

Biotech Daily

Thursday November 21, 2024

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: STARPHARMA UP 9.5%; NEUREN DOWN 9%
- * ALCIDION SIGNS \$3.7m PENINSULA HEALTH MIYA DEAL
- * STARPHARMA 'DEP-SN38 (DEP-IRINOTECAN) COLO-RECTAL CANCER PROMISE'
- * MONASH: 'LXA4 IMPROVES DIABETIC CARDIAC FUNCTION, IN MICE'
- * RACE FINDS 39 FTO-INHIBITORS FOR DRUG DEVELOPMENT
- * OPYL, SOUTHERN CDC TRIALKEY DEAL
- * ARGENICA RECEIVES \$2.8m FEDERAL R&D TAX INCENTIVE
- * RHYTHM AGM 42% REM REPORT 1st STRIKE; 25% OPPOSE DIRECTOR
- * PERCHERON AGM 35% REM REPORT 1st STRIKE; 2 RESOLUTIONS WITHDRAWN
- * ARCHER AGM 23.5% OPPOSE CHAIR OPTIONS
- * ACRUX AGM 21% REMUNERATION REPORT VOTE
- * OPTISCAN AGM WITHDRAWS 10% PLACEMENT CAPACITY
- * OSTEOPORE 11.6m DIRECTOR RIGHTS, 527k M-D SHARES EGM
- * ALGORAE A.I. SYSTEM FINDS 46 'DRUG TARGETS'
- * PAINCHEK REQUESTS 'CAPITAL RAISE' TRADING HALT
- * ELIZABETH JANSEN, STANFORD REDUCE TO 19.6% OF VITURA
- * LINDLEY EDWARDS REPLACES MEMPHASYS CHAIR ROBERT COOKE

MARKET REPORT

The Australian stock market fell 0.04 percent on Thursday November 21, 2024, with the ASX200 down 3.3 points to 8,323.0 points. Ten of the Biotech Daily Top 40 companies were up, 24 fell, five traded unchanged and one was untraded.

Yesterday's 12.5 percent worst, Starpharma, was the best, up one cent or 9.5 percent to 11.5 cents, with 455,461 shares traded. Alcidion climbed 8.2 percent; Aroa, Genetic Signatures and Nanosonics rose more than two percent; with Avita, Impedimed, Medadvisor, Micro-X, Resmed and Resonance up by more than one percent.

Neuren led the falls, down \$1.26 or 9.2 percent to \$12.43, with 1.3 million shares traded. Syntara shed 8.7 percent; Imugene was down 7.5 percent; Immutep and Percheron lost more than six percent; 4D Medical, Mesoblast and Opthea fell more than five percent; Actinogen, EBR and Universal Biosensors lost four percent or more; Dimerix, Nova Eye, Paradigm and Telix were down three percent or more; Orthocell, Polynovo and Prescient shed two percent or more; Clarity, Clinuvel, Cochlear, Proteomics and SDI were down one percent or more; with CSL, Cyclopharm and Emvision down by less than one percent.

ALCIDION GROUP

Alcidion says it has a \$3.7 million contract over five years to provide its Miya Precision patient care management platform to the Mornington, Victoria-based Peninsula Health. Alcidion said Peninsula Health provided services to the Frankston and the Mornington Peninsula communities.

The company said its Miya Precision software provided "the capability to improve access to care and to minimize the administrative burden on frontline hospital staff". Alcidion managing-director Kate Quirke said the company would provide its electronic patient flow management product, including a user interface for demand, capacity, predicted availability and tracking "for all admitted and emergency patients within all Peninsula Health sites, integrated with the existing electronic medical record". Alcidion was up half a cent or 8.2 percent to 6.6 cents with 2.15 million shares traded.

STARPHARMA HOLDINGS

Starpharma says its dendrimer enhanced product (DEP)-SN38 shows "promising efficacy" in five phase I/II colo-rectal cancer patients previously treated with irinotecan. In May, Starpharma said its 114-patient, phase II trial of dendrimer enhanced (DEP)irinotecan with 5-fluorouracil and leucovorin for cancers "met its objectives, with endpoints demonstrating positive anti-tumor efficacy" in colorectal and ovarian cancer patients, with the company saying DEP-irinotecan was "the nano-particle formulation of SN38, the active metabolite of the widely used anti-cancer drug irinotecan" (BD: May 27, 2024). Today, Starpharma chief executive officer Cheryl Maley told Biotech Daily that "DEP-SN38, formerly referred to as DEP-irinotecan, is a novel, water-soluble dendrimer conjugated to SN38 ... [and DEP-SN38] more appropriately describes the candidate". The company had said SN38 was "100-to-1,000-fold more potent than irinotecan, but its formation requires complex liver conversion, leading to high interpatient variability in plasma levels, which complicates optimal dosing and toxicity management". Starpharma said the five heavily pre-treated patients' cancer had progressed following irinotecan exposure and, in some cases, the patients were intolerant of irinotecan. The company said DEP-SN38 "demonstrated promising efficacy, with sustained and durable disease control for up-to 72 weeks in patients previously treated with irinotecan". Starpharma said DEP-SN38 had "a favorable toxicity profile compared with standard irinotecan, contributing to improved quality-of-life experiences for these patients", with one colo-rectal cancer patient treated with DEP-SN38, 5-fluorouracil and leucovorin having "a partial response, with a reduction in the size of their target tumor of more than 30 percent". The company said four patients had stable disease and improved quality-of-life and "two patients continued treatment beyond progression of their disease due to clinical benefit" and one patient with platinum-resistant ovarian cancer, dosed with 45 cycles of treatment, continued DEP-SN38 treatment having achieved disease control for more than 1.7 years. Starpharma said dose-limiting toxicities were observed in one patient, who experienced grade three febrile neutropenia, with neutropenia and gastrointestinal events in other patients "mostly mild-to-moderate, with only one instance of grade three nausea reported, and no cases of severe diarrhoea in any patients".

Starpharma said the poster, titled 'Exceptional Responders in a Phase I/II Clinical Trial of Dendrimer-Enhanced (DEP) SN38 (SN38-SPL9111) for the Treatment of Metastatic Colorectal Cancer (mCRC)' was presented at the Australasian Gastro-Intestinal Trials Group meeting in Brisbane this week.

Starpharma was up one cent or 9.5 percent to 11.5 cents.

MONASH UNIVERSITY

Monash University says the fat molecule lipoxin A4 (LXA4) may "significantly reduce inflammation and improve function for diabetic hearts", in mice.

Monash University said the study found the LXA4, "known for its "calming agent" action in turning off the body's inflammatory response and preventing chronic inflammation, could also serve as a potential new treatment for diabetes-induced heart disease".

The University said its researchers were investigating "the broader applicability of this study to a range of other inflammatory diseases and exploring other drug options to address different aspects of cardio-pulmonary diseases".

Monash University said the research was conducted with Ireland's University College Dublin and the study, titled 'Lipoxin A4 improves cardiac remodeling and function in diabetes-associated cardiac dysfunction' was published in the journal Cardiovascular Diabetology, with the full article available at: https://bit.ly/4929SkV.

The study concluded that treatment with LXA4 "ameliorated diabetes-induced cardiac inflammation ... with ultimate improvement in cardiac function" and Monash University said the development of a stable drug based on the LXA4 molecule was "in progress". Senior author Dr Chengxue (Helena) Qin said the research team "found that LXA4 could halve inflammation and scar formation, specifically in cases of heart disease induced by diabetes, as seen in the pre-clinical animal models ... [showing] the potential of LXA4-based therapies as a promising new way to manage diabetic heart disease."

RACE ONCOLOGY

Race says a Monash University drug discovery program has found "39 unique FTO protein-binding molecules" that could be used to develop drugs for various diseases. In 2022, Race said it began a drug discovery program for inhibitors of the m6A RNA demethylases fatso/fat and obesity associated ALKBH5 proteins (BD: Sep 27, 2022). At that time, the company said changes in expressions of fatso/fat and obesity associated (FTO) or ALKBH5 proteins had "a profound impact on cancer growth, spread and resistance to treatment" and inhibiting FTO or ALKBH5 activity had the potential to "kill or slow the growth of a wide range of cancers".

Today, Race said the program, conducted with the Monash University's fragment platform, used fragment-based screening by nuclear magnetic resonance to identify 39 molecular candidates that specifically bound to the m6A RNA demethylase protein, FTO.

The company said the "confirmed FTO-binding chemical scaffolds provide a platform for the development of novel and patentable molecules with the potential to become new drugs that specifically target the m6A RNA epigenetic pathway".

Race said it would run a hit-to-lead medicinal chemistry program using the hits as starting scaffolds and use synthetic chemistry to turn the hit fragments into drug candidates. The company said the drug candidates would then "be screened for high FTO-inhibitory potency and selectivity, efficacy in animal cancer models, low toxicity and acceptable metabolic properties", which was an expensive undertaking.

Race said it was "currently evaluating options", with no decision made at this stage to advance a hit-to-lead medicinal chemistry program.

Race head of research Prof Mike Kelso said the "identification of chemical 'hits' that bind to a protein target of interest is a critical step in modern drug discovery".

"Our successful FTO program at Monash provides Race with valuable new [intellectual property] in the RNA epi-genetics space, an enormously exciting area at the cutting-edge of oncology research and drug development," Prof Kelso said.

Race was up seven cents or 5.15 percent to \$1.43.

OPYL

Opyl says it will provide its artificial intelligence (A.I.) Trialkey platform for planning clinical trials to Melbourne's Southern Clinical Development Consulting (CDC).

Opyl said Southern Clinical Development Consulting was a clinical research organization (CRO) that supported drug development from pre-clinical stages to first-in-human and late-stage trials.

The company said it would receive a specified fee for each report as part of the six-month deal, with each fee determined by the project and the scope of services required.

Opyl said Trialkey would assist Southern Clinical in "trial design, site feasibility, and patient recruitment strategies to support informed, data-driven decisions".

The company said the agreement could be extended on mutual agreement.

Opyl executive chair Saurabh Jain said the company was "pleased to see Southern CDC adopt our Trialkey platform, taking a step toward our broader strategy of partnering with CRO globally".

"Our goal is to make Trialkey an essential tool in every CRO's service offering, providing the kind of data-driven insights that both CROs and their clients increasingly rely on," Mr Jain said.

Opyl was untraded at 2.7 cents.

ARGENICA THERAPEUTICS

Argenica says it has received \$2,757,459 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Argenica said the incentive related to expenditure for the year to June 30, 2024.

The company said the incentive claim included activities covered by its advanced and overseas finding previously approved by Ausindustry.

Argenica said the funds would "be applied to further developing the company's lead neuro-protective peptide candidate, ARG-007, including completion of the current phase II clinical trial in acute ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions".

Argenica was up 2.5 cents or 3.6 percent to 72.5 cents.

RHYTHM BIOSCIENCES

Rhythm says its annual general meeting voted a 42.17 percent remuneration report first strike and 24.76 percent opposed the re-election of director Sue MacLeman.

Rhythm said the remuneration report was opposed by 28,155,501 votes (42.17%) with 38,610,616 votes (57.83%) in support.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill, and if passed, the directors must stand for re-election within 90 days.

The company said the re-election of Dr MacLeman was opposed by 27,253,815 votes (24.76%), with 82,828,217 votes (75.24%) in favor.

Rhythm said Dr David Atkins election as a director and the special resolution to approve the 10 percent placement facility were passed with more than 91.5 percent support. According to its most recent notice, Rhythm had 248,596,750 shares on issue, meaning that the 28,155,501 votes against the remuneration report amounted to 11.3 percent of the company, sufficient to requisition extraordinary general meetings.

Rhythm was up one cent or 7.7 percent to 14 cents.

PERCHERON THERAPEUTICS

Percheron says its annual general meeting has voted a 34.69 percent remuneration report 'first strike' and up-to 36.55 percent against the prior issue of shares.

Last month, Percheron said the meeting would vote to issue managing-director Dr James Garner and director Dr Ben Gil Price, 3,000,000 options, each (BD: Oct 18, 2024).

Today, the company said the remuneration report was opposed by 138,045,642 votes (34.69%) with 259,838,530 votes (65.31%) in support.

Percheron said the issue of Canaccord advisor options was opposed by 141,646,428 votes (35.11%), with the prior issue of shares opposed by 98,031,552 votes (36.55%). The company said it withdrew special resolutions to approve the 10 percent placement capacity and amend the constitution.

Percheron said that Dr Garner's and Dr Price's options were opposed by 33.10 percent and 30.75 percent of the meeting, respectively, with the re-election of Dr Price facing 22.91 percent opposition, and the appointment of the auditor approved by 90.90 percent. According to its most recent filing, Percheron had 1,059,937,633 shares on issue, meaning that the 141,646,428 votes against the advisor options amounted to 13.4 percent of the company, sufficient to requisition extraordinary general meetings.

Percheron fell half a cent or 6.3 percent to 7.4 cents with 4.45 million shares traded.

ARCHER MATERIALS

Archer says its annual general meeting passed all resolutions but with up-to 23.51 percent against the issue of options to chair Gregory English and two directors.

Last month, Archer said that the meeting would vote to issue 5,000,000 options to Mr English and 3,000,000 options, each, to directors Bernadette Harkin and Kenneth Williams (BD: Oct 21, 2024).

Today, the company said Mr English's options were opposed by 6,025,537 votes (23.51%), with 19,609,329 votes (76.49%) in favor.

Archer said the Ms Harkin and Mr Williams' options were opposed by 21.92 percent and 16.61 percent of the meeting, respectively, the remuneration report was opposed by 3,627,199 votes (14.10%), with the re-election of Mr Williams and the placement capacity approved by more than 91.8 percent of the meeting.

According to its most recent filing, Archer had 254,847,013 shares on issue, meaning that the 6,025,537 votes against Mr English's options amounted to 2.4 percent of the company, not sufficient to requisition extraordinary general meetings.

Archer fell one cent or 3.2 percent to 30 cents.

ACRUX

Acrux says its annual general meeting has passed all resolutions and missed a remuneration report first strike with 21.15 percent opposed and 78.85 percent in favor. Acrux said the remuneration report was opposed by 11,708,684 votes (21.15%) with 43,639,724 votes (78.85%) in support.

The company said the issue of rights to directors in lieu of part of their salaries was opposed by 13.94 percent, the approval of the 10 percent placement capacity faced 11.71 percent dissent, with directors Tim Oldham and Don Brumley re-elected more easily. According to its annual report, Acrux had 290,716,856 shares on issue, meaning that the 11,708,684 votes against the remuneration report amounted to 4.0 percent of the meeting, not sufficient to requisition extraordinary general meetings.

Acrux was up 0.1 cents or 2.2 percent to 4.6 cents.

OPTISCAN IMAGING

Optiscan says it has withdrawn the special resolution to approve the 10 percent placement capacity at its annual general meeting.

Optiscan said the adoption of the remuneration report and re-election of director Ron Song were passed by more than 99.9 percent of the meeting.

Optiscan was unchanged at 16 cents.

OSTEOPORE

Osteopore says its extraordinary general meeting will vote to issue 11,625,000 performance rights to directors and 526,754 shares to managing-director Dr Yujing Lim. Osteopore said investors would vote to issue chair Mark Leong 5,625,000 performance rights, Dr Lim 4,125,000 rights and 625,000 rights, each, to directors Prof Teoh Swee Hin, Daniel Ow and Michael Keenan.

The company said the performance rights would vest in five tranches on milestones relating to the 15-day volume weighted average price of the company's shares and its market capitalization and expire five years from their issue date.

Osteopore said the incentive securities were in addition to the board members' yearly salaries, which ranged from \$40,140 to \$\$191,667 (\$\$A219,089).

The company said the meeting would vote to issue \$20 million in redeemable convertible notes and approve the employee incentive plan and a strategic investment.

The meeting will be held at Level 5, 191 St Georges Terrace, Perth on December 23, 2024, at 11am (AWST).

Osteopore was unchanged at 3.8 cents.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has 46 "drug targets" generated by its artificial intelligence (A.I.)-based operating system that will proceed to pre-clinical studies in oncological indications. Last year, Algorae said it was developing marijuana combination drugs and in September, said it had launched an artificial intelligence (A.I.)-based operating system to predict fixed-dose combination drug targets (BD: Oct 25, 2023, Sep 24, 2024).

Today, the company said the operating system had "generated 46 drug targets". Algorae said following analysis of each drug targets' commercial and intellectual property it intended "to undertake pre-clinical studies in 24 wholly-owned new drug targets" indications including breast and lung cancer, leukaemia, glioblastoma and others. The company said it was in discussions with an Australian-based pharmaceutical drug laboratory to complete the studies in a timely and cost-effective manner, with the results from in-vitro pre-clinical assessments for each target to "verify efficacy and safety, which, if successful, will de-risk further development internally or in partnership with other pharmaceutical companies".

Algorae executive chair David Hainsworth said the operating system was "the only platform of its kind in Australia and ... we've successfully used the platform to expand our therapeutic pipeline by 24 promising new targets".

"This significant expansion highlights the important competitive advantage of A.I. to predict new therapeutic entities ahead of our competitors relying on conventional approaches," Mr Hainsworth said.

"Targets that show promise in laboratory studies will either be developed internally or earmarked for potential development with a partner," Mr Hainsworth said. Algorae was unchanged at 0.7 cents with 12.8 million shares traded.

PAINCHEK

Painchek has requested a trading halt "pending an announcement regarding a capital raise".

Trading will resume on November 25, 2024, or on an earlier announcement. Painchek last traded at 2.8 cents.

VITURA HEALTH

Elizabeth Jansen and the Stanford Investment Trust say they have reduced and been diluted in Vitura from 119,291,098 shares (20.71%) to 113,365,596 shares (19.55%). The Gold Coast-based Ms Jansen said that as trustee for Stanford Investment she bought 100,000 shares on May 6, 2024 for \$11,000, or 11.0 cents a share, and between April 15 and October 28, 2024 sold 5,692,169 shares for \$579,210.6, or an average of 10.2 cents a share.

Ms Jansen said that her holding was diluted after the issue of Vitura shares as part of the company's purchase of Releaf Group through its interest in Flora Holdings Pty Ltd. On Tuesday, Vitura said it would pay \$250,000 in scrip, issue 5,779,274 shares worth \$500,000 and relinquish \$3.8 million of debt to acquire half of marijuana dispensary Releaf Group through its Flora joint-venture with Crisci Group (BD: Nov 20, 2024). Vitura was unchanged at 9.8 cents.

MEMPHASYS

Memphasys says Lindley Edwards has been appointed non-executive chair, replacing Robert Cooke who is stepping down at the annual general meeting.

Memphasys said Ms Edwards had more than 30 years of experience and was currently chief executive officer of AFG Venture Group.

The company said Ms Edwards held a Bachelor of Business from Melbourne's Monash University, a Bachelor of Business from Melbourne's Victoria University and a Doctor of Philosophy from the San Francisco-based Ubiquity University.

The company said it acknowledged "Mr Cooke's significant contributions, which have positioned Memphasys for its next phase of growth".

Memphasys was unchanged at 0.6 cents with 6.4 million shares traded.