Biotech Daily

Monday November 13, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: 4D MEDICAL UP 71%; PATRYS DOWN 10%**

*** PRO MEDICUS $20m OREGON HEALTH VISAGE 7 CONTRACT**

*** 4D MEDICAL JUMPS 71% ON US XV LVAS REIMBURSEMENT**

*** VISIONEERING RIGHTS RAISE $2.4m; $1.5m SHORTFALL**

*** AVITA APPOINTS POLYMEDICS EU DISTRIBUTOR**

*** TELIX TREATS 1st PHASE III TLX591 PROSTATE CANCER PATIENT**

*** NEUREN COMPLETES PHASE II NNZ-2591 PHELAN-MCDERMID TRIAL**

*** AROVELLA TERMINATES DKK1 MD ANDERSON LICENCE**

*** VIVAZOME PRESENTS EXOSOMES DATA**

*** ISLAND SCREENS ISLA-101 ASCENDING DOSE SUBJECTS**

*** PYC 'PYC-003 EFFICACY FOR POLYCYSTIC KIDNEY DISEASE, IN-VITRO'**

*** ARGENICA RECEIVES $2.1m FEDERAL R&D TAX INCENTIVE**

*** CYNATA AGM 19.5% OPPOSE REMUNERATION REPORT, OPTIONS**

*** IMAGION AGM 36% OPPOSE DIRECTOR OPTIONS**

*** BTC AGM: 20% BACK BOARD SPILL; 99% BACK REMUNERATION REPORT**

*** AUSTRALIAN SUPER TAKES 11.45% OF ALCIDION**

*** NEUROSCIENTIFIC LOSES DR LINDA FRIEDLAND, 2 NEW DIRECTORS**

*** EMYRIA LOSES DIRECTOR DR ALISTAIR VICKERY; 'BOARD TRANSITIONS'**

*** CORRECTION: STARPHARMA**

*** BIO-MELBOURNE RETHINKING ANTIMICROBIAL RESISTANCE**

MARKET REPORT

The Australian stock market fell 0.4 percent on Monday November 13, 2023, with the ASX200 down 27.7 points to 6,948.8 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and three were untraded. All three Big Caps fell.

4D Medical was the best, up 32.5 cents or 70.65 percent to 78.5 cents with 7.6 million shares traded.

Prescient climbed 27.6 percent; Actinogen was up 11.1 percent; Imugene and Kazia improved more than nine percent; Micro-X was up eight percent; Atomo and Cyclopharm were up four percent or more; Antisense, Immutep and Pharmaxis were up more than three percent; Alcidion and Medical Developments rose two percent or more; Clinuvel, Impedimed, Paradigm and Polynovo were up more than one percent; with Emvision and Pro Medicus up by less than one percent.

Patrys led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 1.5 million shares traded. Universal Biosensors lost 7.1 percent; Avita fell four percent; Cynata, Dimerix, Resonance, Starpharma and Telix were down more than three percent; Mesoblast and Proteomics shed more than two percent; Amplia was down 1.3 percent; with Cochlear, CSL, Nanosonics, Neuren, Resmed and Volpara down by less than one percent.

PRO MEDICUS

Pro Medicus says it has signed a $20 million, eight-year contract with Portland's Oregon Health and Science University for its Visage 7 diagnostic imaging platform.
Pro Medicus said Oregon Health and Science University included a hospital and children's hospital with a total of 576 licenced beds, as well as a system of clinics in Oregon and southwest Washington state, that employed about 20,000 staff.
The company said through the transactional licencing model contract, its wholly-owned US subsidiary Visage Imaging Inc would implement its internet cloud-engineered Visage 7, including Visage 7's open archive and workflow modules, throughout Oregon Health and Science University.
Pro Medicus said Visage 7 would integrate enterprise distribution of images to Oregon Health and Science University's electronic health record.
Pro Medicus said it planned the roll-out to begin immediately and it expected it to be operational by December 31, 2024.
The company said the contract continued its "rapid expansion into North American academic medical centres".
Pro Medicus chief executive officer Dr Sam Hupert said Oregon Health and Science University added to the company's "rapidly growing list of clients in the Pacific Northwest".
"They also join a long list of Visage 7 clients to opt for a fully cloud-engineered solution, which, as a result of our cloud [picture archiving and communication system] strategy, is becoming the standard in the North American healthcare [information technology] market," Dr Hupert said.
"Our pipeline remains strong and spans all market segments," Dr Hupert said.
"As has been the case with many of our recent contracts, this deal is for our 'full-stack' comprising all three Visage products namely viewer, workflow and archive, a trend we see continuing," Dr Hupert said.
Pro Medicus was up nine cents or 0.11 percent to $85.27 with 104,069 shares traded.

4D MEDICAL

4D Medical says the US Centres for Medicare and Medicaid will reimburse $US299 ($A470) for its XV LVAS scans for lung disease, effective from January 1, 2024.

4D medical said the reimbursement was for lung ventilation analysis software (LVAS) scans in a US hospital outpatient facility for Medicare patients and that it served as a "guide for private health insurers in determining their pricing levels".

The company said the reimbursement would "accelerate utilization of XV LVAS under 4D Medical's existing category III [current procedural terminology] code, a key criterion for the [American Medical Association] when considering granting a category I CPT code".

4D Medical managing director Prof Andreas Fouras said the Medicare reimbursement of $US299 a scan was "a major milestone in our progress to secure reimbursement across the entire US healthcare system and meaningfully removes a barrier to broader adoption across the large network of facilities providing healthcare to the 65 million Americans enrolled in Medicare".

"This ruling will lead to accelerated uptake of XV LVAS, which in turn will support our pursuit of a category I CPT code," Prof Fouras said.

4D Medical rose 32.5 cents or 70.65 percent to 78.5 cents with 7.6 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has raised $2,370,961 of a hoped-for $3.9 million in a five-for-nine, non-renounceable, rights offer at 22 cents per Chess depository interest (CDI).

Last month, Visioneering said it hoped to raise $US2.5 million ($A3.9 million) in the CDI offer and $US120,000 ($A187,000) in a directors' placement (BD: Oct 10, 2023).

Today, the company said its largest CDI holder Thorney Investment Group had taken up its pro-rata entitlement under the offer.

Visioneering said it had received commitments from existing investors to subscribe for an aggregate of about $353,000 of the $1.5 million shortfall and it intended to place additional shortfall securities "in due course but in any case, by February 6, 2024".

Visioneering was unchanged at 22.5 cents.

AVITA MEDICAL

Avita says Polymedics Innovations GmbH will distribute its Recell treatment for thermal burn wounds and full-thickness skin defects in Germany, Austria and Switzerland.

Avita said the Denkendorf, Germany-based Polymedics Innovations commercialized "innovative biomaterials and systems for the treatment of wounds, [and] operates a robust distribution network of over 40 global markets".

The company said the agreement included the option for Polymedics Innovations to expand distribution of Recell to "additional European markets in the future".

Avita did not state the commercial terms of the agreement.

Avita said it would leverage Polymedics Innovations' "deep expertise, well-established infrastructure, and extensive knowledge of these markets to effectively expand its reach".

Avita chief executive officer Jim Corbett said that partnership with Polymedics was "the first step of our strategic global expansion".

Avita fell 15 cents or four percent to $3.56 with 306,139 shares traded.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of up-to 400 patients in its phase III study of TLX591 radio-antibody drug conjugate for metastatic castrate-resistant prostate cancer.

According to a Telix spokesperson, the patient was the first prostate cancer patient to be dosed with an antibody combined with radiotherapy.

The company said the trial would dose patients with its TLX591 prostate-specific membrane antigen targeting radio-antibody drug conjugate therapy, with the standard-of-care androgen receptor inhibition, or taxanes, compared to standard-of-care alone.

Telix said 242 patients had already been treated across eight phase I and II studies of TLX591, including a study which "confirmed the clinical validity" of TLX591's optimal fractionated dosing and product safety profile.

Telix said the trial was a "multi-national, multi-centre, prospective, randomized, controlled, open-label phase III study designed to investigate and confirm the patient benefits and risks associated with TLX591 administered together with standard-of-care".

The company said the first patient was dosed at Perth's St John of God Hospital, Murdoch campus, and that it expected to expand internationally subject to regulatory approvals, including in Europe and the US.

Telix said the planned US arm of the study would include a run-in "to bridge manufacturing data to a commercial-scale process" and that interim analysis for the trial was expected after the first 120 patients had been dosed.

Telix chief medical officer Dr Colin Hayward said "dosing a first patient … is a significant milestone for Telix and will help build on an already extensive data set".

"The current TLX591 experience underlines the potential benefits of an antibody-based approach in combination with real world standards-of-care, including physician choice of [androgen receptor pathway inhibitor] or taxane," Dr Hayward said.

Telix fell 30 cents or 3.2 percent to $9.15 with 552,010 shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has completed its phase II clinical trial of NNZ-2591 for Phelan-McDermid syndrome, with top-line results expected by the end of this year.

In June, Neuren said it had enrolled its up-to 20 children, phase II trial of NNZ-2591 for Phelan-McDermid syndrome (BD: Jun 30, 2023).

The company said that up to one in 8,000 people have Phelan-McDermid syndrome, with no approved medications, drugs, or therapies specifically for the syndrome.

Neuren said the syndrome had "severe quality of life impacts on those living with it, as well as on parents and siblings" with common characteristics developmental and intellectual impairment and developmental delay, delayed or absent speech, autism symptoms, low muscle tone, motor delays, epilepsy, difficulties with toilet training and eating.

The company said it was conducting phase II trials of NNZ-2591 in children with three other neuro-developmental disorders, Pitt Hopkins syndrome, Angelman syndrome and Prader-Willi syndrome; and all four programs had been granted orphan drug designation by the US Food and Drug Administration.

Neuren chief executive officer Jon Pilcher said the company was "grateful to all the people at the trial sites in the US and in the [Phelan-McDermid syndrome] community who have enabled this ground-breaking trial to be completed as we strive to develop a potential first therapy for [Phelan-McDermid syndrome]".

"We look forward to releasing next month the first results of treatment with NNZ-2591 in children with [Phelan-McDermid syndrome]," Mr Pilcher said.

Neuren fell 13 cents or 0.9 percent to $14.33 with 987,536 shares traded.

AROVELLA THERAPEUTICS

Arovella says it has terminated its MD Anderson Cancer Centre licence for the DKK1-targeting technology “to focus resources on its lead program ALA-101” for blood cancers.
In 2021, Arovella said it licenced a monoclonal antibody directed against a DKK1 peptide from Huston’s University of Texas MD Anderson Cancer Center (BD: Dec 13, 2021).
Today, the company said terminating the agreement reduced expenses relating to ongoing licence fees and patent costs for the technology and there was no fee associated with terminating the agreement.
Arovella chief executive officer Dr Michael Baker said “the DKK1-targeting technology is a unique concept with great potential, but it is yet to be validated in clinic as a target for cancer treatment”.
“Our strategy is to focus on delivering best-in-class products to patients as efficiently and quickly as possible in cancers where there is a high unmet need,” Dr Baker said.
“Our strategic review concluded that in addition to our lead asset ALA-101, the Claudin 18.2-targeting technology recently licenced from Sparx Group and the ongoing collaboration with Imugene are higher priorities for Arovella at this time,” Dr Baker said.
Arovella was up 0.7 cents or 7.1 percent to 10.5 cents with 3.7 million shares traded.

VIVAZOME THERAPEUTICS PTY LTD

Vivazome says it has presented data on exosome purification, customization and manufacturing.
Vivazome said it presented three posters at the Australian and New Zealand Society of Extracellular Vesicles (ANZSEV) meeting, the Barossa Valley, South Australia last week, highlighting strategies and technologies for extracellular vesicles.
The company said that the first poster, titled ‘From Laboratory to “Manufacturing Methods and Challenges in Exosome Purification’ outlined its current research-scale purification process for extracellular vesicles and explored options for clinical-scale processing.
Vivazome said the second poster, titled ‘Customisation Strategies and Loading of [Extracellular Vesicles] to Treat Neurological Disease’ focused on strategies for customizing extracellular vesicles, including surface and luminal extracellular vesicle modifications and the associated advantages and considerations.
Vivazome said the final poster, titled ‘Establishing a Robust Exosome Manufacturing Process for Translational Studies’ showed its plan for establishing manufacturing and analytical facilities that would support translational studies, addressing pre-clinical, clinical and regulatory requirements.
The company said the posters collectively showed its “commitment to advancing the field of [extracellular vesicle] therapeutics from research-scale processes to potential clinical applications”.
Vivazome chief scientific officer Dr David Haylock said the company was “delighted to be presenting this work at the ANZSEV meeting as we strive to develop new customized [extracellular vesicle]-based approaches to develop impactful treatments for retinal disease and traumatic brain injury with our esteemed collaborators at Australian National University, The University of Queensland, Cytiva and Seerpharma”.
“These posters highlight the strong progress we are making,” Dr Haylock said.
“Presenting at this excellent event provides an opportunity to showcase the company’s advancements, share insights with peers, and contribute to the broader discussion within the scientific community,” Dr Haylock said.
Vivazome is a private company.

ISLAND PHARMACEUTICALS

Island says it has started screening healthy participants for its single-ascending dose trial of ISLA-101 for dengue fever and other mosquito borne diseases.
In May, Island said it had US Food and Drug Administration approval for an ISLA-101 for dengue fever and other mosquito borne diseases trial (BD: May 16, 2023).
Last week, the company said it had ethics approval to being the trial at Sydney's Scientia Clinical research (BD: Nov 7, 2023).
Today, Island said three cohorts of healthy subjects would receive escalating doses of ISLA-101, with the aim of ensuring that administered doses could safely achieve blood concentrations of ISLA-101 that were predicted to be effective against the dengue virus.
Island managing director Dr David Foster said "following on from ethics approval and also our recent site initiation visit, we are delighted to now be one step closer to dosing subjects in this study".
"With subject screening underway, we expect first patient dosing to occur imminently and look forward to keeping investors updated on the progress of this important study," Dr Foster said.
Island was up 0.7 cents or 9.6 percent to eight cents.

PYC THERAPEUTICS

PYC says laboratory models show its PYC-003 drug candidate is "effective" as a therapy for renal failure in autosomal dominant polycystic kidney disease.
PYC said the study in three-dimensional cyst models using tissue collected directly from polycystic kidney disease patients showed a "reduction in cyst size and frequency following treatment" with PYC-003.
The company said the assay showed "larger cysts in the untreated three-dimensional model when compared to the PYC-003 treated three-dimensional model".
PYC said following the results, it planned to take PYC-003 to human trials and it had planned to submit an investigational new drug application with the US Food and Drug Administration by December 31 2024.
The company said PYC-003 was expected "to have an accelerated pathway through human trials due to the extent of the unmet patient need in [polycystic kidney disease]", with a new drug application submission potentially possible after two clinical trials rather than three.
PYC said polycystic kidney disease was a monogenic disease, meaning that it was caused by a mutation of a single gene, that forms multiple fluid filled cysts throughout the kidney and other organs, with progression of cyst frequency and volume ultimately leading to destruction of the internal architecture and function of the kidney.
The company said drugs targeting monogenetic diseases had "the highest likelihood of demonstrating efficacy in clinical trials and lower probability of off-target safety issues".
PYC was up 0.2 cents or three percent to 6.8 cents with 6.4 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has received $2,089,308 from the Australian Taxation Office under the Federal Research and Development Tax Incentive program.
Argenica said the rebate related to expenditure for the year to June 30, 2023.
The company said it had approval for its overseas research and development expenditure, to be included in its annual rebates up to June 30, 2026.
Argenica was up half a cent or 1.3 percent to 38 cents.

CYNATA THERAPEUTICS

Cynata says its annual general meeting voted 19.48 percent against its remuneration report, with similar opposition to the issue of director options.

Last month, Cynata said its annual general meeting would vote to issue 1,910,000 options to directors worth a total of $145,250 on top of their annual pay, under its employee incentive plan (BD: Oct 12, 2023).

Today, the company said the resolution to adopt the remuneration report was opposed by 15,648,278 votes (19.48%), with 64,685,244 votes (80.52%) in favor.

Cynata said the resolutions to issue options to chair Dr Geoff Brooke and directors Dr Paul Wotton, Janine Rolfe, Dr Darryl Maher and Dr Kilian Kelly faced between 14,744,435 votes (18.35%) and 15,919,801 votes (19.81%) in opposition.

Cynata said the renewal of proportional takeover approval provisions, issue of equity under its employee incentive plan, approval of 10 percent placement facility and the re-election of Dr Maher were opposed by 13.95 percent to 18.35 percent opposition.

According to its most recent notice, the company had 179,631,786 shares on issue, meaning that the largest opposition vote, 15,919,801 votes against the issue of options to Dr Wotton was about 8.9 percent of the company, sufficient to requisition extraordinary general meetings.

Cynata fell half a cent or 3.7 percent to 13 cents.

IMAGION BIOSYSTEMS

Imagion says its extraordinary general meeting voted 36.05 percent against the resolution to approve the issue of 19,500,000 options to its directors.

Last month, Imagion said its extraordinary general meeting would vote to approve a 40-to-one consolidation and issue 64,500,000 options to directors under its employee incentive plan (BD: Oct 13, 2023).

At that time, the company said it had 1,305,766,572 shares on offer, which would be reduced to 32,644,164 shares, and that the consolidation would “result in a more appropriate and effective capital structure” and reduce costs and administrative burden.

Imagion said shareholders would vote to issue 45,000,000 options to recently appointed director Dr Isaac Bright, 4,500,000 options to director Robert Proulx and 3,000,000 options each to directors Dianne Angus, Michael Harsh, David Ludvigson, Jovanka Naumoska and Mark Van Asten.

Today, Imagion said the resolution to approve options to directors received 41,816,945 votes (36.05%) in opposition, with 74,164,791 votes (63.95%) in favor.

The company said the resolution to approve the consolidation of capital faced 38,100,320 votes (30.51%) against, with 86,770,200 votes (69.49%) in favor.

Imagion said the resolutions to approve the future issue of convertible notes to Mercer Street Global, approve the issue of options to chief executive officer Dr Isaac Bright and amend its constitution to increase the employee incentive cap had less than 24 percent opposition.

Imagion said the resolution to elect Dr Isaac Bright as a director was passed with 94.80 percent of the vote.

According to its most recent notice, the company had 1,305,766,572 shares on issue, meaning that the 41,816,945 votes against the issue of options to directors was about 3.2 percent of the company, not sufficient to requisition extraordinary general meetings.

Imagion was up 0.2 cents or 20 percent to 1.2 cents with five million shares traded.

BTC HEALTH

BTC says 20.5 percent of its annual general meeting voted for a board spill resolution percent, with all other resolution passed by 99.75 percent.
Last year, BTC said its 83.66 percent of annual general meeting voted for a remuneration report first strike, requiring a conditional second-strike board spill resolution to be on the ballot paper (BD: Nov 30, 2022).
Today, the company said the remuneration report was supported by 194,007,353 votes (99.82%) in favor, with 356,728 votes (0.18%) against.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 a company sustaining 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 at a meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
BTC said that the board spill resolution had 39,802,991 votes (20.49%) in favor and was opposed by 154,413,104 votes (79.51%).
BTC said the resolutions to re-elect Dr Richard Treagus as director, issue 10,000,000 options to Dr Treagus, approve its 10 percent placement facility and ratify the issue of 42,276,954 shares all passed with more than 99.75 percent in favor.
According to its most recent notice, BTC had 324,123,308 shares on issue, meaning that the 39,802,991 votes in favor of the board spill resolution amounted to 12.3 percent of the company, sufficient to requisition extraordinary general meetings.
BTC was up 0.2 cents or 3.1 percent to 6.7 cents.

ALCIDION GROUP

Australian Super says it has increased its substantial shareholding in Alcidion from 110,991,042 shares (9.50%) to 153,116,042 shares (11.45%).
The Melbourne-based Australian Super said between August 4, 2022 and November 6, 2023 it bought shares at prices between 11 cents and 17 cents a share and converted notes to 30,000,000 shares.
Alcidion was up 0.2 cents or 2.9 percent to 7.2 cents with 1.25 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says Clarke Barlow and Chris Ntoumenopoulos will replace director Dr Linda Friedland, effective from November 17, 2023.
Neuroscientific said Mr Barlow was a financial adviser with 22 years of experience, and is currently a director of Exopharm and was the founder of AMG Acquisition Corp.
The company said Mr Barlow held a Bachelor of Commerce from the University of Western Australia.
Neuroscientific said Mr Ntoumenopoulos was currently managing director of Twenty 1 Corporate and a director at Medibio and had been a founding director of Resapp Health and Race Oncology.
According to his Linkedin profile, Mr Ntoumenopoulos held a Bachelor of Commerce from the University of Western Australia.
Neuroscientific fell 0.1 cents or 1.8 percent to 5.5 cents.

EMYRIA

Emyria says executive director Dr Alistair Vickery has retired and will serve as an advisor, with Dr Stewart Washer and Dr Karen Smith moving to non-executive roles.
Emyria said executive chair Dr Washer would become non-executive chair, with a salary decrease from $200,000 a year to $80,000, and executive director Dr Karen Smith would become non-executive director and receive equal pay to all current non-executive directors.
The company said with these changes, except for managing-director Dr Michael Winlo, all of its board members were non-executive.
Emyria said the board transitions were “expected to halve annual board costs, reflecting the company’s commitment to cost efficiency and a strategic focus on advancing the company’s active 3,4 methylene-dioxy-meth-amphetamine-assisted therapy programs and novel drug development initiatives”.
Emyria said all changes were effective immediately.
Emyria fell one cent or 12.35 percent to 7.1 cents.

CORRECTION: STARPHARMA HOLDINGS

Friday’s edition incorrectly said that Starpharma had appointed Cheryl Maley chief executive officer and managing-director, replacing Dr Jackie Fairley from January 8, 2023.
The date should have been January 8, 2024
The error was made by the Friday sub-editor.
Another sub-editor bites the dust.
Starpharma fell half a cent or 3.6 percent to 13.5 cents with 1.4 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says next week’s Bio-Forum is titled ‘New Frontiers: Rethinking Antimicrobial Resistance’.
The Network said that the discussion coincides with World Antimicrobial Awareness Week and would include speakers from Carb-X, Evohealth, MTP Connect, Australian Anti-Microbial Resistance Network, Monash University and the Sydney Institute for Infectious Diseases.
The Bio-Melbourne Network said that major topics included the “urgent threat to our health security and what can be done about it now and into the future”.
The Network said the event was sponsored by the State Government of Victoria and would be hosted by Davies Collison Cave at Level 15, Orica House, 1 Nicholson Street, Melbourne, and online on November 21, 2023 from 12pm to 2.30pm (AEDT), including networking.
For details and registration, go to: https://bit.ly/3Qz2iW5.