

Biotech Daily

Monday November 25, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: PARADIGM UP 41.5%; NANOSONICS DOWN 7%
- * PAINCHEK RIGHTS TO RAISE \$5.1m
- * FIREBRICK TO SELL NASODINE IN SINGAPORE PHARMACIES
- * TRUSCREEN VIETNAM CERVICAL CANCER SCREENING PROGRAM
- * 4D MEDICAL: CALIFORNIA CT LVAS, LDAF RADIOLOGY DEAL
- * NEUROTECH ADULT NTI164 MARIJUANA SAFETY STUDY APPROVED
- * DORSAVI STARTS BLOCKCHAIN STUDY
- * ARCHER RECEIVES TMR SENSOR PROTOYPES
- * RADIOPHARM AGM 29% REMUNERATION REPORT 1st STRIKE
- * AUDEARA AGM 23% OPPOSE INCENTIVE PLAN INCREASE
- * PARADIGM PLEADS 'SCHULTZ' TO ASX 41% PRICE QUERY
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- * EMYRIA REQUESTS 'CAPITAL RAISING' TRADING HALT
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- * ANTERIS FILES NASDAQ LISTING TO SEC
- * CRYOSITE LOSES CO-CO SEC MICHAEL AUSTIN

MARKET REPORT

The Australian stock market was up 0.28 percent on Monday November 25, 2024, with the ASX200 up 23.8 points to 8,417.6 points. Nineteen of the Biotech Daily Top 40 companies were up, 15 fell and six traded unchanged. All four Big Caps were up.

Paradigm was the best for the second trading day in a row, up 13.5 cents or 41.5 percent to 46 cents, with 9.95 million shares traded (see below). Mesoblast climbed 11.6 percent; 4D Medical was up 11.0 percent; Immutep improved 8.2 percent; Avita climbed 6.9 percent; Atomo was up 5.3 percent; Alcidion improved 4.7 percent; Orthocell and Polynovo were up three percent or more; Cynata, Emvision, Neuren, Prescient, Pro Medicus, Proteomics and SDI rose more than two percent; Clarity, Cochlear, CSL and EBR were up more than one percent; with Opthea, Resmed and Telix up by less than one percent.

Nanosonics led the falls, down 24 cents or 6.9 percent to \$3.22, with 1.15 million shares traded. Compumedics and Impedimed lost more than five percent; Curvebeam, Dimerix and Universal Biosensors fell more than four percent; Actinogen, Medadvisor and Nova Eye were down more than three percent; Imugene shed 2.6 percent; Amplia, Clinuvel, Cyclopharm and Medical Developments were down one percent or more; with Aroa down 0.8 percent.

PAINCHEK

Painchek says it will raise \$5.1 million at 2.5 cents a share in a fully-underwritten, one-foreight, non-renounceable entitlement offer.

Painchek said the issue price was a 14.4 percent discount to the five-day volume weighted average price and a 10.7 percent discount to the last traded price.

The company said investors would receive one attaching option for each share acquired, exercisable at five cents each within 12 months from issue.

Painchek said the funds would be used for the commercialization of its adult pain management application in aged care and home care in Australia, New Zealand and the UK as well as for platform development and US sales, subject to US Food and Drug Administration approval, as well as completing its infant early access program and general working capital.

The company said Canaccord Genuity (Australia) was lead manager and underwriter to the offer and would receive a four percent underwriter fee and two percent management fee of total proceeds of the offer as well as 204,000,000 underwriter options.

Painchek said the offer had a record date of November 28, would open on December 2 and close on December 12, 2024.

Painchek was unchanged at 2.8 cents.

FIREBRICK PHARMA

Firebrick says the Singapore pharmacy chain Guardian Health & Beauty will promote and sell its Nasodine nasal spray in its shops from "early January 2025".

Earlier this year, Firebrick said it had Singaporean Health Sciences Authority approval to market its antiseptic Nasodine nasal spray, which would sell for about \$28 per 25ml bottle (BD: Jun 13, 2024).

At that time, the company said Nasodine was "classified as a topical antiseptic and does not require approval or licencing by Singapore's Health Sciences Authority before sale" but said that it did need prior approval to advertise the product to Singapore consumers. Today, Firebrick said Guardian had 121 pharmacies in Singapore and would "have the exclusive right to sell Nasodine through retail pharmacies for a 12-month period ending January 2026".

The company said it would "assist in the training of Guardian retail pharmacists to sell Nasodine to consumers".

Firebrick said it would pay a \$\$2,000 (\$A2,280) monthly retainer to DKSH Singapore for logistics services as well as 14 percent of invoiced sales to Guardian, which would drop to 12 percent following annual sales reaching \$\$500,000 (\$A570,00).

The company did not disclose the commercial terms of its agreement with Guardian. The company said the agreement did not interfere with ongoing online purchases or its agreement with Innorini Life Sciences to market and sell Nasodine to Singapore healthcare professionals.

Last month, Firebrick said it would pay Innorini Pte Ltd \$6,900 a month to market and sell its antimicrobial Nasodine nasal spray in Singapore (BD: Oct 31, 2024).

Firebrick executive chair Dr Peter Molloy said the distribution and sale of Nasodine at Guardian pharmacies in Singapore "was a major milestone for Firebrick, achieved well ahead of schedule."

"With the expansion of Nasodine marketing from online only sales to promotion through [healthcare professionals] and now through Guardian pharmacies, we are very optimistic about the potential for sales growth in 2025," Dr Molloy said.

Firebrick was unchanged at 5.3 cents.

TRUSCREEN

Truscreen says with Vietnam's Ho Chi Minh City Public Health Association and Gorton Health Services it will conduct a cervical cancer screening program of 260,000 women. Truscreen said the Ho Chi Minh City Public Health Association was established in 2007 and "charged with communication and education on community health management as well as organizing and implementing programs, projects and community health events". The company said the five-year program would use "a proactive screening mode" to contact women directly to encourage them to attend screening and raise awareness. Truscreen said the program would use its optical electric system to screen patients in existing health centres and community health clinics, and the program might be extended to mobile screening as well as to "support and monitor patients with positive test results to attend follow-up treatment, and to continue screening throughout their lives". Truescreen said the program would begin by April 2025, but did not disclose the commercial terms of the agreement.

The company said it was selected by Ho Chi Minh City Public Health Association "for its unique real-time, non-invasive, objective cervical cancer screening technology, requiring no pathology infrastructure, that suits the screening program".

Truscreen chief executive officer Marty Dillon said the non-invasive screening technology was "particularly suited for use in low-and-middle income countries".

Truscreen was up 0.3 cents or 15.8 percent to 2.2 cents.

4D MEDICAL

4D Medical says it will provide its computed tomography (CT) lung ventilation LVAS and lung density LDAF scans to Los Angeles' Imaging Partners of Orange County. 4D Medical said it was its first commercial contract with an independent radiology provider since the US Centers for Medicare & Medicaid Services awarded reimbursement for CT LVAS showing progress in the commercialization of its lung imaging technology. Earlier this year, the company said its CT LVAS would be reimbursed by the US Centers for Medicare & Medicaid Services at \$US650.50 (\$A999.00) per use (BD: May 9, 2024). Today, 4D Medical said the contract would run until March 31, 2026 and provided Imaging Partners of Orange County "with scan analysis, on a subscription basis per patient, billed guarterly" but did not disclose the subscription cost.

The company said its CT LVAS technology gave "detailed analysis of lung ventilation and airflow, assisting clinicians in diagnosing and assessing respiratory diseases more effectively than traditional methods".

The company said its lung density analysis CT LDAF allowed "physicians to quantify lung structure, which side-by-side with lung function, adds significant value in identifying and managing obstructive lung diseases".

4DMedical managing-director Prof Andreas Fouras said the company was "thrilled to secure this commercial contract with [Imaging Partners of Orange County] and are encouraged by rapidly growing interest from pulmonologists in the US".

"With US reimbursement for CT LVAS now established, this contract further validates our technology's value in the clinical setting and strengthens our position in the market as we work to improve diagnostic options for patients suffering from unexplained dyspnoea and other respiratory ailments," Prof Fouras said. "This agreement with [Imaging Partners of Orange County], on the back of the announcement of a commercial contract with [University California San Diego], underscores the growing demand for our innovative respiratory imaging solutions," Prof Fouras said.

4D Medical was up five cents or 11 percent to 50.5 cents with 2.6 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has human research ethics committee approval to begin a pharmacokinetic study of its marijuana-based NTI164 in 12 healthy adult volunteers.

Neurotech said the study would generate clinical data from blood and urine samples on the metabolism and excretion of NTI164 in an adult human population.

The company said the study would administer 20mg/kg of NTI164 to four participants in two doses about 12 hours apart, followed by eight participants who would be dosed with the same regimen of NTI164 for seven consecutive days.

Neurotech said the study would be conducted at Adelaide's Cmax Clinical Research, with results expected by April 2025.

Neurotech executive director Dr Thomas Duthy said although the company had shown "long-term safety and efficacy of NTI164 in paediatric patients across three separate neurological disorders, a [pharmaco-kinetic] study is a requirement for global health regulators, including the US Food and Drug Administration as part of an investigational new drug approval and the Australian Therapeutic Goods Administration as part of the necessary documentation to fulfil the requirements under an accelerated provisional application pathway".

"In parallel, we are currently conducting repeat-dose toxicity studies across two animal species, which we also expect to complete ... [by April 2025] and also represents an important requirement for regulators," Dr Duthy said.

Neurotech fell 0.3 cents or 4.35 percent to 6.6 cents with 1.1 million shares traded.

<u>DORSAVI</u>

Dorsavi says it has begun a proof-of-concept study "to tokenize and securely share clinical device data" generated by its wearable sensor devices and video techniques. Last week, Dorsavi said it had begun a "strategic feasibility study to incorporate 'blockchain technology' into its core data platform" for data collected by its wearable sensors (BD: Nov 20, 2024).

Today, the company said it would "not only demonstrate how clinical data can be securely tokenized and shared, but also set the stage for integrating advanced analytics, artificial intelligence (A.I.), and 'internet of things' (I.O.T) capabilities into the platform".

Dorsavi said the study would use the Oasis Network's blockchain technology, "the 123rd largest blockchain network by market capitalization" to show how clinical data from its wearable devices could be securely shared using the Oasis Network.

The company said blockchain technology would allow "real-time decision-making in healthcare, workplace wellness, and insurance, while ensuring that data privacy and integrity remain paramount".

Dorsavi said as the proof-of-concept study progressed the technology would "evolve, paving the way for wider adoption and global scalability, revolutionizing how health data is handled, shared, and used for better patient outcomes and operational efficiency". The company said the study would "tokenize clinical device data, … enable trusted data

sharing, ... maintain data privacy ... and integrity set the stage for future innovation". Dorsavi said the study was "expected to be completed before the end of 2024 and results are expected to guide further blockchain integration into Dorsavi's platform".

Dorsavi chair Gernot Abl said the proof-of-concept study was "a pivotal step in evaluating the value of blockchain technology to enhance the security, privacy, and accessibility of our clinical data, especially for our most privacy concerned enterprise clients".

Dorsavi was up 0.2 cents or 15.4 percent to 1.5 cents with four million shares traded.

ARCHER MATERIALS

Archer says it has received tunnel magneto-resistance (TMR) sensor prototypes from its foundry partner Multidimension Technology, which will be sent for characterization. Last month, Archer said with Zhangjiagang, China's Multidimension Technology it would develop TMR sensors for applications including medical devices (BD: Oct 10, 2024). Archer said it was sending the TMR sensor prototypes to its research partner, an unnamed Australian university, for characterization.

The company said it would then begin engaging with potential customers to obtain their feedback, to develop and enhance the TMR sensors' performance using its quantum technology.

Archer said the TMR sensors were "quantum magnetic sensors that are highly sensitive, have high bandwidth, and low power consumption compared to the traditional Hall effect sensors, which currently represent the industry standard".

The company said TMR sensors were "used for a range of growing applications including data centres, automotive, medical devices, and internet-of-things and consumer electronics".

A spokesperson for Archer told Biotech Daily that the sensors were 3mm by 3mm in size. Archer executive chair Greg English said "the need to replace traditional sensing

technology usage across large industries provides significant opportunity for Archer". "Receiving this prototype from MDT is a first step in this process of developing our own TMR sensors, which we are bolstering with Archer's quantum mechanics expertise," Mr English said.

Archer was up two cents or 6.9 percent to 31 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its annual general meeting passed all resolutions but voted a 28.86 percent remuneration report first strike.

Last month, Radiopharm said the meeting would vote to issue 55,250,286 incentive options to managing-director Riccardo Canevari and 4,040,404 incentive options to director Ian Turner as well as 8,000,000 remuneration options, each, to its directors and chair in addition to their respective salaries (BD: Oct 25, 2024).

Today, the company said the remuneration report was opposed by 225,885,672 votes (28.86%) with 556,823,552 votes (71.14%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 a company with a vote of 25 percent or more against the remuneration report in two successive annual meetings must vote on a board spill. Radiopharm said the issue of incentive options to Mr Turner and remuneration options to Mr Turner and directors Noel Donnelly, Dr Lella Alland and Hester Larkin were opposed by about 15.6 percent of the company.

The company said chair Paul Hopper and chief financial officer, company secretary and director Phillip Hains' remuneration options, Mr Canevari's incentive options, the election of Mr Hains, the 10 percent placement capacity, the incentive plan and amendments to the constitution faced between 6.06 percent and 8.36 percent dissent.

Radiopharm said the elections of Mr Turner and Mr Donnelly and the ratification of the prior issue of shares passed easily with more than 99.89 percent support.

According to its most recent notice, Radiopharm had 2,172,960,756 shares on issue, meaning that the 225,885,672 votes against the remuneration report amounted to 10.4 percent of the company, sufficient to requisition extraordinary general meetings.

Radiopharm was up 0.1 cents or four percent to 2.6 cents with 2.2 million shares traded

<u>AUDEARA</u>

Audeara says investors passed all resolutions with up-to 23.15 percent against the increased employee incentive plan and shares in-lieu of fees to its chair.

Last month, Audeara said its annual general meeting would vote to issue 4,250,000 options to managing-director Dr James Fielding and director Bill Peng 1,500,000 options, each, and issue chair David Trimboli 1,250,000 options as well as 543,586 shares in lieu of fees (Oct 24, 2024).

Today, the company said the increase in the maximum number of securities under its employee incentive plan was opposed by 9,713,778 votes (23.15%) with 32,249,463 votes (76.85%) in favor.

Audeara said the issue of shares to Mr Trimboli in lieu of fees were opposed by 9,713,778 votes (20.73%) with 37,150,286 votes (79.27%) in support.

The company said amendments to the constitution were faced 10.97 percent dissent, with the remaining resolutions passed with more than 99.98 percent of the meeting.

According to its annual report, Audeara had 145,224,130 shares on issue, meaning that the 9,713,778 votes against the increase in the employee incentive plan and Mr Trimboli's shares amounted to 6.7 percent of the company, sufficient to requisition extraordinary general meetings.

Audeara was unchanged at 4.2 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 40.6 percent from 32 cents on Friday November 22, 2024 to a high of 45 cents today and noted the "significant increase" in the volume of shares traded.

Paradigm said that it expected a response from the US Food and Drug Administration about its revised phase III clinical trial protocol by November 28, 2024 as well as a response to its determination application from the Australian Therapeutic Goods Administration during the December quarter".

Paradigm was up 13.5 cents or 41.5 percent to 46 cents with 9.95 million shares traded.

ANATARA LIFE SCIENCES

Melbourne's Thorney Technologies and Tiga Trading say their substantial holding in Anatara has increased from 6,371,106 shares (7.76%) to 20,442,732 shares (9.83%). Thorney and Thorney Investment Group Australia (Tiga) said with Alex Waislitz they bought shares in rights issues on November 28, 2022 and December 8, 2023 for 3.5 cents and 2.2 cents a share, respectively, as well as 4,750,000 shares in a placement on May 7, 2024 for \$190,000, or four cents a share, and 3,800,000 shares in a placement on November 22, 2024 for \$190,000, or five cents a share.

In 2022, Anatara said it raised \$524,691 of a hoped for \$832,482 in a rights offer at 3.5 cents a share; and last year, said a rights offer at 2.2 cents a share raised about \$657,914 of a hoped-for \$1,055,334 (BD: Oct 21, Nov 25, 2022; Nov 3, Dec 7, 2023).

Earlier this year, the company said it had "firm commitments" to raise \$1.0 million in a placement at four cents a share; and this month, said it had increased a placement at five cents a share from \$660,000 to \$750,000 (BD: May 1, Nov 15, 18, 2024) Anatara was untraded at 5.6 cents.

EMYRIA

Emyria has requested a trading halt "pending the release of an announcement by the company regarding a capital raising".

Trading will resume on November 27, 2024, or on an earlier announcement. Emyria last traded at 3.9 cents.

ISLAND PHARMACEUTICALS

Island has requested a trading halt pending an announcement "in relation to the safety review committee recommendation regarding the phase IIa cohort" of a study. Trading will resume on November 27, 2024, or on an earlier announcement. Island last traded at 16.5 cents.

ANTERIS TECHNOLOGIES

Anteris says it has filed a Form S-1 with the US Securities and Exchange Commission (SEC) for the initial public offer of Anteris Technologies Global Corp on the Nasdaq. In August, Anteris said it intended to redomicile to the US, list on the Nasdaq this year, through the Delaware-based Anteris Technologies Global Corp (ATGC), and remain on the ASX (BD: Aug 13, 2024)

Earlier this month, the company said it would hold its scheme meetings to approve its US re-domicile and Nasdaq listing on December 3, with the record date for the schemes on December 9, 2024 (BD: Nov 13, 2024).

Today, Anteris said "the amount of common stock to be offered and the price range for the proposed offering have not yet been determined".

The company said the offer was "subject to market conditions and there can be no assurances as to whether or when the offering may be completed, or as to the actual size, price or other terms of the offering".

Anteris said TD Cowen, Barclays and Cantor were joint book-running managers for the proposed offer, with Lake Street Capital Markets lead manager and Bell Potter financial adviser in relation to the participation of certain potential Australian investors in the offer. Anteris was up five cents or 0.5 percent to \$9.35.

<u>CRYOSITE</u>

Cryosite says joint company secretary Michael Austin has resigned, effective Friday, November 22, 2024, with Bio101's Hamish George continuing as sole company secretary. Cryosite was untraded at 89.5 cents.