

5 February 2024

BXN AWARDED GMP MANUFACTURING LICENSE FOR MEDICAL CANNABIS

Highlights

- **Bioxyne awarded GMP medical cannabis manufacturing license**
- **Australia's first GMP license to manufacture Psilocybin and MDMA**
- **Bioxyne plans to register the Psilocybin and MDMA capsules on the Australian Register of Therapeutic Goods for export in 2024 to supply companies, universities, and clinical trials around the world.**

Australian life sciences, pharmaceutical and consumer health products Company, **Bioxyne Limited** (ASX Code: BXN) ("Bioxyne" or the "Company") is pleased to announce that its wholly owned subsidiary, Breathe Life Sciences ("BLS") has been awarded a Good Manufacturing Practice ("GMP") license to manufacture medical cannabis.

This is also Australia's first GMP license to manufacture Psilocybin and MDMA. The Company's Therapeutic Goods Administration ("TGA") GMP license covers parts 1 and 2, allowing it to manufacture MDMA (3,4-methylenedioxymethamphetamine) and psilocybin active pharmaceutical ingredients ("APIs") as well as final dose form capsules for supply to authorised prescribers and clinical trials.

Breathe Life Sciences has been building its medical cannabis brand and distribution in Australia since 2022. The Company's medical cannabis manufacturing license is the largest issued to date in terms of scope covering final product dose forms.

Since July 2023, Authorised Prescribers have able to write prescriptions for MDMA and Psilocybin outside of clinical trials, in Australia. Clinical use of MDMA is showing promising results for dealing with PTSD (post-traumatic stress disorder), while results from early-phase clinical trials of Psilocybin have suggested that a single or few sessions of psilocybin-assisted therapy can lead to significant and sustained reductions in depressive symptoms.

Sam Watson, Bioxyne CEO, commented on this significant milestone: *"This award demonstrates BLS commitment to the responsible manufacture of alternative medicines which can provide solutions to mental health disorders resistant to current treatments."*

"BLS aims to be the leading supplier of Psilocybin and MDMA for clinical trials and authorised prescribers, focusing on partnerships with veteran groups, universities (in Australia and abroad), and trial sponsors."

“There is a significant market for these products worldwide which have the potential to plug the gap in existing treatment options.”

Head of GMP Production, Macdarragh O’Neill said:

“This is a monumental achievement for our wholly owned subsidiary, Breath Life Sciences (“BLS”) and Bioxyne; something the Company has been working towards for the last 3 years. Not only will we now be able to significantly scale up our pharmaceutical operations in Australia, our manufacturing license will give us the ability to extend rapidly into international markets in which we are already well established.”

Bioxyne intends to be the leading supplier of Psilocybin and MDMA for clinical trials and authorised prescribers by 2025, focusing on partnerships with veteran groups, universities (in Australia and abroad), trial sponsors and authorised prescribers in Australia.

This announcement has been approved for release by the Board.

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About Bioxyne

Bioxyne Limited (ASX:BXN) is an Australian-headquartered international consumer health and pharmaceutical company (incorporated in 2000) with a focus on clinically effective health and wellness products, psychotropic and investigational medicines.

About Breathe Life Sciences (BLS)

Breathe Life Sciences (“BLS”) is a wholly owned subsidiary of Bioxyne Ltd (BXN:ASX) and licensed manufacturer, sponsor, importer and exporter of controlled substances (S3, S4, S8) in Australia.

BLS was founded in 2018 and has quickly expanded into a multi national business focused on alternative therapeutics and investigational medicines. Our corporate head office is in Sydney, and our operations extend to licensed manufacturing, warehousing, import/export, sales and distribution centers in the Gold Coast (Australia), Nagoya (Japan), Manchester (UK), and Prague (Czechia).

Our business model is focused on manufacture of final dose form / finished products, sales and distribution in each of the territories we serve. We work with raw materials and API suppliers in 5 continents and are a market leader in manufacturing scope and quality.

The BLS logo is derived from a Japanese Maple Leaf, symbolising health, happiness and a long life well lived. While the Japanese Maple is not a medicinal plant, our company purpose is to redefine medicine by taking a holistic approach to healthcare for a healthier and happier tomorrow.

Outside of Australia the BLS Group operates a health and wellness products and brands business focussed on naturally derived active nutraceuticals, wellness and lifestyle supplements and cannabidiol (CBD) based novel foods. It primarily operates in the UK, Europe and Japan, and engages in the following activities:

- (a) owner of Dr Watson® brand in the UK, Japan, Australia and New Zealand – Dr Watson is an internationally recognized health, lifestyle, and prescription products brand. Dr Watson products consist of cannabis-based food supplements, lifestyle products, cosmetics, functional mushrooms and nootropics, and prescription medicines in Australia;
- (b) contract manufacture and wholesale of raw materials and cannabinoid extracts in Japan, UK and Europe;
- (c) white label manufacture of third-party wellness and supplements brands in Japan, UK and Europe in company-owned facilities;
- (d) research and development for third party customers; and
- (e) direct sales via online and wholesale sales of BLS-owned consumer brands, such as Dr Watson® (drwatsoncbd.com, nolcbn.com, drwatsoncbd.de)

Corporate: <https://bioxyne.com>

Australia: <https://bls.com.au>; <https://blsclinics.com.au>

International: <https://breathelifesciences.com>

Dr Watson (UK and EU only): drwatsoncbd.com; drwatsoncbd.de; nolcbn.com