

ASX Announcement

30 October 2025

## September 2025 Quarterly Activity Report (Q1 FY26)

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

### Highlights

- **Patient recruitment momentum progressing for Special Access Program, with initial patients in cohort one for fistulising Crohn's disease approved by TGA post-reporting period.**
- **Dr Catherine Cole appointed as Chief Medical Officer, a physician and recognised leader in haematology, oncology, and bone marrow transplantation.**
- **Experienced cell therapy executive, Nathan Smith appointed as CEO, bringing deep expertise in GMP manufacturing across full therapeutic lifecycle.**
- **NSB partners with leading Biologic Manufacturer, Q-Gen Cell Therapies, commencing technology transfer to scale StemSmart™ for clinical trials and commercialisation.**
- **Previous StemSmart Studies support Renal Transplantation, demonstrating promising results in preventing and treating graft failure and rejection.**
- **Cash balance of ~A\$6.9million at 30 September 2025.**

**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 announce its Appendix 4C and quarterly activity report for the quarter ended 30 September 2025 (the "Quarter" or the "Reporting Period" or "Q1 FY2026").

### OPERATIONAL OVERVIEW

#### Subsequent to Quarter's End

On 7 October 2025, NSB announced that it had its initial three patients in Cohort 1 of its fistulising Crohn's disease Special Access Program approved for treatment by the TGA.

The approval took place under the TGA's Special Access Program (Category B) regulatory scheme, marking a pivotal step in NSB's clinical development work toward using the StemSmart™ MSC technology

for patients with severe and even conventional-treatment-resistant forms of Crohn's disease. The Special Access Program is anticipated for completion mid-CY2026.

This development will assist the Company in being able to use StemSmart™ MSC therapy for approved patients in the next step of its clinical pathway, with the Special Access Program directly supporting the initiation of a Phase 2 Clinical Trial in refractory Crohn's disease that is anticipated for CY2026.

## Neuroscientific Appoints Clinician, Dr Catherine Cole, as Chief Medical Officer

On 25 July 2025, the appointment of Dr Catherine Cole as Chief Medical Officer was announced by the Company. Dr Cole stepped into the role at a key development stage for the Company, around the time when the Special Access Program in fistulising Crohn's disease was beginning to take shape, with results from the first 4 patients anticipated by the end of CY 2025.

Dr Cole has a very impressive clinical career in paediatric and adolescent haematology and oncology, including bone marrow transplantation, and is recognised as a leading physician in Australia and internationally. Dr Cole has served as Head of Haematology and Oncology at Princess Margaret Hospital and Perth Children's Hospital, Director of Hematopoietic Stem Cell Transplantation, and Inaugural Professor of Paediatric Haematology and Oncology at the University of Western Australia. She has also been a member of key regulatory and advisory bodies such as the TGA's Advisory Group for Prescription Medicines and the Pharmaceutical Benefits Advisory Committee for the Australian Department of Health.

Dr Cole has noted the effectiveness of StemSmart™ MSCs in treating patients with Graft Versus Host Disease ("GvHD") through her own clinical work and experience as a practitioner.

## NeuroScientific Appoints Experienced Cell Therapy Executive, Nathan Smith, as CEO

On 28 July 2025 the appointment of Nathan Smith as CEO was announced. Based in Melbourne, Mr. Smith brings extensive experience in cell and gene therapies, having held senior commercial, operational, and strategic roles in both Australia and the United States.

Mr. Smith's career includes leadership positions at **Cell Therapies Pty Ltd** where he served as Director of Business Development as well as key roles at **Genzyme Corporation (USA)**, **Mesoblast Inc. (USA)**, **GlaxoSmithKline (USA)**, and other leading companies in the cell therapy space. Throughout his career, Nathan has led programs across the full therapeutic lifecycle, including pre-clinical development and clinical trials, navigating the regulatory pathway in multiple jurisdictions and the commercial supply of products.

Importantly, Nathan brings deep expertise in GMP manufacturing, an essential pillar for the successful translation and scale-up of any stem cell company. His manufacturing background comes at a pivotal time for NSB as the Company accelerates development of its platform and prepares for future clinical trials and commercialisation.

## Neuroscientific Partners with Leading Australian Biologic Manufacturer

On 31 July 2025, NSB announced it had commenced the transfer of its patented manufacturing process for its mesenchymal stromal cells from Cell and Tissue Therapy WA (Royal Perth Hospital) to Q-Gen Cell Therapeutics ("Q-Gen") of QIMR Berghofer Medical Research Institute ("QIMR Berghofer").

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 specialises in manufacturing cellular immunotherapies for clinical trials, both national and international.

Q-Gen, which holds a TGA licence for cell therapy manufacture and has more than 25 years in cell therapy manufacturing for industry, has the experience, expertise and capacity to manufacture StemSmart™. The commencement of the technology transfer to Q-Gen is an important milestone for the Company to establish its cell manufacturing and enable it to undertake further clinical trials and pursue commercial opportunities.

## Previous StemSmart™ Therapy Supports Clinical Development in Renal Transplantation

On 27 August 2025, the Company announced historical data from two renal transplantation studies, following a continued review of historical studies, data, findings and publications following NSB's acquisition of Isopogen WA Ltd.

### Highlights were as follows:

Both studies support further clinical development and the potential of StemSmart™ MSC in both preventing and treating graft failure and rejection.

The first study included a series of 10 adult patients with **treatment-refractory acute renal rejection**, following renal transplantation. Patients were treated with StemSmart™ MSC on compassionate grounds, as a salvage and adjunctive therapy. These **patients were facing the loss of their donor kidney**. Importantly, positive clinical outcomes from the use of StemSmart™ MSC therapy were observed. **8 out of 10 patients retained their kidney following the StemSmart™ MSC infusion.**

The second study was undertaken in 12 adults **undergoing deceased-donor renal transplantation**, to assess if StemSmart™ MSC therapy was safe and could be tolerated, to potentially alleviate ischaemia-reperfusion injury of transplantation. Ischaemia-reperfusion injury occurs when blood circulation is re-established to the kidney during the transplantation procedure and can result in delayed functioning of the kidney and an increased risk of graft rejection and loss. It is particularly relevant in deceased-donor kidney transplantation. The study demonstrated that StemSmart™ **MSC infusion was well tolerated and safe in patients undergoing renal transplantation, with no infusion related toxicities.** Although the study was not designed to determine efficacy, results were encouraging for an **improvement in delayed graft function immediately post transplantation and kidney graft function was excellent at 3 months and 12 months.**

Although these studies only involve small numbers of patients, they support further clinical development and the potential of StemSmart™ MSC in both preventing and treating graft failure and rejection and improving outcomes in renal transplantation.

## EmtinB Development Update

During the Quarter, the Company made significant progress in advancing its EmtinB program – NSB's novel, tetrameric peptide therapy aimed at treating degenerative optic conditions like glaucoma. The Company is currently moving toward an intravitreal (IVT) formulation that is suitable for ocular administration. The overall objective is to confirm that EmtinB is commercially viable in this route and to

determine a safe and effective dose that achieves pharmacologic activity that is at least twofold below the established NOAEL (No Observed Adverse Effect Level) threshold.

Following the FDA's pre-IND (pre-Investigational New Drug) guidance, key activities for this program have focused on formulation optimisation, analytical method development, and cross-species pharmacology assessments to support clinical relevance. Quotient Sciences – a pharmaceutical drug development and manufacturing accelerator – has been engaged to develop multiple IVT drug product formulations to achieve the characteristics (including pH, osmolality, viscosity, particulate matter, and stability) that are aligned with the FDA and international guidelines (USP, ISO, ICH) for ophthalmic drug products that are delivered via intraocular routes.

In parallel, Eurofins CALIXAR has been contracted to conduct comparative binding and in vitro functional efficacy studies across relevant animal species to confirm appropriate translation from preclinical studies to clinical trials and suggest systemic safety following ocular dosing.

Bachem Holding AG – a peptide and oligo manufacturer and CDMO – has also completed drug substance batch stability retesting. These datasets will underpin formulation selection and readiness for vitreal PK and systemic safety studies (Iris Pharma) using the optimised IVT formulation.

Looking ahead, the next phase will focus on completing IVT drug product formulation optimisation and initiating intravitreal pharmacokinetic studies in rabbits to determine the optimal dosing strategy, as well as confirm ocular safety and systemic exposure profiles. Further analytical method refinements, additional IVT-specific endotoxin, and particulate testing will also be undertaken for both the drug substance itself and drug product (i.e., its final commercial formulation). Armed with the final dosing formulation and optimal dosing strategy, the required GLP toxicity studies can be undertaken in preparation for clinical trials. Together, these studies will address the remaining pre-IND questions and position the program for IND submission.

The EmtinB program represents a novel biologic approach, targeting LRP-1 mediated pathways implicated in neurodegeneration and retinal injury. The progress achieved this Quarter provides NSB with further strong momentum toward clinical readiness and reinforces the program's potential to deliver a first-in-class therapeutic option for unmet needs in treating retinal diseases.

## CORPORATE OVERVIEW

### Corporate Governance & Annual Report

The Company lodged its 2025 Annual Report & Appendix 4E, and Appendix 4G and Corporate Governance Statement, on 28 August 2025.

### Quarterly Cashflow Summary

NeuroScientific's cash position was ~\$6.9 million as at 30 September 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 in the coming calendar year.

Research and development activity payments during the current Quarter were approximately \$39k (\$50k for the prior quarter ["PQ"]).

Staff costs for the Quarter were \$138k (PQ - \$88k), while administration and corporate costs were approximately \$477k (PQ -\$261k).

Payments to related parties during the September 2025 Quarter totalled \$84k and relate to Director fees, salaries and superannuation.

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

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## 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.

## 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.

## Appendix 4C

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

**Name of entity**

NeuroScientific Biopharmaceuticals Limited

**ABN**

13 102 832 995

**Quarter ended ("current quarter")**

30 September 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(39)	(39)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(68)	(68)
(d) leased assets	-	-
(e) staff costs	(138)	(138)
(f) administration and corporate costs	(477)	(477)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	28	28
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	318	318
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(376)</b>	<b>(376)</b>
<b>2. Cash flows from investing activities</b>		
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 (3 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>-</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	7,265	7,265
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(376)	(376)
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 (3 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	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,889</b>	<b>6,889</b>

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	639	3,515
5.2	Call deposits	6,250	3,750
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,889</b>	<b>7,265</b>

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	(84)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p><i>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.</i></p> <p>Item 6.1 above includes Director salaries, fees &amp; superannuation.</p>		

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(376)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,889
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,889
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	18.32
<i>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.</i>	
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	
<i>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.</i>	

**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 October 2025

Authorised by: The Board of Directors