



# Biotech Daily

Friday November 18, 2022

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.23 percent on Friday November 18, with the ASX200 up 16.1 points to 7,151.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and one was untraded.

Resonance was the best, up 0.5 cents or 7.7 percent to seven cents, with 14,030 shares traded. Nova Eye was up 7.1 percent; Alcidion, Emvision and Micro-X climbed six percent or more; Actinogen, Avita and Pharmaxis improved more than four percent; Dimerix was up 3.45 percent; Patrys rose 2.6 percent; Antisense, Kazia, Nanosonics and Proteomics were up one percent or more; with Cochlear, CSL and Neuren up less than one percent.

Universal Biosensors led the falls, down two cents or 7.7 percent to 24 cents, with 176,765 shares traded. Starpharma lost seven percent; Cynata shed 5.7 percent; Cyclopharm, Impedimed and Orthocell fell four percent or more; Immutep and Prescient were down more than three percent; Imugene, Medical Developments, Oncosil and Polynovo shed more than two percent; Clinuvel, Opthea and Telix were down more than one percent; with Genetic Signatures, Next Science, Pro Medicus and Resmed down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: ADHERIUM](#)

**By TIM BOREHAM**

**ASX code:** ADR

**Share price:** 0.4 cents; **Shares on issue:** 4,775,195,536; **Market cap:** \$19.1 million

**Financials (year to June 30 2022):** revenue \$529,000 (up 32%), loss of \$11.22 million (previously a \$15.04 million loss), cash of \$5.28 million (down 65%)

**September quarter 2022:** receipts \$578,000, cash outflows \$3.09 million, cash of \$17.2 million (after a \$13.5 million capital raise finalized in October. A share plan is pending)

**Chief executive:** Rick Legleiter

**Board:** Lou Panaccio (chair) James Ward-Lilley, Jeremy Curnock Cook, Dr William (Bill) Hunter, Bruce McHarrie, George Baran

**Identifiable major shareholders:** Bioscience Managers 23.16%, Trudell Medical 19.91%, Regal Fund Managers 4.91%

Adherium chief Rick Legleiter is crystal clear about what really counts when it comes to commercializing a device - in this case gadgets to improve adherence to medications for asthma and chronic obstructive pulmonary disease (COPD).

“In real estate it’s about location, location, location; in health care it’s about reimbursement, reimbursement and reimbursement,” he says.

“If the products are not getting reimbursed, the doctors aren’t being paid for their services and consumers don’t want to pay. That makes it hard to get market access to scale and grow.”

In effect, Mr Legleiter is referring to the human trait of being willing to spend perhaps \$150 a month on café lattes, but baulking at shelling \$30 or so on something that will improve their health.

Originally, Adherium supplied the big pharmaceutical companies with its Hailie device, for their clinical trials. Now Adherium is moving to another phase altogether, with the rollout of internet-connected devices that generate more meaningful usage data.

This foray is pitched at the emerging remote patient monitoring (RPM) sector, with the company signing up anchor clients and partners to underpin this push.

Having just raised \$13.5 million in a placement, Adherium has the breathing space (pardon the pun) to pursue its remote patient monitoring ambitions.

Adherium is targeting a subset of difficult-to-treat and severe patients, who are at extra risk of dying.

## **About Adherium**

Originally known as Nexus6, Adherium was founded in 2001 by Kiwi engineer Garth Sutherland, who sought a tech-driven approach to managing his own chronic asthma.

The first product, Smartinhaler, stemmed from this.

In 2003, the company produced its first product for clinical trials and in 2009 won US Food and Drug Administration clearance under the 510(k) device pathway.

After a number of seed raisings, 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, Astrazeneca, invested \$3 million.

Mr Sutherland led the company post-listing and until June 2017, when he was replaced by Arik Anderson who in turn was succeeded by Mike Motion. However, Mr Motion did not prove perpetual and was replaced by Mr Legleiter in May 2021.

The Kansas-born Mr Legleiter was formerly the chief executive officer of ASX-listed device play Universal Biosensors and has worked extensively in healthcare in Germany and the US.

Adding later fizz to the Adherium story, ASX respiratory diagnostics counterpart Respiromics made a conditional takeover approach in mid-2021, but the entreaty went nowhere.

## **Pimping up the puffer**

The Hailie sensors wrap around standard inhalers to measure inhalation flow rates, usage and adherence. More than 180,000 Hailies have been sold to date (predominantly for clinical trial use).

The broader Hailie platform provides remote monitoring of medication dosage and adherence for clinicians and other healthcare providers.

The next-generation Bluetooth-enabled Hailies capture data and provide real-time feedback to the patient - and their doctor - through a software application, with the data sharing enabled through software tools.

Hailie is the first and only digital sensor of its ilk with physiological data to be approved under the FDA's 510(k) pathway. The original Hailies are compatible with 90 percent of the top 20 US medication brands by sales volume, while the next-generation ones cover about one-third of the market at this stage.

So far, the Hailie mark twos have been cleared by the FDA for two leading inhalers: Glaxosmithkline's Ellipta and Astrazeneca's Symbicort. An application for Glaxosmithkline's pressured dose inhalers and Teva Pharmaceuticals' Proair has also been lodged

Adherium's key premise is that adherence is poor, with 92 percent of asthma users either deploying a poor technique or not using the inhalers altogether.

"If used incorrectly, the medicine ends up in the mouth and back of their throat rather than their lungs," says Mr Legleiter.

On evidence to date, Adherium claims Haile has improved asthma compliance by 180 percent for kids and reduced "severe exacerbations" in adults by 61 percent.

## **RPM revs up**

In July, US remote monitoring specialist Perigon Health 360 signed up to distribute the next-generation Hailie sensors, while Hailie has also been incorporated into Perigon's proprietary platform, Medesto.

In September, chronic care management leader Dulcian Health agreed to deploy Hailie, thus triggering reimbursement.

In the UK, medical technology mob Helicon Health has also signed up to distribute the Hailies, although reimbursement does not yet apply in the Old Dart.

Adherium teamed up with Carecentra Inc to integrate the New York-based software company's artificial intelligence driven 'behavior shaping' platform. In effect, the resulting respiratory risk management system helps patients with exacerbations before they end up in the emergency department.

## **Reimburse me**

Adherium is leveraging the crucial US reimbursement codes for "remote physiological monitoring" (respiratory flow rates) won back in 2019 (the ensuing pandemic meant not too much happened in the interim).

The scope of reimbursement was expanded to remote monitoring, for inhaler use, in January this year.

Mr Legleiter explains, this reimbursement creates a new revenue source for doctors and hospitals.

For generating the data, the doctors receive a fee of \$US55.72 (\$A82.69) per patient per month and then additional \$US50.18 for a 20-minute consultation, to discuss aspects such as their maximum and average flow rates.

(There wasn't much for the doctors to talk about with the old devices because it was binary outcome: they were either being used, or not)

If the medicos spend another 20 minutes, they get another \$US40.84.

As Mr Legleiter says: “Data is money and Adherium gets paid generating and transmitting patient data and insights.”

Adherium models per-patient revenue of \$US1,270 to \$US1,760 a year of reimbursement for the doctors. For the company itself, this translates to per-patient US\$180 to \$US360 a year, derived from both subscriptions and data.

### **Self-insured employers? Sounds like a plan**

Adherium is also eyeing an alternative market: US companies that run their own health insurance schemes for their employees with a per-member, per-month revenue model.

About three quarters of all US employers with more than 500 staff self-insure with at least one plan.

Typically, these are managed by a health insurer, but the company bears the underwriting risk.

Adherium wants to gather as much ‘real world’ evidence as possible to convince these employers that Hailie would more than pay its way, by way of reduced absenteeism and hospitalizations.

At a time of skills shortages, providing Hailie with health plans could also help to attract and to retain staff.

Adherium hopes to sign its first self-insured payor in the 2023-'24 year.

### **Finances and performance**

In the pandemic era of big-ticket fiscal and monetary stimulus, the denominations of ‘trillions’ and ‘billions’ became devalued as governments and central banks dispensed gazillions of dollars of support.

But in the context of ASX stocks, we’re still impressed when a company issues billions of shares almost equivalent to its market capitalization - as Adherium has done.

In October, the company pocketed \$13.5 million in gross proceeds from a placement of 2.7 billion ordinary shares for the princely consideration of half a cent a share. A follow-on share purchase plan will be announced “in due course”.

The three-stage placement was supported by key Adherium shareholders, Trudell Medical and Bioscience Managers Translation Fund, plus an unnamed institution, now believed to be Sydney’s Regal Funds.

Totaling 2.547 billion shares - give or take - the first two tranches were approved at an extraordinary general meeting in October (they exceeded the company’s placement capacity).

The remaining tranche of 152.5 million shares to Trudell needs to be approved at the company's AGM on November 30, as this will take Trudell beyond the 19.9 percent takeover threshold.

The raising was accompanied by an unlisted option to buy an ordinary share at an exercise price of one cent each by March 31, 2024. Investors receive one option for every two shares subscribed for, which would raise a further \$13.5 million if fully exercised.

As a show of support, chair Lou Panaccio agreed to take up 20 million shares.

Meanwhile, Adherium reported modest revenue of \$529,000 for the year to June 2022 and a \$11.2 million loss. This underlies the importance of the capital raising.

The September quarter sales receipts of \$578,000 reflected clinical trial services and - importantly - the first revenues from remote patient monitoring activities.

Adherium shares over the last 12 months have traded between two cents (October last year) and their current all-time low of 0.4 cents. The stock hit a record 70 cents in October 2015. Post raising, Adherium has more than 4.775 billion shares on issue, so we feel a share consolidation coming on.

### **Dr Boreham's diagnosis:**

Adherium's quest is clear: "our goal is to get to 80,000 patients by 2024, which would be one percent of the 8.5 million serviceable market of severe or difficult to treat patients".

The company also has clear and quantified targets, including one healthcare system in the US (such as a hospital chain), or the local equivalent by 2023, with three by 2024 and 10 by 2025.

Then there are the asthma and chronic obstructive pulmonary disease (COPD) clinics and of course the remote health providers already monitoring for cardiovascular disease or diabetes.

"This is really going to be the new standard for preventative treatment," Mr Legleiter says.

"We want to give the doctors the information to intervene before these patients are admitted to hospital."

He says with elderly COPD patients, there's a tendency to "just get by" and keep a stiff upper lip - probably a blue one.

"You don't want them just getting by because the next thing is they will be in an ambulance," he says. "This technology has a fantastic opportunity to help people."

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he adheres to breathing and that is surely a convenient qualification for writing puff(er) pieces.***

## [ARGENICA THERAPEUTICS](#)

Argenica says its phase I safety and tolerability trial of ARG-007 will progress to a third escalated dose cohort, following a safety committee review.

Argenica said that no serious adverse side effects were observed in the eight participants dosed in its second cohort.

The company said that three participants had “non-serious adverse events that were possibly related to the administration of ARG-007” but the study was blinded and it was not known whether the participants received ARG-007 or placebo.

In September, Argenica said the 32-subject, dose-escalation, phase I trial would assess the safety and tolerability of intra-venous ARG-007, which was intended to reduce brain damage during stroke (BD: Sep 7, 2022).

Argenica said the trial was taking place at the Perth, Western Australia-based Linear Clinical Research.

Argenica fell 1.5 cents or 2.5 percent to 59.5 cents.

## [RESPIRI](#)

Respiri says the Minnesota Lung Centre will assess its Wheezo asthma monitor in its chronic obstructive pulmonary disease and asthma remote patient monitoring system.

Respiri said the Minneapolis-based Lung Centre would employ Wheezo through its partner Access Telehealth over three months for the monitoring of an initial 20 asthma and chronic obstructive pulmonary disease patients.

Respiri chief executive officer Marjan Mikel said the Minnesota Lung Center opportunity was “a watershed moment for Respiri given they are the first major respiratory healthcare organization to choose our Wheezo [remote patient monitoring product].”

Respiri was up 0.2 cents or five percent to 4.2 cents.

## [PARADIGM](#)

Paradigm says it has received \$7,409,117 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Paradigm said the rebate related to research and development expenditure for the year to June 30, 2022.

Paradigm was unchanged at \$1.54.

## [BIOTRON](#)

Biotron says it has received \$1,430,725 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Biotron said the rebate related to research and development expenditure for the year to June 30, 2022.

Biotron was up 0.2 cents or 5.6 percent to 3.8 cents with 4.15 million shares traded.

## [NYRADA](#)

Nyrada says it has received \$1,168,831 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nyrada said the rebate related to research and development expenditure for the year to June 30, 2022.

Nyrada fell 1.5 cents or 11.1 percent to 12 cents.

## IMUGENE

Imugene says investors voted a 27.05 percent remuneration report first strike, with up to 37.1 percent against the issue of up to 27,100,000 options to directors.

Imugene said 459,022,555 votes (27.05%) opposed the adoption of the remuneration, with 1,238,190,075 votes (72.95%) in favor.

The company said the issue of 400,000 options to Dr Jakob Dupont was opposed by 730,803,119 votes (37.13%), with 1,237,199,743 votes (62.87%) in favor.

Imugene said resolutions proposing the grant of options to other directors, the re-election of directors Paul Hopper and Leslie Chong, and the renewal of the employee share option plan faced significant opposition.

According to its most recent filing, Imugene had 6,350,956,474 shares on offer, meaning that the 730,803,119 votes opposing Dr Dupont's options amounted to 11.5 percent of the company, sufficient to requisition extraordinary general meetings.

Imugene fell half a cent or 2.6 percent to 18.5 cents with 20.2 million shares traded.

## MACH7 TECHNOLOGIES

Mach7 says up to 24.7 percent of annual meeting votes opposed the grant of 1110,00 options to four directors and 723,000 rights to managing-director Michael Lampron.

Mach7 said that 17,475,989 votes (24.72%) opposed the grant of options to director Robert Bazzani, with 53,221,472 votes (75.28%) in favour.

The company said resolutions to grant options to Dr Eliot Siegel and Phillippe Houssiau faced similar opposition, with 21.09 percent against the 10 percent placement facility 17.52 percent opposing the issue of options to chair David Chambers and 16.02 percent opposing Mr Lampron's performance rights.

Mach7 said that the remuneration report and amendments to the constitution passed more easily with Mr Bazzani re-elected overwhelmingly.

According to its most recent filing, Mach7 had 238,826,048 shares on offer, meaning that the votes opposing Mr Bazzani's options amounted to 7.3% of the company, sufficient to requisition extraordinary general meetings.

Mach7 was up half a cent or 0.8 percent to 60.5 cents.

## RESMED

Resmed says its annual general meeting voted up to 11.04 percent against the election of directors Richard Sulpizio and Ronald Taylor.

Resmed said 12,686,008 votes (11.04%) opposed Mr Sulpizio election, with 102,238,286 votes (88.96%) in favor, and a similar level opposed Mr Taylor's election.

The company said all other resolutions passed by a wider margin, except the advisory vote on compensation to named executives, which faced 10.06 percent opposition.

According to Resmed's most recent filing the company had the equivalent of 146,459,048 US shares on issue, meaning that the opposition to Mr Sulpizio amounted to 8.66 percent of the company.

As a foreign domiciled company, Resmed is not subject to the ASX rule that five percent of shareholders can requisition extraordinary general meetings.

Resmed fell nine cents or 0.3 percent to \$33.43 with 1.2 million shares traded.



### ANTISENSE THERAPEUTICS

Antisense says shareholders at its annual general meeting voted more than 17 percent opposition to its employee share plan and remuneration report.

Antisense said 34,858,171 votes (17.44%) opposed the employee share plan, with 164,985,021 votes (82.56%) in favor, and the remuneration report faced similar opposition, while 10 percent placement facility faced 10.66 percent opposition.

According to its most recent filing, Antisense had 668,793,978 shares on offer, meaning that the votes against the share plan amounted to 5.21 percent of the company, sufficient to requisition extraordinary general meetings.

Antisense was up 0.1 cents or one percent to 9.9 cents.

### NANOSONICS

Nanosonics says its annual general meeting voted up to 12.6 percent opposition to its omnibus equity plan and employee share plan.

Nanosonics said 23,301,299 votes (12.63%) opposed the omnibus equity plan, with 161,151,734 votes (87.37%) in favor.

The company said the issue of securities under its employee share plan and the issue of 283,930 share appreciation rights and 231,914 performance rights to chief executive officer Michael Kavanagh faced similar opposition.

Nanosonics said that the re-election of director Marie McDonald, the adoption of the remuneration report, the issue of service rights to Mr Kavanagh and an increase in the directors' pay pool all passed by wider margins.

According to its most recent filing, Nanosonics had 302,027,879 shares on issue meaning the votes against the omnibus equity plan amounted to 7.7 percent of the company, sufficient to requisition extraordinary general meetings

Nanosonics was up six cents or 1.3 percent to \$4.58 with 2.1 million shares traded.

### CONTROL BIONICS

Control Bionics says it will release 40,148,122 shares from ASX escrow, as well as 9,604,212 shares from voluntary escrow on December 7, 2022.

According to its most recent filing, following the release from escrow, Control Bionics will have 90,479,028 shares on issue on the ASX.

Control Bionics was untraded at 18 cents.

### VISIONEERING TECHNOLOGIES

Thorney and Tiga say they have increased their substantial holding in Visioneering from 6,001,449 shares (24.35%) to 11,607,173 shares (37.05%).

The Melbourne-based Thorney and Tiga, or Thorney Investment Group Australia, said that between November 7 and November 17, 2022, they bought and converted shares in Visioneering, with the largest single acquisition 4,805,439 shares by conversion of notes for \$1,874,121, or 39 cents a share.

Visioneering was unchanged at 30 cents.

## [MICRO-X](#)

Acorn says it has increased its substantial holding in Micro-X from 30,102,750 shares (6.52%) to 45,097,950 shares (9.29%).

The Melbourne-based Acorn said that between September 7 and November 16, 2022, it bought and sold shares in Acorn, with the largest purchase 13,650,000 shares for \$1,778,404, or 13 cents a share.

Micro-X was up 0.75 cents or six percent to 13.25 cents.