



Biotech Daily

Friday September 11, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMMUTEP UP 27%; PARADIGM DOWN 16%**
- * **DR BOREHAM'S CRUCIBLE: BOTANIX PHARMACEUTICALS**
- * **IMMUTEP: 'EFTI BATCH CAUSED DISCONTINUED TACTI-004 TRIAL'**
- * **PARADIGM DRAWS \$2.8m TRANCHE 4 OF OBSIDIAN NOTE**
- * **PYC DOSES 1st PHASE Ib EXTENSION PKD PATIENT**
- * **CONTROL BIONICS 1.75m CEO JEREMY STEELE OPTIONS AGM**
- * **REGAL REDUCES TO 10% OF ARTRYA**
- * **HARBOUR REDUCES TO 10% OF PACIFIC EDGE**

MARKET REPORT

The Australian stock market fell 0.89 percent on Friday September 11, 2026, with the ASX200 down 78.2 points to 8741.2 points.

Fifteen of the Biotech Daily Top 40 companies were up, 17 fell, seven traded unchanged and one was untraded.

Impedimed was the best (see below), up 1.2 cents or 27.3 percent to 5.6 cents, with 73.3 million shares traded.

Saluda climbed 10 percent; Micro-X was up 5.6 percent; Prescient and Syntara improved more than four percent; Actinogen was up 3.45 percent; Alcidion and Aroa rose more than two percent; Emvision was up 1.2 percent; with Artrya, Clinuvel, Imricor, Nanosonics, Neuren and Resmed up by less than one percent.

Paradigm led the falls, down 4.5 cents or 15.8 percent to 24 cents, with 13.4 million shares traded, followed by Starpharma down eight cents or 10.2 percent to 70.5 cents with 3.9 million shares traded.

Atomo and EBR lost more than seven percent; Imugene and Telix were down more than six percent; 4D Medical, Cyclopharm and Optiscan were down more than three percent; Avita, Cochlear, Compumedics, Medical Developments and Orthocell fell two percent or more; Clarity, CSL, Polynovo, Pro Medicus and Resonance were down one percent or more; with Mesoblast down by 0.9 percent.

DR BOREHAM'S CRUCIBLE: BOTANIX PHARMACEUTICALS

By **TIM BOREHAM**

ASX code: BOT

Share price: 1.9 cents; **Shares on issue:** 2,736,612,800; **Market cap:** \$52.0 million

Chief executive officer: Dr Howie McKibbon

Board: Vince Ippolito (president and executive chair), Dr William Bosch, Dr Stewart Washer, Danny Sharp, Dr Patricia Walker (founder and executive director Matt Callahan stepped down in May last year for medical reasons)

Financials (year to June 30, 2026): revenue \$33.8 million (up 487%), net loss \$69.76 million (\$86.39 million deficit previously), cash of \$36.6 million (down 43%)

Major identifiable holders: Shenasaby Investments (Callahan family) 1.99%, Caperi Pty Ltd 1.92%, Zenith Pacific 1.7%, LLD Diamond Tools 1.4%, Dr Henry William Bosch 0.79%, Dr McKibbon 0.66%, Mr Ippolito 0.61%

Botanix chairman Vince Ippolito highlights the company's impressive feat in bringing a new dermatology drug to the US market.

In June 2024, the US Food and Drug Administration (FDA) approved Botanix's Sofdra, for excessive underarm sweating (primary auxiliary hyperhidrosis). The company started selling in earnest in February 2025 and racked up 105,994 prescriptions in the year to June 30, 2026.

"Seven years ago, we were selling a dream," Mr Ippolito told investors recently. "Some of you might say we were selling a fantasy but ... in pharmaceuticals it's a binary world when you get something approved."

Mr Ippolito adds that the biggest risk in pharmaceuticals is not regulatory assent, but subsequent execution: "The company is executing really, really well," he says.

Sadly, though, Botanix is not a case of achieving the Great American (pharma) Dream, with the company's valuation tumbling 86 percent over the last year.

A heavily discounted capital raising has weighed on the stock, while margins have been lower than what the market expected.

Investors are unimpressed by the generous board and executive remuneration (see below). But management is on a health kick to improve margins, cut costs and boost sales.

Sweating bullets

Primary axillary hyperhidrosis (PAH) is caused by sweat glands becoming overstimulated by acetylcholine binding to M3 receptors, thus triggering the excessive sweat.

PAH afflicts about 10 million Americans, about 3.7 million of whom have sought treatment and is the third biggest dermatological condition behind acne (40-50 million suffers) and atopic dermatitis, or eczema, (20-25 million).

"If it was freezing in here, if I had PAH I would be sweating through my coat," Dr McKibbon told a comfortably warm audience.

Sofdra (sofpironium bromide) selectively binds to - and blocks - the M3 receptors to reduce sweat at the source.

Current treatments include strong topical anti-perspirants, aluminium chloride products and lashings of Brut 33.

In severe cases there's invasive Botox or surgery (nerve cutting)

Botanix claims that Sofdra avoids the common side effects of other therapies. These include drowsiness, constipation, dry mouth and even blurry vision.

Skin in the game

Dr McKibbon has had 25 years' experience in the pharmaceutical industry, starting at Wyatt Pharma "which made everything from [lip balms] to anti-depressants".

Wyatt was sold for \$US20 billion. Dr McKibbon was a junior employee at the time but found such huge amounts to be "interesting".

He then worked for Cephalon when it had a \$US50 million capitalization, before the company went on to be acquired by Teva for \$US6.9 billion.

He met Mr Ippolito at Medicis Pharma "which we built up to be the largest independent dermatology company in the world."

The company sold for \$US2.6 billion. They then went to Nasdaq start-up Anacor, which developed products for eczema and toenail fungus.

Pfizer picked up that one for – "kerching!" - \$US5.2 billion in 2016.

About Botanix

Botanix was founded by parties including lawyer Matt Callahan, Caperi (a financial investor) and scientist Dr William Bosch and back-door listed in July 2016, using the shelf of Perth's Bone Medical.

At the time, Botanix aimed for synthetic cannabinoid treatments for skin diseases including acne, rosacea, atopic dermatitis (eczema) and psoriasis.

After a drug failed its trial in 2019, the company renounced the weed and in 2022 paid \$US4 million to acquire Sofdra from the cash-strapped Nasdaq-listed Brickell Biotech (now Fresh Tracks Therapeutics).

In search of US expertise, the board hired Messrs Ippolito and McKibbon in 2019. Mr Ippolito took over as (executive) chair from the late Graham Griffiths in February of that year. Initially chief operating officer, the Phoenix, Arizona-based Dr McKibbon was anointed CEO in August 2023.

Dr McKibbon said pursuing cannabidiol (CBD) to phase III would have been costly, with no guarantee of success.

"We went to the board and said 'let's look at what's available in the market' and we found Sofdra."

Given Brickell had spent \$US120 million on the drug, “we got a great deal”.

Based in Australia, Botanix is, in effect, a US company (where Sofdra was developed).

In May last year, Mr Callahan stepped down from the Botanix board for health reasons. Mr Callahan co-founded the ASX-listed nerve regeneration play Orthocell and eye drug developer Dimerix as well as the psychedelics play Emyria.

A solid platform

In July last year, Botanix shares lost more than half their value when the company revealed the extent to which intermediaries were eroding the company’s gross to net (GTN) margin.

“They take a lot of money from you,” Dr McKibbon says. “We created a platform where we have direct to patient distribution and skip the wholesaler”.

Typically, a wholesaler takes a 20 percent cut. The ‘captive’ distribution partner is called Sendrx

“Our platform takes the complicated system we have in the US and cuts out the middleman,” Dr McKibbon says.

Sendrx send the prescription straight to the pharmacy electronically, with the chemist holding Sofdra inventory on consignment.

As well as improving margins, the patient is sent a refill automatically, after 27 days.

Dr McKibbon says the average re-fill rate for derma drugs is 1.8 per year. Via the platform, Botanix manages 5.1.

Dr McKibbon says Botanix has been in discussions about distributing other drugs on the platform – a key plank of the company’s productivity improvement drive.

Finances and performance

Botanix reported \$33.8 million of net revenue for the year to June 2026, with a loss of \$69.7 million (improved on the previous \$86.4 million deficit).

The company sold 105,794 prescriptions during the year, up 527 percent. June quarter scripts rose 145 percent to 33,358, while the company shipped a record 12,895 bottles in the month of June.

Botanix chalked up gross revenue for the year of \$US152 million, equating to a GTN ratio of 22 percent (compared with 20 percent a year previously). While a 20 percent GTN is acceptable in the pharmaceutical dermatology world, Botanix strives to increase it to 30 to 40 percent.

In February this year, the company said it would raise \$45 million in a two-tranche placement and share purchase plan at 6.0 cents a share - a massive 45 percent discount.

The offer included one-for-one options, exercisable at 6.0 cents by the end of January 2027. Barring a miracle, that one looks like a duster.

In April last year, Botanix raised \$40 million via a placement at 33 cents apiece (a 7.0 percent discount).

After the FDA's 2024 approval, Botanix tapped investors for \$70 million in a placement at 30 cents a share.

A year ago, the company unveiled a US\$30 million (\$A48 million) 9.9 percent interest per year debt facility with Kreos Capital, an arm of asset management giant Blackrock.

The deal provided \$US20 million to be drawn immediately, with the remainder to be tapped by the end of this month (at Botanix's discretion).

The company strives to achieve profitability by the end of 2027.

At the end of June, Botanix had \$36.6 million in cash.

Over the last 12 months, Botanix shares have perspired between 17 cents in late September last year and late July's all-time low of 1.9 cents. The stock hit a record high of 51.5 cent in mid-February 2025.

Did someone mention tariffs?

The core component of Sofdra is made in Japan, by Kaken Pharma.

Botanix estimates a tariff of \$US10 a bottle, assuming a 15 percent rate. Put in context, the elixir is reimbursed at \$US400 to \$US500 per prescription.

Botanix is in the throes of securing a Michigan based company, Piramal, as a second supplier.

As well as negating tariffs, the company expects the change will reduce the company's cost of goods sold by 25 percent to 40 percent.

In late July, Botanix had about six months of inventory in the US.

Big pay packets raise eyebrows

Botanix's board and executive pay scales have not gone unnoticed, with the company copping a first 'strike' against its remuneration report at last year's AGM.

In the 2025-'26 year, Mr Ippolito received total remuneration of \$2.03 million, \$1.02 million in performance rights.

Dr McKibbon pocketed \$1.98 million, \$1.06 million in non-cash rights.

The four non-executive directors received between \$305,000 and \$321,000. Dr McKibbon said the "incongruent" pay levels in the US was always a challenge for an ASX-listed company.

"It's reasonable to raise the issue," he told an investor who did just that.

Dr McKibbon said the board took remuneration "very seriously", including trimming stipends during the pandemic.

But he said US executives such as chief financial offers and chief operating officers expected US remuneration levels.

"For board executives, we try to make sure we're on the lower end of where we are with our peer group and re-evaluate that each year."

He said that rather than being there for a “cash grab”, executives should take most of their pay in shares as compensation. Relative to Australian companies, US companies favor non-cash incentives.

At this year’s AGM we will know whether the company has done enough to avoid a second strike and a mandatory board spill motion.

Opportunities beckon

Dr McKibbon says 3.7 Americans seeking primary auxiliary hyperhidrosis treatment means that twice as many are not.

Given the 30,000 prescriptions in the June quarter pertained to around 8,000 patients, “we haven’t even touched the tip of the iceberg yet”.

Dr McKibbon said the company was targeting a small cohort of 5,000 US dermatologists, which makes for efficient marketing; and the company wants to expand into tele-health scripts.

European regulators have approved Sofdra. But as is often the case, the company hopes to licence the region, rather than sell directly.

In Japan, Sofdra is licenced to Kaken under a different formulation of the product, Ecclock. Given Japan has one third of the population of the US, prescription volumes are encouraging; and Botanix is eyeing the Australia and Canadian markets, where it also is in “active” licencing discussions.

Dr Boreham’s diagnosis:

In their process of selling \$US10 billion of pharma assets, Mr Ippolito and Dr McKibbon experienced plenty of adversities until the happy endings ensued.

In the case of a previous company, one CEO was writing his own cheques to pay staff.

With another, a major shareholder ordered the company to sack half the staff.

In another instance, a key investor refused to advance more funds.

Eventually, these companies were sold for between \$US1.2 billion and \$US5.4 billion.

“We’ve seen these cycles before,” Mr Ippolito says.

“But if you deliver quarter-after-quarter growth, the value is there.”

Will a third party recognize the company’s unrealized worth?

Dr McKibbon cites “inbound interest” from potential acquirors but says a sale would be a by-product of the Botanix business model working.

“Such exits happen as a natural consequence of improved execution. First and foremost, we wake up every day thinking about how to grow Sofdra.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He wakes up every day thinking about how he will manage to get out of bed.

IMMUTEP

Immutep says a 'root cause analysis' of its Tacti-004 trial discontinuation shows differences between efti manufactured at 200 litre scale and at 2,000 litre scale.

In March, Immutep fell 92.9 percent on news that the 756-patient 'Tacti-004' phase III trial of eftilagimod alfa, or 'efti', with chemotherapy for first line non-small cell lung cancer has been discontinued following an interim futility analysis (BD: Mar 13, 2026)

Today, the company said the differences between the efti used in TACTI-004 and the efti used in earlier studies, for example a difference in N-glycan structure, were "considered potentially relevant given the markedly different immune activation profile observed in TACTI-004 compared to previous trials and the unexpected clinical outcome of the study". Immutep said that the unexpected outcome of the TACTI-004 phase III trial could "not be explained by clinical factors, for example, sub-optimal protocol, substantial imbalance between treatment arms or safety findings or trial execution factors, for example invalid randomization pattern or general clinical trial conduct".

The company said that based on the analysis it has contracted a manufacturing run of efti at 200 litre scale.

Immutep said that 10 batches of efti had been manufactured at 200 litre scale and "used in successful phase I and phase II clinical studies of efti, including TACTI-mel, TACTI-002 and INSIGHT-003".

The company said that, in contrast, TACTI-004 was conducted exclusively with efti manufactured at 2,000 litre scale.

Immutep said it intends to focus the registration-directed clinical development of efti on head and neck squamous cell carcinoma (HNSCC) in patients with negative PD-L1 expression (Combined Positive Score (CPS) < 1), based on clinical efficacy data, including mature overall survival data, in a patient population with high unmet need and limited approved treatment options, and for which efti had US Food and Drug Administration fast track designation; and the neoadjuvant setting of soft tissue sarcoma (STS), based on positive phase II data, including achievement of the primary endpoint, and for which efti received FDA orphan drug designation in April 2026.

The company said the focus reflected "the compelling clinical data generated to date ... [its] interactions with the FDA, regulatory designations obtained, unmet medical need and substantial market potential in these indications" and trial preparations had begun.

Immutep said that "subject to final decisions on strategy and trial design, regulatory interactions, manufacturing timelines, partnering and resources" it was targeting study start by the end of 2027.

The company said that licencing partner, Dr Reddy's Laboratories, had been consulted and was supportive of the approach.

Immutep said it was in preliminary discussions with other parties regarding the proposed development pathway.

Immutep chief executive officer Marc Voigt said that "based on the totality of evidence generated with efti, we believe there is a scientifically and clinically justified path to continue its development".

"This includes clinical and translational data across multiple tumor types, consistent evidence of immune activation, encouraging results in soft tissue sarcoma and head and neck cancer with CPS < 1, and constructive regulatory interactions," Mr Voigt said.

"At the same time, we fully recognize the significance of the TACTI-004 outcome," Mr Voigt said. "Our root cause analysis remains ongoing, including further investigation of smaller differences identified between product batches."

Immutep said development of IMP761 for autoimmune disease continued.

Immutep was up 1.2 cents or 27.3 percent to 5.6 cents with 73.3 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has drawn the remaining \$US2 million (\$A2.8 million), balance of tranche 4 of its \$US27 million Obsidian Global Partners convertible note facility.

Last year, Paradigm said it had the \$US27 million (\$A41.2 million) facility with New York's Obsidian to support its phase III knee osteoarthritis trial (BD: Jul 1, 2025).

Today, Paradigm said the additional capital supported its working capital and its 538-patient "fully-enrolled global phase III clinical trial, evaluating injectable pentosan polysulfate sodium for the treatment of knee osteoarthritis, as ... [it] advances towards its planned interim analysis and subsequent top-line primary endpoint readout".

In August, Paradigm said that the completion of enrolment was "a major operational milestone" with interim analysis on track for September, and top-line results expected by April 2027 (BD: Aug 13, 2026).

Paradigm fell 4.5 cents or 15.8 percent to 24 cents with 13.4 million shares traded.

PYC THERAPEUTICS

PYC says the first open-label extension polycystic kidney disease patient (PKD) has been dosed as part of its up-to 48-patient phase Ib PYC-003 multiple-ascending dose study.

PYC said the extension enabled patients "to receive PYC-003 continuously for a period of up to 24 months, mirroring the duration of the registrational trial set to follow completion of the ongoing phase Ib study".

The company said the patient had received PYC-003 for four months and would continue to receive PYC-003 every six weeks for up to 24 months".

PYC said the study objective was to determine the safety and tolerability profile and optimal dosing regimen of PYC-003 in a repeat dose setting ahead of a proposed transition to a registrational trial.

PYC fell two cents or 0.9 percent to \$2.30 with 3.7 million shares traded.

CONTROL BIONICS

Control Bionics will vote to issue chief executive officer Jeremy Steele 1,750,000 options in four tranches exercisable at 7.5 cents each within five years.

Control Bionics said that the annual general meeting would vote to issue director Stephen Rix 1,044,087 shares in lieu of \$62,356 in director's fees, vote on the remuneration report, re-elect directors Damian Lismore, Prof Nicholas Opie and Mr Rix, and approve the employee option plan and the 10 percent placement capacity.

The meeting will be held at Level 11, 66 Clarence Street, Sydney, on October 13, 2026 at 11am (AEDT).

Control Bionics was up 0.1 cents or 1.7 percent to 6.1 cents.

ARTRYA

Regal Partners Funds Management Pty Ltd says it has reduced its substantial shareholding in Artrya from 17,483,419 shares (11.06%) to 16,286,955 shares (9.97%).

The Sydney-based Regal Partners said that between February 23, 2026 and September 8, 2026 it bought and sold shares, with the most recent sale 233,658 shares for \$923,019 or \$3.95 a share.

Artrya was up two cents or 0.6 percent to \$3.27 with 2.5 million shares traded.

PACIFIC EDGE

Harbour Asset Management says it has reduced its substantial shareholding in Pacific Edge from 130,611,733 shares (11.144%) to 125,753,262 shares (10.126%).

The Wellington, New Zealand-based Harbour said with BNZ Investment Services that since the previous disclosure on May 27, 2026 it bought 8,779,099 shares for \$2,150,683 or 24.5 cents a share and 11,395,796 shares for \$3,158,349 or 27.7 cents a share.

Pacific Edge was untraded at 20.5 cents.