



Biotech Daily

Thursday November 28, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: CURVEBEAM UP 20%; PARADIGM DOWN 21%**
- * **FISHER & PAYKEL H1 REVENUE UP 18% TO \$863m, PROFIT UP 43% TO \$139m**
- * **PRO MEDICUS \$330m TRINITY HEALTH VISAGE DEAL**
- * **CELOSIA RAISES \$17m FOR CTx1000 ALS THERAPY**
- * **IMRICOR, ADIS SIGN A.I. MODULE NORTHSTAR DEAL**
- * **COMPUMEDICS COMPLETES \$4.7m TIANJIN UNI MEG CONTRACT**
- * **CANN RIGHTS RAISE \$2m; \$4.35m SHORTFALL**
- * **CLARITY CU-64-SARTATE NEURO-ENDOCRINE TUMOR TRIAL ASSESSED**
- * **PARADIGM CLEARED FOR US PIVOTAL PPS OSTEO-ARTHRITIS TRIAL**
- * **BIOTRON AGM 55% DEFEAT REM REPORT; LOSES 2 DIRECTORS**
- * **MACH7 32% BLOCK PLACEMENT CAPACITY; REM REPORT 1st STRIKE**
- * **SYNTARA AGM 39.5% OPPOSE EMPLOYEE OPTIONS, RIGHTS PLAN**
- * **MEMPHASYS EXTENDS PETERS INVESTMENTS CONVERTIBLE NOTE**
- * **BIOXYNE PLEADS 'SCHULTZ' TO ASX 69% PRICE QUERY**
- * **CHIMERIC RECEIVES \$4.2m FEDERAL R&D TAX INCENTIVE**
- * **INVION COMPLETES 100-1 CONSOLIDATION**
- * **ACORN TAKES 7.7% OF AMPLIA**
- * **BORI LIBERMAN, JAGEN TAKE 6.5% OF ENLITIC**
- * **CORRECTION: VITURA, GUY HEADLEY, JENELLE FREWEN, DR MARCIA WALKER**
- * **DR RONALD WISE REPLACES INHALERX DIRECTOR DR ANDREW SAICH**
- * **ALGORAE APPOINTS DR SARAH SIGGINS SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market was up 0.45 percent on Thursday November 28, 2024, with the ASX200 up 37.6 points to 8,444.3 points.

Twenty-five of the Biotech Daily Top 40 companies were up, nine fell and six traded unchanged. All four Big Caps were up.

Curvebeam was the best, up two cents or 20.0 percent to 12 cents, with 159,938 shares traded.

Medadvisor, Pro Medicus and Universal Biosensors were up more than eight percent; Cyclopharm climbed 7.5 percent; Clarity and Nova Eye were up more than six percent; Opthea was up 5.4 percent; Actinogen, Dimerix, Percheron and Syntara improved four percent or more; Immutep and Proteomics were up more than three percent; 4D Medical, Aroa, Neuren and SDI rose more than two percent; CSL, EBR, Emvision, Resmed, Resonance and Telix were up more than one percent; with Clinuvel, Cochlear, Genetic Signatures, Orthocell and Polynovo up by less than one percent.

Paradigm led the falls, down 12 cents or 20.9 percent to 45.5 cents, with 8.4 million shares traded. Micro-X lost 3.4 percent; Impedimed and Imugene shed two percent or more; Alcidion, Amplia, Medical Developments and Mesoblast were down more than one percent; with Avita down by 0.5 percent.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says record revenue for the six months to September 30, 2024 was up 18.35 percent to \$NZ951.2 million (\$A862.7 million), with net profit after tax up 42.8 percent to \$NZ153.2 million (\$A138.95 million).

Fisher & Paykel said it had \$NZ591.4 million in revenue from its hospital products, which included humidification products for respiratory, acute and surgical care, up 21 percent on the prior corresponding period.

The company said sales of its homecare products, which included masks and accessories for obstructive sleep apnoea, were up 14 percent on the prior period to a record \$NZ359.4 million.

Fisher & Paykel managing-director Lewis Gradon said the “result was driven primarily by new product introductions and changing clinical practice”.

“Early indications are that a relatively high hospital census during the period may have contributed as well, as hospitals returned to more normalized staffing and capacity, and seasonal hospitalizations in the Northern Hemisphere from 2023-'24 persisted into the beginning of our current financial year,” Mr Gordon said.

The company said it would pay an interim dividend on December 18, 2024 of 18.5 cents per share, up from 18.0 cents the previous year, to shareholders at the record date of December 6, 2024.

Fisher & Paykel said diluted earnings per share were up 41.3 percent to 26.0 NZ cents, with net tangible asset per share up 13.8 percent to \$NZ3.05.

The company said that it had cash and cash equivalents of \$NZ116.6 million at September 30, 2024 compared to \$NZ70.5 million on September 30, 2023.

Fisher & Paykel fell 72 cents or 2.1 percent to \$33.85 cents with 877,543 shares traded.

PRO MEDICUS

Pro Medicus says it has a \$330 million, 10-year contract to provide its Visage imaging and archive management software to Detroit, Michigan's Trinity Health.

Pro Medicus said Trinity Health included "93 hospitals, 107 continuing care locations, 142 urgent care locations and many other health and well-being services, spanning a geographic reach of 26 states, with more than 127,000 colleagues, including 9,300 employed physicians and clinicians, as well as 29,000 affiliated physicians".

The company said the "full stack" contract for its internet cloud-based Visage 7 enterprise imaging platform included Visage 7 open archive and Visage 7 workflow modules which would provide "a unified diagnostic imaging platform".

Pro Medicus said Visage would "complete the migration from Trinity Health's legacy [picture archiving and communication] system comprising nine vendors, to [the] Visage 7 open archive" with Visage 7 providing enterprise distribution of images integrated to Trinity Health's electronic health record.

Pro Medicus said that planning for the rollout was "to commence immediately and will be based on Visage's proven cloud-based implementation process, with multi-phased go-lives targeted to begin in early [July 2025]".

Pro Medicus managing-director Dr Sam Hupert said that Trinity Health was "our largest customer to date and the first with a national footprint".

"Our initiative with Trinity Health is noteworthy for its scope and scale which will see the Visage 7 platform used by over 650 radiologists and thousands of clinicians who will benefit from the proven differentiation of Visage 7," Dr Hupert said.

"Trinity Health, like all recent Visage 7 clients, has opted for a fully cloud-based solution, a trend that is fast 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 core Visage products, a trend we see continuing," Dr Hupert said.

Pro Medicus was up \$19.77 or 8.7 percent to \$248.18 with 365,368 shares traded.

CELOSIA THERAPEUTICS

Macquarie University spin-out Celosia says it has raised \$16.75 million in Series A funding to develop its CTx1000 for amyotrophic lateral sclerosis (ALS).

Celosia said it was launched in 2022 with more than \$2 million in seed funding from the University and a portfolio of patents for gene therapies developed by the University.

The company said it had the exclusive licence of CTx1000 "a novel protein interactor that interacts exclusively with only toxic forms of TDP-43, a protein that is normally found in neurons in the brain and spinal cord, and in diseases such as ALS".

Celosia said that in mice, CTx1000 was "able to pause the progression of ALS at a very advanced stage, even partially reversing the disease in some cases".

The company said the raise was led by Uniseed, with a major contribution from hedge fund manager and ALS patient Iomar Barrett, and support from Unisuper.

Celosia chief medical officer and co-discoverer of the therapy Prof Lars Ittner said that CTx1000 was "a novel disease-modifying therapy for ALS, differentiating itself from other treatments that only target symptoms of the disease".

Celosia chief executive officer Dr Kathryn Sunn said that the investment was "a huge boost for the biotechnology sector and not only validates Celosia's innovative approach but also positions Australia at the forefront of global ALS research".

Celosia is a private company.

IMRICOR MEDICAL SYSTEMS

Imricor says it will build artificial intelligence (A.I.) modules for its Northstar mapping system with Lausanne, Switzerland's Advanced Interactive Systems (Adis).

In 2022, Imricor said that the Northstar-MR used Siemens magnetic resonance imaging (MRI) scanners and removed "the reliance on others to develop 3-D mapping systems needed for complex ablation procedure" (BD: Dec 15, 2022)

Earlier this year, the company said that the US Food and Drug Administration had approved the use of its Northstar mapping system in its trial of interventional cardiac magnetic resonance imaging (ICMR) for atrial flutter ablation (BD: Mar 26, 2024).

Today, Imricor said it had a joint development agreement with Adis from November 2023 and had signed a further licence agreement, defining the commercial terms for selling the Northstar artificial intelligence modules to customers.

The company said it would offer the Northstar modules to customers and share the upfront and software licence revenue with Adis, but did not state commercial terms.

Imricor said the first module the companies were targeting would provide automatic heart segmentation capabilities to Northstar, expected to save time during ICMR procedures.

The company said Northstar and the software were not approved for commercial sale, but regulatory processes were "well progressed, and preparations for planned commercial launches across Europe, the US and the Middle East in 2025 ... underway".

Imricor executive chair Steve Wedan said the company expected "these A.I. modules to increasingly deliver more and more value from the superior imaging capabilities of [magnetic resonance imaging] to our users through Northstar," Mr Wedan said. "It is our goal to make Northstar the indispensable central hub around which any customer's ICMR program is built."

Imricor was up three cents or 2.8 percent to \$1.10 with 954,319 shares traded.

COMPUMEDICS

Compumedics says it has installed its Orion Lifespan magneto-encephalo-graphy (MEG) device at China's Tianjin Normal University.

In 2022, Compumedics said the sale of an Orion Lifespan MEG system to Tianjin Normal University for \$4.2 million was its largest contract to date (BD: Jan 12, 2022).

Today, the company said the installation "established a strong key opinion leader centre of excellence ... in the large and fast-growing Chinese neurosciences marketplace".

Compumedics said "multiple additional sales opportunities for the Orion Lifespan MEG were being positively impacted by the installation".

The company said MEG was a neuro-imaging technique for mapping brain activity by recording magnetic fields produced by electrical currents in the brain using sensitive detectors, Lifespan increased precision and had an integrated brain analysis software.

Compumedics said it was building MEG systems for two additional orders, worth \$9.3 million, with delivery expected during 2025.

Compumedics executive chair Dr David Burton said the company was "delighted to have achieved this significant milestone ... demonstrating our continued commitment to providing world leading neuroimaging solutions".

"This system enables neuro-functional investigations simultaneously, interactively and comparatively across two individuals, thereby contributing to improved neuroscience research and ultimately enhancing brain healthcare," Dr Burton said. "Importantly, this milestone helps advance access to Compumedics and Neuroscan MEG and brain analytics software for the wider MEG and neurology communities," Dr Burton said.

Compumedics was unchanged at 26 cents.

CANN GROUP

Cann says its entitlement offer has raised about \$2.0 million at four cents a share, with the \$4.35 million shortfall to be offered to institutional investors.

Last month, Cann Group said it hoped to raise about \$6.25 million in a one-for-three rights offer at 4.0 cents, a 53.3 percent discount to the five-day volume weighted average price, with one option for every three shares issued (BD: Oct 7, 2024).

Today, the company said the offer was “well supported by the company’s existing retail base”, with the funds to be used for its Botanitech marijuana and vape ranges as well as manufacturing costs of its oil range, cultivation costs for its dried marijuana flowers and repayment of the principal and interest on its loans.

Cann said the shortfall would be offered to sophisticated and professional investors by the lead manager Alpine Capital.

Cann was unchanged at 4.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has assessed all 45 patients in its phase II trial of copper-64 Sartate for neuro-endocrine tumors, with results expected “in the first half of 2025”.

In 2021, Clarity said it had dosed the first ‘Disco’ trial patient, which used positron emission tomography on patients with known or suspected gastro-entero-pancreatic neuro-endocrine tumors, to assess the potential of copper-64-sartate to diagnose the tumors (BD: Apr 15, 2021).

Last year, Clarity said it recruited its phase II ‘Disco’ imaging trial of copper-64-sartate for neuroendocrine tumors early, with 45 patients instead of 63 patients (BD: Dec 18, 2023).

At that time, the company said the original patient number was based on expected differences between imaging with copper-64-sartate and the current standard-of-care 68-gallium-dotatate, but that “pre-planned assessment of the images” generated sufficient evidence to plan for a phase III trial.

Today, Clarity said the trial aimed to show that imaging at later time points enabled by the longer half-life of copper-64 compared to gallium-68 “may lead to better identification of disease”.

Clarity executive chair Dr Alan Taylor said that with “the recent changes to the US Centers for Medicare and Medicaid Services and reimbursement of radio-diagnostics, this market is set to surge”.

Earlier this month, Biotech Daily reported that the US Centers for Medicare and Medicaid Services would reimburse radio-pharmaceuticals and nuclear imaging tests separately, beyond pass-through status (BD: Nov 4, 2024).

“The market opportunity for each radio-diagnostic is now massive, but there are limitations to the current range of products, most notably, the use of short half-life isotopes and short shelf-life products,” Dr Taylor said.

“Imaging at a one-hour time point due to the isotope half-life or product shelf-life, as opposed to patient needs, significantly impacts patient care,” Dr Taylor said.

“Firstly, the scheduling of patients may represent a challenge due to the lack of flexibility for imaging,” Dr Taylor said. “But importantly, later time-point imaging presents significant benefits for doing what cancer diagnostics need to do, and that is finding cancer.”

“At Clarity, we have known this for many years and have demonstrated these benefits time and time again with different products in our targeted copper theranostic platform, including Sartate,” Dr Taylor said.

Dr Taylor said that final results were expected by July 2025, and inform the pivotal trial.

Clarity was up 41 cents or 6.9 percent to \$6.36 with 2.4 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it is allowed to begin a 466-patient, randomized, phase III trial of injectable pentosan poly-sulfate sodium (PPS) for knee osteo-arthritis (OA).

In September, Paradigm said the US Food and Drug Administration provided a “clear pathway” for a phase III trial of PPS for osteo-arthritis (BD: Sep 18, 2024).

Last month, the company said it had filed a revised protocol for its phase III trial of PPS, or Zilosul, for knee osteo-arthritis to the FDA (BD: Oct 31, 2024).

Today, Paradigm said the FDA’s 30-day review period for the phase III trial protocol had concluded and the regulator had raised “no substantive questions or concerns”.

The company said it could proceed with dosing patients with 2.0mg/kg of subcutaneous PPS twice weekly, with preparations for the trial “well advanced”.

Paradigm said it remained “on track to begin patient enrolment in 2025, with an initial up-to 10 clinical sites in Australia, and sites in the US anticipated to follow”.

The company said that the primary endpoint of the phase III trial was “a change from baseline in pain, while key secondary endpoints include pain and functional assessments at multiple timepoints up-to day 404, the patient global impression of change and structural changes as measured by [magnetic resonance imaging] and x-ray”.

Paradigm said the FDA's feedback was integrated into the trial design, clinical endpoints and statistical methodology, with structural changes upgraded to secondary endpoints to enhance their importance in regulatory submissions and potential label claims.

The company said interim analysis assessing early efficacy was planned when 50 percent of subjects reached the day 112 follow-up.

Paradigm said the “milestone enables both progress of the clinical program and enables active engagement with key potential partners who may wish to support and/or co-fund the pivotal phase III clinical trial and future commercialization efforts”.

Paradigm managing-director Paul Rennie said the company was “confident that, based on the clinical and other data generated to date and the enhancements to our trial design, informed by FDA guidance and commercial input, Zilosul is positioned as a leading therapeutic candidate for the large poorly met need of pain associated with knee osteoarthritis”.

“I am excited by the various strategic options available to the company now we have progressed through this critical milestone,” Mr Rennie said.

Paradigm fell 12 cents or 20.9 percent to 45.5 cents with 8.4 million shares traded.

BIOTRON

Biotron says 55.28 percent of its annual general meeting defeated the remuneration report and directors Dr Susan Pond and Prof Stephen Locarnini have retired.

Biotron said the remuneration report was opposed by 48,197,834 votes (55.28%) with 38,993,792 votes (44.72%) in favor.

The company said the re-election of chair Michael Hoy was passed with 28.44 percent dissent.

Biotron said Dr Pond had been a director since March 7, 2012 and Prof Locarnini since October 23, 2018 and thanked them “for their valuable contribution to the company during their time as directors”.

According to its most recent filing, Biotron had 902,342,565 shares on issue, meaning that the 48,197,834 votes against the remuneration report amounted to 5.3 percent of the company, sufficient to requisition extraordinary general meetings.

Biotron fell 0.2 cents or 9.5 percent to 1.9 cents with three million shares traded.

MACH7 TECHNOLOGIES

Mach7 says investors have voted a 26.06 percent remuneration report first strike and defeated the 10 percent placement capacity with 31.68 percent opposition.

Mach7 said the remuneration report was opposed by 34,130,963 votes (26.06%) with 96,858,262 votes (73.94%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive annual meetings must to vote on a board spill.

Mach7 said that the special resolution to approve the 10 percent placement capacity was opposed by 41,807,313 votes (31.68%) with 90,169,264 votes (68.32%) in favor.

Last month, the company said its annual general meeting would vote to issue 800,000 performance rights to managing-director Mike Lampron (BD: Oct 30, 2024).

Today, the company said Mr Lampron's rights were opposed by 26.45 percent, with the election of directors Rebecca Thompson and Robert Bazzani opposed by 20.93 percent and 15.73 percent of the meeting, respectively.

According to its most recent notice, Mach7 had 241,241,047 shares on issue, meaning that the 41,807,313 votes against the placement capacity amounted to 17.3 percent of the company, sufficient to requisition extraordinary general meetings.

Mach7 was up two cents or 5.6 percent to 38 cents with 1.4 million shares traded.

SYNTARA

Syntara says its annual general meeting passed all resolutions, with 39.53 percent opposition to the employee option and performance rights plan.

Last month, Syntara said the meeting would vote to issue 2,771,000 performance rights to managing-director Gary Phillips (BD: Oct 25, 2024).

Today, the company said that employee options and rights plan was opposed by 266,329,914 votes (39.53%) with 407,378,679 votes (60.47%) in favor.

Syntara said the remaining resolutions all passed easily.

According to its most recent filing, Syntara had 1,373,141,705 shares on issue, meaning that the 266,329,914 votes against the options and rights plan amounted to 19.4 percent, sufficient to requisition extraordinary general meetings.

Syntara was up 0.2 cents or 4.2 percent to five cents with 8.9 million shares traded.

MEMPHASYS

Memphasys says it has extended the maturity date of its convertible note agreement with Peters Investments Pty Ltd from December 31, 2024 to June 30, 2025.

Memphasys said that any interest accrued from January 1, 2025 "shall only be repayable in cash".

In 2022, Memphasys said that should major shareholder, the Cottlesloe, Western Australia-based Peters Investments, convert the \$1.35 million note under the current capital structure, it would own about 32 percent of the company. (BD: Jan 19, 2022).

Earlier this year, the company said that Peters Investments agreed to extend the maturity date for its \$3 million convertible note to June 30, 2025 (BD: Sep 12, 2024).

At that time, Memphasys said the extension was conditional on shareholders approving Peters Investments increasing its voting power above 20 percent due to the conversion of convertible notes to shares, prior to November 30, 2024.

Memphasys was unchanged at half a cent.

BIOXYNE

Bioxyne 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 Bioxyne's share price rose 69.2 percent from 1.3 cents to 2.2 cents "in the last few days" and noted a "significant increase" in the volume of shares traded.

Bioxyne was unchanged at 1.8 cents with 14.5 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has received \$4,172,342 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Chimeric said the incentive related to expenditure for the year to June 30, 2024.

Chimeric was unchanged at 0.9 cents with 8.2 million shares traded.

INVION

Invion says it has completed its 100-to-one stock-consolidation and has 68,722,668 post-consolidation shares on issue.

Earlier this month, Invion said its annual general meeting passed all resolutions, but with up-to 15.64 percent against its 100-to-one consolidation (BD: Nov 14, 2024).

Invion fell half a cent or 4.2 percent to 11.5 cents.

AMPLIA THERAPEUTICS

Melbourne's Acorn Capital Ltd says it has increased its substantial shareholding from 10,071,620 shares (6.49%) to 27,583,089 shares (7.70%).

Acorn said it sold shares between August 6 and November 15, 2024, and bought 9,565,217 shares on November 4, 2024 for \$1,100,000, or 11.5 cents a share, and 1,765,623 shares on November 25, 2024 for \$157,486, or 8.9 cents a share.

Yesterday, Amplia said it raised \$13 million at 11.5 cents a share (BD: Nov 1, 2024).

Amplia fell 0.1 cents or 1.15 percent to 8.6 cents with 1.8 million shares traded.

ENLITIC

Jagen Pty Ltd and its relevant entities say they have become substantial shareholders in Enlitic with 37,287,550 shares, or 6.48 percent.

In a barely legible substantial shareholder notice, Jagen said that with the B Liberman Family and BHL Pension it bought 36,000,000 shares in October 2024 for \$1,800,000, or five cents a share.

Previously, Biotech Daily has reported that the South Yarra, Melbourne-based Jagen was an investment vehicle for Mr Liberman (BD: Dec 4, 2018).

Enlitic was unchanged at 6.4 cents.

CORRECTION: VITURA HEALTH

Last month, Biotech Daily correctly reported that Virtura's annual general meeting would vote to appoint Shane Tanner, Rebecca Wilson, Gerard Fogarty and Daniel Birch as directors, but failed to state that directors Jenelle Frewen, Dr Marcia Walker and Guy Headley would step down at the meeting (BD: Oct 23, 2024).

Vitura was up 0.2 cents or two percent to 10 cents.

[INHALERX](#)

Inhalerx says it has appointed Dr Ronald Wise as a director of the company, effective immediately, following the resignation of Dr Andrew Saich.

Inhalerx said that Dr Saich had resigned “due to a significant recent increase in time commitments related to his other business interest in the UK and Europe”.

The company said Dr Wise had been involved in mineral exploration including as founder of Exergy Inc and was co-founding chair of the Curtin University spin-out Selvax Pty Ltd. Inhalerx said Dr Wise held a Bachelor of Science and a Doctor of Philosophy from the University of Western Australia.

Inhalerx was up 0.3 cents or 7.7 percent to 4.2 cents.

[ALGORAE PHARMACEUTICALS](#)

Algorae says it has appointed Dr Sarah Siggins to its scientific advisory board, effective from January 1, 2025.

Algorae said Dr Siggins had more than 14 years of experience developing and medicines in neuroscience, oncology, cardiopulmonary and immunology, including senior roles at Johnson & Johnson’s innovative medicines business.

According to her LinkedIn page, Dr Siggins held a Bachelor of Science from the University of Melbourne and a Doctor of Philosophy from Finland’s University of Helsinki.

Algorae was up 0.1 cents or 16.7 percent to 0.7 cents.