Biotech Daily

Wednesday October 18, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PATRYS UP 14%; DIMERIX DOWN 12%**

*** RHYTHM TELLS ASX: TGA CORRESPONDENCE 'BUSINESS AS USUAL'**

*** STARPHARMA: DEP-CABAZITAXEL 'BEATS STANDARD IN 3 CANCERS'**

*** PARADIGM: PPS 'INCREASES KNEE CARTILAGE, REDUCES BONE LESIONS'**

*** IMAGION MAGSENSE HER2 'SAFE, 8-OF-13 IMAGES READABLE'**

*** TESSELLATE BIO DEVELOPS 'ALT INHIBITORS' FOR CANCER**

*** MAYNE Q1 REVENUE UP 35% TO $92m; 'CASH EBITDA'; BUY-BACK**

*** BLUECHIIP 'COMMITMENTS' FOR $1.6m PLACEMENT**

*** PHARMAUST HOPES OPTIONS RAISE $396k**

*** CLINUVEL STARTS PHASE III SCENESSE VITILIGO TRIAL**

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*** ARGENICA ARG-007 'REDUCES HIE BRAIN INJURY 42%, IN RATS'**

*** NOXOPHARM SOF-VAC 'REDUCES mRNA INFLAMMATION 48%, IN MICE'**

*** CANN GROUP RECEIVES $3.5m FEDERAL R&D TAX INCENTIVE**

*** ADALTA RECEIVES $2m FEDERAL R&D TAX INCENTIVE; EXTENDS LOAN**

*** RADIOPHARM 10m CEO, DIRECTOR OPTIONS AGM**

*** TRIVARX 20-TO-1 CONSOLIDATION**

*** FIL (FIDELITY) TAKES 9.8 OF TRIVARX (MEDIBIO)**

MARKET REPORT

The Australian stock market was up 0.3 percent on Wednesday October 18, 2023, with the ASX200 up 21.5 points to 7,077.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

Yesterday's 12.5 percent worst, Patrys, was today's best, up 0.1 cents or 14.3 percent to 0.8 cents, with 2.3 million shares traded. Paradigm climbed 10.3 percent; Cynata rose eight percent; Actinogen and Neuren were up more than five percent; Genetic Signatures was up 3.2 percent; Imugene improved 2.4 percent; CSL, Emvision and Kazia were up one percent or more; with Clinuvel, Cochlear, Nanosonics, Resmed and Telix up by less than one percent.

Dimerix led the falls, down two cents or 12.1 percent to 14.5 cents, with 8.0 million shares traded. Atomo lost 8.3 percent; Resonance lost 6.25 percent; Compumedics shed 5.9 percent; Nova Eye and Prescient fell more than four percent; both Micro-X and Starpharma were down 3.7 percent; Next Science shed 2.4 percent; Medical Developments, Pro Medicus, SDI and Volpara were down more than one percent; with Polynovo and Proteomics down by less than one percent.

RHYTHM BIOSCIENCES

Rhythm has told the ASX that emails with the Therapeutic Goods Administration about its Colostat application were “business as usual” and not “formal correspondence”.

The ASX said that a 30-page letter from the TGA, obtained under Freedom of Information cited a June 8, 2022 TGA request for more information and a July 6, 2022 Rhythm reply.

The ASX said that in an announcement titled ‘Market Update’ on December 15, 2022 the company said that “on May 12, 2022, [Rhythm] filed its complete submission with the TGA for the listing of Colostat on the Australian Register of Therapeutic Goods …. [and] the TGA has acknowledged it is assessing the filing, with no further formal correspondence being received”.

The ASX noted that in response to an ASX 37.5 percent price fall query, Rhythm cited its October 10 annual general meeting and disclosures at that meeting about changes to the EU in-vitro diagnostic medical devices regulation standards, the TGA’s intention to make “similarly stringent” changes, its intention to submit applications to ensure compliance and that current approvals remained valid (BD: Oct 13, 2023).

The ASX said that Listing Rule 3.1 required a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity’s securities.

The ASX said that section 13 of Guidance Note 14, stated: “ASX has experienced difficulties in the past with announcements that have been given a fairly innocuous header (such as “Chairman’s Address to AGM”) but have had market sensitive material embedded in them”.

“ASX would ask listed entities to ensure that the header to such an announcement clearly identifies the fact that it contains market sensitive information (eg “Chairman’s Address to AGM and Buyback Announcement”) or, better still, that market sensitive announcements are made on a stand-alone basis and not embedded in other announcements that may not be market sensitive,” the ASX said.

Rhythm replied as part of the TGA audit process, there were “typically a number of audit-like process interactions with the assigned TGA team over the review period and the provision to the TGA of additional documentation or information in response”.

The company said that it had engaged an independent third-party consultancy to assist in preparing its Australian Register of Therapeutic Goods (ARTG) listing application and responding to the TGA during the audit process.

“This audit interaction is typical of ARTG applications for such medical devices and in the ASX letter of October 16, 2023 you have referred to two of those audit interactions … whereas there were a number of such interactions,” Rhythm told the ASX.

“The company viewed such standard audit interactions as ‘business as usual’ and therefore not material for disclosure to the ASX … and not constituting the formal communication from the TGA of any decision on [Rhythm’s] ARTG listing application,” the company said. “It is important to note that the TGA audit requests of June 8, 2022 and July 6, 2022 were part of this standard TGA audit process [and] review, and did not contain any assessment of the merits of [Rhythm’s] ARTG listing application.”

“It reflects the typical interaction with the TGA regarding such applications that any applicant customarily experiences and [Rhythm] notes this is consistent with disclosures/approach taken by other ASX-listed life sciences companies,” Rhythm said.

The company said it had not received any indication from the TGA of an assessment or opinion on the merits of the application, so in the December 15, 2022 announcement it stated, after disclosing the TGA had acknowledged receipt of the application that the TGA was “assessing the filing with no further formal [TGA] correspondence being received”.

Rhythm was up two cents or 12.1 percent to 18.5 cents.

STARPHARMA HOLDINGS

Starpharma says its open-label, 75-patient phase II trial shows DEP-cabazitaxel is superior to the standard-of-care with “positive anti-tumor efficacy” for three cancers.

In April, Starpharma said it had dosed all 76 patients in its phase II trial of dendrimer enhanced product (DEP)-cabazitaxel for a range of cancers with “encouraging efficacy signals” (BD: Apr 17, 2023).

Today, the company said that DEP-cabazitaxel was a dendrimer nanoparticle version of cabazitaxel, marketed as or Jevtana, widely used for prostate cancer.

Starpharma said the trial studied the efficacy and safety of DEP-cabazitaxel in 25 heavily pre-treated advanced metastatic castration-resistant prostate cancer patients, 22 platinum-resistant ovarian cancer patients, 15 gastro-oesophageal cancer patients and 13 patients with other cancers, including head and neck cancer, cholangio-carcinoma, or bile duct cancer and thymic carcinoma.

Starpharma said the study showed DEP-cabazitaxel at 20mg/m^2 administered intravenously once every three weeks for up-to 12 cycles was “very well tolerated”.

The company said the percentage of DEP-cabazitaxel treated patients with grade three-or-four non-haematological, treatment-related adverse events was 21.3 percent, about half that reported for Jevtana, which was 40 percent at the same dose.

Starpharma said in prostate cancer patients DEP-cabazitaxel showed a median progression-free survival of 4.4 months, more than 50 percent longer than the published median result of 2.9 months for standard cabazitaxel at the same dose.

The company said that median progression-free survival was 25.7 percent longer than the 3.5 months at the higher dose of 25mg/m^2 of Jevtana.

Starpharma said the trial showed “highly encouraging efficacy” results in heavily pre-treated patients with ovarian cancer, including tumor shrinkage of up-to 40 percent and response durations of up to 34-weeks.

Starpharma said DEP-cabazitaxel resulted in a disease control rate of 66.7 percent for ovarian cancer patients and an objective response rate of 17.6 percent in evaluable ovarian cancer patients despite their heavy pre-treatment.

Starpharma said the trial showed the 15-patients with gastro-oesophageal junction cancers treated with DEP-cabazitaxel had a median progression-free survival of four months and a median overall survival of 8.6 months.

The company said these results compared “very favourably” to standard-of-care paclitaxel treatment, with DEP-cabazitaxel achieving a more than 50 percent longer median progression free survival and a 29 percent longer median overall survival than paclitaxel administered weekly as a second-line treatment.

Starpharma said the other cancer patients included seven head and neck cancer patients, four cholangiocarcinoma patients, one non-small cell lung cancer patient and one thymic carcinoma patient, with patient responses to DEP- cabazitaxel including stable disease and “up-to more than 30 percent” partial response tumor shrinkage.

Starpharma chief executive officer Dr Jackie Fairley said the company was “delighted to report positive final results from our phase II clinical trial of DEP-cabazitaxel, which showed both efficacy and tolerability benefits in advanced prostate cancer patients, compared with the published data for Jevtana”.

“These very positive results for DEP-cabazitaxel in three common and hard-to-treat cancers demonstrate its therapeutic and commercial value as well as its ability to address significant unmet medical need,” Dr Fairley said.

“Many of the patients who participated in the trial had no or very few options, and DEP-cabazitaxel delivered clinically meaningful outcomes,” Dr Fairley said.

Starpharma fell half a cent or 3.7 percent to 13 cents with 17.5 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its injectable pentosan polysulphate sodium (PPS) increased cartilage thickness and reduced bone marrow lesions by two percent.

In 2021, Paradigm said it had dosed the first of 60-patients in its randomized, double-blind, placebo-controlled, phase IIb trial of injectable pentosan polysulphate sodium for knee osteoarthritis pain (BD: Apr 14, 2021).

Today, the company said six-month follow-up analysis using magnetic resonance assessment found a twice-weekly, two milligrams per kilogram dose for six weeks "outperformed the once-weekly" dose and was "consistent with the optimal clinical dose".

Paradigm said subcutaneously-injected PPS increased overall knee cartilage thickness by 0.17mm ($p = 0.05$) compared to an overall decrease of 0.09mm in the placebo group.

The company said PPS resulted in an increase of overall cartilage volume by 1.9 percent ($p = 0.07$) compared to a decrease of 1.58 percent in the placebo group.

Paradigm said patients who received PPS had an average improvement of cartilage thickness in the central medial femur of the knee of 0.06mm at six months compared to placebo patients who lost an average 0.02mm of thickness.

The company said its treatment reduced bone marrow lesion volume by 17 percent compared to placebo, which increased lesion volume by 2.0 percent.

Paradigm said it was working on a Therapeutics Good Administration provisional approval application to expedite the pathway to marketing approval in Australia.

Paradigm chief executive officer Paul Rennie said PPS had shown "that it not only has a durable and beneficial effect on pain, function and the patient's impression of improvement out to 12 months, but we are also seeing it is improving the underlying disease as early as six months following a single six-week treatment course".

"Paradigm aims to reach agreement with the US [Food and Drug Administration] on what data would be necessary to confirm these results in our larger phase 3 program to include disease modifying data on our label at registration," Mr Rennie said.

Paradigm was up 6.5 cents or 10.3 percent to 69.5 cents with 5.2 million shares traded.

IMAGION BIOSYSTEMS

Imagion says a phase I trial shows its Magsense HER2 for detecting breast cancer with magnetic resonance imaging was "safe and well tolerated", with eight readable results.

In June, Imagion said it had enrolled all 13 patients in its trial of Magsense with human epidermal growth factor receptor-2 (HER2) for detecting breast cancer (BD: Jun 21, 2023).

At that time, the company said the trial was "instrumental in revealing the potential clinical utility of the Magsense HER2 imaging agent and confirmation that the company's targeted nanoparticle technology has the potential to change how [magnetic resonance imaging] can be used to specifically detect cancer".

Today, Imagion said three results were unreadable due to the tumor impairing lymphatic drainage of the drug and two images were "marred by common MRI artefacts".

Imagion said seven of the eight readable results aligned with blinded radiologist's reports, with results to be released at a Breast Cancer Symposium in December.

Imagion chief executive officer Dr Isaac Bright said that the company had "allowed us to deliver the world's first molecular [magnetic resonance imaging] contrast agent that may enable clinicians to non-invasively and accurately differentiate metastatic disease from benign lymph nodes in HER2-positive breast cancer patients."

The company said it expected to submit its first investigational new drug application to the US Food and Drug Administration by March 31, 2024.

Imagion was unchanged at 1.2 cents with 21.8 million shares traded.

TESSELATE BIO BV
CHILDREN'S MEDICAL RESEARCH INSTITUTE

Tessellate Bio BV says it has EUR8 million ($A13.3 million) in seed funding to develop 'ALT' inhibitors, to target DNA damage in the treatment of cancers.
The Amsterdam-based Tessellate said it was founded by Sydney's Children's Medical Research Institute's Prof Hilda Pickett and the Lisbon-based Instituto de Medicina Molecular's Prof Claus Azzalin.
The company said that the 'alternative lengthening telomeres' (ALT) mechanism was discovered at the Children's Medical Research Institute in 1995.
Tessellate said that 'alternative lengthening telomeres' was a mechanism in 10 to 15 percent of cancer cells, generally the more rare and aggressive cancers, for lengthening cancer telomeres.
The company said that the more common mechanism of cancer telomere lengthening was through the enzyme, telomerase.
Tessellate chief executive officer Andree Blaukat said that "synthetic lethality is a proven but only partly explored field … [that] would potentially address a huge range of cancer types with highly tumor targeted medicines, a new frontier in precision oncology".
Prof Pickett said it was "fantastic to see the research discoveries made in my lab progress towards the clinic".
"By committing to strong scientific foundations, Tessellate Bio is focused on finding new treatments for cancers that currently have limited treatment options," Prof Pickett said.
Tessellate said it was headquartered in Amsterdam and was building its main research and development operations in the UK, with plans to raise additional financing in 2024.
Tessellate is a private company.

MAYNE PHARMA GROUP

Mayne says revenue for the three months to September 30, 2023 rose 35 percent to $92.3 million compared to the prior quarter, led by women's health and dermatology sales.
Mayne said that it had introduced the "new metric" of cash Ebitda (earnings before interest, tax, depreciation and amortization), that included "the impact of earn-out liabilities, royalties and lease payments".
The company said that cash Ebitda improved from a loss of $19.5 million in the three months to June 30 to a loss of $1.7 million in the three months to September 30, 2023.
Mayne said it expects its business segments "to deliver positive contribution margin in 2023-'24, with positive Ebitda and operating cash flow".
The company said it would seek shareholder approval to increase the share buy-back to up to 15 percent of issued capital in the 12 months following the annual general meeting.
Mayne was up 38 cents or 13.8 percent to $3.13 with 543,866 shares traded.

BLUECHIIP

Bluechiip says it has 'firm commitments' to raise $1.54 million in a placement to institutional and sophisticated investors at 2.1 cents a share.
Bluechiip said chair Iain Kirkwood, chief executive officer Andrew McLellan and director Michael Ohanessian would subscribe for about $90,000, subject to shareholder approval.
The company said it would use the funds for production scaling and sales expansion, especially in North America, as well as for its ongoing working capital needs.
Bluechiip said that MST Financial Services Pty Ltd was lead manager to the placement.
Bluechiip fell 0.2 cents or 7.4 percent to 2.5 cents.

PHARMAUST

Pharmaust says it hopes to raise up-to $396,144 through a one-for one option offer, to be issued at 0.5 cents and exercisable at 15 cents each by April 30, 2026.
Pharmaust said it would offer one option for each existing PAAO listed option held at the expiry and record date of October 31, 2023, with the placement to occur to existing listed option holders after the existing options expire subject to shareholder.
Pharmaust said its directors had advised that they intended to subscribe for their full entitlement, subject to shareholder approval.
The company said the funds would be used for general working capital.
Pharmaust said Blue Ocean Equities Pty Ltd would manage the offer.
Pharmaust chief executive officer Dr Michael Thurn said the company was “poised for significant growth following the completion of its phase II study for the treatment of B-cell lymphoma in dogs and after recently successfully completing dosing in its phase I … study of monepantel in patients with motor neuron disease”.
Pharmaust fell 0.1 cents or 1.3 percent to 7.4 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first of up-to 200-patients in its open-label, randomized phase III trial of Scenesse, afamelanotide 16 milligrams, for vitiligo or depigmented skin.
Clinuvel said the primary endpoint of the study was 50 percent body surface re-pigmentation, with all patients receiving narrowband ultraviolet B light standard-of-care treatment twice-weekly for 20 weeks, and half receiving Scenesse every three weeks, with narrowband ultraviolet B light (NB-UVB).
The company said the study would evaluate whether afamelanotide in combination with NB-UVB provided “faster, deeper, and longer-lasting re-pigmentation of total body surface compared to NB-UVB alone … [and] a number of patient-reported outcomes, including quality of life surveys, will provide data for secondary objectives”.
Clinuvel said that recruitment was expected to be completed within 12 months, depending on its ability to identify suitable patients.
Clinuvel was up 10 cents or 0.6 percent to $15.96.

IMMURON

Immuron says it has enrolled the second cohort of 34 participants in its trial of Travelan to prevent infectious diarrhea caused by enterotoxigenic Escherichia coli.
In July, Immuron said that it had enrolled the first 30-patient cohort in its 60-patient trial of the cow-colostrum-based Travelan for infectious diarrhoea caused by entero-toxigenic Escherichia coli (ETEC), with the final 30 participants to be enrolled and dosed by November 2023 and resulted expected by June 30, 2024 (BD: Jul 25, 2023)
Today, the company said that the study was being led by principal investigator Dr Mohamed Al-Ibrahim at the Pharmaron clinical research facility in Baltimore, Maryland and was designed to evaluate the safety and protective efficacy of Travelan compared to a placebo in a controlled human infection model.
Immuron said that the primary efficacy outcome was the prevention and/or reduction of moderate to severe diarrhea.
The company said that the inpatient phase for the second cohort would be completed by the end of October 2023 and all study participants would return as outpatients for two-week, one-month and six-month follow-up visits.
Immuron fell 0.2 cents or 2.5 percent to 7.9 cents.

ARGENICA THERAPEUTICS

Argenica says ARG-007 reduces newborn brain injury following oxygen deprivation 42 percent compared to therapeutic hypothermia (cold treatment), in infant rats.

Argenica said the study studied hypoxic-ischaemic encephalopathy (HIE) in rats and found that ARG-007 reduced total brain injury by 46 percent compared to saline placebo 48 hours after, with a 42 percent reduction compared to hypothermia, or reduced temperature, standard-of-care therapy.

The company said hypoxic-ischaemic encephalopathy was “a type of newborn brain damage caused by oxygen deprivation and limited blood flow [which] results in damage to brain cells”.

Argenica said that at four weeks, after hypoxic-ischaemic encephalopathy, ARG-007 reduced total brain injury by 52 percent compared to saline placebo, with a 57 percent reduction in total brain injury compared to hypothermia.

The company said the consistency in brain injury reduction indicated ARG-007 was suitable as a combined neuro-protection therapy for hypoxic-ischaemic encephalopathy or as a stand-alone therapy when hypothermia could not be used.

Argenica said the study completed its rat efficacy studies and that it would work with the Perth’s Perron Institute’s Dr Adam Edwards to complete larger animal studies in both term and pre-term models of hypoxic-ischaemic encephalopathy at Denmark’s University of Aarhus and the University of Western Australia, respectively.

Argenica said further studies would examine ARG-007 in models more closely resembling newborn humans, with larger animal models of term hypoxic-ischaemic encephalopathy selected due to their use in validating the current standard-of-care hypothermic treatment.

The company said pilot studies for both pre-clinical trials were in the planning stages and that it expected preliminary data in 2024, with juvenile toxicology studies underway.

Argenica was up one cent or 2.9 percent to 35 cents.

NOXOPHARM

Noxopharm says its Sof-Vac mRNA vaccine enhancer reduces inflammatory responses to mRNA by 48.2 percent, in mice.

In March, Noxopharm said it had chosen a pre-clinical, lead candidate as part of its Sofra pre-clinical platform, called Sofvac, which was “the smallest molecule of its type to have demonstrated strong activity against inflammation” and had licenced the technology from Melbourne’s Hudson Institute of Medical Research (BD: Mar 28, 2023).

Today, Noxopharm said the study showed “a highly significant decrease in levels of nine inflammatory biomarkers ($p < 0.001$) detected in the blood of mice six-hours post-injection with mRNA alone or mRNA co-packaged with Sofvac”.

Noxopharm said many side effects of mRNA vaccines were due to inflammation, and that a reduction in inflammation could enable higher mRNA vaccine doses, allow different vaccines for multiple diseases to be combined into one mRNA vaccine and support the development of future mRNA or RNA drugs that require high and repeated doses.

The company said it had “largely concluded its planned development work” on the Sofra platform and was seeking a commercial partner to take development forward.

Noxopharm chief executive officer Dr Gisela Mautner said the results were “a significant milestone in the development of Sofvac”.

“We have now taken Sofvac to the point where we consider the data is strong enough for it to be of interest to other companies, and so are stepping up our efforts to find the right partner to continue its clinical development,” Dr Mautner said.

Noxopharm rose 1.9 cents or 19.8 percent to 11.5 cents with 12.5 million shares traded.

CANN GROUP

Cann says it has received $3,484,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cann said the rebate related to research and development expenditure for the year to June 30, 2023.
The company said the net proceeds from the rebate following its repayment of all early advances from Radium Capital was $1,915,000 and would be used for cultivating and manufacturing its medicinal cannabis products.
Cann was unchanged at 11.5 cents.

ADALTA

Adalta says it has received $2,350,940 under the Federal Government's Research and Development Tax Incentive program and extended Victoria Government loan.
Adalta said the rebate from the Australian Tax Office related to research and development expenditure for the year to June 30, 2023.
The company said it was finalizing the extension of its $4.0 million loan facility from the Victoria Government's Research and Development Cash Flow Loan Initiative, so that it could repay 50 percent by October 31, 2023, a further 15 percent by January 31, 2024 and the final 35 percent by April 30, 2024.
Adalta said the funds from its research and development tax incentive would be used to pay the 50 percent initial repayment of its loan facility with the Victorian Government.
Adalta was unchanged at 2.4 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its annual general meeting will vote to issue 10,113,668 options to chief executive officer Riccardo Canevari, chair Paul Hopper and director Ian Turner.
Radiopharm said under its employee incentive plan Mr Canevari would receive 7,426,895 options, Mr Hopper would receive 1,235,761 options and Mr Turner would receive 1,451,012 options, exercisable at 11.2 cents each by July 1, 2028 and vesting in three tranches annual for three years.
Radiopharm said the meeting would vote to re-elect director Dr Michael Baker, adopt the remuneration report, approve the 10 percent placement capacity, and issue equity securities under its omnibus incentive plan, as well as amend its constitution.
The meeting will be held online and in person at Level 3, 62 Lygon Street, Carlton, Victoria on November 16, 2023 at 10am (AEDT).
Radiopharm fell half a cent or four percent to 12 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it will conduct a 20-to-one consolidation for shareholders on the record date of October 25, with post-consolidation trading from November 2, 2023.
Last month, the-then Medibio said its extraordinary general meeting would vote to change its name to Trivarx and approve a 20-to-one consolidation, and last week said the meeting approved both resolutions (BD: Sep 6, Oct 11, 2023).
Today, Trivarx said its 6,714,378,022 shares on offer would become 335,718,901 shares post-consolidation.
Trivarx was unchanged at 0.1 cents with 2.1 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

FIL Limited (Fidelity Investment) says it has increased its substantial shareholding in Trivarx from 506,334,415 shares (8.30%) to 656,184,415 shares (9.77%).

The Hong Kong-based FIL said that on October 13, 2023, it bought 149,850,000 pre-consolidation shares for 0.15 cents a share (see above).