NeuroScientific

ASX**NSB**

NeuroScientific Secures **Breakthrough Stem Cell Tech** in **Strategic Acquisition**

June 2025

Disclaimer

NeuroScientific

This presentation has been prepared by NeuroScientific Biopharmaceuticals Ltd (ASX: NSB) based on information available to it as at the date of this presentation. The information in this presentation is provided in summary form and does not contain all information necessary to make an investment decision.

This presentation does not constitute an offer, invitation, solicitation or recommendation with respect to the purchase or sale of any security in NSB, nor does it constitute financial product advice or take into account any individual's investment objectives, taxation situation, financial situation or needs. An investor must not act on the basis of any matter contained in this presentation but must make its own assessment of NSB and conduct its own investigations. Before making an investment decision, investors should consider the appropriateness of the information having regard to their own objectives, financial situation and needs, and seek legal, taxation and financial advice appropriate to their jurisdiction and circumstances. NSB is not licensed to provide financial product advice in respect of its securities or any other financial products. Cooling off rights do not apply to the acquisition of NSB securities.

Although reasonable care has been taken to ensure that the facts stated in this presentation are accurate and that the opinions expressed are fair and reasonable, no representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this presentation. To the maximum extent permitted by law, none of NSB, its officers, directors, employees and agents, nor any other person, accepts any responsibility and liability for the content of this presentation including, without limitation, any liability arising from fault or negligence, for any loss arising from the use of or reliance on any of the information contained in this presentation or otherwise arising in connection with it. The information presented in this presentation is subject to change without notice and NSB does not have any responsibility or obligation to inform you of any matter arising or coming to their notice, after the date of this presentation, which may affect any matter referred to in this presentation. The distribution of this presentation may be restricted by law and you should observe any such restrictions.

Forward Looking Statements

This presentation contains certain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. Such forward looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results or performance of NSB to be materially different from the results or performance expressed or implied by such forward looking statements. Such forward looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the political and economic environment in which NSB will operate in the future, which are subject to change without notice. Past performance is not necessarily a guide to future performance and no representation or warranty is made as to the likelihood of achievement or reasonableness of any forward-looking statements or other forecast. To the full extent permitted by law, NSB and its directors, officers, employees, advisers, agents and intermediaries disclaim any obligation or undertaking to release any updates or revisions to information to reflect any change in any of the information contained in this presentation (including, but not limited to, any assumptions or expectations set out in the presentation).

NeuroScientific

ASX**NSB**

Crohn's Breakthrough? NSB Pushes Stem Cell Treatment Globally

NSB's Focus on Neuroimmune Disorders and Biomedical Innovation

NSB is an ASX-listed biotechnology company dedicated to the research and development of biomedical products targeting neurodegenerative conditions driven by immune-mediated inflammatory disorders. Through cutting-edge innovation, NSB aims to address complex medical needs in areas where current treatment options are limited or ineffective

StemSmart ™

Targeting Crohn's Disease With StemSmart™ Technology

Following its announcement of the acquisition of Isopogen WA[1], NSB is prioritizing the use of its proprietary StemSmart™ technology in a special access program for fistulising Crohn's disease—a particularly challenging form of the condition that resists conventional therapies. If initial outcomes are positive, the company plans to advance to a phase 1/2 clinical trial. This initiative supports NSB's broader objective of gaining regulatory and reimbursement approvals for mesenchymal stromal cell (MSC) therapy in Australia and globally, making the treatment accessible to patients with both fistulising and refractory Crohn's disease.

1. ASX Announcement 27 June 2025 'StemSmart™ Acquisition Complete'

Investor Overview

NeuroScientific

CORPORATE SHARE INFORMATION

AS AT 27 JUNE 2025

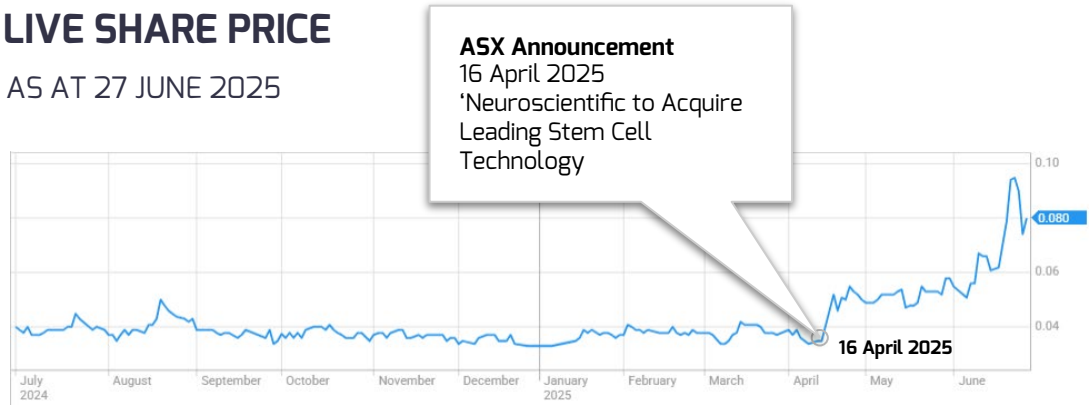
SHARE PRICE	A$0.080
MARKET CAPITALISATION	A$26.5 million

CAPITAL STRUCTURE & CASH ON HAND

	ORDINARY SHARES	PERFORMANCE SHARES	OPTIONS
CAPITAL	333.2 million	57.1 million	45.25 million
CASH	~$7.5 million		

LIVE SHARE PRICE

AS AT 27 JUNE 2025



Board

NeuroScientific

ROB MCKENZIE
LL.B; B.Juris, FAICD
NON-EXECUTIVE CHAIRMAN

Rob is a lawyer with over 35 years' experience in corporate and commercial transactions, restructuring and dispute resolution. He has advised companies on mergers and acquisitions; floats; corporate structuring and restructuring; corporate governance; board and meeting compliance and investment and financial structuring. Rob is currently Chairman of the Perron Institute and was previously on the Takeovers Panel.

PAUL FRY
BBus, C.A.
NON-EXECUTIVE DIRECTOR

Paul was a former Partner of Ernst and Young and PwC in Australia and Canada and consults to companies in a broad range of industries.

Paul's expertise centres around public markets, capital raisings, governance, risk management and corporate transactions. He has been involved with numerous entities listed on the ASX.

DR ANTON UVAROV
PhD, MBA
NON-EXECUTIVE DIRECTOR

Dr Uvarov has significant experience in the healthcare industry with a particular focus on neuroscience. Dr Uvarov started his career in biotechnology investments as an equities analyst with Citigroup and has co-founded numerous publicly listed companies in Australia, including Dimerix (ASX: DXB), Actinogen Medical (ASX: ACW), Neuroscientific Biopharmaceuticals (ASX: NSB), and most recently BlinkLab (ASX: BB1). Anton is currently an executive director at BlinkLab.

CLARKE BARLOW
NON-EXECUTIVE DIRECTOR

Mr. Barlow is a Financial Adviser and Capital Markets Specialist with over 20 years' experience in the Financial Services Industry in Australia and the United Kingdom. Clarke has extensive experience providing corporate advisory services for companies listed on the ASX across a variety of industries, with a particular focus on growth opportunities in the Biotechnology, Technology, Industrial and Resources industries.

Chief Scientific Officer

DR MARIAN STURM
FFSc (RCPA), PhD, MSc, BSc Hons
CSA & CHAIR OF ADVISORY BOARD

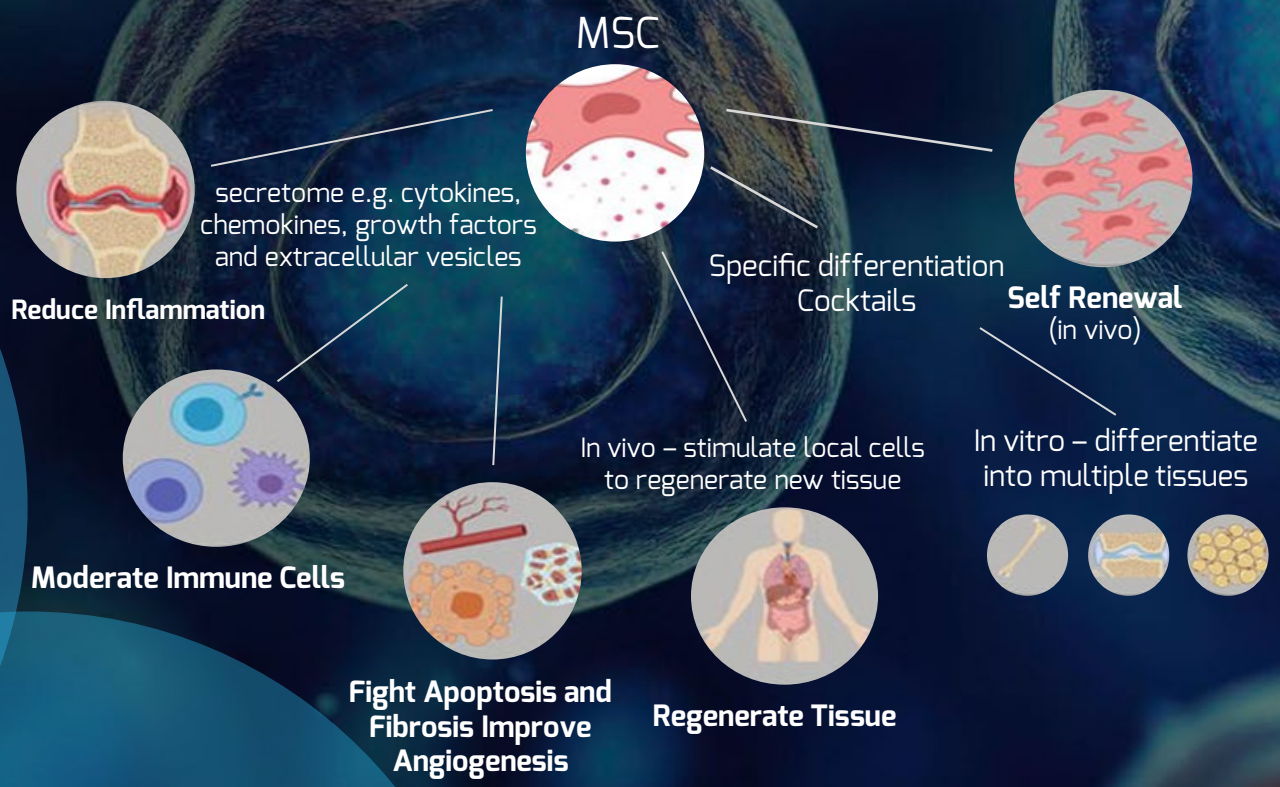
An expert in the research, operational and clinical development of cellular treatments, with over 40 years experience, Marian has been involved in the manufacturing of therapeutic goods for over 20 years and was a member of the TGA Advisory Committee on Biologics since its inauguration in 2012 to 2022.

NeuroScientific

ASX**NSB**

What are Mesenchymal Stem Cells (MSC)

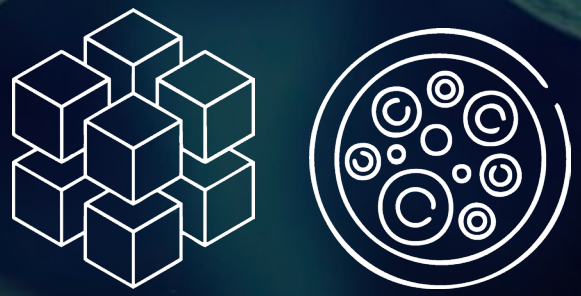
MSC are adult stem cells traditionally harvested from bone marrow. MSC can also be isolated from other tissues.



How does Stem Cell technology work?

Stem cells are often called the “body's building blocks”, as they can potentially develop into any tissue or organ.

Mesenchymal stem cells interact with the immune system, adjusting immune responses and reducing inflammation in target tissue, contributing to disease control and tissue repair.



Introducing StemSmart™

NeuroScientific

StemSmart™ early indications from the Phase 2 trial in refractory Crohn's disease suggest StemSmart™ MSC is potent, efficacious and safe[1]

StemSmart™

High quality product manufactured under StemSmart™ methodology

StemSmart™ is a global patented technology

- Patented process for the manufacturing of cell products, involving the use of proprietary media to improve efficacy and safety
- Primes cells for better response to inflammation

Manufactured under GMP to regulatory standards, with a TGA product license and required quality assurance

StemSmart™ MSC products have been consistently manufactured.

1. ASX Announcement 16 April 2025 'Neuroscientific to Acquire Leading Stem Cell Technology
2. Refer to Annexure 1 for a summary of the details and findings from the Phase 2 trial (also included in NSB ASX Announcement dated 16 April 2025).

Cell therapy for Serious Inflammatory Immune Disorders

NeuroScientific

StemSmart™

Mesenchymal Stem Cells (MSC) have a strong safety profile

MSC require an inflammatory environment to be activated for clinical effect

- MSC work most effectively where there is **HIGH** level of inflammation in the target tissue
- MSC respond to inflammation by secreting factors that reduce the activation and proliferation of immune cells and down-regulate their production of inflammatory mediators
- MSC also secrete substances that can neutralize some inflammatory mediators
- MSC therapy appears most suitable for serious inflammatory/immune disorders

StemSmart™ MSC are primed to respond to inflammation

- MSC are engineered for increased potency, as demonstrated by gene expression and increased production of anti-inflammatory proteins.
- MSC are best used in patients who have not responded to conventional treatments (e.g. steroids, biologics, immunosuppressants & other anti-inflammatory agents) as evidenced by trials/studies

NeuroScientific

ASX**NSB**

Stem Cell Technology for Refractory Crohn's

StemSmart ™

Refractory Crohn's (life threatening)
Unresponsive to conventional therapies (Antibiotics/Steroids/Biologics)
Surgery only option
~30% patients become refractory– don't respond to therapies

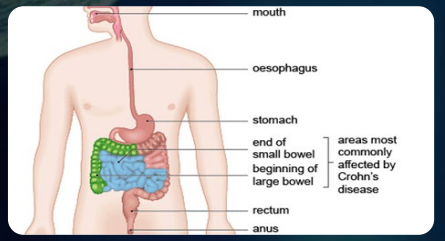
Fistulas
Sores/ulcers, creating abnormal passageway from intestine to another organ or to outside surface of the body
About 30% of Crohn's patients will develop fistulas
Unresolved chronic inflammation

6-8 million

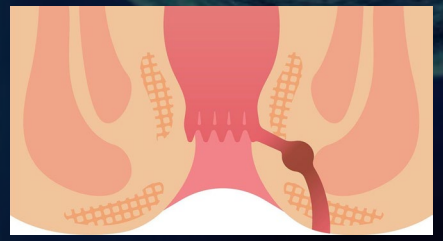
People living with Crohn's disease globally*

What is Crohn's Disease?

- Life-long chronic inflammation of the gut
- Incurable affecting more than 1 million in the USA alone
- Has a chronic relapsing and remitting course, sometimes life-threatening
- Considered an auto-immune disorder, affecting all age groups, with incidence peaking in early adulthood
- Commonly results in perianal Fistulas



Crohn's disease can affect the total length of the GI tract



Fistulas can develop between the anal canal and the skin near the anus

NeuroScientific

ASXNSB

Industry News

United States FDA recently approved the first mesenchymal stromal cell[1]

United States FDA recently approved the first mesenchymal stromal cell (MSC) therapy (Mesoblast ASX Announcement 19.12.2024 (ASX: MSB - MSB market capitalisation as at 18 June 2025 of ~A$2 billion))[1]. While MSC products have been approved in other jurisdictions, the FDA approval of allogenic, bone marrow-derived MSC product for paediatric, steroid-refractory, acute graft-versus-host-disease (GvHD) is momentous.

The International Society for Cell & Gene Therapy (ISCT), the peak international body for cell therapies, described it as a pivotal moment in the history of medicine shaping the future of therapeutics. They further noted that this approval rewards the work of researchers, clinicians, and innovators around the globe who have dedicated their careers to this field. This US decision paves the way for renewed enthusiasm and global investment in clinical research of MSC therapies.

FDA Approval

1. Mesoblast ASX Announcement 19.12.2024 and NSB, ASX Announcement 16 April 2025 'Neuroscientific to Acquire Leading Stem Cell Technology'

Special Access Program[1]

NeuroScientific

Has now commenced

Crohn's Fistulas

Treatment of patients with Crohn's Fistulas on compassionate grounds (SAS)

- Commenced in June 2025[2]
- ≤12 patients
- Non healing fistulas
- Administration of StemSmart™ at weekly intervals, for 4 weeks
- Evaluation at 8-10 weeks
- Performance shares shall convert based on the successful completion of a special access program on achieving a clinical response (see below) in at least 4 patients.

Clinical Response

Defined as:

- As assessed by the treating physician or qualified investigator:
- Closure of ≥ 50% of all fistula openings in a patient or;
- ≥ 50% reduction of fistula discharge in a patient

Next step

for Crohn's fistula – if program successful

- Conduct a trial in Fistulising Crohn's for regulatory acceptance
- Strong clinical trial result may result in expedited regulatory approval (Priority Review Pathway) in Australia

StemSmart ™

1. ASX Announcement 16 April 2025 'Neuroscientific to Acquire Leading Stem Cell Technology & ASX Announcement 23 May 2025 'Special Access Program Set to Commence'
2. ASX Announcement 27 June 2025 'StemSmart™ Acquisition Complete'

Stemsmart™ MSC isn't just for Crohn's Disease

NeuroScientific

Clinical Indication	Description	Trials/studies reported using Stemsmart™ MSC [1]
Refractory GvHD	○ GVHD is a common complication of allogeneic (donor) bone marrow transplant ○ transplanted cells attack and reject the recipient ○ acute GVHD currently occurs in about 30% of patients receiving stem cell transplants to treat blood cancers ○ Resistance to steroid treatment (refractory acute GVHD) develops in 25-30% of cases and has a high mortality	○ Positive and life-saving clinical results of StemSmart™ MSC therapy for adults and children with severe and life-threatening steroid-refractory GVHD, supports the use of StemSmart™ MSC therapy in this clinical indication (Annexure 2 and 3). ○ A Phase I clinical trial in adults with steroid-refractory GVHD (Annexure 2), and a series of children treated on compassionate grounds for steroid-refractory GVHD (Annexure 3) found the majority of adults and children responded to StemSmart™ with a complete or partial resolution of symptoms and improved survival.
Kidney Transplant (rejection)	After kidney transplant, recipient's immune system may reject new kidney: ○ if acute rejection is not controlled, patient may lose kidney ○ patients face years of immuno-suppressant treatment with increased risk of infections & cancer	
Lung Disorders	○ Lung disorders represent an array of conditions and a large global market. ○ **CLAD**: Lung transplant is compromised by chronic lung allograft disorder which results in a survival of 30-40% at 10 years post transplant. Of patients developing CLAD, 65% will decline or die within 12 months. ○ **COPD**: Chronic obstructive pulmonary disease is the 3rd most prevalent disease -causing morbidity and mortality world-wide. It is commonly known as emphysema and is inflammation and fibrosis of the lung, resulting in respiratory failure ○ **Other** potential lung disorders include poorly controlled asthma, interstitial lung disease, severe viral pneumonia, acute respiratory distress and sepsis.	

1. ASX Announcement 19 June 2025 previous StemSmart™ studies demonstrate clinical response in severe GVHD

Key Conditions

NeuroScientific

Focus & Market Size (StemSmart™ MSC addressable markets)

		Global Market	Forecast Increase in Market
Crohn's Disease	• Need for more effective treatments with less side effects • Require additional treatment option for patients who have failed all other medical therapies	**US$13.8 billion** By 2026[1] Increase from US$9.0 billion in 2016	**53%** from 2016
Kidney Transplant	• Need rescue therapies for acute renal rejection • Minimise rejection risk, while reducing toxicity • Need to improve long term patient graft function and patient survival	**US$7.2 billion** in 2030[2] (Global market for organ transplant immuno-suppressants) Increase from US$5.5 billion in 2024	**31%** from 2024
Lung Disorders	• No long-term effective treatment for COPD – results in airflow obstruction (obstructive bronchiolitis and emphysema) • Lung Transplant Rejection • Current treatments cumbersome, ineffective, terminal disease	**US$33 billion** by 2034[3] Increase from US$20 billion in 2024	**65%** from 2024
GvHD	• Patients may develop a severe and life-threatening condition after a bone marrow transplant • Currently low rate of survival in severe refractory GVHD	**US$5.31 billion** in 2032[4] Increase from US$2.55 billion in 2023	**208%** from 2023

1. Crohn's Disease: Dynamic Market Forecast to 2026 - https://www.globaldata.com/store/report/crohns-disease-dynamic-market-forecast-to-2026/
2. Grand View Research - Organ Transplant Immunosuppressant Drugs Market Size - https://www.grandviewresearch.com/horizon/outlook/organ-transplant-immunosuppressant-drugs-market-size/global
3. PharmaPoint: Chronic Obstructive Pulmonary Disease – Global Drug Forecast Market Analysis to 2025 -
*for organ transplant immuno-suppressants - https://www.precedenceresearch.com/chronic-obstructive-pulmonary-disease-treatment-market#:~:text=The%20global%20chronic%20obstructive%20pulmonary,5.14%25%20between%202024%
4. Global Graft versus Host Disease (GVHD) Market 2019-2029 - https://www.globenewswire.com/news-release/2024/11/07/2976830/28124/en/Graft-Versus-Host-Disease-GvHD-Treatment-Industry-Forecast-Report-2024-2032-Global-Market-Size-Forecast-to-Double-with-Emerging-Markets-Offering-Substantial-Growth-Potential.html

NeuroScientific

ASX**NSB**

Key Corporate Factors

Global Crohn's Situation

StemSmart ™ holds significant potential to improve quality of life for a large global market.
Over 6 Million people living with Crohn's globally

Patented Technology

StemSmart ™

Following the successful Phase 2 trial in refractory Crohn's disease (Annexure 1), NSB is undertaking a special access program for fistulising Crohn's disease.

SAS Fistulising Crohn's Program Initiated

Results pending

Market Diversification

The power of StemSmart™

Diversifying research into diseases beyond Crohn's offers broader markets and allows patented technology to be used in other areas of need

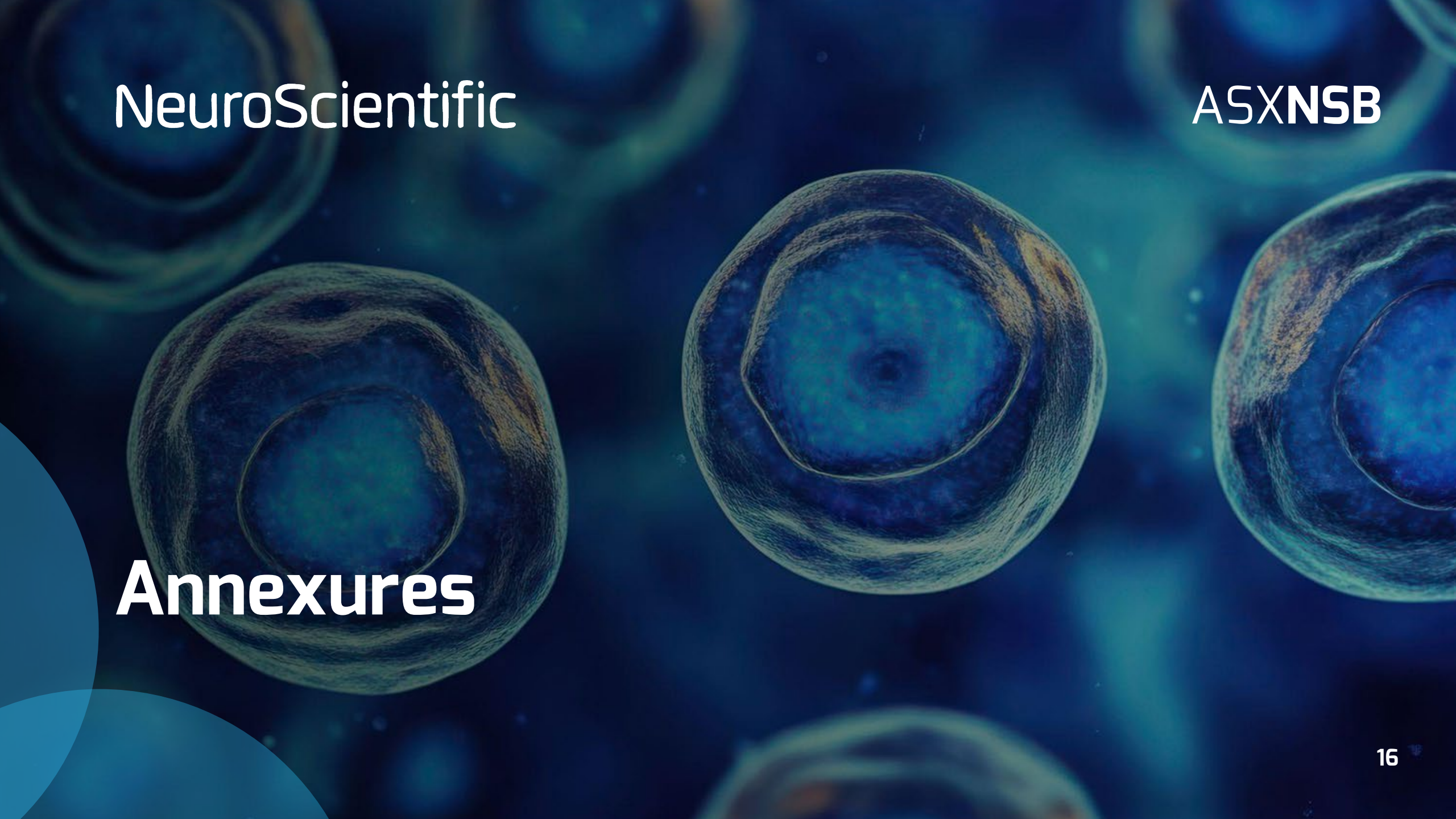
NeuroScientific

ASX**NSB**

For further information, please contact:

Dr Anton Uvarov
Founding Non-Executive Director
+61 8 6268 2641
au@neuroscientific.com

Mr Chris Achurch
Company Secretary
+61 8 6268 2641
chris@westarcapital.com.au



Annexures

Annexure 1

NeuroScientific

Clinical Trial	A Multicentre Australian Phase 2 Study to Evaluate Safety and Efficacy of Mesenchymal Stromal Cells for Treating Biologic Refractory Crohn's Disease
Condition	Crohn's Disease, biologic refractory
Drug	Human, allogeneic, bone-marrow derived, mesenchymal stromal cells (MSC) for infusion
GMP Compliance of Unapproved Biologic Drug	Manufacture in TGA licenced facility (Licence No: 44165/ MI-25112004-LI-000212-1)
Trial Registration	ClinicalTrials.gov ID: NCT01090817
Study Type	Interventional
Phase	Phase 2
Design	Treatment, non-randomised, single-group assignment, open-label, multi-sited
Intervention	MSC infusion (2 x 10^6 cells/kg recipient weight) infused over 15 minutes intravenously weekly for 4 weeks
Primary Outcome Measure	Clinical response to MSC: reduction in Crohn's disease activity score (CDAI) by 100 points or more at 6 weeks post start of therapy.
Primary Measure Description	Clinical parameters used for the determination of Crohn's disease activity, as well colonoscopy and biopsy, as undertaken at screening pre-therapy and at 6 weeks after start of therapy.
Secondary Outcome Measure	1. Incidence of infusion toxicity 2. Induction of remission 3. Improved Quality of Life 4. Endoscopic improvement
Secondary Measure Descriptions	1. Infusion toxicity- patients assessed for 4 hours post infusion 2. CDAI assessed as below 150 indicating remission 3. Increase in IBDQ and AQoL-8D scores measured at 6 weeks 4. Crohn's disease endoscopic improvement score (CDEIS) measured at repeat endoscopy 6 weeks after start of treatment
Actual Enrolment	21 subjects Aged 21-56 years, 10 males CDAI ranging from 256-603 (mean 371)
Completion Date	February 2014
Subject Evaluation	18 subjects with full data sets
Statistical method	Longitudinal random-effects regression for primary outcome measure
Primary Outcome Result	Clinical response (reduction in CDAI >100 points) was observed in 14 of 18 subjects (78%) at day 42. Total group mean CDAI decreased from 366 (median 327; range 256-603) to 214 (median 130; range 44-466) at day 42 (p <0.0001).
Secondary Outcome Results	1. No infusion related adverse reactions occurred. All subjects experienced dysgeusia, known to occur from the cryopreserving agent (DMSO) present in the drug, which resolved within 36 hours. 2. Clinical remission (CDAI <150) occurred in 8 of 18 patients (44%) with a mean CDAI at day 42 of 94 (range 44-130). 3. In 17 evaluable patients, mean IBDQ scores improved from 118 to 143 (p =0 .014) and AQoL from 81 to 70 (p= 0.013). Improvement in quality of life parallelled improvement in CDAI. 4. Endoscopic improvement (CDEIS) occurred in 8 (44%) of 18 subjects by day 42.
Publication	GM Forbes, MJ Sturm, RW Leong, MP Sparrow, D Segaralasingam, AG Cummins, M Phillips, RP Herrmann. A Phase 2 Study of Allogeneic Mesenchymal Stromal Cells for Luminal Crohn's Disease Refractory to Biologic Therapy. Clin Gastroenterology & Hepatology 2014, 12:64-71.

From NSB ASX Announcement 16 April 2025

Annexure 2

NeuroScientific

Clinical Trial	A phase I study to evaluate the potential of mesenchymal stromal cells to treat steroid refractory graft versus host disease (both acute and chronic) after bone marrow transplantation
Condition	Acute and chronic steroid-refractory graft versus host disease following allogeneic bone marrow transplant
Drug	Human, allogeneic, bone-marrow derived, mesenchymal stromal cells (MSC) for infusion
GMP Compliance of Unapproved Biologic Drug	Manufacture in TGA licenced facility (Licence No: 44165/ MI-25112004-LI-000212-1)
Trial Registration	ANZCTR126100000068066
Study Type	Interventional
Phase	Phase 1
Design	Treatment, non-randomised, single-group assignment, open-label
Intervention	Initial intervention of MSC infusion (2 x 10^6 cells/kg recipient weight) infused intravenously twice weekly for 4 weeks, subsequently adjusted to two infusions at weekly intervals.
Primary Outcome Measure	To evaluate safety of infusions of MSC in the management of steroid-refractory acute GVHD (grades 2-4) and chronic GVHD of extensive degree
Primary Measure Description	Clinical observation and measurement of vital signs post infusion for adverse reactions. Monitored for adverse events at regular on-going follow-up.
Secondary Outcome Measure	Best response and overall survival post MSC infusion
Secondary Measure Descriptions	Monitoring of clinical symptoms of GVHD. For acute GVHD, complete response was loss of all symptoms and signs of GVHD, partial response was at least an improvement of one grade or more.For chronic GVHD, complete response was as for acute GVHD and partial response was an improvement in the NIH consensus score of at least one.
Actual Enrolment	19 adult subjects 12 subjects with steroid refractory acute GVHD (grades II-IV), aged 21-68 year; 8 males. 7 subjects with steroid refractory chronic GVHD (NIH consensus score $\geq$2), aged 31-53; 5 males
Recruitment period	September 2007- April 2010
Completion Date	2011
Subject Evaluation	19 subjects 12 subjects with acute GVHD 7 subjects with chronic GVHD
Statistical method	Descriptive methods indicating the overall experience of patients. Survival, described as time from first MSC infusion. Kaplan-Meier method to estimate survival times. The non-parametric log-rank test to examine for differences in survival between groups and to examine trends in survival patterns.
Primary Outcome Result	Infusions (109) were well tolerated with no acute infusion-related toxicities and no subsequent toxicities attributable to MSC infusions noted.
Secondary Outcome Results	The overall response rate for acute GVHD was complete response in 7/12 patients (58%), partial response in 4/12 (33%) patients and no response in 1 patient. Of the patients with chronic GVHD, a complete response was observed in 2/7 (29%) patients, a partial response in 2/7 (29%) and no response in 3 patients (43%). The actuarial 3year survival for patients with acute GVHD was 55%, compared to the expected survival of 15-20%. The median survival of patients with chronic GVHD was 8 months. Complete response to MSC therapy was a statistically significant predictor of survival for acute GVHD patients (X^2 = 11.3, p= 0.0008) but not for chronic GVHD (X^2 = 2.79, p= 0.100)
Publication	Richard Herrmann, Kathryn Shaw, Marian Sturm, Paul Cannel, Julian Cooney, Duncan Purtill, Matthew Wright. Mesenchymal stromal cell therapy for steroid-refractory acute and chronic graft versus host disease, a phase I study. Int J Haem 95 (2), 182-188, Feb 2012.

From NSB ASX Announcement 19 June 2025

Annexure 3

NeuroScientific

Clinical Study	Compassionate use of mesenchymal stromal cells in refractory graft versus host disease after bone marrow transplantation
Condition	Acute and chronic steroid-refractory graft versus host disease following allogeneic bone marrow transplant
Drug	Human, allogeneic, bone-marrow derived, mesenchymal stromal cells (MSC) for infusion
GMP Compliance of Unapproved Biologic Drug	Manufacture in TGA licenced facility (Licence No: 44165/ MI-25112004-LI-000212-1)
Trial Registration	N/A- Compassionate
Study Type	Interventional
Phase	Case series
Design	Treatment, real-life experience
Intervention	MSC infusion (2 x 10^6 cells/kg recipient weight) infused intravenously weekly for 2 or 4 weeks, as indicated.
Primary Outcome Measure	The management of steroid-refractory acute GVHD (grades 2-4) and chronic GVHD of extensive degree, and safety
Primary Measure Description	Monitoring of clinical symptoms of acute and chronic GVHD Clinical observation and measurement of vital signs post infusion for adverse reactions. Monitored for adverse events at regular on-going follow-up.
Secondary Outcome Measure	Overall survival
Secondary Measure Descriptions	Assessment of survival
Actual Enrolment	10 paediatric subjects 6 children with steroid-refractory acute GVHD (grades II-IV), aged 1.8-18 year; 5 male 4 children with steroid-refractory chronic GVHD (grades II-III), aged 5-8 years; 3 male
Treatment period	April 2013- June 2018
Completion Date	2020
Subject Evaluation	9 subjects 5 subjects with acute GVHD 4 subjects with chronic GVHD
Statistical method	Descriptive methods indicating the overall experience of patients. Survival, described as time from first MSC infusion.
Primary Outcome Result	All children showed a response to treatment, with the exception of 1 child where clinical interventions were declined after a single infusion. For 5 acute GVHD patients, 3 had a complete response by day 28; 2 had a partial response. Additional treatment was given to those with only a partial response or who had flares of GVHD. All 4 patients with chronic GVHD responded to treatment, with one child having a complete response. Infusions were well tolerated with no acute infusion-related toxicities and no subsequent toxicities attributable to MSC infusions noted.
Secondary Outcome Results	Acute GVHD: All children survived out to 12 months post-transplant. 3 patients deceased at $\geq$ 1 year due to poor graft function and infection, disease relapse and viral infection. Two patients maintained their response for >2years (> 31 months, >5 years). Chronic GVHD: 1 patient deceased at 3 years due to pulmonary failure Remaining 3 children were alive > 6 years post-transplant but with ongoing chronic GVHD. In total, 5 of the 10 children remained living (50%) and achieved long term survival of at least 2 - 6.6 years post MSC treatment.
Publication	Shanti Ramachandran: Compassionate use of Mesenchymal Stromal Cells in refractory graft-versus-host disease. Oral presentation at Annual Scientific Meeting of Australia and New Zealand Children Haematology-Oncology Group (ANZCHOG) 2016.

From NSB ASX Announcement 19 June 2025

Annexure 4

NeuroScientific

Clinical Trial	A phase II trial of standard of care treatment versus mesenchymal stromal cells therapy together with standard of care treatment for the treatment of de novo acute graft versus host disease following allogeneic bone marrow transplantation
Condition	Newly diagnosed untreated, acute graft versus host disease (grades 2-4) following allogeneic bone marrow transplantation
Drug	Human, allogeneic, bone-marrow derived, mesenchymal stromal cells (MSC) for infusion
GMP Compliance of Unapproved Biologic Drug	Manufacture in TGA licenced facility (Licence No: 44165/ MI-25112004-LI-000212-1)
Trial Registration	NCT01589549
Study Type	Interventional
Phase	Phase 2
Design	Randomised (1:1), parallel assignment, open-label, treatment Recruitment target 66 participants (33 in each arm)
Intervention	One arm will be randomised to receive MSC therapy in addition to corticosteroid therapy. • Active comparator: corticosteroid therapy • Intervention: Mesenchymal stromal cell therapy; (2 x 10^6 cells/kg recipient weight) infused intravenously on day 1 and day 8.
Primary Outcome Measure	Overall survival at 12 months post randomisation
Primary Measure Description	Assessment of survival
Secondary Outcome Measure	• Acute GVHD response at day 28 • Progression-free survival at 12 months • Safety (infusion reactions & major infections)
Secondary Measure Descriptions	Monitoring of clinical symptoms of acute GVHD Monitoring of progression-free survival Clinical observation and monitoring for adverse events post-infusion and at regular on-going follow-up.
Actual Enrolment	30 adult subjects Control: 15 MSC: 15
Recruitment Period	May 2012-April 2017
Completion Date	April 2018
Subject Evaluation	28 subjects Control: 13, median age 55 years (22-64 years) MSC: 15, median age 47 years (20-64 years)
Statistical method	SPSS software and Graphpad Prism
Primary Outcome Result	No difference in survival at 12 months post-randomisation- 53% MSC arm (8 surviving) and 77% control arm (10 surviving) Time to death similar in both arms- MSC: 93 days (range 28-210 days); control: 86 days (range 46-295 days). Causes of death were similar in both groups.
Secondary Outcome Results	Day 28 acute GVHD overall response: -67% for MSC arm (complete response (CR) 47%, partial response (PR) 20% -100% for control arm (CR 62%, PR38%) Salvage therapy was added for 6 patients (40%) MSC and 2 patients (15%) in the control arm Safety: no significant infusion reactions with MSC; no difference in infections

From NSB ASX Announcement 19 June 2025

Annexure 4 (Cont.)

NeuroScientific

Outcome Summary	Early results do not support the use of MSC in addition to corticosteroids at first diagnosis of acute GVHD. Study, which was planned to recruit 66 patients, was terminated early on grounds of futility. Challenges of study: • Recruitment was slower than anticipated due to a decreasing incidence of grade II-IV acute GVHD at our centre (43% in 2012-14 vs 30% in 2015-2016) • 12-month overall survival endpoint is vulnerable to variations in treatment factors outside MSC therapy • Both GVHD response rate and survival in control arm were higher than anticipated, for reasons that are not clear from patient information • Inflammatory status of recipient may affect efficacy of MSC therapy. All patients had received corticosteroids for up to 72 hours prior to MSC therapy. We postulate that steroid pre-treatment may have inhibited MSC activity.
Publication	Early cessation of a randomised study in acute graft versus host disease: upfront mesenchymal stromal cells with corticosteroids versus corticosteroids alone. Duncan Purtill, Melita Cirillo, Janice Fogarty, Dino Tan, Julian Cooney, Matthew Wright, Paul Cannell, Richard Herrmann, Marian Sturm. Bone Marrow Transplantation (2020) 55:2199-2201 https://doi.org/10.1038/s41409-020-0955-9

From NSB ASX Announcement 19 June 2025