



## **BERONI GROUP ACHIEVES FOUR MAJOR PRECLINICAL MILESTONES, ADVANCING GLOBAL LICENSING-READY DRUG PLATFORMS**

**SYDNEY, Australia, July 6, 2026** – Beroni Group Limited (NSX: BTG) (“Beroni”) today announced a series of scientific milestone achievements by its wholly owned subsidiary, Beroni Guangdong Pharmaceuticals (Guangdong) Co., Ltd. These achievements span four advanced therapeutic programs: NAS01 for NASH, two-stage targeted nucleic acid drugs for liver fibrosis and cirrhosis, a microfluidic methotrexate liposome (MTX-Lip) oncology formulation, and brexpiprazole PLGA sustained-release microspheres.

Together, these programs establish a differentiated, high-value pipeline supported by reusable technology platforms with significant commercial potential for global licensing and co-development. All four initiatives have completed regulatory-standard preclinical data packages, backed by filed core invention patents. The flagship asset NAS01 has now advanced into pilot scale-up and GLP-compliant non-clinical studies, substantially reducing technical risks for cross-border strategic cooperation.

The major preclinical milestones are highlighted below.

### *1. World-First Dual-Target siRNA NAS01 for NASH*

NASH affects hundreds of millions worldwide and remains a top strategic priority for global pharmaceutical companies. Milestones achieved:

- **Exclusive two-stage targeting platform with full global IP:** Beroni has developed the world’s first hepatocyte–lipogenic enzyme dual-target siRNA design, independent of overseas GalNAc/LNP patents. This innovation blocks hepatic lipid accumulation at its source and provides full IP ownership for global out-licensing, joint development or platform acquisition.
- **Complete regulatory-grade preclinical data:** NAS01 significantly reduces liver fat deposition and demonstrates excellent safety, with no toxicity at 2000 mg/kg in mice. Comprehensive pharmacokinetic data supports global joint clinical trial planning.
- **Mature scalable manufacturing technology:** Formulation screening, raw material qualification and stability testing (1-year long-term and 1-month accelerated) are complete. Standardized production protocols are ready for technology transfer.
- **GLP pilot scale-up and Pre-IND work initiated:** Fully aligned with NMPA, FDA and EMA standards to ensure stable clinical drug supply.

## 2. *Proprietary Targeted Nucleic Acid Therapeutics for Liver Fibrosis & Cirrhosis*

Liver fibrosis remains irreversible with no approved therapies, making it a global R&D priority. Milestones achieved:

- **Patented APT8 aptamer targeting hepatic stellate cells:** Four core invention patents under examination address the long-standing challenge of non-specific liver drug delivery, enabling flexible worldwide licensing.
- **Two differentiated therapeutic modalities:** Aptamer-conjugated oligonucleotides and AAV5-miR-29a gene therapy both suppress hepatic stellate cell activation to reverse fibrosis, offering clear differentiation from small-molecule competitors.
- **Dual authoritative validation:** Four high-impact Q1 SCI publications and technical recognition from ECsun Research Institute shorten due-diligence cycles for global partners.
- **Synergistic liver disease portfolio:** Combined with NAS01, these assets form a full-cycle therapeutic matrix from early NASH intervention to end-stage fibrosis reversal.

## 3. *Microfluidic Methotrexate Liposomes (MTX-Lip) for Hepatocellular Carcinoma*

A universal modular nano-delivery platform with strong cross-border oncology collaboration potential. Milestones achieved:

- **Proprietary scalable microfluidic production:** Produces highly homogeneous liposomes ( $98.9 \pm 3.4$  nm, PDI=0.192, encapsulation efficiency 44.8%) with consistent batch quality. The process is transferable to all chemotherapeutic agents.
- **Dual differentiated mechanisms:** pH-responsive sustained release reduces systemic toxicity. PEG modification enables tumor accumulation for up to 28 hours via the EPR effect.
- **Complete efficacy and safety data:** MTX-Lip reduces tumor weight by over 50% compared with free methotrexate and alleviates myelosuppression and hepatorenal toxicity. Full datasets support joint global IND filing.

## 4. *Globally Exclusive Long-Acting PLGA Brexpiprazole Microspheres*

No long-acting injectable brexpiprazole microspheres have been launched worldwide as of March 2026. Milestones achieved:

- **Breakthrough microfluidic manufacturing:** Microspheres with particle CV < 5% eliminate the industry-wide release lag phase, enabling immediate steady drug concentrations post-injection.
- **Game-changing clinical benefits:** Converts daily oral dosing to once-monthly injection, addressing the 40%–75% annual discontinuation rate among schizophrenia patients and reducing plasma fluctuation-related adverse reactions.

- **Huge commercial potential:** Oral brexpiprazole generates USD 2 billion annual sales with 29% YoY growth. The long-acting injectable formulation targets poorly adherent high-risk patients, offering multi-billion incremental revenue potential for global licensees.

#### Strategic Value

These milestones collectively establish a diversified, high-end innovative drug matrix spanning anti-tumor nanoformulations, precision nucleic acid therapeutics for liver diseases, and long-acting sustained-release CNS formulations. They significantly strengthen the Beroni's R&D depth, IP protection, global competitiveness and platform valuation. The achievements provide a robust foundation for IND submissions, industrial partnerships and global technology licensing. They offer one-of-a-kind full-stack delivery technology portfolio for MNC acquisition or licensing, diversified first-in-class pipeline for bundled multi-asset cooperation, multi-layered validation to reduce global partners' due diligence costs, and open flexible cooperation framework to accelerate global commercialization.

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#### About Beroni Group Limited

Beroni Group is an international biopharmaceutical enterprise dedicated to the innovation and commercialization of drugs and therapies to combat various global diseases such as cancer and infectious diseases. Its diversified portfolio is comprised of FDA/CE approved virus diagnostic kits, an e-commerce platform for the sale of pharmaceutical products and a development pipeline targeting oncology and cell therapies. Beroni has operations in Australia, United States, China and Japan. It is listed on the National Stock Exchange of Australia. To learn more about Beroni, please visit [www.beronigroup.com](http://www.beronigroup.com).

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