



Biotech Daily

Thursday October 5, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: DIMERIX UP 154%; OPHEA DOWN 6%**
- * **DIMERIX: ADVANZ 'UP TO \$230m' FOR DMX-200 FSGS LICENCE**
- * **RECCE PLACES \$307k RIGHTS SHORTFALL; TOTAL \$11m**
- * **EMYRIA RIGHTS RAISE \$1.2m; TOTAL TO \$3.2m**
- * **RACE STARTS RC220 BISANTRENE TOXICOLOGY, SAFETY STUDIES**
- * **HYDRIX: AVERTIX MERGER TERMINATED, NASDAQ LISTING WITHDRAWN**
- * **INCANNEX NASDAQ SCHEME MEETING; TO LEAVE ASX**
- * **FISHER & PAYKEL APPOINTS CHARLOTTE WALSH FUTURE DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.51 percent on Thursday October 5, 2023, with the ASX200 up 35.3 points to 6,925.5 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and three were untraded. All three Big Caps were up.

Dimerix was the best, up 9.4 cents or 154.1 percent to 15.5 cents, with 72.4 million shares traded (see below).

Nova Eye climbed 14.3 percent; Cyclopharm was up 6.6 percent; Actinogen and Emvision were up five percent or more; 4D Medical and Clinuvel climbed more than four percent; Impedimed and Kazia were up more than three percent; Alcidion, Imugene, Nanosonics, Neuren, Orthocell and Paradigm rose more than two percent; Cochlear, Immutep, Prescient, Resmed and SDI were up more than one percent; with Avita, CSL, Pro Medicus and Telix up by less than one percent.

Yesterday's 9.4 percent best, Opthea, led the falls, down two cents or 5.7 percent to 33 cents, with 268,567 shares traded. Next Science, Pharmaxis, Universal Biosensors and Volpara lost more than five percent; Antisense and Cynata fell four percent or more; Compumedics shed 2.6 percent; with Mesoblast down by 1.4 percent.

DIMERIX

Dimerix says Advanz Pharma will pay up-to \$229.8 million for the rights to DMX-200 for FSGS in Europe, the UK, Canada, Australia and New Zealand.

Dimerix said DMX-200 was currently in a phase III clinical trial for focal segmental glomerulo-sclerosis (FSGS), with the first analysis outcomes expected to be reported on, or around, March 15, 2024.

Last year, the company said it had begun recruitment of the phase III trial to study the efficacy and safety of its DMX-200 in patients with focal segmental glomerulo-sclerosis; and earlier this year, said a second data safety monitoring board review recommended the trial continue unchanged (BD: May 31, 2022; Aug 8, 2023).

Today, Dimerix said that the London-based Advanz Pharma would pay \$10.8 million upfront, and up-to \$219 million in potential milestone payments, with further tiered royalties on net sales, escalating up-to 20 percent if the drug was commercialized.

Dimerix said it would continue to fund and execute the phase III trial of DMX-200 for focal segmental glomerulo-sclerosis, with Advanz Pharma responsible for submission and maintenance of the regulatory dossier in the licenced territories as well as sales and marketing activities.

The company said the phase III, multi-centre, randomised, double-blind, placebo-controlled trial was studying the efficacy and safety of 120 milligrams of DMX-200 twice daily in patients with focal segmental glomerulo-sclerosis who were receiving a stable dose of angiotensin II receptor blocker.

Dimerix said the study was designed to show change in proteinuria and kidney function and aimed at generating sufficient evidence to support marketing approval.

Dimerix said Advanz Pharma had sales in more than 90 countries, a direct commercial presence in more than 20 countries and an global distribution and commercialization partner network.

The company said Advanz Pharma would use its "speciality, hospital and rare disease expertise and commercial platform to register and effectively promote the product and offer great patient access".

Dimerix said it retained all rights to DMX-200 in all other territories and it would form a joint steering committee with Advanz Pharma to allow any data and regulatory filings generated by either party to be used for the development of DMX-200 in the other party's territories.

Dimerix said Advanz had a right of first offer to negotiate a licence to develop and commercialize DMX-200 in any additional indications in the licenced territories.

The company said it continued to pursue and progress licencing opportunities with potential partners outside the Advanz licenced territories.

Dimerix chief executive officer Dr Nina Webster said the company was "delighted to be partnering with Advanz in Europe, UK, Australia, New Zealand and Canada".

"The Advanz team has a proven record in developing and commercializing medicines in areas with no approved therapies and high unmet needs," Dr Webster said.

"Advanz's expertise and resources will be invaluable in supporting Dimerix to advance our shared goal of commercializing this novel treatment, and this partnership recognizes the decade of work by our dedicated team, consultants, trial participants and investigators in developing a new therapy for patients with FSGS," Dr Webster said.

Co-chair of the UK Glomerulo-nephritis clinical study group and the University of Leicester and professor of renal medicine Prof Jonathon Barratt said that "with limited treatment options currently available and many patients who do not adequately respond to existing treatment regimes, there remains a significant unmet need for efficacious focal segmental glomerulosclerosis therapies."

Dimerix was up 9.4 cents or 154.1 percent to 15.5 cents with 72.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has placed the \$307,000 shortfall from its \$3 million entitlement offer, taking the total raised with the entitlement offer and placement to \$11 million.

Earlier this month, Recce said it had commitments for an \$8 million placement at 44 cents a share, and later raised \$2.7 million of a hoped-for \$3 million in a one-for-26, non-renounceable entitlement offer price (BD: Sep 11, 29, 2023)

Today, the company said its directors subscribed for about \$110,000 worth of the shortfall, with shareholder approval to be sought at its annual general meeting expected to be held on or around November 8, 2023.

Recce said the funds would be used for its various clinical trials, building out its infectious diseases portfolio, geographical expansion and general working capital.

Recce fell one cent or 2.3 percent to 43 cents.

EMYRIA

Emyria says its one-for-7.5 shares rights offer raised \$1.18 million of a hoped-for \$3.1 million at 7.5 cents a share, taking the total raised with the placement to \$3.18 million.

Last month, Emyria said it had "firm bids" for the \$2 million placement, to be followed by the \$3.1 million, non-renounceable, entitlement offer (BD: Sep 4, 2023).

Today, the company said that for every two shares purchased under the entitlement offer, investors would receive one attaching option, exercisable at 12 cents each, within three years.

Emyria said its directors and lead manager Sixty Two Capital Pty Ltd reserved the right to place the \$1.92 million shortfall within three months.

Emyria chief executive officer Dr Michael Winlo said the company would now move to advance its 3, 4 methylene-dioxy-meth-amphetamine-therapy roll-out and drug development initiatives.

Emyria fell 0.3 cents or 4.2 percent to 6.9 cents.

RACE ONCOLOGY

Race says it will run toxicology and safety pharmacology studies of its RC220 formulation of bisantrene for peripheral infusion.

Race said it had signed contracts worth \$2.74 million with the Stilwell, Kansas-based Attentive Science and Adelaide's Agilex Biolabs to complete the studies which were required to support clinical trials of the formulation.

The company said although its RC220 formulation of bisantrene contained the same active ingredient as previous formulations it was considered a "new drug product" and must pass a panel of toxicology and safety pharmacology studies to show its safety profile in humans and establish a safe starting dose for phase I dose-escalation studies.

Race said the studies would commence immediately with final reporting expected by July 2024, and that "most expenses" were expected to be eligible for the Federal Government Research and Development Tax Incentive.

Race executive director Dr Pete Smith said the studies were "a significant milestone for Race and the clinical and commercial development of RC220 by establishing bisantrene's known safety profile in its new formulation".

Race fell one cent or 1.2 percent to 85.5 cents.

[HYDRIX](#)

Hydrix says Avertix Medical Inc, formerly Angel Medical Systems, and Bioplus Acquisition Corp have terminated their proposed merger and withdrawn their Nasdaq listing.

In May, Hydrix said that Angel Medical would merge with Bioplus Acquisition to become Avertix Medical, valued at \$US195 million and its one million Angel shares would be about 29 percent of the merged company; later that month, it said Avertix Medical had applied to be listed on the Nasdaq (BD: May 4, 16, 2023).

At that time, the company said it had a distribution agreement for Avertix's Guardian heart device, its portfolio would increase from \$1.15 million to \$6.0 million once Avertix had listed with a share price of \$US10.00 and it was eligible for a further \$2.5 million pending milestones.

Today, Hydrix said the two companies mutually agreed to terminate the business combination agreement and that Avertix had further advised that it intended to continue executing business objectives as a private entity "for now".

Hydrix was up 0.1 cents or 3.85 percent to 2.7 cents.

[INCANNEX HEALTHCARE](#)

Incannex says Incannex Healthcare Inc will acquire 100 percent of its shares and become the new parent entity of Incannex group, with all Incannex options to be cancelled.

In July, Incannex said it intended to redomicile to the US and list its shares on the Nasdaq through the Delaware corporation Incannex Healthcare Inc (BD: Jul 10, 2023).

Today, the company said it had a Federal Court of Australia order to convene a scheme meeting to vote on the share scheme and option scheme, respectively.

Incannex said it would issue an explanatory statement on or before October 9, 2023, with the meeting to be held at Level 23, Rialto South Tower, 525 Collins Street, Melbourne, on November 8, 2023 at 10am (AEDT).

Incannex was unchanged at 6.5 cents with 2.2 million shares traded.

[FISHER & PAYKEL HEALTHCARE CORPORATION](#)

Fisher & Paykel Healthcare says it has selected Charlotte Walshe to participate in its future directors program, effective from January 1, 2024.

Fisher & Paykel said Ms Walshe had more than 20 years of experience in a range of sectors including chief executive roles with medical device manufacturer Jade Software Corporation and health informatics provider Dynamic Controls.

The company said Ms Walshe held a Bachelor of Science and a Master of Science from New Zealand's University of Canterbury.

Fisher & Paykel said its current future director candidate Tracey Barron was completing her term with the company on December 1, 2023.

Fisher & Paykel chair Scott St John said the Institute of Directors initiative allowed "the board to benefit from new perspectives while giving the emerging directors an opportunity to develop their governance competencies".

Fisher & Paykel was up 50 cents or 2.5 percent to \$20.78 with 195,674 shares traded.