



Biotech Daily

Friday December 13, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MESOBLAST UP 14%; CURVEBEAM DOWN 11%**
- * **DR BOREHAM'S A TO Z OF BIOTECHS IN 2024**
- * **QUT DEVELOPS BODY-HEAT POWERED WEARABLE SENSORS**
- * **ONCOSIL SHARE PLAN RAISES \$1m; TOTAL \$8m**
- * **ANTEOTECH RIGHTS RAISE \$810k, \$4.2m SHORTFALL; TOTAL \$4.3m**
- * **ACRUX, TRUPHARMA LAUNCH ANAL FISSURE NITRO-GLYCERIN IN US**
- * **DORSAVI VIDEO MOVEMENT ANALYZER US LAUNCH**
- * **ENLITIC 35.4m BOARD OPTIONS EGM**
- * **AUDEARA DIRECTOR BILL PENG DILUTED TO 5.8%**
- * **RENERVE M-D DR JULIAN CHICK TAKES 9.85%**

MARKET REPORT

The Australian stock market fell 0.41 percent on Friday December 13, 2024, with the ASX200 down 34.3 points to 8,296.0 points. Eleven of the Biotech Daily Top 40 companies were up, 24 fell and five traded unchanged.

Mesoblast was the best, up 22.5 cents or 13.9 percent to \$1.84, with 15.6 million shares traded. Orthocell climbed 10.1 percent; EBR improved five percent; Syntara was up 3.1 percent; Prescient rose 2.4 percent; 4D Medical, Aroa, Genetic Signatures, Medadvisor and Telix were up more than one percent; with Cochlear, and Neuren up by less than one percent.

Curvebeam led the falls, down 1.5 cents or 10.7 percent to 12.5 cents, with 128,969 shares traded.

Cynata lost 10 percent; Paradigm was down 9.5 percent; Micro-X fell 8.3 percent; Emvision and Percheron were down more than six percent; Avita and Starpharma fell more than four percent; Cyclopharm was down 3.65 percent; Atomo, Clinuvel, Immutep, Imugene, Opthea and Proteomics shed more than two percent; Amplia, Compumedics, Impedimed, Medical Developments, Polynovo, Resonance and SDI were down more than one percent; with Clarity, CSL, Nanosonics, Pro Medicus and Resmed down by less than one percent.

[DR BOREHAM'S A TO Z OF BIOTECHS IN 2024](#)

From artificial intelligence (A.I.) to zygotes, the biotech sector this year delivered the A to Z of excitement, intrigue, occasional disappointment and downright disaster.

His virtual stethoscope on hand, Dr Boreham was on duty to diagnose every announcement (okay - almost every pronouncement), ranging from genuine regulatory approvals and commercial deals, to brazen attempts to spinning out failed trails.

The year started with deep pessimism but looks like ending with a powerful rally amid a flurry of trial results, approvals and – of course – capital raisings. So, here's the towering year cut to alphabetic brevity:

A is for A.I., as in artificial intelligence, not artificial insemination. Only the bravest device and diagnostic plays don't purport to be using the tool – but there's a gaping chasm between real A.I. and tricked up humanoid intelligence known as 'algos' (algorithms).

Still, A.I. is radically automating surgical procedures. All the robots need to do is to perfect their golf swing and surgeons will be headed the way of facsimiles (still used in the pathology sector, by the way) and Sony Beta tapes.

B is for goodbye to Biden and probably most of his healthcare reforms including the ambitious Moonshot cancer eradication program.

B is for Bcal Diagnostics, which is on-track for a commercial launch of its blood-based breast cancer detection tool in early 2025.

B is also for the baloney about pending big-ticket partnerships and regulatory approvals that never happen, multi-billion dollar 'addressable markets' and failed trials morphing into successful ones with data mining.

C is for the culprits who know who they are.

C is for 'Cannabis corner' where shares have disappointed, but a standout among the weeds is Neurotech International with its proposed cannabinoid-based treatment for childhood neurological disorders.

C is also for a cascade of capital raisings. Many were small, but Telix Pharmaceuticals and Opthea blazed the way with raisings of \$650 million and \$220 million respectively.

D is for Dimerix, a sector winner on the back of two distribution deals that had front-end cash. We await the results of the company's phase III trial for the rare kidney disease focal segmental glomerulosclerosis (FSGS), due next year.

D is also for depression, not a reference to the US Democrats but work by Actinogen (depression and Alzheimer's), Trivarx (depression and sleep) and Avecho (pot).

E is for Emvision, which hopes to start a pivotal trial for its portable stroke detection unit by March next year.

F is for failure. In a year of soaring sectoral success, there are always casualties as well.

The private point-of-care diagnostics house Ellume called in the receivers in June, reportedly owing \$200 million to creditors. Genetic Technologies appointed voluntary administrators in November, after a capital raising fell well-short of the minimum.

In October, Patrys cancelled its lead DNA damage repair program, citing “manufacturing challenges” and in a rare setback, CSL axed its drug candidate for acute myocardial infarction? Missed its primary endpoint in an expansive – and expensive – trial.

Oh, **F**ruitcake!

G is for the great windfall for Neuren, which last month pocketed \$US50 million from its share of an FDA rare paediatric disease priority review voucher, and a similar amount in royalties from Daybue (trofinetide) sales.

G is also for Genetic Signatures, which won long-awaited FDA approval for its Easyscreen molecular test that detects eight gastro-intestinal parasites at once.

H is for ‘hero’ stock Pro Medicus, now valued at \$24 billion and worth more than the smallest of biotech’s former Big Three, Cochlear. So, make that the biotech Big Four

I is for IPOs (and lack thereof). Conditions remained subdued, but Blinklab (autism testing) joined the bourse in early April, breaking an eight-month drought, while Renerve (nerve repair) and Vitrafy (cryogenics) debuted last month.

I is for drug repurposer Island Pharmaceuticals and its quest to rid the world of the rapidly spreading, mosquito-borne dengue fever.

I is also for immune-oncology houses Immutep and Imugene and their steady stream of trial updates. The challenge is not to confuse the two companies and work out which trial is which, bearing in mind that neither has an approved therapy.

J is for janus kinase (JAK) inhibitor, which delivered its inventors, Prof Andrew Wilks and Dr Chris Burns, the \$250,000 Prime Minister’s Prize for Innovation. JAKs had their day in the sun when the FDA in late 2023 approved the locally developed JAK-based Ojjaara (momelotinib) for myelofibrosis. Ojjaara was invented by the head of Amplia Therapeutics, Dr Burns and founder of the formerly ASX-listed Cytobia, Prof Wilks. And Prime Minister Anthony Albanese awarded the prize in October this year.

K is for Kiwi companies. Key contributors to the ASX biotech sector, via the likes of Aroa Truscreen, Pacific Edge and the overlooked Resmed rival Fisher & Paykel Health. Neuren also had NZ roots, while breast imager Volpara was taken over and delisted in May.

L is for leadership changes at more than a dozen companies, with a high female representation among incoming CEOs.

At Genetic Signatures, Allison Rossiter succeeded Dr John Melki.

At Impedimed, Dr Parmjot Bains took over from Richard Valencia.

At Somnomed, Karen Borg took over from Neil Verdall-Austin

At Chimeric Therapeutics, Jennifer Chow suddenly departed in favor of Dr Rebecca McQualter, while at Starpharma Cheryl Maley took over from Dr Jackie Fairley.

Going against the trend, at Opthea the US-based Dr Fred Guerard replaced founder Dr Megan Baldwin. At Cann Group, Peter Koetsier took over from Jenni Pilcher.

In April, Pharmaust (now Neurizon) announced the departure of CEO Dr Michael Thurn and his re-appointment on May 31 – surely the shortest resignation in biotech history. At Vitura Health, Geoff Cockerill replaced Rodney Cocks.

M is for Making America Healthy Again by vilifying vaccines and established medical science.

M is also for stem cell developer Mesoblast, which has regained investor favor on expectations it will finally, finally win FDA approval (for paediatric graft-versus-host disease). D (decision) day is expected on or before January 7 next year.

N is for name change, with Pharmaust becoming Neurizon, Cronos Australia morphing into Vitura Health and Regeneus regenerating into Cambium Bio. MGC Pharmaceuticals became Argent Biopharma and LBT Innovations is now Clever Culture Systems.

Are the marketing moniker gurus wasting their time? As James Garner, the head of Percheron (formerly Antisense Therapeutics) remarked: “You could call it Potato Therapeutics and it would just be the same.”

N is also for Nasdaq, with Telix and Radiopharm pursuing secondary listings on the tech-heavy exchange. Late last year, Incannex Healthcare redomiciled to the Nasdaq and heart valve innovator Anteris Technologies plans to do so next year.

O is for the semaglutide injectable obesity drugs, best known as the branded Ozempic. Their emergence has prompted speculation about reduced need for sleep apnoea aids (sorry, Resmed) and dialysis (sorry, CSL).

Is it really the end of what TV reporters breathlessly describe as ‘obesity epidemic’? We say **F**, as in Fat Chance.

O is also for Opthea, which has two extensive phase III trials for wet AMD, a leading cause of blindness. We’ll ‘see’ next year when the first results are out. They will be company making – or company breaking.

P is for psychedelic therapies and the fortunes of dabblers Bioxyne, Tryptamine Therapeutics, Emyria and – on the periphery – Little Green Pharma. The FDA is far from convinced – but new health czar Robert F Kennedy Junior is an ardent fan and any bureaucrat troubled by the science can either tune in or drop out.

Q is for ‘quite impressive’, as in the sector’s outperformance relative to the broader market. **Q** is also for ‘quality’ which sums up most of Australia’s medical research.

R is for radio-therapies and diagnostics. The rise and rise of Telix is well documented, but Clarity Pharmaceuticals and Radiopharm have also emerged from the doldrums.

S is for success. Companies chalking impressive share gains this year include Invion, Clarity, Mesoblast, Polynovo, Actinogen, Genetic Signatures, Syntara, Immutep and the slow-burn success of SDI, a supplier and exporter of dental consumables since 1972.

T is for Telix and Trump. But they've both had more than their fair share of airtime so we will give a mention to Truscreen – the only company we know that is targeting non-developed countries for its cervical cancer screening tool.

U is for unusual, a trait we would ascribe to Opyl's algorithmic tool that claims to predict the likelihood of a trial succeeding. The company will start the 'world's first' biotech fund run by A.I., so we will soon see how this brave new world pans out.

V is for vaccines. We're going to be hearing a lot more about the V-word in the world of RFK Junior.

V is also for the US veterans' market, a healthcare system that rivals the size of Australia's. The sector is being targeted by lung imaging plays 4D Medical, Cyclopharm and Singular Health.

W is for the buzzing wound care space: Polynovo, Avita and Aroa are encroaching the US market one dressing at a time, although Next Science appears to have been left behind.

X is for (e)xiting companies: Volpara and Ellume aside, Rhinomed went private and Visioneering plans to do the same, while Allegra Medical Technologies was taken over by an entity associated with a director. Argent Biopharma sought better fortunes on the London exchange but decided to stay here.

X is also for (e)xaggerated claims about the size of an addressable market and the scope of a new product to disrupt well-established technologies.

Y is for "yes" from the FDA for Botanix and its treatment for excessive sweating – a case of persistence and perspiration. It was also yes for Echo IQ for its aortic stenosis detection diagnostic and Orthocell's nerve repair cuff, Remplir, while LTR Pharma is on the up-and-up after winning local consent for its Spontan erectile dysfunction nasal spray.

Z is also for zygote, "a diploid cell formed by the fusion of two haploid gametes during fertilization in eukaryotic organisms with sexual reproduction". Our coverage admittedly was zygote-free but if you haven't heard at least one new biotech term a year, it's been a wasted 12 months.

Z is also for zzzz and the quest to put the insomnia epidemic (that word again) to bed once and for all. The long-standing Compumedics has an increasingly snazzy array of sleep diagnostic gizmos. Trivarx is exploring the link between bad sleep and depression.

Meanwhile, Avecho is running a phase III trial to prove that cannabinoids may cause drowsiness ... who would have thought?

Speaking of rest, Dr Boreham's Crucible is taking one. Jab another vial of Ozempic for a guilt-free festive season and have a great one.

QUEENSLAND UNIVERSITY OF TECHNOLOGY

Queensland University of Technology (QUT) says it has developed “an ultra-thin, flexible film ... [to power] wearable devices using body heat eliminating the need for batteries”.

The University said most previous research used “bismuth telluride-based thermoelectrics, valued for its high properties that convert heat into electricity which makes it ideal for low-power applications like heart rate, temperature or movement monitors”.

QUT said that the research paper, titled ‘Nanobinders advance screen-printed flexible thermoelectrics’, was published in Science at: <https://bit.ly/3BoWawc>.

Queensland University of Technology researcher Prof Zhi-Gang Chen said that “flexible thermo-electric devices can be worn comfortably on the skin where they effectively turn the temperature difference between the human body and surrounding air into electricity”.

“They could also be applied in a tight space, such as inside a computer or mobile phone, to help cool chips and improve performance,” Prof Chen said.

“Other potential applications range from personal thermal management – where body heat could power a wearable heating, ventilating and air conditioning system,” Prof Chen said.

“However, challenges like limited flexibility, complex manufacturing, high costs and insufficient performance have hindered these devices from reaching commercial scale,” Prof Chen said.

“We created a printable A4-sized film with record-high thermoelectric performance, exceptional flexibility, scalability and low cost, making it one of the best flexible thermoelectrics available,” Prof Chen said.

“This flexibility in materials shows the wide-ranging possibilities our approach offers for advancing flexible thermoelectric technology,” Prof Chen said.

The University said it “introduced a cost-effective technology for making flexible thermoelectric films by using tiny crystals, or ‘nano-binders’, that form a consistent layer of bismuth telluride sheets, boosting both efficiency and flexibility”.

QUT said researchers used “‘solvo-thermal synthesis’ which formed nano-crystals in a solvent under high temperature and pressure, combined with ‘screen-printing’ and ‘sintering’”.

The University said ‘screen-printing’ allowed for large-scale film production and ‘sintering’ heated the films to near-melting point, bonding the particles together.

QUT said the technique could work with other systems, such as silver selenide-based thermo-electrics, which were potentially cheaper and more sustainable than traditional materials.

ONCOSIL MEDICAL

Oncosil says it has raised \$1 million in a share purchase plan at one cent a share, taking the total raised with the placement to \$8 million.

Earlier this year, Oncosil said it had “commitments” to raise \$7.0 million in a placement at one cent a share, with a \$1.0 million share purchase plan to follow (BD: Oct 28, 2024).

At that time, Biotech Daily calculated the 1.0 cent a share issue price was a 23.1 percent discount to Oncosil’s last closing price of 1.3 cents.

Today, the company said the options were exercisable at 1.5 cents each by December 20, 2027.

Oncosil said the funds would be used for its Macquarie Park manufacturing facility, funding of clinical trials and working capital.

The company said the share plan raised \$690,000 from eligible shareholders and the remaining \$310,000 under a shortfall commitment.

Oncosil was unchanged at 0.7 cents with 3.2 million shares traded.

ANTEOTECH

Anteotech says it has raised \$810,606 of a hoped-for \$4,979,540 at two cents a share in a rights offer, taking the total to \$4,310,606 and leaving a \$4,168,934 shortfall.

Last month, Anteotech said it had “commitments” to raise \$3.5 million in a placement and hoped for \$5.0 million in a one-for-10 entitlement offer (BD: Nov 13, 2024).

At that time, the company said the issue price was a 25.0 percent discount to the 15-day volume weighted average price, and a 25.9 percent discount to the closing price on November 8, 2024.

Anteotech said the shortfall shares “may be placed by the company in consultation with the joint lead managers, to new investors within three months of the closing date”.

Anteotech was unchanged at 1.8 cents with 15.2 million shares traded.

ACRUX

Acrux says the Tampa, Florida-based Trupharma LLC has begun launch activities for its generic nitroglycerin ointment for pain relating to chronic anal fissures.

In 2020, Acrux said Trupharma would exclusively market and sell six of its existing products in the US; and earlier this year, said Trupharma had begun selling its dapsona 5.0 percent topical gel for acne vulgaris (BD: May 29, 2020; Apr 3, 2024).

Last week, the company said the US Food and Drug Administration approved generic Rectiv, 0.4 percent nitro-glycerin ointment, for chronic anal fissure pain (BD: Dec 4, 2024).

Today, Acrux said the ointment was “its fourth commercialized product in the US”.

Acrux managing-director Michael Kotsanis said the company was “excited to again commercially partner with Trupharma for another ... product which has been developed in house by the Acrux [research and development] team”.

“This further demonstrates the capability of the Acrux team to execute the company’s strategy to develop and commercialize our pipeline of topical products,” Mr Kotsanis said.

“Commercial rights for the product are available for countries outside the US,” he said.

Acrux was up 0.1 cents or 3.1 percent to 3.3 cents with two million shares traded.

DORSAVI

Dorsavi says its video movement analysis software for upper limb, lower limb and running analysis is commercially available following beta testing in 15 US states.

Dorsavi said the launch of its artificial intelligence (A.I.) motion analysis product was “a significant milestone in Dorsavi’s product evolution and expands the company’s suite of non-intrusive, high-precision movement tracking solutions by utilizing video capture from a range of devices to deliver advanced movement analysis”.

The company said the video application did not require physical sensors and reduced “set-up time by 90 percent, allowing clinicians to communicate more efficiently with their patients and create more revenue for their clinic”.

Dorsavi said a monthly subscription for a single module of the software cost \$A59.00 in Australia and \$US59.00 in the US, and included unlimited daily sessions, video scroll, multiple subject creation, customizable reporting and facial blurring.

The company said it was “ready to accept subscriptions from the physical therapy market” and planned to commercialize the product through its 25,000 health contacts, the majority of which are US physical therapists.

Dorsavi said that “in early 2025” it would expand outreach through marketing and influencer campaigns and work with strategic partners.

Dorsavi fell 0.1 cents or 7.1 percent to 1.3 cents with 8.1 million shares traded.

ENLITIC

Enlitic says an extraordinary general meeting will vote to issue a total 35,400,000 options to its managing-director, chair and two directors.

Enlitic said investors would vote to issue 23,000,000 options to managing-director Michael Sistenich, 6,800,000 options to chair Lawrence Gozlan and 2,800,000 options, each, to directors Lisa Pettigrew and Sergio Duchini.

The company said the equity incentive plan options would be exercisable at a 15 percent premium to the closing price of its Chess depository interests prior to grant date within 10 years.

Enlitic said the options were in addition to Mr Sistenich's \$US334,500 (\$A525,907) yearly total salary, Mr Gozlan's \$US100,000 (\$A157,201) remuneration and Ms Pettigrew and Mr Duchini's \$US60,000 (\$A94,321) director fees.

The meeting will be held online on January 14, 2025 at 10am (AEDT).

Enlitic was up 0.7 cents or 9.6 percent to eight cents.

AUDEARA

Audeara executive director Hsin-Chieh (Bill) Peng says his 10,227,380 share-holding has been diluted from 7.14 percent to 5.84 percent in a placement.

The Brisbane-based Mr Peng said that with BP Peng Pty Ltd he was diluted due to a placement on December 23, 2022.

In 2022, Audeara said it had raised \$2.8 million at 10 cents a share in a placement to the Taiwan-based Clinico Inc chief executive officer David Lin (BD: Nov 22, 2022).

Last week, the company said it had "commitments" to raise \$1.35 million at four cents a share, with Mr Peng, chair David Trimboli and managing-director Dr James Fielding participating in the placement (BD: Dec 5, 2024).

Audeara was unchanged at 4.4 cents with one share traded.

RENERVE

Renerve managing-director Dr Julian Chick says he has increased his substantial shareholding from 13,925,188 (9.82%) to 13,983,888 shares (9.85%).

The Melbourne-based Dr Chick said that with Violeta Traicevski and Viomaj Pty Ltd he purchased 58,700 shares on December 13, 2024 for \$9,979, or 17 cents a share.

Renerve was up half a cent or 3.45 percent to 15 cents.