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Bioxyne Commercialises GMP-Manufactured Psilocybin Capsules

Key Highlights

- BXN has secured initial purchase orders of GMP-manufactured psilocybin capsules in Australia, marking early commercial traction
- As Australia's TGA GMP-licensed psilocybin manufacturer BXN delivers pharmaceutical-grade products that meets Australian and international standards
- Capsules supplied to authorised prescribers in Queensland and Western Australia via the TGA Authorised Prescriber pathway, offering hope for patients with treatment-resistant depression.
- This milestone validates Bioxyne's strategic investment in psychedelic therapeutics and supports scalable growth in Australia's emerging regulated psychedelic therapy market
- Psilocybin is an emerging, locally manufactured therapy that may offer improved outcomes for up to 300,000 Australians whose symptoms have proven resistant to standard treatment approaches.

Bioxyne Limited (ASX: BXN) ("Bioxyne" or "the Company), an Australian pharmaceutical company focused on the development and commercialisation of innovative medicines and active pharmaceutical ingredients, is pleased to announce, through its wholly owned subsidiary **Breathe Life Sciences (BLS),** has secured initial purchase orders for the supply of GMP-manufactured psilocybin capsules (BLSPSIL25). These capsules are intended for investigational use in treatment-resistant depression (TRD) and exploratory research into other mental health conditions in Australia, including anxiety disorders, substance use disorders, and post-traumatic stress disorder (PTSD).According to the Australian Bureau of Statistics (ABS) National Study of Mental Health and Wellbeing 2020-22 ~4.9% (~1,000,000) of Australians aged 16–85 had a depressive episode in the past 12 months.[1]**Approximately ~30%**

[1] https://minerva-access.unimelb.edu.au/bitstreams/f8e8627c-16b1-4ef8-9798-bed79ab19b32/download?utm_source=chatgpt.com

of people with major depressive disorder (MDD) meet criteria for TRD (defined as non-response to at least two adequate antidepressant trials).[2]

BLSPSIL25 is being provided to authorised prescribers delivering psychedelic-assisted therapy services in Queensland and Western Australia (and potentially expanding to other states) via the Authorised Prescriber pathway. BLS has successfully manufactured and released BLSPSIL25 capsules that fully comply with Australian and international pharmaceutical standards, underscoring the Company's advanced manufacturing expertise in this rapidly emerging therapeutic field.

Initial orders involve the supply of 250 doses of BLSPSIL25 to authorised prescribers in Queensland and Western Australia, supporting treatment for approximately 60 patients over the next 12 months. This represents only a small fraction of Australia's estimated addressable market of approximately 300,000 patients living with treatment-resistant depression (TRD). The Company is prepared to significantly scale manufacturing and supply over the next 12 months to meet anticipated demand across Australia.

Chief Executive Officer Sam Watson commented:

"Medical psilocybin and psychedelic-assisted therapy are emerging as a new class of innovative medicine, with relevance to some of the world's largest and most costly mental health conditions. In Australia and globally, this is a highly regulated, high-barrier market where pharmaceutical manufacturing precision and control are essential. Bioxyne is translating its psychedelic manufacturing capabilities into early commercial results and positive patient outcomes. For Bioxyne, these initial supply agreements reflect disciplined execution at the outset of a multi-billion-dollar opportunity with the potential to meaningfully improve quality of life for millions of people."

Mental health challenges remain significant in Australia with approximately 43% of adults experiencing a mental illness at some point in their lifetime[3] and depression affecting about one in seven over their lifetime[4].

Critically, an estimated one-third of individuals with major depressive disorder do not respond adequately to traditional antidepressant treatments[5], leaving many in prolonged distress. There is a growing need for innovative treatment options, such as psilocybin-assisted therapy, which may offer new hope and improved quality of life for patients who do not respond to existing treatment options.

According to research by Mordor Intelligence, the global psychedelic drugs market is projected to grow, from ~ USD 3-4 billion in 2025 to USD 8-13 billion by the early 2030s (CAGR of 13-15%)[6]., driven by increasing acceptance and demand for psychedelic medicines and assisted therapy worldwide.

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[2] https://www.sciencedirect.com/science/article/pii/S2772598724000230?utm_source=chatgpt.com

[3] *https://www.abs.gov.au/statistics/health/mental-health/national-study-mental-health-and-wellbeing/2020-2022*

[4] *Commonly cited by Beyond Blue, Black Dog Institute, healthdirect.gov.au, and NHMRC*

[5] *Consistent with Australian clinical sources including NHMRC, RACGP-aligned publications*

[6] *Roots Analysis, Mordor Intelligence, Coherent Market Insights – 2025/2026 reports https://www.mordorintelligence.com/industry-reports/psychedelic-drugs-market*

BXN's local manufautirng capabilities and its fulfillment of these initial orders enhances access for the Australian mental health sector to locally produced, GMP-compliant medication, complementing existing options and supporting scalable, compliant supply for patients with unmet needs.

Current Regulatory Status of Psilocybin in Key Markets

Due to progressive regulation and local manufacturing capabilities, Australia is poised to be a global leader in regulated psilocybin-assisted therapy, being the first country to allow authorised psychiatrists to prescribe psilocybin for treatment-resistant depression under the TGA's Authorised Prescriber scheme (effective July 2023).[7]

In Europe, progress is country-specific. Key advancements include Germany's 2025 EU-first compassionate use program for TRD at specialised facilities, and Czechia's regulations effective January 2026 permitting medical psilocybin for severe, treatment-resistant depression. Switzerland maintains its long-standing compassionate framework. These developments, combined with ongoing large-scale trials, signal strong potential for future harmonisation and long-term growth opportunities for GMP-certified innovators like Bioxyne.

Image 1: BXN's GMP-compliant psilocybin manufacturing operations at Breathe Life Sciences

This milestone represents the beginning of significant global opportunity in psychedelic therapeutics. Bioxyne already supplies high-quality, GMP-complaint medicinal cannabis across Australia, U.K and Europe. It is also advancing its MDMA portfolio, having fulfilled orders

[7] *TGA official announcement (3 Feb 2023): https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists*

for Australia's first domestically manufactured GMP-compliant MDMA capsules to support clinical trials and authorised prescribers. These initial psilocybin orders serve as a clear validation of the Company's scalable manufacturing platform and growing international network. Beyond BLSPSIL25, the pipeline includes potential variants (e.g., BLSPSIL10 and BLSPSIL15 for flexible dosing) and broader psychedelic offerings, enabling Bioxyne to capture increasing demand as regulatory pathways evolve worldwide.

Approved by the Board of Bioxyne Limited for release to the ASX.

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About Bioxyne Ltd.

Bioxyne Limited is an Australian pharmaceutical company focused on the development and commercialisation of innovative medicines and active pharmaceutical ingredients. Through its subsidiary, Breathe Life Sciences, Bioxyne is expanding into the production of psychedelic compounds for therapeutic use.

About Breathe Life Sciences (BLS)

Breathe Life Sciences ("BLS") is a wholly owned subsidiary of Bioxyne Ltd (BXN:ASX) and GMP-licensed manufacturer, wholesaler, importer and exporter of controlled substances (S3, S4, S8, S9), including medicinal cannabis, Psilocybin, and MDMA.

BLS was founded in 2018 and has quickly expanded into a multi-national business focused on alternative therapeutics and investigational medicines. The company's corporate head office is in Sydney, with operations and licensed manufacturing, warehousing, import/export, sales and distribution centres in Queensland (Australia), Nagoya (Japan), Scotland (UK), and Prague (Czechia).

The BLS business model is focused on manufacturing final dose form medicines, sales and distribution. BLS sources raw materials and API from suppliers in 5 continents and is the Australian market leading manufacturer of therapeutic goods including cannabis, MDMA, and Psilocybin.

Outside of Australia the BLS Group operates in pharmaceuticals, medical cannabis, consumer health products, and novel foods (CBD). In the UK, Europe and Japan, the Company engages in the following activities:

a) Owner of the Dr Watson® brand in the UK, Japan, Australia and New Zealand. Internationally recognised for its cannabis-based food supplements, lifestyle products, functional mushrooms and nootropics, and prescription-only medicines. .

b) Contract medicine manufacture and white label manufacture of medicinal products for human use..

c) Wholesale distribution, import and export of controlled drugs, finished medicinal products, and active pharmaceutical ingredients.

d) Research and development of novel medicines.

e) Direct sales via online and wholesale of BLS-owned consumer brands, such as Dr Watson®

- **United Kingdom:** drwatsoncbd.com
- **UK / EU:** breathelifesciences.com

f) Export and supply of medicinal cannabis products and manufacturing services to UK and European markets.

Corporate: bioxyne.com

Australia: bls.com.au

International: breathelifesciences.com