

## NEUROSCIENTIFIC TO ACQUIRE LEADING STEM CELL TECHNOLOGY

NeuroScientific Biopharmaceuticals Ltd (**ASX:NSB**) to acquire StemSmart™ patented Stem Cell technology (**StemSmart**), for the manufacture of life-changing cellular medicine, Mesenchymal Stromal Cells (**MSC**), from Isopogen WA Ltd (**Isopogen WA**).

### About StemSmart Acquisition

- Early indications from the Phase 2 trial in refractory Crohn's disease suggest StemSmart™ MSC is potent, efficacious and safe (refer to **Annexure 1** for a summary of the details and findings from the Phase 2 trial).
- StemSmart™ MSC is derived from adult human donor bone marrow. The MSCs are isolated and grown in culture, before the patented StemSmart™ manufacturing process is applied to improve the cells' clinical efficacy.
- StemSmart™ MSC works by interacting with a patient's immune system to modulate immune responses.
- MSCs respond to inflammation by secreting factors that reduce the activation and proliferation of immune cells and down-regulate their production of inflammatory mediators.
- Patients both locally and interstate have already received StemSmart™ MSC therapy on compassionate grounds, for a variety of serious and life-threatening clinical conditions, with multiple strong positive clinical responses.
- Special Access Program in fistulising Crohn's disease to commence immediately following completion of the Acquisition (defined below).

### The Growing Importance of Stem Cell Therapy

- Stem cell therapy is a cornerstone of modern medicine. Stem Cells have the unique ability to develop into different cell types in the body and are often hailed as the body's master cells.
- Stem cell therapies are rapidly gaining global recognition as a transformative therapeutic modality.
- The US FDA recently approved the first mesenchymal stromal cell (MSC) therapy (Mesoblast ASX Announcement 19.12.2024 (ASX: MSB)). This decision paves the way for renewed enthusiasm and global investment in clinical research of MSC therapies.

### StemSmart Key Addressable Markets

- **Crohn's Disease:** Global market US\$13.8 billion by 2026<sup>1</sup>;
- **Kidney Transplant:** Global market for organ transplant immuno-suppressants, increasing to US\$7.2 billion by 2030<sup>2</sup> (majority for renal);
- **Lung Disorders:** Global market US\$33 billion by 2034<sup>3</sup>; and
- **GvHD:** Global market increasing to US\$0.640 billion in 2026<sup>4</sup>.

## StemSmart™ and Crohn's Disease

- The StemSmart™ MSC patented technology's immediate focus will be to undertake a Special Access Program ("**Program**") in fistulising Crohn's disease. There is a strong need for alternative and effective treatments for Crohn's Disease, with fewer side effects.
- Fistulas are one of the most severe and debilitating complications associated with Crohn's disease.
- Fistulising Crohn's disease is challenging to treat, and sustained healing has proven limited with standard therapies. If successful, this Program is intended to progress to a Phase 1/2 clinical trial.
- Previously, a Phase 2 trial of 18 patients with refractory Crohn's disease who received StemSmart™ MSC therapy demonstrated promising results, with the majority of patients experiencing clinical improvement and many, clinical remission (refer to **Annexure 1** for a summary of the details and findings from the Phase 2 trial).

## Acquisition of StemSmart

- NSB proposing to acquire 100% of the issued capital of Isopogen WA, which holds or has the right to exploit the StemSmart™ patented Stem Cell technology (**StemSmart**).
- Binding share sale agreements have already been signed with the Key Sellers of Isopogen WA (defined below), who collectively hold 51.4% of the issued capital of Isopogen WA.

## Capital Raising and Proposed Appointments

- Firm commitments received to raise \$3.5 million (before costs) at a share price of \$0.035 each via a placement to professional, sophisticated and qualifying investors.
- Proposed appointments of Robert McKenzie and Paul Fry to the board of directors and Marian Sturm as Chief Scientific Adviser.
- Post completion cash on hand of approximately A\$7.5million.

**NeuroScientific founding Director, Dr Anton Uvarov** said, *"We're incredibly excited to add mesenchymal stem cell technology to our growing portfolio. This acquisition not only complements our existing pipeline of therapeutic peptides, but also strategically positions us at the forefront of next-generation biologics. Stem cell therapies are rapidly gaining global recognition as a transformative therapeutic modality, especially with recent FDA approvals highlighting their clinical potential. We see this as a powerful opportunity to expand our impact in regenerative medicine and deliver innovative solutions to patients across a range of conditions."*

<sup>1</sup>[www.globaldata.com/store/report/crohns-disease-dynamic-market-forecast-to-2026/](http://www.globaldata.com/store/report/crohns-disease-dynamic-market-forecast-to-2026/)

<sup>2</sup>[www.grandviewresearch.com/horizon/outlook/organ-transplant-immunosuppressant-drugs-market-size/global](http://www.grandviewresearch.com/horizon/outlook/organ-transplant-immunosuppressant-drugs-market-size/global)

<sup>3</sup>[www.precedenceresearch.com/chronic-obstructive-pulmonary-disease-treatment-market#:~:text=The%20global%20chronic%20obstructive%20pulmonary,5.14%25%20between%202024%20and%202034.](http://www.precedenceresearch.com/chronic-obstructive-pulmonary-disease-treatment-market#:~:text=The%20global%20chronic%20obstructive%20pulmonary,5.14%25%20between%202024%20and%202034.)

<sup>4</sup>[www.visiongain.com/report/global-graft-versus-host-disease-gvhd-market-2019-2029/](http://www.visiongain.com/report/global-graft-versus-host-disease-gvhd-market-2019-2029/)

NeuroScientific Biopharmaceuticals Ltd (**ASX:NSB**) ("**NeuroScientific**" or "**the Company**") is pleased to announce that it has entered into binding agreements in relation to the Company's proposed acquisition of 100% of the issued shares in the capital of Isopogen WA (**Acquisition**). Isopogen WA holds 100% of the issued shares in Isopogen Pty Ltd (both referred to hereafter as **Isopogen**), which holds or has the rights to exploit the StemSmart™ patented technology. Isopogen WA is a public unlisted biotech company advancing innovative cell therapies using its proprietary platform technology StemSmart™ through its wholly owned subsidiary Isopogen Pty Ltd.

The Acquisition is subject to a number of conditions precedent, including each of the shareholders of Isopogen WA signing a separate share sale agreement with the Company. The Company has received signed share sale agreements from each of the Key Sellers (defined below), which collectively hold 51.4% of the issued share capital of Isopogen WA.

Contemporaneous with the Acquisition, the Company has received firm commitments to raise up to \$3.5 million (before costs) under a Placement (defined below) and intends to appoint current Isopogen WA directors Robert McKenzie and Paul Fry to the Company's board of directors to progress the development of StemSmart.

## **Alignment with NeuroScientific and StemSmart**

NeuroScientific is engaged in the business of research and development of biomedical products for the treatment of neurodegenerative conditions which are immune-mediated inflammatory disorders.

Isopogen is also engaged in the business of research and development of biomedical products for the treatment of degenerative conditions which are immune-mediated inflammatory disorders, most particularly StemSmart™ product technology for the manufacture of a cell-based therapy that targets inflammatory and immune-based disorders.

StemSmart™ cells have potent anti-inflammatory and immunomodulatory properties and a multifaceted and complex interaction with the body's immune system, secreting factors in response to inflammatory stimuli. Their actions result in a dampening of inflammation and the moderation of immune responses, inducing immune tolerance and encouraging tissue repair.

The significance of StemSmart™ MSC therapy is in the application to conditions of unmet clinical need, either where patients have failed standard of care medical treatments and there is no, or limited, effective medical treatments available. This includes many immune/inflammatory disorders such as refractory Crohn's disease, acute renal rejection and steroid refractory graft versus host disease (complication of bone marrow transplant). The Company believes there are numerous autoimmune conditions where patients may benefit from treatment with StemSmart™ MSC.

Importantly, a number of patients have received StemSmart™ MSC therapy on compassionate grounds, for a variety of serious and life-threatening clinical conditions. In particular, recipients include both adults and children with GVHD (graft-versus-host disease). Requests for treatment have come from both local and interstate hospitals and good clinical responses have been observed.

GVHD is a serious complication that can occur after donor bone marrow transplant, where the donor's immune cells attack the recipient's tissues, potentially causing damage to organs and tissues.

## Strategy

The focus of the Company in the 12 months following completion of the Acquisition will be to undertake a Special Access Program in fistulising Crohn's disease, a condition which is challenging to treat and where sustained healing has proven limited with standard therapies. If successful, this Program is intended to progress to a Phase 1/2 clinical trial.

Isopogen also plans to initiate well designed and appropriately funded Phase 1, 2 and 3 trials over the next 24 months, to progress the technology for regulatory approval in other indications, including refractory Crohn's disease, lung disease, including other inflammatory and immune based disorders.

The Company's long-term goal for Isopogen's StemSmart™ is to have MSC therapy achieve regulatory and re-imbursement approval in Australia and other jurisdictions for initial indications of fistulising Crohn's disease and refractory Crohn's disease and for the treatment to be accessible to patients.

Importantly, the United States FDA recently approved the first mesenchymal stromal cell (MSC) therapy (Mesoblast ASX Announcement 19.12.2024 (ASX: MSB)). 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.

### Projected 12-Month Use of Funds (StemSmart)

Activity	\$
Stemsmart™ Clinical Activity	\$419,025
Stemsmart™ Manufacturing	\$976,250
Regulatory Strategy, Medical Advisory/Governance and Quality Assurance and Accreditation	\$510,912
Intellectual Property	\$143,813
<b>Total</b>	<b>\$2,050,000</b>

### Projected 12-Month Use of Funds (EmtinB)

The forecast is based on the Company undertaking two rabbit studies, for completion over the next 12 months.

Activity	\$
Ophthalmology – Safety <sup>1</sup>	\$400,000
Ophthalmology – Pharmacokinetics <sup>2</sup>	\$250,000
R&D/Product support studies	\$185,000
<b>Total</b>	<b>\$835,000</b>

<sup>1</sup> Glucagon-Like Peptide (GLP) 13-week Intravitreal study in Rabbits (Safety).

<sup>2</sup> Non-GLP Pharmacokinetics Study.

The above tables are a statement of current intentions as at the date of this announcement. Investors should note that, as with any budget, the allocation of funds set out in the above tables may change depending on a number of factors, including study results, market conditions, the development of new opportunities and/or any number of other factors, and actual expenditure levels may differ significantly from the above estimates.

## Acquisition Terms

In connection with the Acquisition, the Company has entered into separate binding share sale agreements with the key shareholders of Isopogen WA Ltd (**Isopogen WA**), being the entities affiliated with the current Isopogen WA directors (together, the **Key Sellers**). The Key Sellers collectively hold 51.4% of the issued share capital of Isopogen WA.

The Acquisition is subject to a number of conditions precedent, including receipt of necessary shareholder and regulatory approvals, and each other shareholder of Isopogen WA (**Minority Sellers**) signing a separate share sale agreement on the same terms as those signed by each Key Seller (**SSA**).

The Company and Key Sellers are currently soliciting executed agreements from the Minority Sellers. The Company believes it will receive executed SSAs from each Minority Seller but cannot provide any certainty as to whether this will occur, and the Company does not propose to proceed with the Acquisition if it does not receive executed SSAs from each Minority Seller.

None of the Key Sellers or Minority Sellers are related parties of the Company.<sup>1</sup>

### The key commercial terms of each SSA are as follows:

#### Consideration

The Company has agreed to provide the following consideration in return for the Acquisition:

- (a) 85,714,286 fully paid ordinary shares in the capital of the Company (**Consideration Shares**); and
- (b) 57,142,857 performance shares that will convert into fully paid ordinary shares in the capital of the Company (**Shares**) on a one-for-one basis, subject to the satisfaction of the Milestone outlined below (**Performance Shares**),

(together, the **Consideration**). In addition, the Company has agreed to issue 2,857,143 Shares to an adviser of Isopogen (Bennett Litigation and Commercial Law), in full and final satisfaction of an existing debt owed by Isopogen WA (**Debt Conversion Shares**). The Debt Conversion Shares will be issued at a deemed issue price of 3.5 cents, being equal to the issue price under the Placement (defined below).

The Consideration Shares will be subject to voluntary escrow for a period of 12 months from the date of issue. Each Isopogen WA shareholder will receive the Consideration in their respective proportion determined on the basis of the number of Isopogen WA shares held by that shareholder as at completion of the Acquisition (**Completion**) divided by the total number of Isopogen WA shares on issue as at Completion.

---

<sup>1</sup> Other than the Key Seller entities affiliated with Paul Fry and Robert McKenzie, as Messrs Fry and McKenzie are proposed directors of the Company following Completion.

Based on the number of Isopogen WA shares on issue, the Consideration represents an offer of 0.6093 Consideration Shares and 0.4062 Performance Shares for every 1 Isopogen WA share acquired.

### **Milestone**

The Performance Shares shall convert into ordinary Shares on a one-for-one basis upon the Successful Completion of a Special Access Program (the **Milestone**), as defined below:

- (a) **Special Access Program** means a program supported by Isopogen, conducted under a Special Access Scheme, involving the use of allogeneic bone marrow-derived mesenchymal stromal cells for the treatment of refractory fistulising Crohn's disease.
- (b) **Special Access Scheme (SAS)** means the Special Access Scheme, a regulatory pathway administered by the Therapeutic Goods Administration (TGA) in Australia that allows healthcare practitioners to prescribe and administer unapproved therapeutic goods to individual patients on a case-by-case basis, where conventional treatments have failed, are unsuitable, or unavailable. It provides a legal and controlled mechanism for accessing investigational therapies outside of formal clinical trials.
- (c) **Successful Completion** means the achievement of a Clinical Response in the Special Access Program, involving up to 12 patients, where:
  - a. **Clinical Response** is defined as either:
    - closure of  $\geq 50\%$  of fistula openings in a patient, or
    - a decrease in fistula discharge in a patient of  $\geq 50\%$ ,as assessed by the treating physician or qualified investigator, in at least 4 patients.
  - b. **fistula** refers to an abnormal tract connecting the intestine to another organ or to the external surface of the body.

Successful Completion must be achieved within 3 years from the date of the general meeting in which the Company's shareholders approve the issue of the Performance Shares (**General Meeting**).

### **Conditions Precedent**

Completion is subject to the satisfaction or waiver of various conditions precedent, including (but not limited to) the following:

- each Isopogen WA shareholder executing an SSA in respect of their Isopogen WA shares and the Company be entitled to complete under each SSA;
- the Company obtaining shareholder approval pursuant to ASX Listing Rules 7.1 and 10.11 (to the extent required) for the issue of the Consideration Shares, Performance Shares, Placement Shares (defined below) and Debt Conversion Shares at the General Meeting;
- the parties obtaining any required third party approvals, consents and waivers and regulatory approvals to give effect to the Acquisition; and
- no material adverse change having occurred with respect to Isopogen.

Each SSA may be terminated in certain circumstances including (but not limited to) by either the Company or the Isopogen WA shareholder if the conditions precedent are not satisfied (or waived, as permitted) within 120 days of the signing of the relevant SSA.

ASX has confirmed that ASX Listing Rules 11.1.2 and 11.1.3 do not apply to the Acquisition. Accordingly, the Company is not required to re-comply with the ASX admission requirements as a result of the Acquisition.

## Placement

The Company has received firm commitments for a placement to raise up to \$3.5 million (before costs) via the issue of up to 100,000,000 Shares (**Placement Shares**) at an issue price of 3.5 cents per Placement Share to professional, sophisticated and qualifying investors subject to shareholder approval at the General Meeting (**Placement**). The Placement includes participation by the Company's non-executive director Anton Uvarov, who has subscribed for 2,650,000 Placement Shares (value of \$92,750), subject to shareholder approval pursuant to ASX Listing Rule 10.11 at the General Meeting.

The issue of the Placement Shares is also conditional on Completion of the Acquisition.

Proceeds from the Placement will be primarily applied towards:

- satisfying the 12-month funding requirements for StemSmart™ and EmtinB as set out in the tables above;
- costs of the Acquisition and Placement; and
- general working capital costs.

Westar Capital Limited acted as lead manager to the Placement and will receive a 6% capital raising fee and, subject to receipt of shareholder approval at the General Meeting, up to 40 million unquoted options exercisable at \$0.07 each and expiring three years from their date of issue (**Lead Manager Options**). Of these Lead Manager Options, 14 million are proposed to be issued to the Company's directors (or their respective nominees) subject to receipt of shareholder approval pursuant to ASX Listing Rule 10.11 at the General Meeting.

## Capital Structure

The anticipated effect of the Acquisition and Placement on the Company's capital structure as at the date of this announcement is shown in the following table:

	Ordinary Shares	Performance Shares	Options
<b>Opening</b>	<b>144,604,870</b>	-	<b>6,000,000</b>
Consideration Shares	85,714,286	-	-
Performance Shares	-	57,142,857	-
Debt Conversion Shares	2,857,143	-	-
Placement Shares	100,000,000	-	-
Lead Manager Options	-	-	40,000,000
<b>TOTAL<sup>1</sup></b>	<b>333,176,299</b>	<b>57,142,857</b>	<b>46,000,000</b>

<sup>1</sup> Assumes the Acquisition completes, and the Company's shareholders approve the issue of each of these securities at the General Meeting.

## Indicative Timetable

Event	Date
Despatch of Notice of Meeting	Targeting mid-May 2025
General Meeting	Targeting mid-June 2025
Completion of Acquisition and issue of Consideration Shares, Performance Shares, Debt Conversion Shares, Placement Shares and Lead Manager Options	Shortly after receipt of shareholder approvals at General Meeting

*\* The above timetable is indicative only and remains subject to change at the Company's discretion, subject to compliance with the Corporations Act, the ASX Listing Rules and other applicable laws. The Company reserves the right to change the timetable, subject to regulatory requirements.*

## EmtinB

The Company's Existing Business and product portfolio includes EmtinB™, a therapeutic peptide initially targeting Alzheimer's disease and glaucoma, as well as other Emtin peptides (EmtinAc, EmtinAn, and EmtinBn) which have demonstrated similar therapeutic potential as EmtinB™.

In 2023, it was determined that the development of EmtinB™ should focus on the ophthalmology program, where EmtinB™ is administered locally, via intravitreal injection.

In June 2024, the Company met with the US Food and Drug Administration (**FDA**) on its planned non-clinical and clinical development program of EmtinB as a treatment for adults with advanced glaucoma via a pre-Investigational New Drug type B meeting (pre-IND meeting). During the meeting, the FDA provided guidance and recommendations on the required pre-clinical studies that the Company must undertake prior to progressing EmtinB towards a first-in-human trial.

Based on this guidance, the Company has planned a non-GLP study to assess the pharmacokinetics (PK) of intravitreally administered EmtinB in male and female rabbits. In parallel, the Company has planned a 13-week evaluation of ocular tolerance, systemic toxicity and pharmacokinetic in vitreous following repeated intravitreal administration in pigmented rabbits. These studies have been represented in the projected 12-month use of funds table above.

## Proposed Director Appointments

**Robert McKenzie** (LL.B; B.Juris, FAICD)

Rob is a lawyer with over 40 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. He was national head of reconstruction and insolvency at Clayton Utz, one of Australia's major national law firms.



Rob is Chairman of the Perron Institute, a Director of Australian Institute of Neuro-rehabilitation and Director and Chair of the Risk committee for the WA State Government's Keystart Loans.

Rob has also chaired the Law Council of Australia's National Insolvency and Reconstruction, WA Corporation's committees and the Law Society of Western Australia's Commercial Law Committee. Rob was also a member of the Federal Government's Takeovers.

**Paul Fry (BBus)**

Paul has over 40 years' experience in international senior finance and commercial executive roles in public practice and industry, in various countries.

He is a former Partner of Ernst and Young and PwC in Australia and Canada and has consulted to companies in a broad range of industries.

His expertise centres around public markets, capital raisings, governance, risk management and managing corporate transactions. He has advised and negotiated numerous projects including M&A, fund raisings, asset disposals and development projects. Paul has experience with companies listed on various exchanges including ASX and TSX.

**Proposed Chief Scientific Adviser**

**Marian Sturm** BSc (Hons), MSc, PhD, FFSc (RCPA)

Marian worked for the public health sector for more than 40 years and has extensive experience in both the manufacture and regulation of clinical products for transplantation/ application and in research and development. Until her retirement in 2021, Marian was Facility Director of the Cell & Tissue Therapies WA (CTTWA) at Royal Perth Hospital, a TGA licensed manufacturing, FACT and NATA accredited facility. CTTWA provided an adult and paediatric clinical service, manufacturing products for clinical therapy, including haemopoietic stem cells for bone marrow transplant. Marian has been actively involved in the development and clinical translation of emerging biotherapies, in particular mesenchymal stromal (stem) cells, CAR T-cells and in tissue engineering. Marian held an adjunct Associate Professorship with the Centre of Cell Therapy & Regenerative Medicine, School of Biomedical Sciences, University of Western Australia and was an inaugural member of the TGA Advisory Committee on Biologics for 11 years. She is considered a leading expert in cell therapies in Australia, particularly in stem cell therapies.

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

**This announcement is intended to lift the Company's trading halt.**

-ENDS-

For more information please contact:

Chris Achurch (Company Secretary)

+61 8 6268 2641

### ***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.

There can be no assurance that the Acquisition will be completed or that plans of the directors and management of the Company will proceed as currently expected or will ultimately be successful. 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.

**Annexure 1**

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 <sup>6</sup> 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 paralleled 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.