Biotech Daily

Wednesday November 20, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 14%; STARPHARMA DOWN 12.5%**

*** PROTAGONIST: 'JNJ-2113 (PN-235) BEATS PLACEBO FOR PSORIASIS'**

*** CORRECTION: RESONANCE**

*** VITURA $4.55m FOR J-V TO ACQUIRE RELEAF ASSETS**

*** CLINUVEL ASKS EMA TO INCREASE SCENESSE EPP ANNUAL DOSE**

*** PAINCHEK FILES ADULT PAIN SOFTWARE TO FDA**

*** DIMERIX PHASE III DMX-200 FSGS TRIAL PASSES 5th REVIEW**

*** DORSAVI BLOCKCHAIN FOR SENSOR DATA SECURITY**

*** GENETIC TECHNOLOGIES APPOINTS FTI ADMINISTRATORS**

*** 4D MEDICAL AGM 32% REMUNERATION REPORT 1st STRIKE**

*** PARADIGM AGM 25% OPPOSE AMOS MELTZER ELECTION**

*** CLARITY AGM UP-TO 13.6% OPPOSE DIRECTOR OPTIONS**

*** GENETIC SIGNATURES AGM 9.6% OPPOSE RIGHTS PLAN**

*** HERAMED 15.8m M-D PERFORMANCE RIGHTS EGM**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday November 20, 2024, with the ASX200 down 47.7 points to 8,326.3 points. Nine of the Biotech Daily Top 40 companies were up, 22 fell and nine traded unchanged.

Paradigm was the best, up 3.5 cents or 14.3 percent to 28 cents, with 2.8 million shares traded. Medadvisor improved 7.3 percent; Nova Eye climbed 6.7 percent; Emvision was up 4.3 percent; Avita, Opthea and Syntara rose more than two percent; with CSL Nanosonics, Percheron and Pro Medicus up by one percent or more.

Starpharma led the falls, down 1.5 cents or 12.5 percent to 10.5 cents, with 812,222 shares traded. Resonance lost 11.9 percent; Neuren was down 7.5 percent; 4D Medical and Compumedics shed more than six percent; Amplia was down 5.3 percent; Immutep and Imugene fell more than four percent; Clarity and Proteomics were down more than three percent; Aroa, Cynata, Dimerix, Genetic Signatures and Prescient shed more than two percent; Clinuvel, Cochlear, Mesoblast, Orthocell, Polynovo and SDI were down one percent or more; with EBR, Resmed and Telix down by less than one percent.

PROTAGONIST THERAPEUTICS

Protagonist says two phase III studies show oral icotrokinra, or JNJ-2113, led to "significant skin clearance versus placebo in … moderate to severe plaque psoriasis".

Last year, Brisbane's Protagonist said its 255-patient, phase IIb trial of JNJ-2113 met its primary endpoint, with a statistically significant reduction of psoriasis lesions at week-16 compared to placebo (BD: Mar 8, 2023).

At that time, the company said it would take JNJ-2113 to a phase III study, which would qualify it for $US50 million ($A76.5 million) milestone payments under its licencing agreement with Johnson & Johnson; and meeting primary endpoints in that study would qualify it for a further $US115 million ($A176 million) milestone payment.

Protagonist said the results were from its 684-patient 'Iconic-Lead' phase III study and 311-patient 'Iconic-Total' phase III study, both in collaboration with Johnson & Johnson, of JNJ-2113 in patients 12 years of age and older with moderate to severe plaque psoriasis.

The company said JNJ-2113, formerly PN-235, was a targeted oral peptide that blocked the IL-23 inhibitor, which underpinned "the inflammatory response in moderate-to-severe plaque [psoriasis] and other IL-23-mediated diseases".

Protagonist said the 'Iconic-Lead' study showed 64.7 percent of patients treated once-daily with icotrokinra achieved IGA scores of 0/1 at 16 weeks, meaning "clear or almost clear skin", compared to 8.3 percent of patients for placebo.

The company said investigator global assessment (IGA) was a five-point scale with a severity ranging from 0 to 4, where 0 indicates clear, one is minimal, two is mild, three is moderate, and four indicates severe disease.,

Protagonist said the 'Iconic-Lead' study showed 49.6 percent of patients treated with icotrokinra achieved a more than 90 percent reduction in surface area of psoriasis plaques, or PASI 90, compared to 4.4 percent on placebo.

The company said at 24 weeks further increased response rates were observed with 74.1 percent of patients treated with icotrokinra achieving IGA scores of 0/1, and 64.9 percent achieving PASI 90.

Protagonist said the phase III 'Iconic-Total' study showed once-daily icotrokinra met the primary endpoint of IGA of 0/1 at week 16 compared to placebo.

The company said safety data was found to be consistent with phase II studies, with a similar proportion of patients experienced adverse events on treatment and placebo.

Protagonist said comprehensive results from both studies were being prepared for presentation and would be shared with health authorities in planned submissions.

The company said it was eligible for up-to $US630 million in future development and sales milestone payments, and sales royalties of six-to-10 percent.

Protagonist said it expected results from two phase III studies of icotrokinra compared with both placebo and deucravacitinib in plaque psoriasis in by July 2025.

The company said it would begin a phase III study of icotrokinra in psoriatric arthritis "in the beginning of 2025".

Protagonist chief executive officer Dr Dinesh Patel said the results highlighted "icotrokinra's potential as a best-in-class oral agent providing an ideal combination of significant skin clearance with demonstrated tolerability in a once-daily pill for treating plaque psoriasis".

"These results also continue to validate Protagonist's innovative peptide technology platform and its effectiveness in creating highly differentiated new chemical entities to address unmet needs in various disease areas," Dr Patel said.

According to Commsec, on the Nasdaq, Protagonist closed down $US1.74 ($A2.66) or 4.31 percent to $US38.65 ($A59.18) with 3.045 million shares traded.

RESONANCE HEALTH

Last night's edition incorrectly said Resonance had a $13,775,000 agreement to provide trial services to an unnamed "international, publicly-listed pharmaceutical company".
In fact, Resonance disclosed the company as the Mumbai, India-based Sun Pharmaceutical Industries.
The mistake was made by the terminated Tuesday sub-editor.
We apologize unreservedly to Resonance Health.
Resonance fell 0.7 cents or 11.9 percent to 5.2 cents.

VITURA HEALTH

Vitura says it will pay $750,000 and relinquish $3.8 million of debt to acquire half of marijuana dispensary Releaf Group through its Flora joint-venture with Crisci Group.
Last year, Vitura said it had an unincorporated joint venture with Melbourne's Releaf Group to prescribe medicinal cannabis through a Releaf-branded version of its Canview platform, with the venture expected to increase the number of medical marijuana products prescribed through Canview (BD: May 16, 2023).
Today, Vitura interim chief executive officer Tom Howitt told Biotech Daily that the Flora joint venture with Crisci "bought most of the assets of Releaf" from its receivers with Vitura paying $250,000 in cash, $500,000 in shares and relinquishing $3.8 million in debt.
Mr Howitt said that Crisci "contributed funds and services" for its share of the joint-venture.
Yesterday, the company said it had approached the national compounding pharmacy provider Crisci Group, which was the holder of the four largest Releaf franchises, to "join forces with it to acquire the Releaf assets and resurrect the Releaf business".
Vitura said its 50-50 joint venture with Crisci, Flora Holdings Pty Ltd, had acquired the majority of the assets owned by Releaf Group and its subsidiaries.
The company said Releaf was placed into receivership and voluntary administration earlier this month and that it was owed "about $3.8 million by Releaf in respect of medicinal cannabis products purchased by Releaf through … the company's Canview platform, together with accrued interest and default fees".
Vitura said it had paid $250,000 in cash, issued 5,779,274 shares and relinquished its rights to recover its debt of $3.8 million in exchange for its 50 percent shareholding in the joint-venture, and by extension, Releaf.
The company said the shares were issued at 8.652 cents a share, a 10 percent discount to the five-day volume weighted average price, equal to about $500,000.
Vitura said that as well as its 50 percent share of Releaf it would receive "favorable rights to distribute, wherever possible, all medicinal cannabis products prescribed to Releaf patients, where such products are available on its Canview platform".
The company said the assets acquired included Releaf's premises, intellectual property, patient contact lists, goodwill, inventory, information technology contracts, manuals, merchandise, plant and equipment and certain trade receivables.
Vitura said that it believed "the number of patients registered with Releaf as at November 6, 2024 was almost 30,000".
Vitura chair Robert Iervasi said Vitura was ""confident that the Flora partners will be successful in rebuilding the confidence of the extensive Releaf patient cohort and expanding our offerings in future to provide both existing and future patients with a first-class patient experience".
"This transaction also aligns with our previously announced strategy reset whereby we committed to growing our reach through investing in clinics and doctors," Mr Iervasi said.
Vitura was unchanged at 9.8 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has asked the European regulator to increase the maximum Scenesse (afamelanotide 16mg) dose for erythropoietic protoporphyria from four to six a year.
Clinuvel said that it was “in late-stage discussions” with the European Medicines Agency (EMA) to expand the yearly number of Scenesse doses for adults with erythropoietic protoporphyria (EPP) and expected a response by April 2025.
In 2016, Clinuvel said European marketing authorization for Scenesse was “under a strict risk management plan”; and in 2019, said the US Food and Drug Administration had approved Scenesse for EPP (BD: May 18, 2016; Oct 9, 2019)
Today, the company said the European Medicines Agency would “decide over the coming months” whether to maintain the existing Scenesse label including an annual frequency of prescription of four times a year, or expand it to six doses a year.
Clinuvel said European physicians had treated patients with one dose every two months “to ensure that their patients receive year-round photo-protection”.
The company said feedback from clinics and patients as well as peer-reviewed literature, showed it was “medically necessary for some patients to receive continuous treatment”.
Clinuvel said that EMA approval of the increased frequency “would be harmonized with that approved in other jurisdictions including by the US Food and Drug Administration … enabling European EPP patients to receive year-round treatment”.
The company said that based on analyses of patients receiving more than four implants, it was “apparent that the safety profile of the drug has remained unchanged and favorable”.
Clinuvel chief scientific officer Dr Dennis Wright said that more than “16,000 doses of Scenesse have been administered to EPP patients globally, with some patients having received continuous treatment since 2006.”
“It is apparent from analyzing two decades of use, that prescribing a physiological hormone is favorable in EPP, based on the safety data which have been submitted annually to the EMA,” Dr Wright said. “Long-term safety is a key advantage over prospective drug candidates in development for EPP.”
Clinuvel fell 22 cents or 1.6 percent to $13.40 with 86,974 shares traded.

PAINCHEK

Painchek says it has applied for US Food and Drug Administration de-novo status for its adult facial pain assessment and monitoring application for smartphones and tablets.
Last month, Painchek said that it had “completed the majority” of requirements for an FDA de-novo application for its pain application (BD: Oct 2, 2024).
At that time, the company said it completed its US validation study in July 2024, involving 105 volunteers at five aged care homes, with results being included in the report.
Later, Painchek said it would file “positive results” from a validation study of the application with the FDA (BD: Oct 29, 2024).
Today, the company said FDA de-novo clearance would provide an important predicate for its infant pain assessment application and support the expansion of the adult application to US markets, including home care and hospitals.
Painchek managing-director Philip Daffas said that “should Painchek Adult successfully obtain FDA regulatory clearance, Painchek would be the first of its kind FDA-cleared pain assessment tool in the US specifically designed for aged-care residents with moderate to severe dementia who are unable to reliably self-report their pain”.
“Having commercially proven the adult [application] in Australia and the UK we believe we can rapidly repeat the market penetration rates in the US,” Mr Daffas said.
Painchek was unchanged at 2.8 cents with 3.6 million shares traded.

DIMERIX

Dimerix says it has approval to continue its 286-patient, phase III trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS) kidney disease with “no safety concerns”.
In 2022, Dimerix said it had recruited the first of 286 patients in the trial of DMX200 for kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).
Today, Dimerix said it had completed the fifth scheduled independent data monitoring committee review, which evaluated the available study data for participant safety, study conduct and progress, with the next scheduled committee meeting planned by July 2025.
Dimerix chief medical officer Dr David Fuller said that the recommendation of the committee confirmed “the strong emerging safety profile of DMX-200 and suggests that DMX-200 does not add a burden of side effects to patients, compared to commonly used treatments such as high dose steroids and immune-suppressants”.
Dimerix fell one cent or 2.9 percent to 33.5 cents with 4.05 million shares traded.

DORSAVI

Dorsavi says it has begun a “strategic feasibility study to incorporate ‘blockchain technology’ into its core data platform” for data collected by its wearable sensors.
Dorsavi said its platform currently supported “millions of data transfers annually”, capturing about 10,000 data points per session, including joint angles, muscle activity, gait parameters, and postural alignment.
The company said its sensors continuously tracked movement patterns, with real-time data syncing for immediate analysis and long-term monitoring.
Dorsavi said blockchain technology “could provide a tamper-proof framework for data storage and sharing, reducing vulnerabilities associated with centralized systems”.
The company said by synchronizing information on a shared database, blockchain could “enable timely secure data sharing” but did not explain how blockchain operated.
Dorsavi chief executive officer Dr Andrew Ronchi said blockchain technology was “a natural progression”.
“Our enterprise clients already demand the highest levels of data security, privacy, and compliance, and we believe blockchain could help us further meet and exceed those expectations and help redefine how sensitive health data is managed, shared, and secured,” Dr Ronchi said.
Dorsavi was up 0.1 cents or 7.7 percent to 1.4 cents with 65.1 million shares traded.

GENETIC TECHNOLOGIES

FTI Consulting says its Ross Blakeley and Paul Harlond have been appointed as voluntary administrators of Genetic Technologies, effective from November 20, 2024.
FTI Consulting said Genetic Technologies had determined that “voluntary administration is now the most appropriate way forward” after the company was “unsuccessful in raising the minimum required capital … and alternative strategic partnerships”.
In September, Genetic Technologies said its rights offer at four cents a share had raised $324,648, leaving a $3,553,145 shortfall; and later, the ASX suspended Genetic Technologies for not meeting “the minimum subscription condition under the non-renounceable entitlement offer” (BD: Sep 12, 17, 2024).
Last month, the company requested an extension to its suspension following a trading halt for its “operational review and progress on its fund raising” (BD: Jul 26; Oct 17, 21, 2024).
Genetic Technologies was in a suspension and last traded at 3.9 cents.

4D MEDICAL

4D Medical says its annual general meeting voted a 32.01 percent remuneration report 'first strike', with up to 33.57 percent opposing director options.
Last month, 4D Medical said the meeting would vote to issue 1,092,539 options and 197,934 restricted stock units to directors (BD: Oct 21, 2024).
Today, the company said the remuneration report was opposed by 8,988,736 votes (32.01%) with 19,089,225 votes (67.99%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011, a company with a vote of 25 percent or more against the report in two successive annual meetings is required to vote on a board spill.
4D said the 10 percent placement capacity was opposed by 10,068,149 votes (10.68%) with the issue of options and restricted stock units to directors faced opposition ranging from 10.34 percent of the meeting to 33.57 percent.
According to its most recent filing, 4D Medical had 411,227,914 shares on issue, meaning that the 10,068,149 votes against the placement capacity amounted to 2.45 percent of the company, not sufficient to requisition extraordinary general meetings.
4D Medical fell 3.5 cents or 6.9 percent to 47.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its annual general meeting passed all resolutions with up-to 24.97 percent against the re-election of non-executive director Amos Meltzer.
Paradigm said the remuneration report was passed by 81.76 percent of the meeting, and the board spill resolution was withdrawn, chair Paul Rennie's performance rights were opposed by 20.15 percent, with Dr Donna Skerrett's rights facing 13.66 percent dissent.
The company said Mr Meltzer's re-election was opposed by 24,678,173 votes (24.97%).
Paradigm said the ratification of the prior issue of options, the approval of the placement capacity and the election of Matthew Fry passed with more than 90 percent in support.
According to its most recent notice, Paradigm had 349,946,718 shares on issue, meaning that the 24,678,173 votes against Mr Meltzer's re-election amounted to about 7.05 percent of the company, sufficient to requisition extraordinary general meeting.
Paradigm was up 3.5 cents or 14.3 percent to 28 cents with 2.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says its annual general meeting has approved all resolutions but with up-to 13.59 percent against the issue of options to three directors.
Last month, Clarity said investors would vote to issue options to chair Dr Alan Taylor, chief operating officer Dr Colin Biggin, chief executive officer Michelle Parker and directors Dr Chris Roberts, Dr Thomas Ramdahl and Rosanne Robinson (BD: Oct 18, 2024).
Today, the company said Ms Robinson's options were opposed by 19,361,784 votes (13.55%), with Dr Roberts and Dr Ramdahl's options facing 13.54 percent dissent, with Dr Taylor, Dr Biggin and Ms Parker's options opposed by 7.15 percent.
The company said amendments to the constitution, the adoption of the remuneration report and the re-election of director Dr Biggin were opposed by about eight percent of the meeting, with the remaining resolutions passing more easily.
According to its most recent notice, Clarity had 320,211,465 shares on issue, meaning that the votes against Ms Robinson's options amounted to about 6.05 percent of the company, sufficient to requisition extraordinary general meetings.
Clarity fell 21 cents or 3.35 percent to $6.06 with 1.3 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says its annual general meeting has passed all resolutions with up-to 9.6 percent against the approval of its rights plan.

Last month, the company said investors would vote to issue 500,000 options to director Neil Gunn and up the director fee pool 55.55 percent to $700,000 (BD: Oct 21, 2024).

Today, Genetic Signatures said its rights plan was opposed by 13,621,890 votes (9.63%), with 127,822,308 votes (90.37%) in support.

The company said the increase in the director fee pool and the issue of options to Mr Gunn were opposed by 4.93 percent and 4.78 percent, respectively.

Genetic Signatures said the remaining resolutions were passed more easily with between 95.72 percent and 98.86 percent of the meeting in favor.

According to its most recent filing, Genetic Signatures had 226,872,162 shares on issue, meaning that the 13,621,890 votes against the rights plan amounted to 6.0 percent of the company, sufficient to requisition extraordinary general meetings.

Genetic Signatures fell two cents or 2.8 percent to 70 cents.

HERAMED

Heramed says its extraordinary general meeting will vote to issue 15,800,000 performance rights to managing-director Anoushka Gungadin.

Earlier this year, Heramed said it had appointed Anoushka Gungadin as its chief executive officer (BD: Apr 10, 2024).

In July, the company said Ms Gungadin would receive a salary of $308,000 a year excluding superannuation as well as 50 percent of her salary as short-term incentives and 15,800,000 long-term incentive performance rights (BD: Jul 24, 2024).

Today, Heramed said the performance rights would be issued at the five-day volume weighted average price prior to the issue date in six tranches of 2,633,860 rights, each, pending milestones relating to the company's share-price and the amount of accumulated users of its Heracare foetal monitoring technology.

The company said the meeting would vote to ratify the prior issue of shares and options and adopt the employee incentive plan.

The meeting will be held at Bio101, 201/697 Burke Road, Camberwell, Melbourne on December 19, 2024 at 1pm (AEDT).

Heramed was untraded at 2.1 cents.