

Biotech Daily

Friday June 20, 2025

Daily news on ASX-listed biotechnology companies

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- * MEMPHASYS RE-APPOINTS VITASORA M-D MARJAN MIKEL DIRECTOR

MARKET REPORT

The Australian stock market fell 0.21 percent on Friday June 20, 2025, with the ASX200 down 18.2 points to 8,505.5 points. Fourteen of the Biotech Daily Top 40 companies were up, 17 fell, eight traded unchanged and one was untraded. All four Big Caps were up.

Dimerix was the best, up 5.5 cents or 10.8 percent to 56.5 cents, with 2.9 million shares traded. Imugene improved 7.7 percent; Impedimed climbed 6.9 percent; Botanix was up 5.3 percent; 4D Medical and Prescient were up four percent or more; Genetic Signatures was up 3.1 percent; Aroa, Cochlear and Compumedics rose two percent or more; Avita, Polynovo, Pro Medicus, Proteomics and Resmed were up one percent or more; with CSL, Nanosonics and Neuren up by less than one percent.

Yesterday's 190.1 percent best, Amplia, led the falls, down three cents or 12.8 percent to 20.5 cents, with 46.4 million shares traded. Syntara lost 7.55 percent; Actinogen, Clarity, Micro-X and Resonance were down five percent or more; Curvebeam and Optiscan fell more than four percent; Alcidion, Cyclopharm, Emvision, Mesoblast and Starpharma shed one percent or more; with Clinuvel, Orthocell, SDI and Telix down less than one percent.

DR BOREHAM'S CRUCIBLE: BOTANIX PHARMACEUTICALS

By TIM BOREHAM

ASX code: BOT

Share price: 30 cents

Shares on issue: 1,960,869,049

Market cap: \$588.3 million

Chief executive officer: Dr Howie McKibbon

Board: Vince Ippolito (executive chair), Dr William Bosch, Dr Stewart Washer, Danny Sharp (founder and executive director Matt Callahan stepped down on May 23 to attend to a medical issue)

Financials (March quarter 2024): receipts from product sales \$326,000, receipts from royalties \$218,000, operating outflows \$19.96 million, cash of \$28 million (ahead of \$40 million capital raising and this month's \$US20 million debt drawdown)

Major identifiable holders: Insignia Financial 8.3%, Shenasaby Investments (Callahan family) 4%, Caperi Pty Ltd 2.9%, Zenith Pacific 1.2%, Dr Henry William Bosch 1%

Botanix CEO Dr Howie McKibbon says investors shouldn't just rely on management's assertion that its anti-sweating drug Sofdra has – and we paraphrase – "the potential to be the world's most successful dermatology drug".

Ask Blackrock. With \$US11.5 trillion in assets, Blackrock can afford extensive due diligence.

The world's biggest asset manager has extended a \$US30 million (\$48 million) debt package via its venture capital funder, Kreos Capital.

Dr McKibbon says Botanix doesn't need the dosh - one-third of which is not drawn down immediately - for its current Sofdra roll-out in the US.

"But if an acquisition opportunity emerges, it does not have to hinge on a capital raising," he says. "It allows us to be nimble."

"We will look to leverage that relationship in future as other opportunities emerge," Dr McKibbon says.

Meanwhile, three months after the US Sofdra launch, prescriptions have exceeded management's expectations.

Sweating bullets

Sofdra tackles primary axillary hyperhidrosis (PAH), or excessive underarm sweating, to the extent that it affects a person's daily lives.

With around 16 million sufferers in the US, hyperhidrosis is the third most common skin condition behind acne (40-50 million sufferers) and atopic dermatitis (20-25 million).

About 10 million Americans have PAH, of which seven million have been diagnosed. The condition accounted for 3.7 million doctor visits last year.

The condition is defined as sweating beyond the body's need to cool itself. Sufferers can sweat through multiple layers of clothing in mid-winter.

"It doesn't have to be severe; it has to be enough to affect your daily life," Dr McKibbon says.

PAH is caused by sweat glands becoming overstimulated by acetylcholine binding to M3 receptors, thus triggering the excessive sweat.

Sofdra selectively binds to - and blocks - the M3 receptors to reduce sweat at the source.

Current treatments include strong topical anti-perspirants and aluminium chloride. In severe cases there's invasive Botox or surgery (nerve cutting, which can result in over compensatory sweating in other areas).

About Botanix

Nominally headquartered in Perth but based in Philadelphia, Botanix was founded by parties including Matt Callahan, Caperi (a financial investor) and scientist and non-executive director Dr William Bosch.

Aptly, the Philadelphia-based Mr Callahan is a lawyer. He also founded Iceutica Inc and Churchill Pharma, having co-invented Iceutica's drug delivery platform.

The company back-door listed in July 2016, using the shelf of Perth-based biotech Bone Medical.

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

In October 2019, the company's pimple hopes were popped when a phase II trial of its synthetic cannabinoid did not meet its primary endpoint. But a phase Ib atopic dermatitis study showed better results.

Renouncing the weed, in 2022 the company acquired Sofdra (sofpironium bromide) from the cash-strapped Nasdag-listed Brickell Biotech, now Fresh Tracks Therapeutics.

The price - an upfront \$US4 million plus various other milestones and royalties – hardly reflected the \$US120 million Brickell had invested to get the drug beyond phase III stage.

"It was during Covid and they basically ran out of money, which was their loss and our benefit," Botanix founder Matt Callahan said.

After earlier prevarication the US Food and Drug Administration approved Sofdra as a topical treatment in June 2024 - and it's been off the races for the company since then.

Wealth of experience

Given they have been involved in developing around 30 approved drugs, the Botanix top brass can't claim ignorance about the gritty realities of drug development.

Taking over as (executive) chair from the late Graham Griffiths in February 2019, Vince Ippolito was chief commercial officer with the Nasdaq-listed inflammatory diseases house Anacor - which Pfizer acquired for \$US5.2 billion in 2016.

The company's chief operating officer since May 2019, Dr McKibbon was anointed CEO in August 2023.

Based in Phoenix, Arizona, Dr McKibbon was formerly an executive at Dermavant Sciences and held senior positions at Anacor and Medicis.

Mr Callahan, meanwhile, co-founded the ASX-listed nerve regeneration play Orthocell and eye drug developer Dimerix as well as the psychotropic play Emyria. On May 23, Mr Callahan stepped down from the Botanix board temporarily for health reasons.

"He's OK and he will be back sooner rather than later," Dr McKibbon says.

Roll up! Roll up! for the roll-out

In mid-April the company said by the end of the first week of the US launch, 125 doctors had written a script. One tube of Sofdra lasts for 30 days.

Four months later, subscriber numbers had grown to 500.

"These doctors are very easily activated," Dr McKibbon says. "They didn't have to hear the message multiple times, it happened immediately."

"Most importantly, our refill rates are well above industry standards," Dr McKibbon says. "After three months we are getting 3.1 [repeat] fills [per script] which surpasses the average topical dermatology prescription of two per year."

Dr McKibbon says six refills are "definitely in sight" but naturally the company is aiming for 12, which signifies full ongoing patient compliance.

Who pays?

Not the patients, who are covered by Medicaid or - in most cases - insurers.

US reimbursement is complex, but typically a refill attracts a payment of \$US400 to \$US500. The first tube might not be reimbursed, in which case the company will provide it for nothing.

In theory, patients need to use Sofdra for the term of their natural lives. But full compliance is rare with any drug.

Patients are more likely to use Sofdra when they are younger and care more about being whiffy, such as in courtship stage.

Reaching out

Botanix is expanding its 27 strong sales force to 33. The company doesn't need a huge army of sales representatives because prescriptions are issued by about 5,000 dermatologists. (Unlike Australia, US nurse practitioners can prescribe).

Put in perspective, the acne treatment Solodyn (minocycline) - the most widely prescribed dermatology drug - at peak had 1,900 prescribers issuing 1.3 million prescriptions a year.

Dr McKibbon was intimately involved with Solodyn's development when he was at Dermavant.

"In dermatology it's amazing how much you can do with so few doctors," Dr McKibbon says. "As a specialty, it is very attractive because it is concentrated."

Meanwhile, the company accesses physicians by means such as leaflets in waiting rooms.

Finances and performance

In its initial US sales period, Botanix generated \$326,000 of receipts from product sales in the March 2024 quarter.

The company also reports revenue of \$4.99 million, with \$47,000 of sales in February stiffening to \$3.26 million in March.

The company also banked \$218,000 of royalty receipts, courtesy of a licencing deal with Japan's Kaken which sells a different formulation of the product, Ecclock.

In mid-April, Botanix raised \$40 million of equity, via an institutional placement at 33 cents apiece (a 7.0 percent discount).

Post last year's FDA approval, Botanix went to market for \$70 million in an institutional placement - as you do – at 30 cents a share.

Last week the company unveiled a US\$30 million (\$A48 million) debt facility with Kreos Capital.

The facility provides for \$US20 million to be drawn now, with the remainder to be tapped by October 1, 2026 (Botanix does not have to avail of these funds).

Under certain conditions, Kreos Capital can convert 20 percent of the loan into Botanix shares, at 33 cents apiece.

Kreos also pockets just over three million warrants to acquire Botanix shares, also at 33 cents, within the next five years.

The Kreos debt bears a 9.9 percent interest rate.

Botanix now has cash of more than \$60 million - enough to fund the Sofdra rollout.

Dr McKibbon says the company strives to be cash flow positive "within the next 12 to 15 months".

Without too much perspiration, Botanix shares climbed from their 12-month low of 31 cents on November 19 last year, to a record 52 cents on February 19 this year.

Botanix shares were promoted to the ASX300 index, on March 23 this year.

In its 'Alan Bond' moment, in July 2023 bought-back up to US\$172 million of potential milestones and royalties payable to Fresh Tracks, for a mere US\$8.25 million.

Return to SendRx

Unusually, Botanix created its own platform, SendRx as a captive distribution partner ('Rx' as in medicinal prescription - geddit?).

Every Sofdra script is sent to Senderx, a concierge service that gains reimbursement and ships the drug to the patient.

"This yields a better net price because we skip the wholesaler (and their typical 20 percent cut)," Dr McKibbon says.

"We pay Senderx a flat fee of about three percent, so we save 17 percent and make more money than we normally would."

The platform also provides Botanix real-time data on frequency of physician visits, shipping times and such.

Most importantly, Senderx automatically sends the repeats.

Dr McKibbon says the platform could be used as a springboard for an acquired therapy.

"In future we could take an underperforming drug and it would be five times as valuable in our hands."

Dr Boreham's diagnosis:

As outlined at the start of this piece, Dr McKibbon makes the seemingly outlandish claim that Sofdra could become the world's most successful dermatology drug.

Come to think of it, the gap between Sofdra's 500 prescribers and Solodyn's 1900 isn't that wide - and Sofdra has only been selling for a few weeks.

"Physicians seem to be clamouring for the product," Dr McKibbon says.

He notes that Botanix is an early mover in hyperhidrosis and "sometimes the pioneers catch the arrows".

Botanix certainly is in rarefied company, given the FDA approved 50 drugs last year.

In terms of ASX drug developers, only a handful have won US approval and have gone on to be commercialized.

Despite the company's progress, Botanix shares have fallen 34 percent in the year to date, which we will attribute to the slings and arrows of outrageous fortunes.

Biotech valuations generally have been under pressure because of US President Donald Trump's edicts on tariffs and Most Favoured Nation drug pricing mechanisms (which don't affect Botanix).

However, Botanix hasn't been immune from the increase in short selling activity across the sector.

Currently, 3.66 percent of the Botanix register is 'shorted', compared with none at the start of February.

The next few months will show whether Botanix can fire off a few arrows from its own quiver as the US roll-out intensifies.

While it's early days for the roll-out, the company looks to be able to generate early meaningful revenues without too much – er - sweat.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he's got a few other feathers to his bow and won't quiver at a challenge – or sweat bullets

MTP CONNECT

MTP Connect says it has invested \$12.07 million in 14 life sciences companies to support the development of heart disease and diabetes drugs and devices.

MTP Connect said the funding was through its Target Translation Research Accelerator (TTRA) program, a Federal Government Medical Research Future Fund initiative.

The organization said the companies awarded funding were developing drugs or devices that aimed "to reduce the burden of cardiovascular disease and complications of diabetes, type 1 and type 2, for patients, carers, families and communities".

MTP Connect said the funding included a \$1,000,000 tranche A investment to Argenica for its phase IIb/III trial of ARG-007 for acute ischaemic stroke (see below).

At Bio in Boston, MTP Connect chief executive officer Stuart Dignam said the funding was "critical to backing Australian innovations to tackle these significant chronic health problems and scale in our backyard rather than offshore".

"The capital markets, especially when you're at an early stage with your innovation, are particularly tough, and now they have heightened global business uncertainty and tariff turmoil to contend with," Mr Dignam said.

"Following an open and rigorous assessment process, we're backing established [small and medium enterprises], start-ups and spin-outs in New South Wales, South Australia, Tasmania, Victoria and Western Australia," Mr Dignam said.

"MTP Connect's investment, combined with the matching industry contributions, represents a near \$30 million down-payment on the future of Australia's brilliant life science innovators," Mr Dignam said.

"In addition to vital funding, these 14 companies will receive ongoing acceleration support through mentoring and access to specialist advice from MTP Connect, and guidance from our industry impact partners, CSL and Roche Diagnostics so they can tap into the best of global industry expertise," Mr Dignam said.

"We'll be working with these companies over the next few years and making additional funding available on a competitive basis for those hitting their commercialization milestones," Mr Dignam said.

"We want to see these homegrown innovations scale in Australia first, rather than offshore and drive sovereign success which will power local job creation and improve health outcomes for Australians and others around the world," Mr Dignam said.

The full list of funding recipients is available at: http://bit.ly/44dooEt.

ARGENICA THERAPEUTICS

Argenica says it has been awarded up-to \$1.5 million from MTP Connect to fund its phase IIb/III trial of ARG-007 for acute ischaemic stroke.

Earlier this year, Argenica said it dosed all 92 patients in its phase II trial of ARG-007 for acute ischaemic stroke, with results expected by October 2025 (BD: Apr 11, 2025).

Last week, the company said the US Food and Drug Administration had put its investigational new drug application for a US phase III trial of ARG-007 for acute ischaemic stroke on "clinical hold" (BD: Jun 10, 2025).

At that time, Argenica said the FDA hold did not impact its Australian phase II trial.

Today, the company said the funding would be "paid in two tranches, with the first tranche totalling \$1 million and a further \$500,000 provided on ... completion of activities under the first tranche and if the project demonstrates high commercial potential".

Argenica said the planned phase IIb/III program followed its recently completed phase II clinical trial conducted in Australia, with data still expected by October 2025.

Argenica fell one cent or 1.4 percent to 71 cents.

MACH7 TECHNOLOGIES

Mach7 says it has signed a \$5 million, five-year licence agreement amendment with an unnamed "US-based radiology marketplace".

Mach7 said the amended agreement was for additional Eunity viewer and Enterprise radiology imaging system licences and extended the term of the licence by three years. The company said the revised agreement was effective from June 1, 2025 and was a \$3 million increase in total contract value over the original agreement.

Mach7 managing-director Mike Lampron said the deal highlighted the company's "focus on building lasting relationships with our customers and the importance of our 'land and expand' strategy".

Mach7 was up 1.5 cents or 4.55 percent to 34.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has launched its Promarker D blood test for predicting diabetes-related chronic kidney disease in the US.

Proteomics said it launched the test at the 85th Scientific Sessions of the American Diabetes Association in Chicago, Illinois, from June 20 to 23, 2025.

The company said that initially the test would be available in California and provided by its recently opened Clinical Laboratory Improvement Amendment-certified laboratory in Irvine, California and supported plans for the broader US roll-out.

Proteomics managing-director Dr Richard Lipscombe said the company was "excited to introduce Promarker D to the US at such a prestigious event".

"This marks a significant milestone in our global commercialization strategy and underscores our commitment to addressing the diabetes epidemic," Dr Lipscombe said. In 2023, Proteomics said it had an exclusive licence with Sonic Healthcare USA for the use and distribution of its Promarker D test in the US, which Proteomics later terminated citing failure to meet agreed targets (BD: May 10, 2023; Sep 11, 2024).

Proteomics was up half a cent or 1.4 percent to 36 cents.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says NUZ-001 (monepantel) effectively crosses the blood-brain barrier, in mice. Earlier this year, Neurizon said NUZ-001 had a "small but significant survival effect on TDP-43-mediated cell death", in mouse motor neuron cells (BD: Apr 4, 2025).

Today, the company said a pharmaco-kinetic study showed a single administration of NUZ-001 and its active metabolite NUZ-001 sulfone led to "brain concentrations consistent with those shown to reverse pathological [transactive response] DNA-binding protein 43 aggregation in patient-derived induced pluripotent stem cells".

Neurizon said the results showed "the ability to achieve target-relevant [central nervous system] exposure" validating NUZ-001 to act on brain disease mechanisms.

The company said the study supported "broader applications across TDP-43 proteinopathies, including fronto-temporal dementia, Alzheimer's disease, and limbic predominant age-related TDP-43 encephalopathy".

Last month, Neurizon said data from its 12-patient, phase I study showed NUZ-001 for amyotrophic lateral sclerosis significantly increased survival (p = 0.000717) and reduced the risk of death by 78.5 percent (p = 0.0015) compared to controls (BD: May 5, 2025). Neurizon was up half a cent or 2.9 percent to 17.5 cents.

INHALERX

Inhalerx says it has received \$402,000 from the Australian Tax Office under the Federal Government's Research and Development Tax Incentive program.

Inhalerx said the incentive related to research and development for the year to June 30, 2024, with the funds to be used for working capital and to partially repay amounts drawndown from its \$38.5 million Clendon Biotech Capital funding facility.

Last year, the company said it would borrow up-to \$38,475,110 from Clendon Biotech Capital at 15 percent per annum interest and 38,449,145 options (BD: Oct 18, 2024). Inhalerx was up 0.3 cents or 6.7 percent to 4.8 cents.

BLINKLAB

Perth's Yulia Uvarova has increased her substantial share-holding in Blinklab and has been diluted from 8,500,000 shares (8.57%) to 9,150,000 shares (7.37%).

Ms Uvarova said that shareholding and as trustee for Techinvest Nominees was diluted on May 8, 2025, but did not disclose the cost of the 650,000 shares increase, as required under the Corporations Act (2001).

Last month, the company said it raised \$7.66 million at 30.0 cents a share, a 15.8 percent discount to the 15-day volume weighted average price (BD: May 1, 2025).

Last year, Blinklab said it would develop an autism and neurological disorder test, with coinventors Dr Anton Uvarov and Dr Henk-Jan Boele appointed directors (BD: Apr 4, 2024). In its prospectus, Blinklab said Dr Uvarov held 8,325,000 shares indirectly through Ms Uvarova, and that Techinvest Nominees was "an entity associated with Dr Uvarov". Blinklab was up 1.5 cents or 3.4 percent to 45.5 cents.

BLINKLAB

The Leiden, Netherlands-based Blinklab chief executive officer Dr Hendrikus Boele says his 6,750,000 share-holding was diluted from 6.81 percent to 5.43 percent (see above).

MEMPHASYS

Memphasys says it has re-appointed Vitasora, formerly Respiri, managing-director Marjan Mikel as a non-executive director, effective immediately.

Memphasys said Mr Mikel had been a non-executive director of the company from June 2018 to March 2020.

In 2020, Memphasys said it appointed Paul Wright as a director, replacing Mr Mikel, who had been appointed chief executive officer of the then Respiri (BD: Mar 13, 2020).

The company said Mr Mikel was currently the managing-director of Vitasora, founded Healthy Sleep Solutions and worked for IMS Health, Merck Sharp & Dohme, Pharmacia and Searle in Australia, the Asia-Pacific and Europe.

Memphasys said Mr Mikel held a Bachelor of Science from the University of Sydney and a Master of Commerce from Sydney's University of New South Wales.

Memphasys was up 0.1 cents or 25 percent to 0.5 cents with two million shares traded.