Biotech Daily

Friday June 13, 2025

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.21 percent on Friday June 13, 2025, with the ASX200 down 17.7 points to 8,547.4 points. Eight of the Biotech Daily Top 40 companies were up, 27 fell and five traded unchanged.

Yesterday's 5.6 percent equal worst, Universal Biosensors, was today's best, up 0.9 cents or 26.5 percent to 4.3 cents, with 214,194 shares traded. Genetic Signatures climbed 7.7 percent; Starpharma was up 3.9 percent; Alcidion and Medical Developments rose more than two percent; Aroa, Compumedics and Curvebeam were up one percent or more; with Cochlear up by 0.2 percent.

Resonance led the falls, down 0.4 cents or 9.8 percent to 3.7 cents, with 198,653 shares traded. Botanix, Clarity, EBR and Optiscan lost more than seven percent; Amplia, Dimerix, Micro-X and Polynovo were down more than six percent; Neuren fell 5.8 percent; Clinuvel, Impedimed, Mesoblast, Pro Medicus, Proteomics and Telix were down three percent or more; Atomo, Avita, Cynata, Emvision and Medadvisor shed more than two percent; Cyclopharm, Orthocell, Paradigm, Prescient, SDI and Syntara were down more than one percent; with CSL, Nanosonics and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: ADHERIUM

By TIM BOREHAM

ASX code: ADR

Share price: 0.7 cents; **Shares on issue:** 758,185,209; **Market cap:** $5.3 million

Financials (March quarter 2025): customer receipts $771,000, cash outflows $2.21 million, cash on hand $684,000 (ahead of $900,000 convertible note raising in May)

Chief executive: Jeremy Curnock Cook (interim)

Board: Lou Panaccio (chair), Mr Curnock Cook, Kevin Gessner, Bruce McHarrie, George Baran

Identifiable major shareholders: Regal Funds Management 24%, Trudell Medical 18%, Phillips Asset Management (Bioscience Medical Translation Fund) 16%

When it comes to medication adherence, humans are strange beasts in that they will go out of their way not to take crucial therapies in the manner intended.

In the case of asthma and chronic obstructive pulmonary disease (COPD), 'puffer' compliance is notoriously low: a staggering 92 percent of asthma users either deploy a poor technique or don't use their inhalers at all.

Children might spray the treatment like a perfume and not inhale it into the lungs. Or the medicine can end up in the back of the throat rather than the bellows.

On the evidence to date, Adherium claims its wrap-around connected Haile monitoring device has improved asthma compliance by 180 percent for kids and reduced "severe exacerbations" in adults by 61 percent.

"Not being able to do one of the most fundamental things in life – breathing – is one of the worst things imaginable," Adherium director Keven Gessner says.

Avoiding the 'frog in boiling water' syndrome

Mr Gessner likens asthma episodes to a frog in boiling water, which doesn't feel the rising heat until it's too late and has croaked it.

"Sometimes asthma and COPD is like sitting in that boiling water, because you get so used to not feeling well that you slowly get sicker and sicker and you don't realize it's boiling until it's too late," he says.

Mr Gessner says most asthma episodes are preventable, while COPD patients could lead much better lives with correct compliance.

A fresh board appointee, the US-based Mr Gessner has a day job at Pfizer, where he is vice president in areas related to digital and remote patient monitoring.

Moulded by his own experience with family and friends, he was drawn to Adherium and its mission of improving monitoring for some of the world's 300 million asthma and 384 million COPD sufferers.

Asthma self-help spurns new company

Originally known as Nexus6, Adherium was founded in New Zealand 2001 by former Microsoft software engineer Garth Sutherland, with the remit of managing his own asthma.

The initial product, the Smartinhaler, was used widely in clinical trials. In 2009, it won US Food and Drug Administration (FDA) clearance under the 510(k)-device pathway.

Adherium debuted on the ASX on August 26, 2015, having raised $35 million at 50 cents apiece in the initial public offer.

A foundation client, pharma company Astrazeneca, invested $3 million.

In mid-2021 fellow ASX-listed respiratory diagnostics counterpart Respiri made a conditional takeover for Adherium, but the entreaty ran out of breath.

The updated device, Hailie, won FDA 510(k) clearance in April 2024 and is approved for use with 15 different puffers.

Initially, Adherium expected Astrazeneca would take the running on Hailie - but that was not to be.

Instead, Adherium operates through key US partner channels. These include hospital groups, payors and hybrid care/payor organizations.

Payment depends on whether Adherium or the partner oversees the ongoing monitoring.

CE-Oh - they've gone

Mr Sutherland led the company until June 2017, after which he was succeeded by Arik Anderson, Mike Motion and Rick Legleiter.

Mr Legleiter stepped down in mid-January 2024 and on February 1 he was replaced with another US candidate, Dr Paul Mastoridis.

In October 2024, the company said the board and Dr Mastoridis had been unable to agree on his employment terms and that Dr Mastoridis would leave in January 2025.

Since then, the company has been in “ongoing dialogue with Dr Mastoridis and his lawyers regarding his cessation of employment”.

Mr Curnock Cook is the interim CEO and the managing partner of long-term shareholder, Bioscience Managers

US focus

Adherium’s Hailie device wraps around conventional puffers and sends digital information about actual flow rates into the lungs. This enables the device to predict medical episodes earlier and avoid hospitalizations.

In 2022, Clinical evidence suggested Hailie had improved asthma compliance by 180 percent for kids and reduced "severe exacerbations" in adults by 61 percent.

But to gain traction, physicians must be paid for their time and the company needs to get a decent cut as well.

Adherium is focused on the US market, where a reimbursement breakthrough three years ago enables just that, with the company signing up partnerships covering one million asthma and COPD patients.

All hail Hailie

Hailie can be used with about 90 percent of the inhalers on the market, including Glaxosmithkline’s Ellipta and Astrazeneca’s Symbicort.

The Bluetooth-enabled Hailies capture physiological data like inhalation flow rates and provide real-time feedback through a software application to both the patient and their doctor.

It also knows whether the device has been shaken (primed).

“You can’t fake our meds,” Mr Gessner says. “If you push it and it shoots out into the air, it senses there has been no inspiration. We make sure the patient it is using the medication correctly and getting the clinical benefit of the drug.”

Crucially, Hailie can also detect whether the patient is losing their ability to inhale properly.

With physician intervention, the device can rescue the ‘frog’ before hospitalization stage.

The company cites 50 peer review studies validating Hailie’s efficacy.

Partnering up

The company operates by two structures, whereby it either oversees the monitoring itself or via a partner.

The company has signed up Allergy Partners, the biggest US asthma medical group with 140 locations in 20 states, servicing 300,000 asthmatics.

“We recruit the patients and monitor them,” Mr Gessner says. “If needs be, we will call up the patient with permission from their GP.”

The second example is a partnership with Intermountain Health, an ‘integrated delivery network’ with 33 hospitals and 85 clinics servicing 250,000 patients.

“They are also payors, so benefit from the fewer hospitalizations.”

Intermountain currently has 730 patients on its program.

The third is AMC Health, the biggest private US remote patient monitoring company with 100,000 patients on its books. To date, AMC Health has ordered 750 Hailies.

Sizing up the opportunity

From its modest base of 1,200 patients at the end of March, Adherium has targeted coverage of 9,000 by the end of 2025.

Allergy Group is expected to sign-up 5,000 patients, with Intermountain and AMC contributing 2,000 each.

Under a 2022 reimbursement breakthrough, Hailie was classed under a Centers for Medicare and Medicaid code, with private payors extending coverage in 2023.

The code provides for a $US55 initial payment and $US50 for every 20 minutes of care time.

This averages out around $US160 per patient per month

Currently the physicians are pocketing $US109 per patient: “revenue that didn’t exist until we came along,” Mr Curnock Cook says.

The company believes this number can increase to $US120-130 per month.

As for Adherium, it expects to pocket $US50-75 per month per patient when it does the onboarding and monitoring and $US30-35 per month when it doesn’t.

Mr Curnock Cook says that with growing interest from payors, the company should have access to two million patients, but the company will take a conservative approach to growth.

Propeller stops turning

Resmed's experience with its acquired Propeller Health business highlights the difficulty of navigating the complex US health and reimbursement channels.

Even sleep apnoea giant Resmed has mis-stepped, having acquired the Wisconsin-based digital therapeutics company Propeller for $US225 million in early 2019.

Resmed has quietly absorbed Propeller into its software-as-a-service business and its website no longer refers to Propeller puffer compliance devices in its suite of products.

Adherium contends that Resmed overlooked the importance of winning physicians' advocacy of the device.

The Bluetooth-connected Propellers measured the number of times the puffer had been pumped, but not flow rates into the lung.

"It measured whether the button had been pressed, but the spray could go anywhere," Mr Gessner says.

Finances and performance

Adherium reported customer receipts of $771,000 in the March 2025 quarter, compared with $148,000 in the December 2024 stanza, with net operating cash outflows of $2.21 million, taking the deficit for the first nine months of the financial year to $8.68 million, and end-of-quarter cash of $684,000, compared with $387,000 at the end of December.

The increase is explained by a $2.6 million convertible note issue, announced in mid-March. The raising was contributed to equally by Bioscience Managers and Trudell Medical, which is associated with director George Baran.

In May, Adherium issued a further $900,000 convertible note, mainly to the same parties.

The notes have a nine-month maturity with a 10 percent a year interest rate.

In mid-March, the company said it was planning a capital raising and "it is comfortable that it is able to do".

The Hailie devices are made in Thailand with components from Singapore, but management expects little impact from the Trump administration's tariff plans.

Adherium shares have ranged between two cents (at various times, most recently late January) and the current lows.

In late 2023, the company consolidated its shares on a one-for-15 basis, from a tad under five billion shares to around 333 million.

Allowing for this, Adherium shares hit a five-year peak of 64 cents in August 2021.

Wot about us?

The lack of reimbursement means Hailie is not available in Australia, but Mr Curnock Cook has urged the Federal Government to add Hailie to its Medicare urgent care clinics.

The company is seeking Federal funding for a program to deliver the Hailie technology to about 5,000 people with severe asthma over three years, at 10 of the urgent care clinics.

“$10 million should do it,” Mr Curnock Cook says.

“Why not use this Australian-based tech to do something serious?”

Adherium says in the 2020-’21-year, asthma patients present 56,600 times to emergency departments, with half of the subsequent hospitalizations relating to asthma.

Dr Boreham’s diagnosis:

Mr Gessner says that given the complexity of the US healthcare maze, Adherium’s network would take decades to replicate.

He adds that no party loses with Hailie.

“Not only are we being paid, but the physicians are getting paid, and the payors can see they can save a ton of money by keeping patients out of hospital.”

So, the big picture is robust.

But investors could be excused for thinking the company has run out of breath, with the shares declining 65 percent over the last year.

Or has Adherium gone beyond the speculative ‘pimping the puffer’ to deliver the goods, having spent $150 million to get to this point?

“We have been around for 13 years, but we are no longer the company we were even a year ago,” Mr Curnock Cook says.

“By the middle of next year there will be no question as to whether we are a real business or not.

“The question is how big and how we manage the growth.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He still inhales and exhales, but finds watching biotech stocks can be an exercise in holding one's breath.

CLARITY PHARMACEUTICALS

Clarity says its 53-patient, phase II trial shows copper-64 Sar-Bombesin can detect "prostate cancer in patients … who are negative or equivocal on standard-of-care".

In 2023, Clarity said it imaged all 50 patients in its non-randomized, open-label 'Sabre' phase II trial, of 64-copper Sar-Bombesin with positron emission tomography (PET) and computed tomography (CT) for detecting prostate cancer (BD: Nov 7, 2023).

Today, the company said copper-64 Sar-Bombesin identified lesions in about 35.2 percent of the 47 evaluable patients on same-day imaging and 27.7 percent of patients on next-day imaging, using the mean average of three blinded central readers.

Clarity said "despite biopsy not being [standard-of-care] for this patient populations, approximately 16 percent of patients who were positive on copper-64 Sar-Bombesin PET/CT were biopsied in the 'Sabre' study".

The company said "all lesions assessed by histopathology were positive for prostate cancer, indicated a 100 percent true-positive rate among those biopsied lesions".

Clarity executive chair Dr Alan Taylor told Biotech Daily the company "found lesions in about one third of patients that were otherwise undetectable by standard-of-care imaging".

"For the biopsies that we were able to do, all four biopsies in three patients were positive," Dr Taylor said.

"We couldn't biopsy the other patients for a range of reasons, primarily the site of the lesion," Dr Taylor said.

The company said participant-level correct detection rate was 14.9 percent on same-day imaging and ranged from 4.3 percent to 14.9 percent on next-day imaging across the three readers.

Clarity said region-level positive predictive value ranged from 22.6 percent to 47.1 percent on same-day imaging, with next-day imaging between 22.2 percent and 37.5 percent.

The company said the correct detection rate and positive predictive value results were impacted by the large number of lesions that were detected but unable to be verified.

Clarity said a total of 49 lesions on same-day imaging and 52 lesions on next-day imaging were identified on copper-64 Sar-Bombesin PET/CT scans "despite these patients having negative or equivocal standard-of-care scans prior to study entry".

The company said copper-64 Sar-Bombesin at 200 megabecquerels (MBq) was safe and well-tolerated with two participants reporting mild adverse events which were resolved within two days of onset.

"The 'Sabre' trial represents an important milestone for Clarity, setting a new benchmark by seeking to identify lesions that do not express [prostate specific membrane antigen]," Dr Taylor said.

"This trial, which is Clarity's first sponsored study with copper-64 Sar-Bombesin, has now shown that this product can provide a solution where the current diagnostic options fall short; and improve lesion detection beyond what is achievable with [standard-of-care] PSMA-targeted imaging," Dr Taylor said.

"Verification of the findings by other means, such as [standard-of-care] imaging, was further complicated by the very nature of the trial, which specifically enrolled patients who were negative or equivocal on all available [standard-of-care] imaging," Dr Taylor said.

"These inherent challenges led to a high number of lesions not being confirmed as true-positives in the study," Dr Taylor said.

"However, the fact that prostate cancer was confirmed in all copper-64 Sar-Bombesin PET-positive lesions, that were biopsied, strongly reinforces the potential clinical value of this agent and the need it may fulfil within the current diagnostic landscape," Dr Taylor said.

Clarity fell 18 cents or 7.7 percent to $2.16 with 3.6 million shares traded.

GEORGE MEDICINES

George Medicines says it has US Food and Drug Administration approval for its Widaplik, formerly GMRx2, for adult hypertension.

A media release from the London and Boston-based George Medicines said it was a spin-out of Sydney's George Institute for Global Health and a member of the Melbourne-based Brandon Capital's Biocatalyst.

Last year, the company said a 1,385-patient, phase III trial showed its GMRx2 triple-combination pill of telmisartan, amlodipine and indapamide was more effective than dual combinations of amlodipine for hypertension (BD: Nov 26, 2024).

Today, George Medicines said Widaplik was a single pill combination and was available in a standard dose and two low doses.

The company said it was "the first and only FDA-approved triple combination medication for use as an initial therapy in patients likely to need multiple drugs to achieve blood pressure goals".

George said it expected a US commercial launch of Widaplik by 2026.

George chief executive officer Mark Mallon said "most patients with hypertension will require two or more medicines to bring their blood pressure under control".

"Widaplik can provide patients with hypertension, including those who are starting treatment, with a different approach to control their blood pressure," Mr Mallon said.

Mr Malon said that further regulatory submissions were expected in 2025.

George Medicines is a private company.

SYNTARA

Syntara says 24-week data from its phase II trial shows SNT-5505 led to eight of 11 evaluable patients with a 50 percent or more improvement of myelofibrosis symptoms.

Last year, Syntara said it dosed all 15 patients in the phase II trial of SNT-5505 with ruxolitinib for the bone marrow cancer myelofibrosis (BD: Jul 31, 2024).

Later, the company said six of 13 evaluable myelofibrosis patients in the phase II trial had a 50 percent improvement of symptoms from baseline at 12 weeks of treatment, with nine patients achieving stable or reduced spleen volume (BD: Dec 10, 2024).

Today, Syntara said that eight of 11 evaluable patients (72.7%) had more than a 50 percent reduction in myelofibrosis total symptom score; and four of nine (44.4%) evaluable patients had a spleen volume reduction of 25 percent at week-24 or beyond.

The company said "there were no increases in dosage of concomitant ruxolitinib that might otherwise explain the impact of SNT-5505 on spleen volume".

Syntara said the continued improvement in patient symptoms and spleen volume was "a novel finding that differentiates SNT-5505 from [myelofibrosis] drugs on market and in later stages of development".

The company said the results showed "the potential of SNT-5505 to be used in combination with [Janus kinase] inhibitors to change the long-term outcomes for [myelofibrosis] patients"; with SNT-5505 safe and well-tolerated, with no treatment related serious adverse events related to SNT-5505.

Syntara said it would engage with the US Food and Drug Administration by October 2025 on the study results as well as the trial design for a phase III study.

Syntara managing-director Gary Phillips said the sustained and increasing improvements in both symptom burden and spleen volume as well as the excellent safety and tolerability continued "to differentiate SNT-5505 from other drugs in this space".

"We are particularly encouraged by the durability of the responses," Mr Phillips said.

Syntara fell 0.1 cents or 1.5 percent to 6.7 cents with 28.95 million shares traded.

MYRIO THERAPEUTICS

Melbourne's Myrio says the US Food and Drug Administration has approved a 38-patient, phase I trial of its PHOX2B PC CAR-T for relapsed neuroblastoma.

Myrio said that with an approved investigational new drug application it would begin enrolment at Pennsylvania's Children's Hospital of Philadelphia in mid-2025.

The company said it had co-developed a chimeric antigen receptor (CAR) T-cell therapy for neuroblastoma with the Children's Hospital of Philadelphia and found "a functionally relevant and highly specific protein, called PHOX2B, was identified in neuroblastoma cells" and a PHOX2B peptide could be a target for immunotherapy.

According to the company's website, Dr Graeme Wald was its chief executive officer, and it was co-founded by chief science officer and director Matthew Beasley as well as chief operating officer and director Dr Ben Kiefel.

Dr Wald said FDA approval to open the trial was "a major step forward for Myrio".

"It is the culmination of many years of work at Myrio in developing bispecific binders to human leukocyte antigens (HLA) for the treatment of solid tumours," Dr Wald said.

Myrio said it had "developed a highly specific binder to the PHOX2B peptide-major histocompatibility complex target using its unique [retained display] technology".

The company said its retained display (RED) discovery platform was "geared towards the discovery of highly stable, full human, [single-chain variable fragment] binders against peptides presented on the surface of solid cancer cells as presented by the HLA complex".

According to the US National Library of Medicine, human leukocyte antigens were genes in major histocompatibility complexes that help code for proteins and played "a significant role in disease and immune defence".

Myrio said its binder had been engineered into a CAR-T product with the Children's Hospital of Philadelphia and unlike other binders which target a single HLA-allotype its binder was "capable of recognizing the peptide in multiple HLA-allotypes, a phenomenon referred to as breaking HLA restriction".

The company said recognizing the peptide in multiple HLA-allotypes meant it could "treat a broader population of patients using the same immunotherapy".

Myrio is a private company.

AUSTRALIAN NATIONAL UNIVERSITY

The Australian National University says it will conduct an up-to 140-patient trial of its PMR-116 for MYC cancers "that are currently undruggable ... later this year".

The University said PMR-116 was an anti-cancer drug being developed by a team led by its Prof Ross Hannan, with the San Diego, California-based Pimera Therapeutics.

The University said the drug inhibited an enzyme to disrupt ribosomal biogenesis, a process hijacked in MYC-driven cancers and had "shown promising results in various cancers in pre-clinical studies".

ANU said the MYC protein regulated cell growth, was "often implicated in cancer, contributing to tumor development", one of the most notorious cancer-causing genes, with tumors driven by MYC over-expression often among the most aggressive.

The University study lead Prof Mark Polizzotto told Biotech Daily the study would enrol 60 patients in the first safety and tolerability stage, with 80 more patients in the second stage, pending results, to assess the primary endpoint of overall response rate.

ANU said the trial would study PMR-116 for a range of MYC-driven cancers, including prostate, breast, ovarian and haematological cancers, at Canberra Hospital, Melbourne's Peter MacCallum Cancer Centre and Sydney's St Vincent's Hospital.

CONTROL BIONICS

Control Bionics says it expects record revenue for the year to June 30, 2025, with unaudited 11-month revenue to May 31, 2025 up 14 percent to about $5.4 million.

Last year, Control Bionics said revenue for the year to June 30, 2024 fell 5.17 percent to $5,350,774, with loss after tax up 5.02 percent to $5,913,779 (BD: Aug 28, 2024).

Today, the company said the increased revenue was “driven by strong performance in the US and growth in Australia” from sales of its disability communications technology including Neuronode.

Control Bionics said it was trialling its Neurostrip wearable sensors in Japan, the US and Australia and its Neurobounce continued “to gain commercial traction as a compelling application of our [electromyography] technology in the sports performance market”.

Last year, the company said it had acquired 20 percent of the Salt Lake City, Utah’s Neuro Elite Athletics for $US250,000 ($A392,000) and that its Neurostrip wearable sensors would be used by Neuro Elite Athletics for training US athletes and for rehabilitation by Stroke Lab in Japan (BD: Dec 16, 2024).

At that time, Control Bionics said Neuro Elite Athletics used its Neurostrip electro-myography product in its Neurobounce program, which trained athletes to increase their vertical leap “by five to 15 cm … in just eight sessions”.

Today, the company said it had completed the first Neurobounce program in Australia with five basketballers from Melbourne’s Sports Education and Development Australia (SEDA) College, which showed that in four weeks all participants “increased their vertical jump eight by at least 5.0cm”.

Control Bionics said one basketballer “achieved an extraordinary 14.0cm increase in vertical jump height”, with sprint pace improved materially across the group.

Control Bionics was up 0.1 cents or 3.3 percent to 3.1 cents.

ADALTA

Adalta says it has placed $193,830 of its $209,548 shortfall from its one-for-three entitlement offer at 0.3 cents a share, taking the total raised to $1,284,282.

Last week, Adalta said that it had raised $1,090,452 of a hoped for $1,300,000 at 0.3 cents a share, a 50.8 percent discount to the 15-day volume weighted average price, in its two-for-three rights offer (BD: May 1, Jun 3, 2025).

The company said at that time that it had a $209,548 shortfall.

Today, Adalta said that the shortfall was taken up by an unnamed “single, sophisticated investor” and it would issue options to the investor, which were exercisable at one cent each by June 3, 2028.

Adalta said that as part of the shortfall, placement shares and options previously issued to two of its non-executive directors would be sold to the investor “on the same terms as other securities issued”.

The company said that “due to an administrative error in the calculation of entitlements and the application of subscription funds, these securities were incorrectly applied for and paid for by the directors as part of the rights issue, resulting in their allocations exceeding their entitlements”.

Adalta said the funds raised would be used for product licencing in its “East to West” cellular immuno-therapy program, business development transactions for AD-214 and WD034 as well as evaluating other strategic options and general working capital.

Adalta was unchanged at 0.25 cents.

INVION

Invion says it expects to raise between $1 million and $16 million through the issue of 77 “loyalty options” for every 100 shares owned, as well as “piggyback options”.
Invion said that eligible shareholders could subscribed for 77 “loyalty options” for every 100 shares held at the record date, at an issue price of 1.5 cents per option.
The company said the options were exercisable at 14 cents each until June 30, 2027.
Invion said for every two “loyalty options” exercised before December 31, 2025, shareholders would receive one “piggyback option” at no cost, exercisable at 21 cents each until June 30, 2027.
The company said the offer was expected to raise up-to about $1 million, if investors took up their entitlements, with an additional about $16 million to be raised subject to the exercise of all “loyalty options” and “piggyback options”.
Invion said the funds raised would be used for its phase I/II non-melanoma skin cancer trial, a phase I/II anogenital cancer trial and working capital.
The company said an indicative timetable including the record date, opening date and closing date of the offer would “be release to the ASX in due course”.
Invion was up 1.5 cents or 12.5 percent to 13.5 cents.

DIMERIX

Dimerix says it has randomized 200 patients in its up-to 286-patient, ‘Action’ phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS).
In 2022, Dimerix said it had recruited the first of 286 patients in the trial of DMX200 for FSGS kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).
Last month, the company said it completed the sixth scheduled independent data monitoring committee review, which evaluated the available study data for participant safety, study conduct and progress, with no changes (BD: May 22, 2025).
Today, Dimerix said based on expected recruitment rates at each site, full recruitment of patients was “on track to complete in the second half of calendar year 2025”.
Dimerix fell 3.5 cents or 6.25 percent to 52.5 cents with 2.3 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed a nine-year-old erythropoietic protoporphyria patient with Scenesse, in Switzerland, the youngest known patient to have received the drug.
In 2022, Clinuvel said it applied to the European Medicines Agency (EMA) to expand the Scenesse, or afamelanotide 16mg, label to include adolescent patients with EPP light intolerance (BD: Sep 5, 2022).
In 2023, the company said the EMA wanted more data for the application and last year, said it withdrew the submission and was “preparing a future submission containing additional data” (BD: Sep 5; Jun 3, 2024).
Earlier this year, the company said its 28-patient trial of Scenesse for erythropoietic EPP showed it had an “equivalent safety profile between adults and adolescents”, with higher active drug detectable in adolescent patient blood samples (BD: Feb 10, 2025).
Today, Clinuvel said the nine-year-old female patient was treated with Scenesse in Switzerland and was suffering from severe phototoxicity.
The company said it aimed to refile an application to extend Scenesse for use in adolescent patients to the EMA “later this year”.
Clinuvel fell 35 cents or 3.4 percent to $9.83 with 145,977 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says Dr Philippe Wolgen has returned to the business as full-time managing-director, with Lachlan Hay to continue as chief executive officer until October 2025.
Earlier this year, Clinuvel said chief operations officer Mr Hay was appointed acting chief executive officer and that its existing executive team would assume managing-director Dr Phillipe Wolgen's day-to-day responsibilities for up to three months, while Dr Wolgen took temporary leave to seek medical treatment (BD: Mar 18, 2025).
Today, the company said Dr Wolgen would "focus in the short-term on advancing specific product development and corporate projects".
Dr Wolgen said "while I remain active in the business and its direction, I have advised the board that the temporary reduction of my operational involvement will result in the fastest path to full health".
"Time away from the day-to-day demands of running the group has given me the opportunity to consider where management energy should be focused and how we structure the next critical phase of Clinuvel, with much of this work to be delivered in the next three months," Dr Wolgen said.

BTC HEALTH

BTC says it has appointed Martin Kahanovitz as a non-executive director of the company.
BTC said Mr Kahanovitz was chief financial officer of the Kahma Healthcare Group and a director of the Biologicals and Vaccine Institute of Southern Africa Pty Ltd.
The company said that Mr Kahanovitz had about 30 years' experience in the biotechnology, pharmaceutical and medical industries.
BTC said Martin Kahanovitz was chief commercial officer Josh Kahanovitz's uncle.
BTC was unchanged at 5.2 cents.