm and Pharmaxis shed more than five percent; Actinogen fell four percent; Clinuvel, Immutep, Kazia, Micro-X, Orthocell and Pro Medicus were down one percent or more; with Cochlear, Polynovo and Proteomics down less than one percent.

LUMOS DIAGNOSTICS

Lumos says it has an $8 million, two-year, convertible note facility from the New York-based Lind Partners and Melbourne's SBC Global Investment Fund.
Lumos said that notes would be convertible at the lesser of a 100 percent premium to the 5-day volume-weighted average price, or 90 percent of the average of the five lowest daily volume-weighted average prices during the 20 trading days preceding the date of share issuance, but not less than 2.5 cents a share.
The company said it would receive an initial $4 million tranche, with a second $4 million tranche subject to mutual agreement.
Lumos said that in the event the conversion price would be less than the floor price, the company had the option to satisfy the conversion in cash, shares or a mix of both, or, with the consent of the Investor, reduce any share issue obligation, in excess of the amount that would be required at the floor price, by setting it off against the placement shares.
The company said that as partial consideration for the convertible note agreements, it would issue 12,000,000 placement shares to the investors on a delayed payment basis within five days of the purchase date in respect of the first of the two-tranche agreement.
Lumos said that Bell Potter Securities was its adviser for the convertible note agreements
Lumos fell half a cent or 8.6 percent to 5.3 cents.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says it has received approval from the US Food and Drug Administration for its Stela composite amalgam replacement product.
SDI said growing consumer preference away from silver amalgam towards tooth-colored fillings provided the industry with a challenge, given amalgam's "unmatched durability, low cost, and ease to place".
The company said Stela was designed to satisfy these requirements and it would introduce the product to US dentists and key opinion leaders before a formal product launch by October 2023.
The company said it was seeking regulatory approval from other bodies, including the Australian Therapeutic Goods Administration, and that following the FDA's approval, it expected others to follow.
SDI chief executive officer Samantha Cheetham said she was "thrilled to have received FDA approval" for Stela and thank the research and development team and partners at the University of New South Wales, University of Wollongong and University of Sydney.
SDI was up four cents or 4.65 percent to 90 cents.

STARPHARMA

Starpharma says it will launch its Viraleze anti-Covid nasal spray at pharmacies in Hong Kong and Macau this week.
In October, Starpharma said it had appointed Hong Kong's Hengan Pharmacare Company to sell and distribute Viraleze in Hong Kong and Macau (BD: Oct 21, 2022).
Today, Starpharma chief executive officer Dr Jackie Fairley said the company was "delighted to see our new partner Hengan Group launch Viraleze in Hong Kong and Macau so quickly and through leading pharmacies and online channels".
Starpharma said Viraleze contained SPL7013, the active ingredient in Vivagel BV for bacterial vaginosis and its Vivagel condom coatings.
Starpharma was up four cents or 7.55 percent to 57 cents.

INVEX THERAPEUTICS

Invex says the first of 240 patients in its phase III trial of Presendin for idiopathic intracranial hypertension has been randomized in the study.
Invex said the 24-week, randomized, placebo-controlled, double-blind trial would evaluate the safety and efficacy of Presendin with the primary endpoint the change in intracranial pressure, and secondary endpoints of vision and headache outcomes.
Invex chair Dr Jason Loveridge said that randomizing the first patient "marks a significant milestone for the company and [idiopathic intracranial hypertension] patients generally".
"Given the clinical results we have achieved to date, we believe Presendin has the potential to improve clinical outcomes and the quality of life for these … patients in a safe and effective manner, where current therapies remain lacking," Dr Loveridge said.
Invex fell two cents or 3.5 percent to 55 cents.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has approved its 38-patient Sar-Bombesin diagnostic and therapeutic trial for castrate-resistant prostate cancer.
Clarity said that it would begin its 'Combat' phase I/II dose escalation trial to establish the safety and efficacy of 64-copper and 67-copper sarcophagine (Sar) Bombesin in prostate specific membrane antigen-negative, metastatic, castrate-resistant prostate cancer.
Clarity chair Dr Alan Taylor said the trial "marks our third therapy program and sixth program overall, in the targeted copper [diagnostic and therapeutic] pipeline that is progressing through clinical trials in the US" and was expected to begin by July 2023.
Clarity was up 7.5 cents or 8.1 percent to $1.00.

CHIMERIC THERAPEUTICS

Chimeric says it has licenced exclusive global rights to the CHM0201 Core-natural killer (NK) cell platform from the Cleveland, Ohio-based Case Western University.
The company said that it would the upfront fees for the Core-NK platform for oncology, immune disorders, and viral infectious diseases would be funded from its cash reserves.
Chimeric said the Core-NK platform used a "genetically-modified feeder cell line to activate and expand universal off-the-shelf allogeneic NK cell products derived from healthy donors [and] the expanded Core-NK cells exhibit enhanced cytotoxicity, metabolism and expression of activating receptors compared to fresh, activated NK cells".
In March, Chimeric said one of nine "heavily pre-treated" cancer patients in its phase I trial of CHM0201 achieved a complete response at 100 days (BD: Mar 7, 2022).
At that time, the company said the phase I trial of its "clinically validated, off the shelf, robust, enhanced natural killer cell" (Core NK) platform, or CHM0201, was an open label trial designed to establish that escalating doses generated from third-party adult donors could be infused without inducing graft-versus-host disease or other significant toxicities.
Chimeric said that of the nine patients, three had blood cancers and six had solid tumors, with results showing the patients with blood cancers achieving "stable disease" at day 28; and of the six patients with the solid tumors, colorectal cancer and colon cancer, two had stable disease by day 28, and one "maintained their disease stability at day 100".
Today, Chimeric managing-director Jennifer Chow said that the transaction "builds significant value for Chimeric, first by bringing a highly promising and clinically de-risked asset with CHM0201 fully into our portfolio and second by establishing the foundation for a suite of next-generation genetically modified [natural killer] cell products."
Chimeric was up 0.4 cents or 4.6 percent to 9.1 cents with one million shares traded.

CRESO PHARMA, ZELIRA THERAPEUTICS, HEALTH HOUSE INTERNATIONAL

Creso says it will acquire Health House for about $4.6 million and pay Zelira $550,000 in cash and $800,000 in Creso shares to resolve the Health House loan.

In February, Zelira said it would acquire Health House International in scrip for 19.45 percent of the expanded company and lend the Perth-based medical marijuana distributor $1.5 million, conditional on due diligence and a formal scheme implementation deed, among other standard conditions (BD: Feb 24, 2022).

Biotech Daily calculated at that time that Zelira would issue Health House 399,400,517 shares valued at $9,585,612, but $7,721,210 after allowing for the dilution.

In June, Zelira said it had terminated its proposed scheme of arrangement with Health House "given the substantial change in market conditions" and as a result Health House would have to pay it $50,000 immediately, as well as repay its $1.5 million working capital facility loan, plus interest, within 60 days (BD: Jun 22, 2022).

In August, Creso said it had a non-binding agreement with Perth's Health House for up to $4,630,388 in shares and options (BD: Aug 1, 2022).

Separately, Health House said Creso would acquire it for a 67 percent premium to its market capitalization based on the closing price of Health House shares on July 27, 2022 of 12 cents a share and Creso's share price of 4.9 cents a share at the same date and take about 7.3 percent of Creso.

In September, Creso said it would lend Health House $700,000 for "general corporate purposes and working capital" and use the loan to complete a scheme implementation deed and report (BD: Sep 5, 2022).

Creso said it had provided $500,000 to Health House, at 12 percent a year, with repayment by November 30, 2022, with its loan ranking second to the security held by Zelira; and later that week, Zelira said it had received $400,000 from Health House and extended the term of the balance to October 31, 2022 (BD: Sep 8, 2022).

Today, Zelira said that if Creso shareholder approval was not obtained for the issue of shares by December 31, 2022, Health House would remain liable to Zelira in the amount of the residual amount under the loan and Zelira might immediately call on Health House to repay this amount to Zelira on demand.

In separate announcements, Health House said it had a scheme implementation deed with Creso and Creso had increased its loan to $3,400,000.

Health House said it would be issued 107,683,442 Creso shares, worth $2.15 million at the current price of two cents a share, which could be reduced subject to debts at the implementation date, representing 5.5 percent of Creso, and valuing Health House at a 200 percent premium to its market capitalization at November 18, 2022.

Creso said it would acquire Health House for about $4.6 million based on a share price of 4.3 cents a share.

Health House said the scheme was not subject to finance, but was subject to provisions, including exclusivity and break fees of $100,000 in certain circumstances, and that part of the loan included $400,000 to pay an assumed debt to Celtic Capital Pty Ltd.

Health House said the merger with Creso would "create a global organization with strong medicinal cannabis production and distribution capabilities".

The company said the scheme deed was expected to be executed on November 25, the Australian Securities and Investments Commission review would be completed and a court hearing held on January 20, the Health House scheme meeting to be held on February 17, the record date of March 10 and implementation on March 17, 2023.

Creso fell 0.2 cents or 9.1 percent to two cents with 41.9 million shares traded.

Health House was in an ASX suspension and last traded at 1.3 cents.

Zelira fell one cent or one percent to 99 cents.

CANN GROUP

Cann Group says it has dosed the last of 257 patients in its phase III trial of its low-dose Satipharm marijuana-based cannabidiol (CBD) capsules for sleep disturbance.
Cann said the results were expected “early in the 2023 year” after which it expected to submit a drug registration application to the Australian Therapeutic Goods Administration.
Cann Group chief executive officer Peter Crock said that dosing the last patient was “a great achievement as part of our over-the counter CBD strategy and shows how quickly we are working towards a definitive outcome”.
Cann Group was up 0.5 cents or 2.2 percent to 23.5 cents.

ZELIRA THERAPEUTICS

Zelira says it has completed enrolment of a 60-patient trial to evaluate the safety, tolerability and efficacy of ZLD007 for diabetic nerve pain.
In May, Zelira said it had enrolled 20-patients in the investigative drug arm of its observational study of marijuana products for diabetic nerve pain (BD: May 30, 2022).
Today, the company said the multi-arm, head-to-head trial would evaluate its marijuana-based drug against an existing drug.
Zelira said one arm of 20 patients would continue taking the unnamed reference drug, a second arm would add its one capsule twice daily, and if there was no response after two weeks the investigator could raise the dosing to three times or four times daily.
The company said that third cohort of 20 patients would take ZLD007 twice a day and could be increased to three or four times a day.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received $3,897,543 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 June 30, 2022.
Universal Biosensors was up one cent or 4.2 percent to 25 cents.

ARTRYA

Artrya says that it will release 25,634,357 shares from voluntary escrow on November 26, 2022.
Artrya said it would release 15,610,470 shares and 12,000,000 options from ASX escrow on November 26, 2023.
According to its most recent filing, Artrya had 62,793,523 shares on issue.
Artrya fell nine cents or 15.5 percent to 49 cents.

HEXIMA

Hexima says it will release 7,300,878 shares from ASX escrow on December 1, 2022.
In its most recent filing, Hexima had 159,738,751 shares on issue implying that after the release from escrow there would be 167,039,629 shares available for trading, with no further shares in ASX escrow.
Hexima fell 0.1 cents or 6.25 percent to 1.5 cents with 1.7 million shares traded.

AUDEARA

Audeara has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on November 23, 2022, or on an earlier announcement.
Audeara last traded at 8.1 cents.

VECTUS BIOSYSTEMS

Vectus has requested a trading halt “pending an announcement to the market concerning the finalization of a material fundraising”.
Trading will resume on November 23, 2022, or on an earlier announcement
Vectus last traded at 96 cents.

ISLAND PHARMACEUTICALS

Jason Alan Carroll says he has increased his substantial holding in Island from 9,900,000 shares (12.18%) to 10,938,466 shares (13.46%).
The Melbourne-based Mr Carrol said that between May 4 and November 18, 2022 he bought and sold shares, with the largest acquisition 320,436 shares for $43,339, or 15.1 cents a share.
Island fell half a cent or 2.5 percent to 19.5 cents.

HEXIMA

Merchant Group Australia says it has increased its substantial holding in Hexima from 14,550,000 shares (8.71%) to 16,314,000 shares (9.77%).
The Perth-based Merchant said that between November 10 and November 17, 2022, it bought 1,764,000 shares for $28,840 or 1.6 cents a share.