NeuroScientific

ASX:NSB

ASX Announcement
30 January 2026

December 2025 Quarterly Activity Report (Q2 FY26)

Building Towards Phase 2 Clinical Trial of StemSmart™ for Crohn's Disease

Highlights

- **StemSmart™ Special Access Program:** Treating patients with Fistulising Crohn's Disease, with multiple patients approved and undergoing treatment with StemSmart™ therapeutic (and initial results, demonstrating "Clinical Response" following the Reporting Period).
- **Phase 2 Clinical Trial Preparation:** Real-world clinical data generated under the Special Access Program continues to inform Phase 2 clinical trial design and broader clinical development strategy.
- **Appointment of a Clinical & Scientific Advisory Board:** Strengthening of clinical, scientific and translational expertise to support the ongoing development of the StemSmart™ platform and progression toward Phase 2 clinical trials.
- **Manufacturing Technology Transfer:** Activities progressed for technology transfer to Q-Gen and scale-up of manufacturing, supporting future clinical and supply chain readiness.
- **Strong Financial Position:** Cash and cash equivalents of approximately $6.4 million, providing funding to continue planned clinical development activities.

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific" or "NSB" or the "Company"), an innovative Australian biotechnology company developing novel technologies targeted at immune-mediated inflammatory diseases, is pleased to provide its Appendix 4C and Quarterly Activity Report for the period ended 31 December 2025 (the "Quarter" or the "Reporting Period").

During the December 2025 Quarter, NeuroScientific continued to advance the clinical and operational development of its proprietary StemSmart™ mesenchymal stem cell ("MSC") platform, with a particular focus on progressing the Special Access Program (the "Program") for patients with Fistulising Crohn's Disease under the Therapeutic Goods Administration's ("TGA") Special Access Scheme ("SAS"). The Program commenced, with initial results demonstrating a "Clinical Response" following the Reporting Period. Meanwhile, major operations such as manufacturing technology transfer to Q-Gen, and clinical planning and regulatory work to support the Company's planned Phase 2 clinical trial program have progressed.

Commenting on the activities for the Quarter, NeuroScientific's CEO, Mr Nathan Smith, stated: *"This December Quarter was an important period of execution for NeuroScientific as we continue to move swiftly since the acquisition of the StemSmart™ technology in June of 2025. As we have commenced with this journey, the most recent Quarter has continued to reflect the work of the last, with a disciplined approach to building the foundations that are required for the clinical development of StemSmart™ in a 'patient-centric' manner.*

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Treating patients with a severe, debilitating, and often treatment-resistant condition like Fistulising Crohn's Disease under our ongoing Special Access Program has generated valuable clinical insights for StemSmart™, primarily as the first demonstration of what we see as the potential posed by this technology since its acquisition.

Most importantly, the positive response for patients who have lived with such a life-altering condition, facing very limited treatment options, underscores the mission and vision we have for this Company."

OVERVIEW OF OPERATIONS

During the December 2025 Quarter, major milestones centred around NSB's StemSmart™ Special Access Program, clinical development of the StemSmart™ product and Phase 2 clinical trial preparation, and the appointment of the Company's new Clinical & Scientific Advisory Board.

StemSmart™ Special Access Program for Fistulising Crohn's Disease

On 7 October 2025, NeuroScientific announced that the first three patients in Cohort 1 of its Special Access Program for Fistulising Crohn's Disease had been approved by the TGA for treatment under its Special Access Scheme Category B Pathway.

The Company then facilitated patient recruitment and treatment coordination for the Special Access Program, targeting patients with severe, treatment-resistant Fistulising Crohn's Disease who have exhausted available conventional and existing approved therapies. The Program is intended to enable eligible patients to receive treatment with NSB's patented StemSmart™ MSC product in a real-world clinical setting where they still have unmet medical needs that aren't being addressed by existing therapeutic options – sometimes referred to as being treated "on compassionate grounds".

On 11 November 2025, NSB then announced that its fourth patient had commenced treatment under the Special Access Program, leading to a total of four patients undergoing treatment with StemSmart™ at the time. Treatment data being generated from the Program also informs the design and execution of the Company's planned Phase 2 clinical trial program for Refractory Crohn's Disease, anticipated to commence in CY2026.

Subsequent to the end of the Reporting Period, on 13 January 2026, NeuroScientific announced a successful clinical outcome for three (3) patients treated under the Special Access Program for Fistulising Crohn's Disease.

Of the four (4) patients treated in Cohort 1, three (3) achieved a "Clinical Response" to treatment with the StemSmart™ therapeutic, defined as either the closure of ≥50% of fistula openings, or a ≥50% decrease in fistula discharge in a patient, assessed by the treating physician or qualified investigator. The remaining patient was announced to have demonstrated a partial response and improvement from the treatment but requires further assessment to determine a final result.

These outcomes provide validation of the StemSmart™ platform since its acquisition in CY2025, demonstrating the potential of the MSC therapeutic in a real-world clinical setting and further supporting the Company's continued progression of Phase 2 start-up activities.

Clinical Development and Phase 2 Trial Preparation

On 11 November 2025, and concurrently with the announced progression of the SAS Program, NSB also confirmed that real-world treatment data generated through the Special Access Program was being used to directly support Phase 2 clinical trial design, alongside broader clinical development and regulatory planning activities – reiterating the Company's disciplined approach to its clinical work and moving with a patient-centred approach to the development of its proprietary technology and therapeutic.

Throughout the Quarter, NSB continued with its clinical planning activities, including engagement with treating clinicians and review of emerging treatment outcomes from the Special Access Program. These activities were focused on ensuring that clinical insights generated under compassionate access conditions were appropriately incorporated into future trial protocols and development strategies.

Manufacturing Technology Transfer and Supply Chain Readiness

On 7 October 2025, NeuroScientific confirmed that manufacturing technology transfer activities for its patented StemSmart™ manufacturing process continue to progress in parallel with the Company's clinical development efforts, continuing the transfer of its proprietary manufacturing process to its contracted manufacturing partner, Q-Gen.

This process was reiterated as part of the Company's approach to supporting the establishment of GMP-compliant production capability required for future clinical trials, as well as for scale-up in service of commercialisation. Manufacturing readiness remains a key operational focus as the Company worked to secure its StemSmart™ supply chain and align manufacturing capability with anticipated Phase 2 clinical trial requirements.

EmtinB Development Update

During the Quarter, the Company continued to advance EmtinB, its novel peptide therapeutic program targeting pathways involved in retinal degeneration, including glaucoma. Progress during the period builds on the momentum reported last quarter and keeps the program aligned with FDA pre-IND guidance.

Formulation and Manufacturing Progress

The Company continues to progress EmtinB toward an intravitreal (IVT) formulation suitable for ocular administration. Work during the Quarter concentrated on optimising formulation characteristics required for intraocular delivery, including stability, solubility, and compatibility with international ophthalmic standards. Independent third-party specialists are developing and assessing multiple potential IVT formulations to support selection of a final clinical candidate.

The overall objective remains to identify a commercially viable IVT formulation and confirm a safe and effective dose that achieves pharmacological activity at least two-fold below the established NOAEL threshold.

Non-Clinical and Translational Studies

During the Quarter, the Company progressed non-clinical studies designed to support translation from preclinical models to human clinical trials, consistent with FDA pre-IND expectations. These studies focus on confirming target engagement across relevant species and developing a biological activity assay that can be validated for clinical use.

Together, this data is intended to support dosing rationale, and biological relevance and, once validated, provide an acceptable biological activity/potency assay ahead of any clinical development.

Next Development Phase

Following completion of IVT formulation optimisation, the next phase of the program would focus on initiating intravitreal pharmacokinetic and ocular safety studies.

These studies are expected to:

- Inform optimal dosing strategy
- Confirm minimal systemic exposure following ocular administration
- Support preparation for additional GLP toxicology studies

Successful completion of this work is expected to position the EmtinB program for IND-enabling toxicology studies and eventual IND submission.

Strategic Outlook

As EmtinB continues to progress toward clinical readiness, the Company has begun evaluating potential partnership pathways for the clinical development of the program. This includes assessing the level of interest from external parties and considering structures that could support efficient advancement through clinical trials while maximising long-term value for shareholders.

CORPORATE OVERVIEW

On 6 November 2025, NSB announced the establishment of its new Clinical & Scientific Advisory Board, which will be chaired by the Company's Chief Medical Officer, Dr Catherine Cole, and includes Chief Scientific Officer, Dr Marian Sturm.

Members also include Dr Ashley Irish, a clinical nephrologist and renal transplant specialist with vast experience in immune-mediated kidney disease and transplantation; Dr Lena Thin, a consultant gastroenterologist with a specialist focus on inflammatory bowel disease and clinical trials; Dr Michael Musk, a respiratory physician and lung transplant specialist; and Professor Yuben Moodley, a respiratory physician and researcher with expertise in pulmonary fibrosis, chronic lung disease and cell biology.

The Clinical & Scientific Advisory Board was formed to provide expert guidance across scientific innovation, clinical indications, and patient treatment, and further strengthens NSB's clinical and translational expertise as it progresses the clinical development of its patented StemSmart™ platform.

Quarterly Cashflow Summary

NeuroScientific' s cash position was ~$6.4 million as at 31 December 2025.

The Company has maintained a strong cash position and expenses continue to be managed with discipline as NSB works towards its next capital-intensive activities.

Research and development activity payments during the current Quarter were approximately $315k.

Staff costs not classified within research and development were $21k for the Quarter, while administration and corporate costs were $193k.

Payments to related parties during the December 2025 Quarter totalled $80k and relate to Director fees, salaries and superannuation.

StemSmart™ Key Addressable Markets

- **Crohn's Disease:** Global market US$13.8 billion by 2026;
- **Kidney Transplant:** Global market for organ transplant immuno-suppressants, increasing to US$7.2 billion by 2030 (majority for renal);
- **Lung Disorders:** Global market US$33 billion by 2034; and
- **GvHD**: Global market increasing to US$5.31 billion in 2032.

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

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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 form of the condition that is often resistant to conventional forms of treatment. Outcomes of this Program are intended to support the development of the future Phase 2 clinical trial in the broader indication of refractory Crohn's disease, planned for 2026. 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.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
NeuroScientific Biopharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
13 102 832 995	31 December 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(315)	(354)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(39)	(107)
	(d) leased assets	-	-
	(e) staff costs	(21)	(159)
	(f) administration and corporate costs	(193)	(670)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	36	64
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	318
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(532)**	**(908)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,889	7,265
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(532)	(908)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,357**	**6,357**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	607	639
5.2	Call deposits	5,750	6,250
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**6,357**	**6,889**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(80)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Item 6.1 above includes Director salaries, fees & superannuation.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(532)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,357
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,357
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	11.95

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: n/a

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: n/a

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: n/a

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30 January 2026

Authorised by: The Board of Directors