Biotech Daily

Thursday April 17, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CLARITY UP 13%; GENETIC SIGNATURES DOWN 12%**

*** DR BOREHAM'S CRUCIBLE: EBR SYSTEMS INC**

*** AUDEARA 9-MONTH RECEIPTS UP 11% TO $4m**

*** PYC RIGHTS RAISE $146m**

*** RECCE PLACEMENT RAISES $5m**

*** ANATARA: 'GARP MISSES IBS EFFICACY ENDPOINT'**

*** QIMR LIFE SCIENCE INCUBATOR**

*** MESOBLAST EXPANDS US RYONCIL COVERAGE TO 104m LIVES**

*** LUMOS FEBRIDX COVERED BY 2 US MEDICARE CONTRACTORS**

*** IMRICOR ADVANTAGE-MR WINS CE MARK**

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*** NYRADA EGM 53% OPPOSE DIRECTOR WARRANTS**

*** IMEX POTENTIAL BOARD SPILL AGM**

*** GREENCAPE, CHALLENGER TAKE 7% OF IMRICOR**

*** ROPEHAWN TAKES 7.8% OF RENERVE**

*** NEURIZON APPOINTS CRO, CSO, CMA**

MARKET REPORT

The Australian stock market was up 0.78 percent on Thursday April 17, 2025, with the ASX200 up 60.2 points to 7,819.1 points. Fifteen of the Biotech Daily Top 40 companies were up, 17 fell, six traded unchanged and two were untraded.

Clarity was the best, up 22 cents or 13.1 percent to $1.90, with 4.2 million shares traded. Percheron climbed 9.1 percent; Atomo and Polynovo were up five percent or more; Immutep was up 4.4 percent; Actinogen, Neuren and Universal Biosensors climbed more than three percent; Prescient rose 2.3 percent; Clinuvel, Dimerix, Mesoblast, Pro Medicus and Resmed were up more than one percent; with Avita, Cochlear, Cyclopharm and EBR up by less than one percent.

Genetic Signatures led the falls, down 5.5 cents or 11.8 percent to 41 cents, with 152,366 shares traded. Nanosonics lost 8.0 percent; Imugene, Paradigm and Resonance were down more than seven percent; Impedimed was down 5.7 percent; Aroa and Orthocell fell more than four percent; Medical Developments and Starpharma were down three percent or more; Alcidion and Compumedics shed more than two percent; 4D Medical, CSL, Medadvisor, SDI and Syntara were down more than one percent; with Telix down by 0.7 percent.

DR BOREHAM'S CRUCIBLE: EBR SYSTEMS INC

By TIM BOREHAM

ASX Code: EBR

Share price: $1.365; **Shares on issue** (CDIs): 372,896,324; **Market cap:** $509.0 million

CEO: John McCutcheon

Board: Allan Will (executive chair), Mr McCutcheon, Dr Christopher Nave, Trevor Moody, Dr Bronwyn Evans, Dr David Steinhaus, Karen Drexler

Financials (calendar 2024): income nil, net loss $US41.2 million (previous loss $US32.7 million), cash balance $US64.5 million (at December 31, 2024)

Major identifiable shareholders: Hostplus 11.5%, HESTA 8.6%, Brandon Capital (partners and clients) 5.6%, MH Carnegie Funds 11.0%, Split Rock Partners LP 7.2%

The US Food and Drug Administration might be in a mess, but a slew of ASX biotechs can't complain that the agency's approval process has stalled.

This month, the FDA approved Artrya's arterial plaque detection tool, Salix Coronary Anatomy and then gave the nod to Orthocell's nerve repair device, Remplir. The private Headsafe MFG won assent for its wearable concussion headset.

Now, EBR Systems joins the happy list after the FDA brandished the 'approved' stamp on the company's novel wireless pacemaker device, Wise, the only leadless left ventricular endocardial pacing device and the only one able to deliver cardiac resynchronization therapy (CRT).

"It's a spectacular day for us and for shareholders," Mr McCutcheon said. "It changes us from a clinical company [to one] with a commercial footing where it's more about execution and growth."

Investors were less chuffed and wiped 22 percent off the stock, apparently because of profit taking on the back of the company's stellar share run.

EBR plans to sell to selected heart surgeons by the end of the year, in a $US3.6 billion addressable market. To date, EBR has spent $US340 million to develop Wise.

Three Wise guys

What happens when an electro-physiologist, an ultrasound scientist and pacemaker engineer walk into a bar?

You don't get a joke, but a better way to undergo cardiac resynchronization therapy (CRT) by accessing the left ventricle and removing annoying leads that are prone to failure.

The trio, Dr Debra Echt, Dr Axel Brisken and Richard Riley founded the Silicon Valley based EBR in 2003. Cryptologists would pick up that ‘EBR’ combines their initials.

Dr Echt saw a problem with leads and thought there was a better way to defibrillate (reduce dangerous rapid heartbeat) the heart.

With a background in sales and marketing in the heart device sector, Mr McCutcheon joined EBR in 2019.

EBR listed on the ASX on November 24, 2021, having raised $110 million at $1.08 apiece.

In May 2023, EBR reported its 183-patient, pivotal study for its Wise device met its primary safety and efficacy endpoints, for patients with acute and chronic lead failures and high-risk upgrades.

European authorities approved the device in October 2015, but regulatory upheaval there meant that selling initially in the US was more attractive.

More than 500 patients have been embedded with Wise to date, with the first Australian patient implanted in February 2018. This use relates to trials and special access schemes.

The heart of the matter

Wise stands for ‘wireless stimulation endocardially’ – but we all knew that already.

CRT involves inserting electrodes in the left and right ventricles of the heart, as well as on occasion the right atrium, to treat heart failure by coordinating the function of the left and right ventricles via a pacemaker.

If the right ventricle contracts before the left one, desynchrony occurs and the ticker does not pump blood adequately.

CRT is a subset of the cardiac rhythm management sector, which includes bradycardia pacing (for slow heart beats) and defibrillations via high voltage leads added to the pacemaker.

Pacemakers have saved many lives, but the trouble is about four percent of the embedded leads fail every year.

The longer the pacemaker is in there, the higher the chance of failure.

One reason the left ventricle is trickier is because it circulates arterial blood straight to the brain. The right side (venous blood) circulates through the lungs and is less prone to clotting.

To avoid clots, the left-side leads are currently placed in the surrounding coronary sinus, with stimulation occurring outside the chamber.

Being wireless, Wise obviates this problem.

A very handy grain of ‘rice’

The size of a grain of cooked rice – and we’re talking Jasmine rather than the fatter Arborio – Wise, powered by a subcutaneous battery, is embedded in the heart to provide left ventricle pacing stimulation.

A transmitter picks up the groove of the right ventricle and sends a signal to the Wise electrode, which converts ultrasound energy to electrical energy to stimulate the left ventricle. The transmitter sits between the ribs and is flush to the skin, so it is unobtrusive and not noticeable to the patient.

What’s the target market?

Wise provides the only way for patients to upgrade from leadless pacemakers to CRT.

To be clear, other wireless pacemakers have been developed, but they cater for the right ventricle. Wise is designed to be used alongside them. Medtronic was the first five years ago with Micra and then Abbott followed with Aveir. Boston Scientific awaits approval of a third device, Empower.

These right-side devices pace for non-heart failure arrythmias such as bradycardia (slow heartbeat).

“In these cases, the arrhythmias are treated in the right ventricle. But with heart failure, the left ventricle needs to be included for the condition to be treated effectively.”

Use strictly as directed

The FDA has bestowed broad indications for Wise, the first provision being the patients are at least 22 years old and have an implanted right ventricular pacing system. The allowed uses cover four sectors comprising the $US3.6 billion market, including high-risk leadless upgrades, high-risk conventional upgrades and acute and chronic lead failure.

High-risk upgrades mean the surgeons have attempted to place a lead in the coronary sinus to access the left ventricle. Or the procedure has been deemed to be too dangerous in the first place.

Another scenario is when a patient with a lead-based pacemaker progresses to needing CRT, but a left ventricle lead would be too risky. About 30 percent of this cohort will require CRT within four years.

In these cases, the patient might be re-installed with a leadless right ventricle device, in conjunction with Wise. In other cases, leads may have been removed because of infection and re-installing them risks further infection.

The biggest single opportunity lies with chronic lead failures, a $US1.45 billion a year market.

Finances and performance

EBR lost just under $US11 million in the fourth (December 2024) quarter, with a full year loss of $US41.2 million compared with a $US32.7 million loss previously.

Research and development costs came in at $US6.65 million. But they trended down to $US601,300 in the December quarter from $US2.5 million in the March stanza, because the company has been capitalizing its pre-launch inventory purchases.

But it's swings and roundabouts, with product manufacturing and operating costs up from $US493,000 in the March quarter to $US2.3 million in the December quarter (for a year's total of $US4.25 million).

In October last year EBR raised $50 million in a placement and share purchase plan (SPP), at 82 cents apiece. In mid-2023 the company raised $35 million, also in a placement and SPP, at 91 cents apiece.

At the time, EBR also drew $US20 million of debt on a $US50 million deal with Runway Growth Capital in mid-2022. The first $US20 was drawn at the signing of the deal.

With $US66 million ($105 million) of cash on hand, EBR says it is adequately funded for "initial" commercialization.

Over the last 12 months, EBR shares have ranged between 83 cents (September last year) and an all-time high of just over $2.00 (late March this year). Despite the post-approval pull-back – and an attempted rebound fizzled out - the stock has gained about 64 percent over the last year.

EBR has a bevy of big-ticket names on the register, including industrialist Mark Carnegie, Brandon Capital and industry super funds HESTA, Hostplus and Australian Super.

Since last October, EBR has been exempt from ASX reporting requirements and falls under US reporting rules.

Rearing to go

EBR has been building inventory and amassing a small direct sales force.

For those worried about tariffs, EBR recently took out an 11-year lease on an expanded, 4,750 square metre production facility at Santa Clara, in the heart of Silicon Valley.

Given the cardiac community is small, EBR will sell directly in the US initially, but is amenable to using distributors elsewhere.

Mr McCutcheon cautions investors not to expect a "rocket-ship take-off": initial uptake could be slow, as clinicians familiarize themselves with the product. The company sees first use by 20 to 40 heart centres, with first adopters likely to use them for 10 to 25 percent of procedures. He says EBR has a "clear path" to US reimbursement, expected by October this year.

The company has modelled per-procedure public and private reimbursement at $US45,000, but Mr McCutcheon says: “we certainly want to get more than that”.

EBR has been accepted into the “new technology add-on payment” pathway and other exotic reimbursement conduits.

Mr McCutcheon adds that pacemakers were becoming commoditized until Medtronic entered the market with Micra five years ago.

“Now, it is the most dynamic and fastest growing part of the market, because of wireless devices,” he says. “That’s a proxy for our future and how it will parlay into our success.”

Dr Boreham’s diagnosis:

As Mr McCutcheon notes, EBR has now grown-up and reached the life sciences equivalent of adulthood.

But he well knows that commercial-stage companies can have growing pains and stresses the rollout will be measured enough to pick up problems before they become big ones.

“I’ve done a lot of new technology launches, but as smart as we think we are, there’s always something we didn’t learn.”

In 2021 alone, the FDA ordered recalls on certain Medtronic and Abbott pacemakers and Medtronic defibrillators, owing to premature battery depletion.

Another commercial reality is that major product rollouts involve buckets of money.

While EBR has $105 million, broker Bell Potter expects the company will raise a similar amount this year to complete US commercialization in the US and attack other markets.

Bell Potter also forecasts EBR will post a $US48 million loss this year and deficits of $US52 million and $US42 million in 2026 and 2027.

Still, with its FDA certificate safely in its corporate paws, EBR becomes a de-risked company more befitting its $500 million-plus market valuation.

One oddity of it all is why the wise guys at the heart device giants haven’t devised their own left ventricle devices. The simple reason is that’s it’s hard and when you are making a lot of money from what you are currently doing, you just keep doing it.

“We are going to own our space for some time, we don’t see any threats on the horizon,” he says. “Everything looks like it is going our way.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He sees no threats on the horizon and everything is going his way, not that he earns that much from doing what he’s doing.

AUDEARA

Audeara says receipts from customers for the nine months to March 31, 2025 was up 54.2 percent to $3,942,000, compared to the previous corresponding period.
Audeara said receipts from sales of its hearing earbuds and hearing health products for the three months to March 31, 2025 were up 46.0 percent to a record $1,635,000, compared to the prior corresponding period.
The company said nine-month receipts of $3.9 million were up 11 percent on the $3.5 million in receipts during the 12 months to June 30, 2024.
Audeara managing-director Dr James Fielding said the three-month result was “one of significant progress for Audeara, underpinned by exceptional operational and financial momentum”.
“This has led to a record in cash receipts on a quarterly basis, as well as year to date receipts now eclipsing the entirety of the previous financial year,” Dr Fielding said.
The company said it had a cash burn of $73,000 for the three months, with cash and cash equivalents of $1,881,000 at March 31, 2025 compared to $2,081,000 at March 31, 2024.
Audeara was up 0.1 cents or 3.3 percent to 3.1 cents.

PYC THERAPEUTICS

PYC says it has raised the total $146 million in its fully-subscribed, underwritten, one-for-four entitlement offer at $1.25 a share.
In February, PYC said it hoped to raise up-to $146 million at $1.25 a share in a one-for-four, non-renounceable institutional and retail rights offer, with the issue price a 4.9 percent discount to the five-day volume weighted average price (BD: Feb 17, 2025).
At the time, the company said the rights offer was underwritten up-to $70 million by shareholders Custom Binders, John Baird, Sami Zouad, Adrian Bonaddio and the Papy Family Trust, and that chair Alan Tribe’s Australian Land Pty Ltd, which owned 34 percent of its issued capital, had subscribed for $35 million under the offer.
Last week, PYC said its underwriter of $13 million from the rights offer had a “liquidity issue”, with the payment expected to be received by April 30, 2025 (BD: Apr 9, 2025).
Today, PYC said it would use the funds for human safety and efficacy read-outs of its multiple first-in-class drug candidates “over the course of the next 24 months”.
PYC fell 2.5 cents or 2.4 percent to $1.03.

RECCE PHARMACEUTICALS

Recce says it has completed its $5.0 million placement at 28.0 cents a share to an unnamed “existing Australian-based private investor”.
Last week, Recce said it raised $5.0 million at 28.0 cents a share in a placement to an unnamed “Australian-based private investor, with a one-for-six, pro-rata, non-underwritten rights offer for up-to $10.8 million to follow (BD: Apr 10, 2025).
At the time, the company said the offer price was a 19.8 percent to the five-day volume weighted average price.
Today, Recce said the funds raised would be used for its phase III trial of topical R327 gel for diabetic foot infection in Indonesia and its phase IIII trial of topical R327 gel for acute bacterial skin and skin structure infections in Australia.
The company said the rights offer had a record date of April 16, would open on April 22 and close on May 5, 2025.
Recce was up half a cent or 1.75 percent to 29 cents.

ANATARA LIFESCIENCES

Anatara says its 78-volunteer, phase II trial of 'Garp' for irritable bowel syndrome (IBS) showed "the primary endpoint for efficacy … was not met" with no safety concerns.

In 2023, Anatara said stage one of the phase II trial of its gastro-intestinal reprogramming, or Garp, for irritable bowel syndrome reduced irritable bowel syndrome by 56 percent, met safety objectives and was statistically significant for anxiety and depression, but not quality of life (BD: Oct 6, 17, 2023).

Last year, the company said it had enrolled the minimum 60 patients in stage two of the trial, and Garp was a "multi-component, coated complementary medicine" that included its pineapple stem-based bromelain, for irritable bowel syndrome (BD: Dec 4, 2024).

Last month, Anatara fell as much as 74 percent on news that the primary endpoint for the trial was "unlikely to be met" (BD: Mar 10, 2025).

Today, the company said the trial showed a "consistent and sustained improvement" in irritable bowel syndrome symptom scoring system (IBS-SSS), with a reduction of more than 40 percent, which was not statistically significant when compared to placebo.

Anatara said Garp showed statistically significant improvement in the secondary endpoints of a reduction in anxiety scores and hospital anxiety depression scale scores at eight weeks of treatment ($p = 0.034$ and $p = 0.025$, respectively).

The company said that two weeks after the eight-week treatment, the Garp cohort arm of the trial had a "perception of having had an 'adequate response' that is statistically highly significant versus placebo".

Anatara said the adequate response results could "be extrapolated to support the Garp mechanism-of-action of restoring and maintaining the gastro-intestinal tract lining as a barrier and the homeostasis of the microbiome dynamics, thereby maintaining a response post-treatment".

The company said there were "no biomarkers for objective assessment of IBS disease activity and the scoring systems are subjective and drawn-out".

Anatara said the data "revealed no concerning safety signals and that the product was well tolerated … [and] noted "the value of obtaining safety data, especially from a cohort of 78 participants assigned to the Garp product treatment arms in a randomized, placebo-controlled, double-blind trial".

Last month, the company said it had allocated "more than $250,000" to proof-of-concept studies for anti-obesity drug research, in mice (BD: Mar 10, 2025).

Today, Anatara said that "while committed to the anti-obesity project" it would assess other opportunities and directions, and that the Garp project was its priority.

The company said that "only essential roles will be maintained around the retracted activities until the company's direction is further defined".

Anatara executive chair Dr David Brookes said not reaching significance for the primary efficacy endpoint in any trial had "to be a real disappointment for all involved, as it is the common goal, however the trial has still delivered significant findings".

"The Garp product appears to outperform placebo for IBS-SSS reduction but does not reach statistical significance, and the secondary endpoints suggest broader benefits consistent with the hypothesis on the mechanism-of-action," Dr Brookes said.

"In particular, the statistically significant improvement in mild background anxiety points to support for the benefits to the gut-brain axis through assisting the homeostasis of the microbiome dynamics," Dr Brookes said.

"We will be endeavoring to maximize the value of the Garp project while progressing the anti-obesity project concept, and there is already a focus on other opportunities and future directions," Dr Brookes said.

Anatara was unchanged at 0.6 cents with 44.2 million shares traded.

QUEENSLAND INSTITUTE OF MEDICAL RESEARCH BERGHOFER

Queensland Institute of Medical Research Berghofer says that with Altea Investments it will establish a branch of Singapore's Life Science Incubator.

QIMR Berghofer said that Altea Investments was "a portfolio company of Rava Partners, Hillhouse Investment's real assets strategy" and the Queensland office would be the third Life Science Incubator hub, to be operational from October 2025.

The Institute said that the collaboration, to be known as LSI@QIMR Berghofer, aimed "to foster a dynamic ecosystem of health innovation and accelerate biomedical breakthroughs by providing infrastructure, resources, and commercialization opportunities for emerging life science ventures" but did not state whether funding was part of the Life Science Incubator.

QIMR said the partnership would be "a catalyst for collaboration between scientists, investors, startups, and industry, strengthening the financial sustainability and global competitiveness of its partners".

QIMR Berghofer director Prof Fabienne Mackay said the initiative was "a significant milestone for Queensland's biomedical sector".

Altea chief investment officer John Ratcliffe said the company's "core remit was to invest in life sciences infrastructure that provides strategic opportunity and shapes the future of health innovation".

"By supporting purpose-built co-working spaces for medical research, we're helping create the conditions where breakthrough discoveries can thrive," Mr Ratcliffe said.

"These environments foster collaboration, accelerate commercialization and bring together the brightest minds in science and technology," Mr Ratcliffe said.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved expanded coverage for Ryoncil to a further about 104,000,000 insured Americans.

Last year, Mesoblast said the FDA had approved Ryoncil (remestemcel-L, previously known as MSC-100-IV) for children aged two months and older with steroid refractory graft versus host disease (GvHD) (BD: Dec 19, 2024).

Today, the company said that "to date, 37 of the 51 [US] states provide fee-for-service Medicaid coverage for Ryoncil through orphan drug lists or medical exception process, representing 20,000,000 covered lives, or 80 percent of the total Medicaid fee-for-service lives covered".

The company said the remainder would "come on-line [on] July 1, 2025 with mandatory coverage for 24,000,000 lives".

Mesoblast said "commercial plans representing private payers and managed Medicaid have published policies, prior authorization, and formulary lists in place for Ryoncil covering 84,000,000 lives".

"This number does not include the medical exceptions policies for Ryoncil which are in place with the majority of commercial payers," the company said.

The company said many plans did "not publish policies for ultra-rare diseases such as steroid-refractory acute graft versus host disease …, so the number to date is an underestimate of the total commercial coverage already achieved".

Mesoblast was up three cents or 1.85 percent to $1.65 with 4.1 million shares traded.

LUMOS DIAGNOSTICS

Lumos says its Febridx test has been added to the Medicare Fee Schedule in the Palmetto and Novitas regions of the US, at $US41.38 ($A65.09) per test.

In 2023, Lumos said it had received US Food and Drug Administration clearance to market and sell its Febridx point-of-care, finger-prick blood test to differentiate bacterial from viral respiratory infections, following a 2022 rejection as it "did not demonstrate substantial equivalence to the predicate device" (BD: Jul 11, 2022; Jul 3, 2023).

Last year, the company said the US Centers for Medicare and Medicaid Services would reimburse its Febridx infection test $US41.38 a test (BD: Dec 5, 2024).

Today, Lumos said it was in discussions with the remaining five Medicare Administration Contractors, with steps underway to "formalize inclusion to their Medicare fee schedule".

According to the US Centers for Medicare and Medicaid Services website, Palmetto covered Alabama, Georgia and Tennessee, while Novitas covered Arkansas, Colorado, Delaware, the District of Columbia, Louisiana, Maryland, Mississippi, New Mexico, Oklahoma, Pennsylvania and Texas.

Lumos managing director Doug Ward said it was "extremely pleasing to achieve some early wins with two of the seven US Medicare Administration Contractors".

"This is an important and critical step in building the reimbursement framework to support clinical adoption for Febridx," Mr Ward said.

"Manufactured proudly in the US, Febridx is not only addressing a critical clinical need in primary care, urgent care, and emergency medicine, but it is also supporting American jobs and innovation in point-of-care diagnostics," Mr Ward said.

"Lumos looks forward to the day that Febridx has broad US reimbursement coverage across both public and private insurers and the team is working to deliver on that objective," Mr Ward sad.

Lumos was up 0.3 cents or 13.6 percent to 2.5 cents with 13.3 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has Conformité Européenne (CE) mark certification to sell its Advantage-magnetic resonance (MR) recorder and stimulator in the Europe Union.

Last year, Imricor said it had CE mark certification for its Vision-magnetic resonance imaging ablation catheter in the European Union (BD: Mar 6, 2024).

In February, the company said it had CE mark approval for its second-generation Vision-MR ablation catheter for atrial flutter (BD: Feb 19, 2025).

Today, Imricor said the approval was granted under European Union Medical Device Regulations, with commercial launch of its Vision-MR catheter expected in June.

Imricor chair Steve Wedan said "as of today, our entire commercial product portfolio in Europe is approved under [medical device regulations]".

"This was a huge undertaking over the past several years to transition from the old European medical device directive rules to the new, more stringent medical device regulations," Mr Wedan said.

"We will soon commence phasing out the first-generation products from the market, replacing them with these new … CE mark approved devices," Mr Wedan said.

Imricor was up 1.5 cents or one percent to $1.47.

CLARITY PHARMACEUTICALS

Clarity says it has received $11,146,204 under the Federal Government under its Research and Development Tax Incentive program, and will close two trials.

Clarity said it would prioritize its copper-64 and copper-67 Sar-Bis-prostate specific membrane antigen (PSMA) therapeutic and diagnostic trials for prostate cancer, copper-64 Sartate for neuro-endocrine tumors and copper-64 Sar-Bombesin for breast and prostate cancers.

The company said it would close its copper-64 and copper-67 Sartate diagnostic and therapeutic trial for paediatric neuroblastoma as well as its copper-64 and copper-67 Sar-Bombesin trial for castration-resistant prostate cancer (BD: Jul 26, Sep 13, 2023).

Clarity executive chair Dr Alan Taylor said while the company's "current funds are sufficient to continue pursuing our ultimate goal of improving treatment outcomes for people with cancer, we cannot ignore the recent headwinds in financial markets since the US Presidential election in November 2024".

"Some of the most prominent and relevant issues include a fall of over 30 percent in the XBI (US Biotech Index) from its peak in November 2024 to its low in April 2025, as well as corrections in global market indexes, including the S&P500 and Nasdaq in the US, as well as the All Ordinaries and the ASX200 in Australia," Dr Taylor said.

Dr Taylor said other relevant issues were "changes within the US Food and Drug Administration; global tariff and trade war concerns and the collapse of Opthea".

"Despite being external to the company, all of these events have had a deleterious effect on our share price," Dr Taylor said.

"Clarity has taken the view that it is prudent to stretch out the funding runway during this period of volatility by focusing the company's strategy on high-value projects and clinical programs that have high probabilities of success and provide early opportunities for commercialization and to extend our runway into the second half of 2026," Dr Taylor said.

Clarity was up 22 cents or 13.1 percent to $1.90 with 4.2 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has a three-year contract for the Los Angeles, California-based Nusano Inc to supply "high volume" copper-64 for its radio-pharmaceutical products.

Clarity said Nusano's 190,000 square foot factory in West Valley City, Utah could produce more than 37,000 GBq (Gigabecquerels) of copper-64, equal to 18,000 patient doses at 200 MBq (Megabecquerels) per dose with a 48-hour shelf-life, "far in excess of commercial scale demands across multiple large indications".

The company said the agreement complimented its existing US-based suppliers to "ensure seamless, abundant production of this diagnostic isotope as the company is progressing a number of late-stage clinical trials and fast approaching commercialization".

Clarity said Nusano planned to produce other isotopes including copper-67 and actinium-225, both of which were used in its products, in 2025 and 2026.

The company said the deal was effective from yesterday and would have automatic renewal for successive two-year periods.

Clarity executive chair Dr Alan Taylor said "the ability to make isotopes and products in the US for the treatment of the American people is an important advantage in the current geo-political and economic environment".

"By building a supply chain that is fully integrated, from high-volume isotope production, to centralized product manufacture, to delivering these ready-to-use diagnostics to imaging sites in every state of the US on time and on demand, we are aiming to build a model that is impervious to economic and political instability," Dr Taylor said.

INHALERX

Inhalerx says it has appointed Melbourne's Ingenu CRO Pty Ltd as contract research organization for a phase I trial of its marijuana-based IRX-616a for panic disorder.
Inhalerx said the randomized, double-blind, placebo-controlled, single-ascending dose trial would evaluate the efficacy, safety and tolerability of its IRX-616a marijuana inhaler in healthy volunteers, but did not disclose the number of patients.
Last month, Inhalerx said it had a study order with Ingenu CRO Pty Ltd for a phase II trial of IRX-211 marijuana for breakthrough cancer pain (BD: Mar 13, 2025).
In February, Inhalerx said investors would vote to approve Ingenu as its contract research organization, with Ingenu a subsidiary of substantial shareholder Cannvalate Pty Ltd, of which its chief executive officer Darryl Davies and advisor Dr Sud Agarwal were directors, later approving the appointment (BD: Feb 5, 2025).
Today, Inhalerx chief executive officer Darryl Davies said the study order allowed for drug manufacturing timelines to be secured and planning for the phase II trial this year.
Inhalerx was up 0.7 cents or 38.9 percent to 2.5 cents.

NYRADA

Nyrada says its extraordinary general meeting has voted up-to 52.93 percent against the issue of warrants to its directors.
Last month, Nyrada said the meeting would vote to issue chair John Moore 3,600,000 warrants as well as 1,800,000 warrants, each, to directors Marcus Frampton, Dr Rüdiger Weseloh, Dr Ian Dixon and Ruediger Weseloh (BD: Mar 12, 2025).
Today, the company said the issue of warrants to Dr Dixon was defeated with 38,826,596 votes (52.93%) in opposition and 34,533,856 votes (47.07%) in favor.
Nyrada said the issue of warrants to other directors passed, opposed by to 41.58 percent; with the issue of Chess depository interests and broker options passed overwhelmingly.
According to its most recent notice, Nyrada had 210,333,705 shares on issue, meaning that the votes against Dr Dixon's warrants amounted to about 18.5 percent of the company, sufficient to requisition extraordinary general meetings.
Nyrada was unchanged at 11 cents.

IMEX HEALTH SERVICES

Imex says its annual general meeting will vote on its remuneration report and a potential 'second strike' board spill.
Last year, Imex said its shareholders voted up-to 44.1 percent against the issue of options to directors, as well as a 27.03 percent remuneration report first strike (BD: Apr 23, 2024).
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 if passed the directors must stand for re-election within 90 days.
Today, Imex said shareholders would vote to issue 175,810 options to Dr Arango, 37,356 options, each, to Mr Banks, Dr Lingard and Mr Palacio, and 74,711 options to Mr Flynn.
Imex said the meeting would vote on the remuneration report, re-elect Mr Palacio as a director, approve the 10 percent placement capacity, ratify the issue of placement securities and issue placement shares to its managing-director and directors.
The meeting will be held at Level 7, 32 Martin Place, Sydney on May 19, 2025 at 11am (AEST).
Imex was unchanged at 36 cents.

IMRICOR MEDICAL SYSTEMS

Martin Place, Sydney's Greencape Capital Pty Ltd says it has increased its substantial shareholding in Imricor from 20,046,165 shares (6.26%) to 23,277,925 shares (7.27%).
A separate substantial shareholder notice from the Martin Place, Sydney-based Challenger Ltd said it increased its substantial shareholding from 20,046,165 shares (6.26%) to 23,277,925 shares (7.27%).
Earlier this month, a Challenger executive told Biotech Daily that it had a relevant interest in the Imricor securities due to its more than 20 percent holding of Greencape Capital Pty Ltd (BD: Apr 2, 2025).
Today, Greencape said that on April 11, 2025 it bought 229,748 shares for $332,096, or $1.445 a share and on April 14, 2025 purchased 3,002,012 shares for $4,202,919, or $1.400 a share.

RENERVE

Ropehawn Investments Pty Ltd says it has increased its substantial shareholding in Renerve from 8,617,123 shares (6.08%) to 11,096,139 shares (7.79%).
The Melbourne-based Ropehawn said that between January 24 and April 10, 2025 it bought 2,478,672 shares for $285,277, or 11.5 cents a share.
Renerve was unchanged at 10.5 cents.

NEURIZON THERAPEUTICS

Neurizon says it has appointed Kathryn Williams chief regulatory officer, Dr Jeffrey Brown chief scientific officer and Dr Chris Freitag chief medical advisor.
Neurizon said Ms Williams had more than 20 years of industry experience, including working with the US Food and Drug Administration, the European Medical Association and the Australian Therapeutics Good Administration, and had been head of regulatory affairs at Clarity as well as working for Merck, Sandoz, Sanofi and Genzyme.
The company said Dr Brown had worked for Amgen, Pfizer, Bristol-Myers Squib, Alexion, Wave, Voyager and Deep Genomics in research and development and was currently a director of Huntington's Disease Society of America and had "strong ties" with Neurizon's clinical partner Massachusetts General Hospital.
Neurizon said Dr Freitag was a member of its scientific advisory board, had worked for Roche, Shire, BTG (formerly British Technology Group) and Debiopharm, and was chief medical officer to "several emerging biotech companies" dealing with neuro-degenerative diseases, paediatric rare diseases and oncology.
The company said the appointments provided it with "broader expertise in regulatory affairs, clinical development and commercialization".
Neurizon was up two cents or 20 percent to 12 cents.