Biotech Daily

Monday October 28, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 7%; UNIVERSAL BIOSENSORS DOWN 7%**

*** ARAVAX ENROLS PHASE II PVX108 PEANUT ALLERGY TRIAL**

*** ONCOSIL PLACEMENT RAISES $7m; $1m SHARE PLAN TO GO**

*** NYRADA PLACEMENT RAISES $3.4m; $1m PLAN TO GO**

*** MACH7 $4.3m LICENCE EXPANSION, 2 RENEWALS**

*** PERCHERON TO EXTEND PHASE IIb AVICURSEN DMD ACCESS**

*** RECCE: 'R327 CURES OR IMPROVES BACTERIAL INFECTIONS'**

*** A.C.T. GOVERNMENT OKAYS EMYRIA PSILOCYBIN PSYCHIATRISTS**

*** DIMERIX PHASE III DMX200 FSGS ENDPOINTS 'MAY SUFFICE FOR FDA'**

*** SYNTARA RECEIVES $4.6m FEDERAL R&D TAX INCENTIVE**

*** MEMPHASYS AGM UP-TO 15.9% OPPOSE TOP-UP OFFER**

*** STARPHARMA 5.2m M-D CHERYL MALEY RIGHTS AGM**

*** TRIVARX 12m DIRECTOR OPTIONS AGM**

*** CURVEBEAM 2.8m CEO, COO OPTIONS AGM**

*** TRYPTAMINE REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** THORNEY, TIGA TAKE 19.8% OF LITTLE GREEN PHARMA**

*** GINA RINEHART, HANCOCK PROSPECTING BELOW 5% OF LITTLE GREEN**

*** INVION DIRECTOR MELANIE LEYDIN REPLACES CO SEC TAI MINH PHAN**

*** MICHAEL SAPOUNTZIS REPLACES ALCIDION CO SEC MELANIE LEYDIN**

*** DIMERIX APPOINTS DR LAURA MARIANA MEDICAL ADVISOR**

MARKET REPORT

The Australian stock market was up 0.12 percent on Monday October 28, 2024, with the ASX200 up 10.2 points to 8,221.5 points.

Fifteen of the Biotech Daily Top 40 companies were up, 13 fell and 12 traded unchanged.

Prescient was the best, up 0.3 cents or 6.8 percent to 4.7 cents, with 534,308 shares traded. Mesoblast, Resmed and SDI climbed more than three percent; Dimerix, Opthea, Pro Medicus, Proteomics and Telix rose two percent or more; 4D Medical, Clarity, Genetic Signatures, Immutep, Neuren and Starpharma were up one percent or more; with Cochlear and Cyclopharm up by less than one percent.

Universal Biosensors led the falls, down one cent or 7.1 percent to 13 cents, with 40,000 shares traded.

Amplia lost 6.9 percent; Alcidion and Orthocell fell more than five percent; Imugene, Paradigm and Percheron shed two percent or more; Actinogen, Impedimed and Medadvisor were down more than one percent; with Aroa, CSL, Nanosonics and Polynovo down by less than one percent.

ARAVAX PTY LTD

Aravax says it has enrolled all 95 patients, aged four to 17 years old, in its double-blind, placebo-controlled phase II study of PVX108 as a treatment for peanut allergies.

In 2019, Melbourne's Aravax said that its 48-patient, phase I, dose-escalation PVX108 trial showed "a highly favorable safety profile, even in patients with severe peanut allergies" (BD: Feb 26, 2019).

In 2022, the company said it had raised $30 million in series B funding with Brandon Capital and Tattarang's Tenmile for a phase II trial of PVX108 (BD: Dec 20, 2022).

Earlier this year, the Victoria Government said Breakthrough Victoria had invested $12 million of $33.65 million in Aravax for its peanut allergy treatment (BD: Jan 23, 2024).

Today, the company said its PVX108 was an immunotherapy designed to 're-train' the immune system by administering engineered peptides to precisely target T cells and reverse the course of allergic disease.

Aravax said that unlike most treatments available, or under development for peanut allergy, PVX108 did not contain peanut proteins which put patients at significant risk of serious side effects, leading to complex and burdensome dosing regimens.

The company said the phase II study's primary endpoint was the "ratio of maximum tolerated dose of peanut protein in a controlled food challenge at the end of the study period relative to baseline".

Aravax said the study was conducted under a US Food and Drug Administration investigational new drug application at eight sites in the US and six in Australia, with headline results expected by June 30, 2026.

Aravax chief executive officer Dr Pascal Hickey said "the timely completion of recruitment across multiple sites in the US and Australia, is a significant step for Aravax".

"There remains a critical need for better treatments for serious food allergies," Dr Hickey said. "PVX108 has been designed to provide a safe and convenient treatment which has the potential to reverse the course of allergic disease."

Aravax is a private company.

ONCOSIL MEDICAL

Oncosil says it has “commitments” to raise $7.0 million in a placement at one cent a share, with a $1.0 million share purchase plan to follow.
Biotech Daily calculates the 1.0 cent a share issue price is a 23.1 percent discount to the last closing price of 1.3 cents.
The company said investors would receive one option for every share bought, exercisable at 1.5 cents each within three years from issue.
Oncosil said the funds raised were for its Macquarie Park manufacturing facility, funding pancreatic cancer trials with chemotherapy and other working capital costs.
The company said chair Douglas Cubbin had committed about $100,000 to the placement, subject to approval; and Bell Potter was the lead manager to the raise, receiving seven options for every $1.00 raised and had “a binding commitment from an institutional fund” to subscribed for any share plan shortfall securities.
The company said the share plan had a record date of October 25, would open on November 6 and close on November 21, 2024.
Oncosil fell 0.2 cents or 15.4 percent to 1.1 cents with 54.9 million shares traded.

NYRADA

Nyrada says it has raised $3.36 million in a placement at 12 cents per Chess depository interest (CDI), with a $1.0 million purchase plan to follow.
Nyrada said the placement price was a 16.2 percent discount to the five-day volume weighted average price and a 14.3 percent discount to the last traded price.
The company said the funds were for its phase Ia trial of NYR-BI03, US Food and Drug Administration investigational new drug applications, research and development of NYR-BI03 for heart disease and other indications as well as working capital.
Nyrada said directors would take-up $70,000 in the placement, subject to approval.
The company said Canary Capital was the lead manager to the raise and Foster Stockbroking was co-manager, with Canary to be paid six percent in fees as well as 2,500,000 options, exercisable at 20 cents each by December 31, 2027.
Nyrada said the share purchase plan had a record date of October 25, would open on November 4 and close on December 2, 2024.
Nyrada fell 1.5 cents or 10.7 percent to 12.5 cents with 1.5 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has an Enterprise imaging licence expansion with an existing customer worth about $2.5 million and two renewals worth a combined $1.8 million.
Mach7 said the five-year expansion was signed with an unnamed “large [integrated delivery network] located in the Midwest of the US”, included an additional Eunity viewer, vendor neutral archive licencing and was an expansion of an existing agreement.
Mach7 said the expansion would add $1.3 million to software revenue in the December 31, 2024 quarter, increasing annual recurring revenue by $244,000 for five years.
Mach7 said the two renewals had a total contract value of $1.8 million and would add $114,000 in annual recurring revenue for the next five years.
Mach7 managing-director Mike Lampron said the agreements showed the success of the company’s “‘land and expand’ strategy and the importance of building lasting relationships with our customers”.
Mach7 was up two cents or 3.9 percent to 53 cents.

PERCHERON (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says it will open an expanded access program for its 48-patient, phase IIb trial of avicursen, formerly ATL1102, for Duchenne muscular dystrophy (DMD).

Last year, the then Antisense said it had dosed the first of 45 patients in its double-blind, placebo controlled, phase IIb study of ATL1102 in non-ambulant boys with DMD, conducted in Turkey, the UK, Bulgaria and Australia (BD: Jun 8, 28, 2023).

Earlier this year, Percheron said it had enrolled all 48 patients in the study, with data "expected in December 2024" (BD: May 29, 2024).

Today, the company said "following requests from investigators in the trial" it had been exploring opportunities to make avicursen available to patients who completed participation in the trial and wanted to remain on treatment.

Percheron said it expected to provide avicursen on compassionate grounds to patients who completed the six-month or 12-month treatment in the trial "in four of the five participating countries, with the first patients to begin treatment in 2024".

The company said it was working with the "relevant trial sites and regulatory agencies to complete the procedural and regulatory requirements associated with provision of a medicine that is not yet approved".

Percheron did not name the four countries in which it would conduct the expanded access program.

The company said phase IIb data was "expected to be received in December 2024".

Percheron fell 0.2 cents or 2.5 percent to 7.9 cents with 13.6 million shares traded.

RECCE PHARMACEUTICALS

Recce says data from 14-patients in its phase II trial of R327 topical gel shows it is safe and led to a "complete cure or improvement" for bacterial skin infections.

Earlier this month, Recce said it has dosed 15 of 30 patients in a phase II trial of its R327 topical gel for bacterial skin infections and skin structure infections, including diabetic foot infections (BD: Oct 9, 2024).

Today, the company said interim data showed four patients were cured by day seven, two patients were cured in 14 days weeks, five patients showed improvement by day seven and two patients were improved by day 14, with one patient withdrawn.

Recce said that although "no serious adverse events were noted, one patient was discontinued due to pain at the wound site which was judged to be unlikely related to R327".

The company said conditions treated included diabetic foot ulcer, eczema, scratch and puncture wound infections, with outcomes measured by the Lipsky clinical resolution of infection scale.

Recce said the findings "further underscore the strong safety profile of Recce's innovative anti-infective therapy", with no safety concerns found by the non-data safety monitoring board.

The company said the trial was "on-track to be completed within the calendar year".

Recce managing-director James Graham said the company was "extremely encouraged by the feedback from the non-data safety monitoring board and the ongoing safety and efficacious profile of R327".

"The absence of serious adverse events, coupled with the wide range of broad-spectrum efficacy across challenging wound infections, reinforces the potential of R327 to address unmet medical needs in the treatment of serious bacterial infections," Mr Graham said.

Recce fell 2.5 cents or 4.95 percent to 48 cents.

EMYRIA

Emyria says its psychiatrists have “received endorsement” from the Australian Capital Territory Health ethics committee for its psilocybin-assisted therapy program.
Emyria said the approval was the first of a two-step evaluation, with final approval from the Australian Therapeutic Goods Administration expected “within the next month”.
The company said if it received TGA approval it would “be amongst a select group capable of offering both MDMA [3,4-methylene-dioxy-meth-amphetamine] and psilocybin-assisted therapies, to eligible patients”.
Emyria was up 0.3 cents or 9.4 percent to 3.5 cents.

DIMERIX

Dimerix says its phase III trial of DMX200 for focal segmental glomerulo-sclerosis (FSGS) endpoints may be sufficient for US Food and Drug Administration approval.
In 2021, Dimerix said that it had the first approval to start its up-to 250-patient, phase III trial of DMX- 200 for FSGS kidney disease; and in 2022, it said it had Danish Medicines Agency approval (BD: Oct 21, 2021; Feb 1, 2022).
Later, the company said the FDA had approved its phase III ‘Action3’ study of DMX-200 in up to 286 FSGS patients under an investigational new drug application; and later, said it had dosed the first patient in the trial (BD: May 9, 31, 2022).
At that time, Dimerix said that the trial was being conducted at 75 locations in 12 countries, with 19 sites in the US and it expected the first interim analysis by July 2023.
The company said that the trial had two interim analysis points designed to capture evidence of proteinuria and estimated glomerular filtration rate, eGFR or kidney function, to generate sufficient evidence to support accelerated marketing approval.
Earlier this year, Dimerix said an interim analysis of its phase III trial in FSGS showed that DMX-200 reduced proteinuria more than placebo (BD: Mar 11, 2024).
Today, the company said a scientific workshop held in Washington D.C. from October 7 to 8 and published on October 25, 2024 “provided strong data to support the relationship between a reduction in proteinuria and the reduced risk of kidney disease progression”.
The company said following a workshop, titled ‘Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis’, or Parasol, and subject to FDA confirmation, a reduction in proteinuria might become a validated endpoint FDA approval.
Dimerix said the FDA “may now have sufficient data to grant FDA approval on proteinuria endpoints, as an alternative to eGFR alone or proteinuria and eGFR”.
The company said that it was likely it “may now have a range of proteinuria endpoints that could be acceptable as a primary endpoint for FDA approval”.
Dimerix said 129 patients had been randomized and dosed in the phase III trial, with interim analysis planned after the first 144 patients reached 35-week treatment, “expected around mid-2025”.
The company said no changes were anticipated for the study design given both eGFR and proteinuria data were already being collected for a total period of two years.
Dimerix was up one cent or 2.4 percent to 43 cents with 2.6 million shares traded.

SYNTARA

Syntara says it has received $4,564,373 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Syntara said the incentive related to expenditure for the year to June 30, 2024.
Syntara was unchanged at 4.7 cents with 1.75 million shares traded.

MEMPHASYS

Memphasys says its annual general meeting has passed all resolutions but with up-to 15.90 percent against the issue of securities under a top-up offer.
Memphasys said the top-up offer was opposed by 116,960,431 votes (15.90%), with 618,779,342 votes (84.10%) in favor.
The company said the other 10 resolutions passed with more than 99.24 percent support.
According to its investor presentation today, Memphasys had about 1,367,700,000 shares on issue, meaning that the votes against the top-up offer amounted to about 8.55 percent of the company, sufficient to requisition extraordinary general meetings.
Memphasys was unchanged at 0.8 cents.

STARPHARMA HOLDINGS

Starpharma says its annual general meeting will vote to issue 5,202,703 performance rights to managing-director Cheryl Maley.
Last year, Starpharma said Ms Maley would replace Dr Jackie Fairley as chief executive officer and managing-director from January 8, 2024 (BD: Nov 10, 2023).
Today, the company said investors would vote to issue Ms Maley 1,238,739 short-term incentive rights and 3,963,964 long-term incentive rights with a face-value of $137,500 and $440,000, respectively.
Starpharma said the short-term rights would vest on June 30, 2026 and the long-term rights on September 30, 2027, pending performance milestones relating to developing and monetizing its dendrimer enhanced product (DEP) portfolio.
The company said the options were in addition to Ms Maley's $550,000 fixed annual salary, inclusive of superannuation.
Starpharma said shareholders would vote to adopt the remuneration report, re-elect Lynda Cheng as a director and re-insert the proportional takeover provisions.
The meeting will be held online and at RACV City Club, 501 Bourke Street, Melbourne, on November 26, 2024 at 2pm (AEDT).
Starpharma was up 0.1 cents or 1.1 percent to 9.1 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says its annual general meeting will vote to issue 4,000,000 options, each, to chair David Trimboli and directors Dr Anthony Keating and Christopher Ntoumenopoulos.
Trivarx said the options were exercisable at 4.5 cents each within three years from the issue date and were in addition to the Mr Trimboli's $72,000 yearly pay, Dr Keating's $96,000 annual salary and Mr Ntoumenopoulos' $60,000 fees.
The company said investors would vote to issue Mr Trimboli $24,000 in shares, $5,000 in shares to Dr Keating and $20,000 in shares to Mr Ntoumenopoulos, in lieu of part of their fees, with the shares valued at 2.2 cents a share.
The company said shareholders would vote to increase the maximum awards under the employee incentive plan from 16,750,000 awards to 40,000,000 awards.
Trivarx said the meeting would vote to issue former director Dr Thomas Young shares in lieu of outstanding fees, adopt the remuneration report, re-elect Mr Ntoumenopoulos, Dr Keating and John Mathias as directors, replace the constitution and approve the 10 percent placement capacity.
The meeting will be held at 647 Beaufort Street, Perth, on November 28, 20245 at 9am (AWST).
Trivarx fell 0.1 cents or 5.6 percent to 1.7 cents.

CURVEBEAM A.I.

Curvebeam says investors will vote to issue 1,409,032 priced options, each, to chief executive officer Greg Brown and executive director Arun Singh.
Curvebeam said its annual general meeting would vote to issue the options as part of Mr Brown and Mr Singh's long-term incentive for the year to June 30, 2025, exercisable at 31 cents each within six years from the grant date.
The company said the option price was "a 67 percent premium to the 18 cent price at which shares were issued pursuant to the company's most recent capital raising".
Curvebeam said Mr Singh was a director as well as chief operating officer and chief technology officer, and that the options were in addition to Mr Brown and Mr Singh's $436,800 fixed yearly salaries.
The company said the meeting would vote to adopt the remuneration report, re-elect Kate Robb as a director and approve an additional 10 percent placement capacity.
The meeting will be held online on November 26, 2024 at 9am (AEDT).
Curvebeam was unchanged at 13 cents.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine has requested a trading halt "pending an announcement by the company in relation to a capital raising program".
Trading will resume on October 30, 2024, or on an earlier announcement.
Tryptamine last traded at 2.3 cents.

LITTLE GREEN PHARMA

Thorney Investment Group says it has increased its substantial shareholding in Little Green Pharma from 33,312,402 shares (11.18%) to 59,962,402 shares (19.80%).
The Melbourne-based Thorney Investment Group, with Tiga Trading, Alex Waislitz, Avee Waislitz and Jasforce Pty Ltd, said that between May 5 and October 23, 2024 it bought shares on market, with the single largest purchase 23,321,678 shares on October 23, 2024 for $2,565,385, or 11.0 cents a share.
Little Green Pharma fell half a cent or 3.45 percent to 14 cents.

LITTLE GREEN PHARMA

Georgina Hope Rinehart with Hancock Prospecting Pty Ltd says she has ceased her substantial shareholding in Little Green Pharma.
The Perth-based Ms Rinehart said that between October 7 and 23, 2024 she sold 24,840,039 shares on-market for between 8.0 cents a share and 16 cents a share.
Last year, Ms Rinehart said she held 26,739,029 shares, or 8.93 percent of Little Green.
According to its most recent filing, Little Green Pharma had 302,872,995 shares on issue, meaning that Ms Rinehart's remaining 1,898,990 share-holding amounted to about 0.63 percent of the company.

INVION

Invion says its company secretary Tai Minh Phan has resigned and will be replaced by director Melanie Leydin, effective from today.
Invion was unchanged at 0.2 cents with 3.7 million shares traded.

ALCIDION GROUP

Alcidion says Michael Sapountzis, from the company secretarial firm Vistra, has replaced Melanie Leydin, also from the firm, as its company secretary.
Alcidion said the change was “an internal transfer of responsibilities and Mr Sapountzis has previously provided corporate secretarial services to Alcidion”.
Alcidion fell 0.3 cents or 5.4 percent to 5.3 cents with 1.1 million shares traded.

DIMERIX

Dimerix says it has appointed the Ann Arbor-based University of Michigan’s kidney disease progression researcher Dr Laura Mariana to its medical advisory board.