Biotech Daily

Tuesday May 7, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PARADIGM UP 8.5%**
- GENETIC SIGNATURES, STARPHARMA DOWN 4%

*** BRANDON CUREATOR $7.2m FOR 8 BIOTECHS**

*** 4D MEDICAL US VETERANS XV IMAGING STUDY**

*** EYEPOINT FALLS 43% ON DURAVYU MISSING TRIAL PRIMARY ENDPOINT**

*** CANN UNNAMED LENDER $5m LOAN**

*** CONTROL BIONICS, TOHO LAMAC TO SELL NEUROSTRIP IN JAPAN**

*** ECHO IQ FILES ECHOSOLV TO FDA**

*** RECCE WINS CHINA ANTI-INFECTIVES PATENT**

*** VISIONEERING 61% EQUITY PLAN INCREASE, 706k CEO STOCK AGM**

*** PHARMAUST REQUESTS 'BOARD COMPOSITION' TRADING HALT**

MARKET REPORT

The Australian stock market was up 1.44 percent on Tuesday May 7, 2024, with the ASX200 up 110.9 points to 7,793.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and three were untraded. All three Big Caps were up.

Paradigm was the best, up two cents or 8.5 percent to 25.5 cents, with 1.3 million shares traded.

Universal Biosensors climbed 6.7 percent; Avita was up 4.9 percent; Actinogen, Immutep, Nanosonics and Polynovo improved more than three percent; Clinuvel, Micro-X, Neuren, Next Science and SDI rose more than two percent; Cochlear, CSL, Mesoblast, Nova Eye and Pro Medicus were up more than one percent; with Resmed up by 0.25 percent.

Genetic Signatures and Starpharma led the falls, both down 4.0 percent to 72 cents and 12 cents, respectively, with 116,933 shares and 296,212 shares traded, respectively.

Atomo, Clarity, Medical Developments, Orthocell and Proteomics lost more than three percent; Curvebeam and Prescient shed more than two percent; Alcidion, Dimerix, Emvision, Impedimed and Imugene were down more than one percent; with 4D Medical, Cyclopharm and Telix down by less than one percent.

BRANDON CAPITAL

Brandon Capital says it has provided $7.21 million through its Cureator program to support eight clinical and pre-clinical stage biotechnology companies.

Brandon Capital said the investment was supported by a grant from the Federal Government's Medical Research Future Fund's early-stage translation and commercialization support program.

The company said it had invested $5.84 million in five clinical-stage companies including Ena Respiratory, GPN Vaccines, Oncostrike Biopharma, Polyactiva and Respirion Pharmaceuticals.

Brandon Capital said the remaining $1.7 million was given to the pre-clinical-stage companies Currus Biologics, Frontier Inflammasome Therapeutics and Setonix Pharmaceuticals.

The company said that, to date, its Cureator program had supported 42 clinical and pre-clinical stage companies, with "one more competitive round of top-up funding for the pre-clinical stream funding recipients expected this year".

Brandon Capital said the funding would allow the companies "to explore the efficacy of novel drugs or innovative applications for existing medications".

Brandon Capital's Cureator program head Dr Amanda Vrselja said "to date, Cureator-backed companies have secured $45.7 million in private sector capital cash and in-kind support, which is a fantastic leverage on the $37.4 million deployed by the program".

"With more in the pipeline, this achievement affirms Cureator's place in the innovation infrastructure supporting Australia's economic transformation beyond mining," Dr Vrselja said.

4D MEDICAL

4D Medical says it will run a 40-patient, functional lung imaging study of its XV technology with the West Los Angeles Department of Veterans Affairs (VA) Medical Center.

4D Medical said it had signed a cooperative research and development agreement to use its XV technology "across the spectrum of chronic respiratory conditions presenting with undifferentiated symptoms" but did not mention the commercial terms of the agreement.

The company said the study would use its technology "to correlate regional ventilation and ventilation heterogeneity with quality-of-life, the six-minute walk test and dyspnoea scores to determine if changes can be identified in lung function post-treatment", with data to be used to optimize treatment pathways including re-hospitalization or medical follow-up.

4D Medical said its XV technology measured the motion of the lungs, determining airway volumes and regional lung ventilation during spontaneous breathing to allow physicians to identify respiratory deficiencies earlier and with greater sensitivity.

The company said its XV technology was the basis for its XV lung ventilation analysis software (XV LVAS) and computer tomography-enabled counterpart software (CT LVAS).

4D Medical managing-director Prof Andreas Fouras said the company was targeting the Department of Veterans Affairs "through a two-prong approach, top-down and bottom-up, with the desired outcome being a multi-site pilot [program] leading to a national roll-out".

"We have discussed recent progress in our top-down efforts, including language in the recent budget and public support from the US Senate," Prof Fouras said.

"Today we announce yet another bottom-up success with another VA site utilizing our technology with the ultimate goal of improving veteran health," Prof Fouras said.

"Having VA doctors using our products in this way grows confidence in our solutions and builds momentum and support for a large-scale rollout within the VA," Prof Fouras said.

4D Medical fell half a cent or 0.9 percent to 57 cents.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA CORP)

Eyepoint fell 43.3 percent after its 77-patient, phase II trial of Duravyu for non-proliferative diabetic retinopathy “did not meet the pre-specified primary endpoint”.

Eyepoint said Duravyu, formerly EYP-1901, was the administration of the tyrosine kinase inhibitor, vorolanib, into the eye using its Durasert intra-vitreal, micro-insert drug delivery device, with the primary endpoint an “improvement of at least two [diabetic retinopathy severity scale] levels as of week 36 after the Duravyu injection”.

In 2018, the then Psivida said the US Food and Drug Administration had accepted its new drug application for its Durasert device for posterior segment uveitis and it would rebrand to Eyepoint Pharmaceuticals and delist from the ASX (BD: Mar 29, 2018).

Last June, the company said it enrolled all 77 patients in the phase II trial of the then EYP-1901 for non-proliferative diabetic retinopathy (NPDR), exceeding the 60-patient target.

In December, Eyepoint climbed 200.5 percent on its 160-patient phase II trial of EYP-1901 for wet age-related macular degeneration results and raised $US230 million ($A350.1 million) (BD: Dec 12, 2023).

Today, Eyepoint said top-line results showed five percent of patients in the 3mg arm and no patients in the 2mg arm had a more than or equal to two-step improvement in diabetic retinopathy severity scale score at nine months compared to five percent for control.

The company said other results included 86 percent of patients in the 3mg arm and 80 percent of patients in the 2mg arm showing stable or improved disease at nine months compared to 70 percent in the control arm.

Eyepoint said no patients in the 3mg arm and 5.0 percent of patients in the 2mg arm worsened at nine months compared to 10 percent in the control arm and that the trial showed “continue favorable safety and tolerability profile, with no Duravyu-related ocular or systemic serious adverse events reported”.

The company said it expected to begin its first phase III pivotal trial in wet age-related macular degeneration (AMD) this year, with a second phase III pivotal trial in wet AMD to follow and results from its phase II trial in diabetic macular edema expected in 2025.

Eyepoint managing-director Dr Jay Duker said “although the trial did not meet the pre-specified primary endpoint, we are encouraged that Duravyu continues to be well-tolerated and appears to reduce rates of NPDR progression at nine months.”

Dr Duker said the company would analyze the 12-month data “to gain the clarity needed to assess the future of Duravyu as a potential treatment for NPDR” and remained “laser-focused on … the first pivotal, non-inferiority clinical trial for wet AMD” this year.

On the Nasdaq, Eyepoint fell $US8.54 or 43.26 percent to $US11.20 ($A16.90) with 9.6 million shares traded.

CANN GROUP

Cann says it has a $5,000,000 loan from an unnamed “prominent Australian private credit fund” at 15 percent interest a year, to be paid monthly by May 7, 2025.

Cann said it had drawn down the lump sum and that the loan included an up-front fee of three percent of the principal, or $150,000, a $65,000 “work fee” and a one percent, or $50,000, broker fee.

Biotech Daily calculates that with the $750,000 in simple interest, the fees take the total repayments for the loan to $1,015,000 or 20.3 percent of the $5,000,000 loan.

The company said it had taken a second mortgage on its Mildura marijuana plant to secure the loan with the unnamed creditor, behind the National Australia Bank mortgage.

Cann said that the funds were “necessary to continue operations for the next 12 months”.

Cann was in a suspension and last traded at 6.2 cents.

CONTROL BIONICS

Control Bionics says it has partnered with Tokyo's Toho Lamac Co to commercialize its Neurostrip wearable electro-myography diagnostic device in Japan.
Control Bionics said Toho Lamac was an import and wholesale company that had "recently launched its new healthcare business and this division will work … to launch the Neurostrip into Japan" but did not mention the commercial terms of the agreement.
The company Neurostrip used its Neuronode technology to detect brain signals sent to any skeletal muscle and provided it with "the opportunity to enter new markets such as health diagnostics, sports performance and rehabilitation".
Control Bionics said its Neuronode technology detected signals from the brain to skeletal muscle, captured as electro-myography and sent wirelessly to a personal computer, enabling speech and other computer-controlled functions such as email, texting and wheelchair movement.
Control Bionics chief executive officer Jeremy Steele said the company would be "working closely with the Toho Lamac team through 2024 to develop our go-to market strategies for the Japanese market," Mr Steele said.
Control Bionics was up half a cent or 12.5 percent to 4.5 cents.

ECHO IQ

Echo IQ says it has submitted its US Food and Drug Administration 510(k) application for market clearance of its Echosolv algorithm for detecting aortic stenosis.
Echo IQ said Echosolv was an algorithm that used cardiac data from "millions of echo-cardiographic data points" to detect aortic stenosis, or the narrowing of the aortic valve.
The company said under the 510(k) expedited process it expected a decision from the FDA regarding clearance within 90 days from the date of submission.
Echo IQ said that subject to no requests for additional information it expected clearance to market "early in August 2024".
Echo IQ executive chair Andrew Grover said submission was "a major milestone in [the company's] regulatory compliance strategy".
"We are confident that clearance from the regulator, which is expected in 90 days, will unlock a significant opportunity for commercial deployment," Mr Grover said.
"Our team has nurtured a robust pipeline of potential customers, laying the groundwork for future growth and success," Mr Grover said.
Echo IQ fell one cent or 7.4 percent to 12.5 cents.

RECCE PHARMACEUTICALS

Recce says the China National Intellectual Property Administration has granted a patent family for its R327 and R529 anti-infectives for a range of common infections.
Recce said the patent, titled 'Copolymer and Method for Treatment of Bacterial Infection' would protect its intellectual property in China until 2035.
The company said the patent was the last of its wholly-owned family patents, with its anti-infectives patent-protected in "all major pharmaceutical markets" including Australia, the US, Europe, Germany, Spain, France, the UK, Italy, Sweden and Japan.
Recce chief executive officer James Graham thanked the China National Intellectual Property Administration for recognizing the potential of Recce's anti-infectives.
"We are proud to have now completed our portfolio of family two patents and now have coverage globally until at least 2035," Mr Graham said.
Recce was up half a cent or 0.8 percent to 66.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says investors will vote to increase its employee equity incentive plan by 60.5 percent and issue chief executive officer Dr Juan Aragón 705,584 restricted securities.
Visioneering said its annual general meeting would vote to increase the shares reserved under its 2017 equity incentive plan to issue to employees in lieu of cash payments from a limit of 5,291,025 securities to 8,491,025 securities.
The company said the resolution was a result of the number of shares remaining available for issue under the 2017 plan not being sufficient for it "to implement certain proposed measures".
Visioneering said investors would vote to issue Dr Aragón 425,000 restricted stock units under the equity incentive plan, valued at $93,500 based on its closing price on the day Dr Aragón joined the company.
The company said shareholders would vote to issue Dr Aragón an additional 280,584 restricted shares in lieu of $US200,000 ($A302,000) cash as part of his short-term incentive.
Visioneering said that the proposed securities were in addition to Dr Aragón's yearly salary of $US400,000.
The company said the meeting would vote to re-elect directors Kathleen Miller and Andrew Silverberg and approve the 10 percent placement facility.
The meeting will be held online on May 23, 2024 at 8am (AEST).
Visioneering was unchanged at 10 cents.

PHARMAUST

Pharmaust has requested a trading halt "pending an announcement in relation to the composition of the board".
Trading will resume on May 9, 2024, or on an earlier announcement
Pharmaust last traded at 22 cents.