

22 July 2026

BLS Signs Non-Binding Heads of Agreement with Trexapharm for Australian Commercialisation of TrexAVIVE®

- BLS has entered a non-binding Heads of Agreement with Australian biopharmaceutical company, Trexapharm Pty Ltd for the proposed commercialisation of TREXAVIVE®, a proprietary, patented neurotherapy for treatment-resistant depression
- Proposed collaboration would see BLS appointed Trexapharm's preferred Australian commercial partner, supporting psychiatrists and clinics and patient access pathways
- The parties will explore Australian manufacturing of TREXAVIVE®, including subcutaneous infusion and nasal spray delivery systems
- Collaboration expands BLS's mental health medicine offering beyond cannabis based medicinal products and psychedelic medicines into a differentiated, non-sedating Central Nervous System (CNS) therapeutic platform
- Parties intend to explore opportunities in veteran and defence mental health, international expansion, manufacturing and supply, and potential strategic investment

BLS Pharmaceuticals Limited (ASX: BLS) ("BLS" or "the Company") is pleased to advise it has entered into a non-binding Heads of Agreement (HoA) with Australian based Trexapharm Pty Ltd ("Trexapharm"), a privately held CNS-focused drug development company, to establish a strategic collaboration for the Australian commercialisation of TREXAVIVE®, Trexapharm's proprietary neurotherapy for treatment-resistant depression.

The collaboration will establish BLS as Trexapharm's preferred Australian commercial partner, leveraging the Company's pharmaceutical manufacturing capabilities, commercial infrastructure and established healthcare relationships to support patient access and future commercialisation of TREXAVIVE® in Australia.

Managing Director, Sam Watson, commented:

"Treatment-resistant depression is not just a diagnosis, it is a daily battle for millions of people that harms motivation, relationships and hope. Too many patients simply run out of options when standard therapies fail. This proposed collaboration gives us the opportunity to support the introduction of differentiated, non-sedating treatment options to Australian psychiatrists and their patients, alongside our existing work in medicinal cannabis and psychedelic

medicines.

As BLS Pharmaceuticals continues to grow as an international pharmaceutical manufacturer and supplier, TREXAVIVE® would broaden our mental health offering and further demonstrate the value of the commercial platform and healthcare relationships we have built. Most importantly, it has the potential to give patients another option when conventional care has let them down."

Trexapharm Executive Chairman, Lee Rodne, commented:

"We have been looking for the right commercial partner to help bring TREXAVIVE® to Australian patients, and BLS stood out because of its established pharmaceutical manufacturing capabilities, commercial infrastructure and growing leadership in regulated mental health therapies.

We believe this collaboration provides a strong platform to expand patient access while continuing the clinical development of TREXAVIVE®, and we look forward to working together as the relationship evolves."

TREXAVIVE®

TREXAVIVE® is a proprietary, patented neurotherapy being developed for treatment-resistant depression, Major Depression Disorder, and trauma-related disorders, including post-traumatic stress disorder. Designed as a non-sedating outpatient therapy, it combines low doses of flumazenil and naltrexone for administration within existing psychiatric settings.

Early clinical experience has demonstrated encouraging preliminary safety, tolerability and efficacy signals, including symptom improvement observed from Day 4 in a small open-label study involving 10 patients who had previously failed at least three therapies. These findings remain preliminary and require confirmation in larger controlled clinical studies.

Unlike some next-generation mental health treatments, TREXAVIVE® has been designed for administration within existing outpatient psychiatric workflows without the sedation, dissociation or specialised hospital infrastructure often required by alternative therapies. This outpatient model aligns with BLS's established commercial infrastructure, healthcare relationships and growing capabilities across regulated mental health therapeutics.

Proposed Australian Commercial Collaboration

Under the Heads of Agreement, BLS will become Trexapharm's preferred Australian commercial partner for TREXAVIVE®, leveraging its established relationships with psychiatrists, mental health clinics and healthcare providers to support the therapy's introduction into the Australian market.

The collaboration will support patient access through the Therapeutic Goods Administration's Special Access Scheme (SAS) Category B and Authorised Prescriber pathways, while also evaluating future manufacturing and supply opportunities as the program progresses.

Trexapharm will retain responsibility for the clinical development of TREXAVIVE® and retains ownership of its intellectual property, which is protected by patents in Australia and the United States, together with additional international patent applications.



Beyond Australia, the parties intend to explore opportunities into international markets, including the United Kingdom, while also considering manufacturing and supply arrangements, veteran and defence mental health initiatives, broader commercial rights and partnerships and potential strategic investment opportunities.

The Heads of Agreement is non-binding and provides the framework for the parties to negotiate definitive commercial agreements.

Approved by the Board of BLS Pharmaceuticals Limited for release to the ASX.

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About Trexapharm

Trexapharm Pty Ltd is an Australian biopharmaceutical company focused on developing science-led therapies for complex mental health conditions. The Company's lead therapy, TREXAVIVE®, is a proprietary, patented neurotherapy being developed for treatment-resistant depression and trauma-related disorders. Trexapharm's development strategy combines repurposed compounds, targeted delivery technologies and practical regulatory pathways to improve patient access to innovative therapies.

About BLS Pharmaceuticals Limited

BLS Pharmaceuticals Limited (ASX:BLS) is an Australian pharmaceutical company focused on the manufacture, development and commercialisation of regulated therapeutic products and active pharmaceutical ingredients. Through its wholly owned subsidiary, Breathe Life Sciences, the Company operates a GMP-licensed manufacturing, import, export and distribution platform spanning medicinal cannabis, psychedelic medicines and other controlled pharmaceutical products.

BLS maintains operations across Australia, Europe, the United Kingdom and Japan, supplying pharmaceutical products and manufacturing services to regulated international markets through a growing network of commercial partners.

About Breathe Life Sciences

Breathe Life Sciences is a wholly owned subsidiary of BLS Pharmaceuticals Limited and a GMP-licensed manufacturer, wholesaler, importer and exporter of controlled substances, including medicinal cannabis, psilocybin and MDMA.

Established in 2018, Breathe Life Sciences has developed an international pharmaceutical manufacturing and distribution platform with operations across Australia, Japan, Scotland (UK) and Europe. The business specialises in final dose-form manufacturing, pharmaceutical distribution, contract manufacturing, international supply and the development of regulated therapeutic products.

Breathe Life Sciences sources pharmaceutical raw materials and active pharmaceutical ingredients from a global supplier network and manufactures products for both its own brands and third-party customers. The Company owns the Dr Watson® brand portfolio across multiple international markets and supplies pharmaceutical products, active pharmaceutical ingredients and manufacturing services to customers globally.

In addition to its medicinal cannabis operations, Breathe Life Sciences holds licences and capabilities supporting the manufacture, import, export and distribution of a range of regulated pharmaceutical products, positioning the business to participate in emerging therapeutic markets, including psychedelic medicines.

Corporate: blspharma.com

Australia: bls.com.au

International: breathelifesciences.com