

21 August 2024

Bioxyne Successfully Delivers Australia's First Pharmaceutical Cannabis Gummies Manufactured Under GMP Licence

Highlights:

- Bioxyne's Breathe Life Sciences has now successfully manufactured GMP THC Gummies fulfilling its first commercial run of edible cannabis products.
- In July 2024 Breathe Life Sciences received deposits on purchase orders for ~\$2m of THC Gummies, a milestone marking the first commercial purchase of Australian-made edible cannabis products manufactured under the company's TGA GMP Licence.
- In July 2024 BLS also signed a 2-year manufacture and supply agreement for a forecast minimum of \$28m of THC Gummies to one of Australia's largest cannabis companies.
- BLS is scaling up its gummy manufacturing capabilities from 2 million single doses per month to 6 million to meet anticipated market demand.
- Bioxyne has positioned itself to be a leading supplier of alternative pharmaceutical goods, including cannabis products, Psilocybin and MDMA for supply to authorized prescribers and clinical trials in both domestic and international markets.

Bioxyne Limited (**ASX:BXN**) ("**Bioxyne**" or the "**Company**"), Australian pharmaceutical and consumer health products company and parent company of Breathe Life Sciences ("**BLS**"), is pleased to announce that it has successfully manufactured and delivered Australia's first pharmaceutical cannabis pastilles ("**Gummies**" or "**Edibles**") under its Good Manufacturing Practice ("**GMP**") certification.

Commenting on the milestone, Sam Watson, Founder & CEO of BLS and Managing Director of BXN, stated: *"BLS is the first Australian manufacturer to complete a commercial production run of pharmaceutical grade GMP-certified THC gummies. As a leading Australian cannabis manufacturer, we are supplying our pharmaceutical goods to both domestic and international markets, using established relationships and existing supply channels."*

Overview

BLS received its first commercial purchase orders for pharmaceutical cannabis pastilles (gummies and other edible medicines) in July 2024 leading to its initial commercial production runs. Total purchase orders received between 12 July and 12 August 2024 total ~\$2m.

This total includes the supply to one of Australia's top 5 alternative (Authorised Prescriber) medicine clinics, which has executed an agreement with BLS to manufacture and supply a forecasted minimum \$28m of THC gummy products over the next 24-months.

Terms of the agreement provide for 50% of the purchase order to be paid upfront in the first three months of the contract and the balance on agreed payment terms.

The gummies are manufactured and packaged as three different products according to three distinct formulations with different dosages of cannabidiol ("**CBD**") and/or delta-9-tetrahydrocannabinol ("**THC**"), the two primary active pharmaceutical ingredients in cannabis, each with distinct therapeutic benefits.

In addition to manufacturing the gummies, BLS is responsible for all quality assurance, laboratory product testing and packaging in accordance with its GMP license and as part of its supply agreements. The initial purchase orders are underway and scheduled to be completed by mid-September 2024.

Operational Update

After being awarded a GMP licence for the manufacture of medicinal cannabis by the Therapeutic Goods Administration (**TGA**) earlier this year¹, BLS has completed a series of initial validation batches of pharmaceutical grade cannabis edibles. Since then, BLS has been scaling its gummy manufacturing capacity to meet anticipated demand of the entire Australian market as of 2024.

Currently gummy products prescribed to patients in Australia are manufactured overseas and imported. The TGA licensing of BLS with a comprehensive GMP Licence for cannabis products in February 2024, has enabled the Company to be a first mover in this emerging high growth domestic market opportunity.

¹ ASX Announcement (5 February 2024) – "*BXN Awarded GMP Manufacturing Licence for Medical Cannabis*"

Edible Product Market

In Australia, pastilles (or prescription edibles) are expected to grow from approximately 1% of the ~\$500m per year (2023) Australian medical cannabis market to more than 20% by 2030 when the market is expected to surpass \$750m in revenue ². This presents a potential \$150m per year opportunity by 2030. By comparison, edibles account for almost one third (~32%) of the ~CAD\$5 billion per year Canadian market³, where over 50 million packaged units of edible cannabis products were sold in 2023 to cannabis consumers.⁴

Jason Stephens, General Manager of BLS Australia commented: *“This is a significant milestone for Australian pharmaceutical manufacturing and the medical cannabis industry as a whole. Australia is fast becoming a global medical cannabis hub and BLS is quickly becoming a substantial proponent of that. Our focus is building strong ties with our business customers and providing high-quality GMP-certified manufacturing services.”*

Australia is rapidly becoming a world leader in both cannabis and psychedelic medicines. BLS is exceptionally well-positioned to become Australia’s leading manufacturer and supplier of GMP-certified cannabis, MDMA, and psilocybin products.

This announcement has been approved by the Board of Bioxyne Limited.

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² <https://www.statista.com/outlook/hmo/cannabis/medical-cannabis/australia>

³ <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/market/edible.html>;

<https://mjbizdaily.com/canadian-recreational-cannabis-sales-surpass-ca5-billion-in-2023/>

⁴ Government of Canada (Health Canada) – data reported under the Cannabis Tracking System Ministerial Order (viewed 12 August 2024): <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/market/edible.html>

About the Good Manufacturing Practice (GMP) Licence:

The GMP licence, awarded by the Therapeutic Goods Administration (TGA) of Australia, is a set of guidelines and principles that set out for how manufacturers of medicines and active pharmaceutical ingredients (APIs) are to ensure they are of high quality. Australian manufacturers of medicines are required to obtain a licence in order to manufacture such goods, and in order to do so, are required to comply with the Code of GMP that is relevant to their goods.

About Bioxyne Limited:

Bioxyne Limited (ASX:BXN) is an Australian life sciences and health products business. In June 2023 Bioxyne acquired BLS in an all shares transaction becoming the parent company of Breathe Life Sciences ("BLS") and DR Watson®. The Group, which is headquartered in Sydney and has offices in London, Manchester, Prague, Brisbane, and Nagoya, manufactures and distributes novel pharmaceuticals and consumer health products globally.

About Breathe Life Sciences:

Bioxyne Limited's wholly owned subsidiary, Breathe Life Sciences (BLS), manufactures, commercializes, and distributes medical cannabis, psychedelics, novel foods and consumer health products under our own brands and for third party brands.

BLS' goal is to become the market leading Australian manufacturer of novel pharmaceuticals and medicine products derived from Cannabis, Psilocybe Cubensis, and MDMA. In Australia, BLS is licensed to manufacture MDMA and Psilocybin products for commercial supply to authorised prescribers and clinical trials in Australia and global export markets. In the UK and Europe BLS is a market leader in the supply of CBD (Cannabidiol) and functional mushroom products to national retailers and Amazon. BLS manufactures private, white label, and under its own brands in its UK and EU facilities.