

Biotech Daily

Wednesday November 24, 2021

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: PROTEOMICS UP 11%; KAZIA DOWN 7%
- * TISSUE REPAIR FALLS 41% ON \$22m WOUND HEALING IPO; TOTAL \$29.5m
- * RACE SHARE PLAN FOR \$30m
- * IMRICOR APPLIES FOR FDA IDE FOR ICMR PRODUCTS
- * EMVISION WINS \$240k ADVANCE QUEENSLAND FELLOWSHIP
- * PROTEOMICS: PROMARKERD TAKES THE DE-NOVO FDA ROUTE
- * EMYRIA RECEIVES \$1.2m FEDERAL R&D TAX INCENTIVE
- * INVEX WITHDRAWS 2.5m 'PERFORMANCE SHARES' AGM RESOLUTIONS
- * NOVA EYE DROPS 2.25m OPTIONS RESOLUTIONS; ALEX SUNDICH GOES
- * PROBIOTEC AGM: 12% OPPOSE WESLEY STRINGER RIGHTS; GREG LAN GOES
- * AUSTCO AVOIDS 2nd STRIKE, 23% OPPOSE DIRECTOR BRETT BURNS
- * GENETIC TECHNOLOGIES AGM: 22% OPPOSE M-D DR JERZY MUCHNICKI
- * AVITA MOVES FINANCIAL YEAR TO CALENDAR YEAR
- * INVION TO RELEASE 220m 'UNLIMITED GROUP' ESCROW SHARES
- * SELECTOR TAKES 5% OF NANOSONICS
- * SIO REDUCES TO 14% OF ANTERIS
- * RESONANCE APPOINTS PROF JOHN OLYNYK CMO

MARKET REPORT

The Australian stock market fell 0.15 percent on Wednesday November 24, 2021, with the ASX200 down 11.2 points to 7,399.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and two were untraded.

Proteomics was the best for the second day in a row, up 11 cents or 11 percent to \$1.11, with 245,570 shares traded. Resonance climbed 9.1 percent; Volpara was up 7.8 percent; LBT and Paradigm were up more than five percent; Starpharma and Universal Biosensors improved four percent or more; Polynovo and Telix were up three percent or more; Cynata and Nanosonics rose two percent or more; Avita, Compumedics, Mesoblast, Orthocell and Uscom were up one percent or more; with CSL and Opthea up by less than one percent.

Kazia led the falls, down 10 cents or 6.7 percent to \$1.40, with 134,684 shares traded. Imugene and Prescient fell more than four percent; Alterity, Genetic Signatures and Immutep were down more than three percent; Antisense, Dimerix, Next Science, Nova Eye, Optiscan and Patrys shed two percent or more; Medical Developments, Neuren and Resmed were down more than one percent; with Clinuvel, Cochlear and Pro Medicus down by less than one percent.

TISSUE REPAIR

Tissue Repair fell as much as 41.3 percent to 67.5 cents last Thursday following a \$22 million initial public offer at \$1.15 to develop its Glucoprime TR-987 for wound healing. Biotech Daily apologizes to readers for not being alerted to the company prior to yesterday.

Tissue Repair said that the active ingredient of its topical treatment for wound repair TR-987 was Glucoprime, invented by former Novogen chief executive officer, now Noxopharm chief executive officer Prof Graham Kelly.

Yesterday, the company said that it had completed manufacturing two pilot batches of Glucoprime with contract manufacturer Sequens and "achieved equivalency across two measures so far, molecular weight and potency, with both pilot batches compared to the reference [active pharmaceutical ingredient] ... used in the phase IIb trial"

Tissue Repair said that data on manufacturing consistency was a core requirement for the US Food and Drug Administration dossier as it seeks approval for a phase III trial program and was on-track to complete manufacturing in 2022.

The company said it was "confident" it would obtain FDA approval for the trial which was fully-funded following the \$22 million offer and it had \$27 million in cash.

Tissue Repair said it raised \$7.5 million in April 2021 for a total of \$29.5 million in 2021.

The company said it was founded in 2012, and had "developed a unique active ingredient ... for wound healing and delivered topically ... targeting applications in the chronic wound and cosmetic procedure markets".

Tissue Repair said that Glucoprime or TR-987 "behaves like a decoy cell and simulates a yeast infection resulting in the stimulation of the body's own wound repair pathways ... [and] provides a platform for the opportunity to develop a range of products that have the potential to treat a broad range of conditions across the wound care market".

The company said that in 2020, it completed a phase IIb chronic wound trial achieving "a positive signal of efficacy" that warranted progression to phase III clinical trials.

Tissue Repair said its chair was Jack Lowenstein, co-founder Tony Charara was an executive director, with non-executive directors Bryan Gray, Prof Craig Stamp and Polynovo's acting chief executive officer Max Johnston.

The company said that its chief operations officer was Dr Darryl Reed, the head of chemistry and controls was Dr Pramod Nednoor and the head of clinical and regulatory affairs was Mark Waring.

The Tissue Repair prospectus said that Mr Waring worked with Prof Kelly "to describe many new biologically active isoflavones and the early development of the TR-987 technology for wound healing".

According to his Linkedin page, Mr Waring was Novogen's head of clinical and technical affairs from 1995 to 2003 and was currently Noxopharm's head of US operations, but is not listed on the company's website.

In 2011, the then Novogen (later renamed Kazia Therapeutics) said it sold its isoflavone-based intellectual property portfolio for shares worth \$4 million to former US-based 65 percent subsidiary Marshall Edwards (BD: May 10, 2011).

Today, Mr Charara told Biotech Daily that TR-987 "is an entirely new molecule, initially developed at Novogen".

Tissue Repair said that its head of manufacturing was Bill Bost with Mark Jones the company's chief financial officer.

The company said that the scientific advisory board included Prof Kelly, Dr Thomas Serena, Prof Michael Woodward and Prof Dr Vaclav Vetvicka.

Bell Potter Securities and Morgans Corporate were joint lead managers to the offer. Tissue Repair fell five cents or 7.75 percent to 59.5 cents.

RACE ONCOLOGY

Race says it hopes to raise up to \$29.7 million in a non-underwritten share purchase plan at \$3.00 a share to fund its programs.

Race said the proceeds would be used to fund phase I/II trials of Zantrene, or bisantrene, for fat mass and obesity associated protein and relapsed or refractory acute myeloid leukaemia, as well as pre-clinical cardio-protection studies and the development of new molecules, as well as other potential trials.

The company said the share plan would have a record date of November 22, would open on November 23 and close on December 17, 2021.

Race fell 53 cents or 14.1 percent to \$3.24 with 1.6 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has filed an investigational device exemption to the US Food and Drug Administration for its interventional cardiac magnetic resonance imaging products. Imricor said approval of the investigational device exemption would allow it to begin a clinical study aimed at gaining the clinical data to support the approval of several interventional cardiac magnetic resonance (ICMR) ablation devices including the Vision-magnetic resonance (MR) ablation catheter, Vision MR diagnostic catheter, Vision MR resonance dispersive electrode, Advantage MR resonance [electrophysiology] recorder and stimulator and the Osypka HAT500 ablation generator and irrigation pump. Imricor chief executive officer Steve Wedan said the application was "an important milestone in our strategic plan to expand the geographies in which ICMR ablations can be performed".

Imricor fell 10 cents or 7.4 percent to \$1.125.

EMVISION MEDICAL DEVICES

Emvision says that in collaboration with the University of Queensland, Dr Guohun Zhu has won a \$240,000 three-year research fellowship for its portable brain scanner. Emvision said the Advance Queensland Industry Research Fellowship was in addition to existing fellowships and the fellow would be co-located between the University of Queensland and Emvision to "add capacity to Emvision's artificial intelligence capabilities". The company did not disclose whether it had appointed anyone to the position. Emvision was up 11 cents or 4.1 percent to \$2.81.

PROTEOMICS INTERNATIONAL

Proteomics says the US Food and Drug Administration advises that its Promarkerd test for diabetic kidney disease should follow a de-novo classification pathway.

Proteomics said the de novo pathway addressed new devices of low to moderate risk, such as blood tests, that do not have a valid predicate device, and the FDA advised that Promarkerd was considered closest to the acute kidney injury test system but the 510(k) route was not available because currently "there was no substantially equivalent device". The company said that the de-novo classification would have marketing advantages on approval by the FDA and it would prepare a full product application for the FDA proposing Promarkerd as a class IIa in-vitro diagnostic.

The company said it would submit an application by April 2022, with the FDA timeline for review about 12 months.

Proteomics was up 11 cents or 11 percent to \$1.11.

EMYRIA

Emyria says it has received \$\$1,162,134 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Emyria said the rebate related expenditure for the year to June 30, 2021.

Emyria was up one cent or 2.35 percent to 43.5 cents with 3.1 million shares traded.

INVEX THERAPEUTICS

Invex says it has withdrawn six resolutions to issue 2,500,000 performance shares to five directors, ahead of tomorrow's annual general meeting.

Last month, Invex said its annual general meeting would vote to issue 800,000 performance shares to chair Dr Jason Loveridge, 700,000 shares to chief scientific officer Prof Alexandra Sinclair, 500,000 shares to executive director Dr Tom Duthy and 250,000 shares each to David McAuliffe and Dr Megan Baldwin (BD: Oct 25, 2021).

Today, Invex said it confirmed the withdrawal "following shareholder feedback received on the performance milestones of these incentive securities, despite the performance milestones being conditioned on the overall initiation and recruitment success of the planned ... phase III registration trial of Presendin in Europe, UK and Australia". Invex was unchanged at 63 cents.

NOVA EYE MEDICAL

Nova Eye says it has withdrawn resolutions to issue 2,250,000 options to five directors and director Alex Sundich has resigned, ahead of today's annual general meeting. Nova Eye said the resolutions dealt with the re-election of Mr Sundich, the refresh of the employee incentive plan and the issue of options to directors.

Last month, the company said shareholders would vote to issue 500,000 options to chair Victor Previn and 350,000 shares each to directors Alex Sundich, Mike Southard and Rahmon Coupe, exercisable at a 135 percent of the 7-day volume weighted average price to the meeting by November 23, 2024 (BD: Oct 21, 2021).

Today, Nova Eye said that following "discussions with major shareholders it has become apparent that there is insufficient support for this resolution".

In a separate announcement, Nova Eye said that 15-year director Mr Sundich had resigned, effective immediately.

Nova Eye fell one cent or 2.6 percent to 37 cents.

PROBIOTEC

Probiotec said all resolutions were carried but faced up to 12 percent opposition towards the issue of performance rights to chief executive officer Wesley Stringer.

Probiotec said the resolution to issue 150,000 performance rights to Mr Stringer was opposed by 4,726,545 votes (12.3%) with 33,645,263 votes (87.7%) in favor.

The company said that resolutions to adopt the remuneration report, re-elect directors Jonathan Wenig and Simon Gray, and the loan of up to \$2,668,176 to Mr Stringer to exercise 1,260,000 options were passed more easily.

According to its most recent filing, Probiotec had 76,616,091 shares on offer, meaning the votes opposing Mr Stringer's performance rights amounted to 6.2 percent of the company, sufficient to requisition extraordinary general meetings.

Separately, in an Appendix 3Z final director's interest notice, four-year director Greg Lan said he had left the company.

Probiotec was up 14 cents or 6.8 percent to \$2.20.

AUSTCO HEALTHCARE (FORMERLY AZURE HEALTHCARE)

Austco says its annual general meeting easily avoided a remuneration report second strike but 22.60 percent opposed the re-election of director Brett Burns.

Austco said Mr Burns re-election was opposed by 44,530,453 votes (22.60%) with 152,512,203 votes (77.40%) in favor.

Last year, the then Azure annual general meeting voted a remuneration report 'first strike' with 73,196,758 votes or 36.19 percent against the report (BD: Nov 24, 2020).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any 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 at the later meeting and if passed by more than 50 percent of votes the directors must stand for re-election at a subsequent meeting within 90 days.

Today, the company said the remuneration report was passed easily with 147,800,831 votes (99.49%) in favor.

Austco said all other resolutions including the increase to the directors' aggregate fee pool, the issue of options to Clayton Astles, approval of the additional 10 percent placement capacity and the amendment to the constitution were passed easily, with the conditional spill resolution receiving 98.38 percent opposition.

According to its most recent filing, Austro had 284,188,951 shares on issue meaning that the opposition to Mr Burns amounted to 15.7 percent of the company, sufficient to requisition extraordinary general meetings.

Austco was up half a cent or 3.6 percent to 14.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says up to 22 percent of annual general meeting votes opposed the re-election of managing-director Dr Jerzy Muchnicki.

Genetic Technologies said 302,407,169 votes (22.25%) opposed the re-election of Dr Muchnicki with 1,056,989,829 votes (77.75%) in favor.

The company said 20.78 percent of the meeting opposed the increased placement capacity with all other resolutions facing between 12.66 percent and 16.49 percent dissent.

According to its most recent filing, the company had 9,230,027,643 shares on issue meaning the votes against Dr Muchnicki amounted to 3.3 percent of the company, not to requisition an extraordinary general meeting.

Genetic Technologies was unchanged at 0.6 cents with 39.3 million shares traded.

AVITA MEDICAL

Avita says it has moved its financial year from June 30 to December 31 and its first full calendar year will be the year ended December 31, 2022.

Avita said its fiscal quarters would remain in calendar quarters.

Last year, Avita said it had approval for the move to the US from its shareholders and the Federal Court of Australia and had transferred all shares to the Delaware-based Avita US (BD: Jun 15, 22, 29, 2020).

Avita was up four cents or one percent to \$4.09 cents.

INVION

Invion says 220,682,156 shares will be released from voluntary escrow on December 1, 2021.

Last year, Invion said that Hong Kong's Unlimited Innovation Group had conducted an inspecie distribution of 220,682,156 shares to 49 group members who had agreed to voluntary escrow arrangements ranging from three to 12 months (BD: Dec 4, 2020). According to its most recent filing, the company has 5,864,809,083 shares on offer. Invion was up 0.1 cents or 5.6 percent to 1.9 cents with 23.9 million shares traded.

NANOSONICS

Sydney's Selector Funds Management says it has become a substantial shareholder in Nanosonics with 15,410,874 shares or 5.11 percent.

Selector Funds said it bought the shares between March 1, 2019, and November 22, 2021 but failed to disclose the prices paid, as required under the Corporations Act 2001. Nanosonics was up 11 cents or two percent to \$5.57 with 1.2 million shares traded.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

New York's Sio Partners says it has reduced its shareholding in Anteris Technologies from 1,311,079 shares (19.96%) to 1,262,680 shares (14.38%).

Sio said it bought and sold shares between May 24 and November 23, 2021, with the single largest sale 72,784 shares for \$736,574 or \$10.12 a share.

In 2018 and 2019, Anteris said it raised \$18,964,198 at eight cents a share (before a 100-to-one consolidation) and Sio Partners would underwrite up to \$6 million and "up to a further \$6.3 million in underwriting" (BD: Dec 14, 2018; Jan 21, 2019). Anteris was unchanged at \$10.00.

RESONANCE HEALTH

Resonance says it has appointed Prof John Olynyk as chief medical officer.

Resonance said Prof Olynyk was currently the dean of clinical research and professor of translational medicine at Perth's Edith Cowan University and previously was a consulting hepatologist at Fiona Stanley Hospital, as well as a medical advisor to Haemochromatosis Australia and Red Cross Lifeblood Australia.

The company said Prof Olynyk had contributed to more than 250 published articles, 180 conference abstracts, and had authored 11 book chapters.

Resonance said that Prof Olynyk held a Bachelor of Medicine and Bachelor of Surgery form the University of Western Australia.

Resonance was up one cent or 9.1 percent to 12 cents.