NeuroScientific

ASX:NSB

ASX Announcement
17 March 2026

StemSmart™ Manufacturing Scale-Up Transfer Advances

Technology Transfer Manufacturing Run Commences at Q-Gen as Planned Phase 2 Trial Preparations Progress

Highlights

- **First technology transfer manufacturing run for StemSmart™ has initiated at leading Australian cell therapy manufacturer, Q-Gen Cell Therapeutics[1].**
- **Commencement of the tech transfer run represents a major milestone in transferring the patented StemSmart™ manufacturing process to a large clinical-scale contract manufacturer capable of supplying Phase 2 clinical trials and beyond.**
- **Q-Gen Cell Therapeutics, located within QIMR Berghofer in Brisbane, is one of the largest cell therapy contract manufacturers in Australia, with 13 cleanrooms dedicated to cell manufacturing and quality control.**
- **Completion of the StemSmart™ manufacturing process transfer is targeted for 2H 2026, subject to successful validation and TGA audit, with Q-Gen expected to receive an expansion of its TGA manufacturing license to include the StemSmart™ process.**
- **In parallel, NSB continues Phase 2 clinical trial start-up activities targeting initiation in 2H 2026.**
- **These activities establish the foundation for entry into the ~US$13 billion Global Crohn's disease market[2].**
- **StemSmart™ is positioned as a platform mesenchymal cell therapy with potential additional clinical opportunities in conditions characterised by inflammation, including organ transplant rejection, lung inflammatory disease and graft-vs-host disease.**

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific", "NSB" or the "Company"), an innovative Australian biotechnology company developing novel technologies targeted at immune-mediated inflammatory diseases, is pleased to announce that the first technology transfer manufacturing run of its patented StemSmart™ mesenchymal stem cell ("MSC") process has been initiated at Q-Gen Cell Therapeutics ("Q-Gen").

This marks a major milestone required to successfully transfer the patented StemSmart™ manufacturing process to the contract manufacturer with the scale and capability to supply products for late-stage clinical trials.

Q-Gen, located within QIMR Berghofer in Brisbane, is one of the largest cell therapy contract manufacturers in Australia, with 13 cleanrooms dedicated to cell manufacturing and quality control. Q-Gen, which holds a TGA licence for cell therapy manufacture and has more than 25 years in cell

+61 8 6268 2641 ir@neuroscientific.com Level 4, 216 St Georges Terrace, PERTH, WA, AUSTRALIA, 6000

therapy manufacturing for industry, has the experience, expertise and capacity to manufacture StemSmart™ to meet NSB's commercialisation goals.

NSB Chief Executive Officer, Mr Nathan Smith, commented:

> *"The initiation of the first tech transfer run at Q-Gen is an important step in securing our supply chain for our commercialisation goals. Our partnership with Q-Gen is critical in ensuring patients receive high-quality StemSmart™ products that meet global regulatory standards. Along with our recent successful patient outcomes from the fistulising Crohn's disease Special Access Program, we are setting the foundation for our upcoming Phase 2 clinical trial."*

NSB Chief Scientific Officer, Dr Marian Sturm, commented:

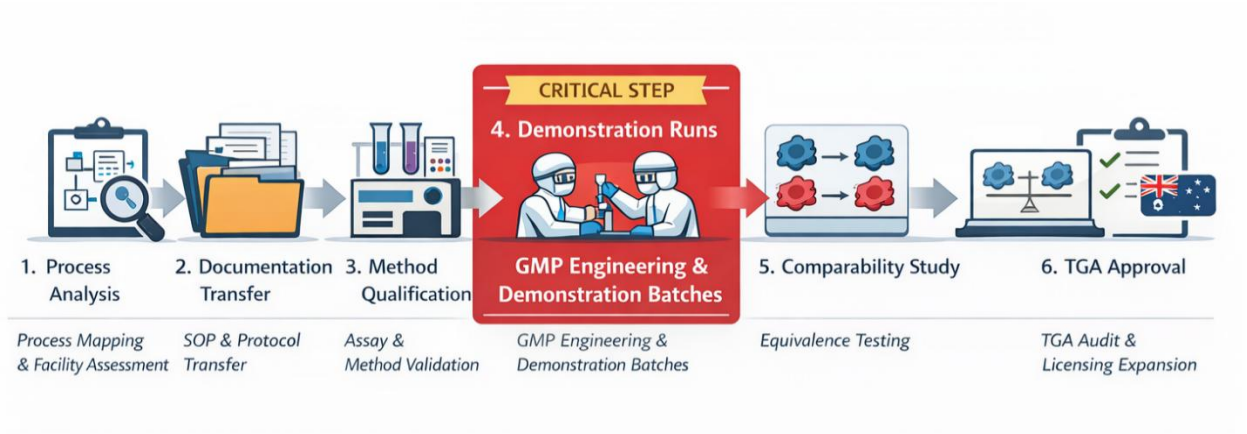
> *"I am excited by the commencement of the first tech transfer manufacturing run at Q-Gen. It represents a significant milestone and is the culmination of an extensive amount of work by both Q-Gen and NSB. Q-Gen have demonstrated their professionalism, capability and experience in integrating NSB manufacturing technology into their Quality system, sourcing appropriate material suppliers and in implementing the testing platforms. NSB is confident that Q-Gen will successfully complete the technology transfer and manufacture product for our clinical trials.*

StemSmart™ Manufacturing Technology Transfer Milestone

The Company confirms that the initial technology transfer run has commenced as part of the planned transfer of its patented StemSmart™ mesenchymal stem cell manufacturing process to Q-Gen, a large-scale GMP contract manufacturer.

The technology transfer program comprises six key stages:

1. Process mapping and facility assessment,
2. Documentation and SOP transfer,
3. Analytical method qualification,
4. GMP engineering and demonstration runs,
5. Product comparability assessment, and
6. Regulatory audit and licence by the Australian Therapeutic Goods Administration (TGA).



The GMP engineering and demonstration runs represent the critical validation phase of the transfer, requiring the manufacture of consecutive compliant batches that meet predefined release and potency specifications. Successful completion of these runs is required prior to formal comparability review and TGA inspection.

The full technology transfer program remains on schedule for completion in 2H 2026. Upon successful TGA audit, Q-Gen's manufacturing licence is expected to be expanded to include mesenchymal stem cell manufacture, including the StemSmart™ process, enabling supply of clinical-scale product for Phase 2 studies and beyond.

Clinical Development Strategy – Crohn's Disease

In parallel with manufacturing scale-up, NSB is progressing clinical trial start-up activities, including clinical protocol development and regulatory planning to support the initiation of its planned Phase 2 clinical trial in Crohn's disease, targeted for 2H 2026.

Crohn's disease represents a significant and growing global therapeutic market, projected to reach approximately US$13.8 billion by 2026. Despite the availability of multiple biologic and small-molecule therapies, a substantial proportion of patients either fail to respond, lose response over time, or experience significant adverse effects. Patients with refractory or fistulising disease remain particularly difficult to treat, highlighting a continued and meaningful unmet clinical need for novel therapies with differentiated mechanisms of action and improved safety profiles.

StemSmart™ is designed to modulate pathological immune responses and reduce inflammation. Beyond Crohn's disease, the Company believes the platform has broader applicability across other immune-mediated inflammatory conditions.

[1] ASX Announcement (31 July 2025) – *"NeuroScientific Partners with Leading Biologic Manufacturer"*
[2] ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology"*

This announcement is authorised by the Board of NeuroScientific Biopharmaceuticals Ltd.

+61 8 6268 2641 ir@neuroscientific.com Level 4, 216 St Georges Terrace, PERTH, WA, AUSTRALIA, 6000

For more information, please contact:

Nathan Smith
Chief Executive Officer
NeuroScientific Biopharmaceuticals Ltd
ir@neuroscientific.com

Jane Morgan
Investor & Media Relations
Jane Morgan Management
jm@janemorganmanagement.com.au

About NeuroScientific Biopharmaceuticals Ltd

NeuroScientific Biopharmaceuticals Limited (ASX: NSB) is a biotechnology company focused on the development of novel therapeutics targeting immune-mediated inflammatory disorders. The Company's research is centred on modulating pathological immune responses involved in chronic and degenerative conditions, particularly where current therapeutic options demonstrate limited efficacy or durability. NSB applies advanced preclinical and translational strategies to support the development of first-in-class or best-in-class biologics addressing significant unmet clinical need.

Targeting Crohn's Disease with StemSmart™ Technology

Following the acquisition of Isopogen WA Ltd, NSB is prioritizing the application of its proprietary StemSmart technology through a SAS program targeting fistulising Crohn's disease—a severe and treatment-resistant form of the condition. Favourable outcomes will support the Company's progression to a Phase 2 clinical trial to further evaluate safety and preliminary efficacy in refractory and/or fistulising Crohn's disease. This initiative aligns with NSB's broader strategy to obtain regulatory and reimbursement approval for its MSC therapy both in Australia and internationally, with the goal of making the treatment available to patients with fistulising and refractory Crohn's disease, for whom current therapies remain inadequate.

About EmtinB™

EmtinB™ is a peptide-based compound that binds to surface-based cell receptors from the LDLR family, activating intracellular signalling pathways that stimulate neuroprotection, neuroregeneration and modulate neuroinflammation. EmtinB™ is modelled on a specific active domain of the complex human protein called Metallothionein-IIA, which is produced as part of the human body's innate immune response to cell injury. Our preclinical research has established that EmtinB™ is highly specific and selective for its target receptor, safe and well tolerated at high concentrations.

Forward Looking Statements

This announcement may contain certain "forward-looking statements". Forward looking statements can generally be identified by the use of forward-looking words such as, "expect", "should", "could", "may", "predict", "plan", "will", "believe", "forecast", "estimate", "target" and other similar expressions. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions. Forward-looking statements including projections, guidance on future earnings and estimates are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

You are strongly cautioned not to place undue reliance on forward looking statements, including in respect of the financial or operating outlook for the Company. Except as required by law or any relevant listing rules of

the ASX, the Company assumes no obligation to provide any additional or updated information or to update any forward looking statements, whether as a result of new information, future events or results, or otherwise. Nothing in this announcement will, under any circumstances (including by reason of this announcement remaining available and not being superseded or replaced by any other presentation or publication with respect to the Company, or the subject matter of this announcement), create an implication that there has been no change in the affairs of the Company since the date of this announcement.