ASX:MSX

miro sciences

Formally NeuroScientific Biopharmaceuticals (ASX: NSB)

StemSmart™

Advancing Towards a New Treatment for Severe Crohn's Disease



November 2026

Miro Sciences Ltd
ABN 13 102 832 995

Disclaimer

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Company Snapshot

Corporate Share Information

As at November 2026

SHARE PRICE	A$0.05
MARKET CAPITALISATION	~A$19.5 million

Capital Structure & Cash On Hand

	ORDINARY SHARES	PERFORMANCE SHARES	OPTIONS
CAPITAL	389.72 million	1.50 million	43.25 million
CASH	~A$3.9 million (30/9/2026)		



Crohn's Disease: a Large Market in Need

Large patient population, rising burden, limited durable treatment options

US$13B+

Global Crohn's Disease market[1,2]

6-8M

Patients with Crohn's Disease globally[1,2]

~30%

Do not respond to standard therapies[3]

Zero

Approved treatment options once standard therapies fail[3]

- A chronic condition, with the progressive disease burden rising
- Fistulising Crohn's Disease causes severe, life-altering complications
- Surgery often becomes inevitable where options are limited

We are targeting the least-served segment: patients who have exhausted current options

1.ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology."*
2.Crohn's Disease: Dynamic Market Forecast to 2026, GlobalData. *https://www.globaldata.com/store/report/crohns-disease-dynamic-market-forecast-to-2026/*
3.ASX Announcement (19 June 2025) – *"Previous StemSmart Studies Demonstrate Clinical Response"*

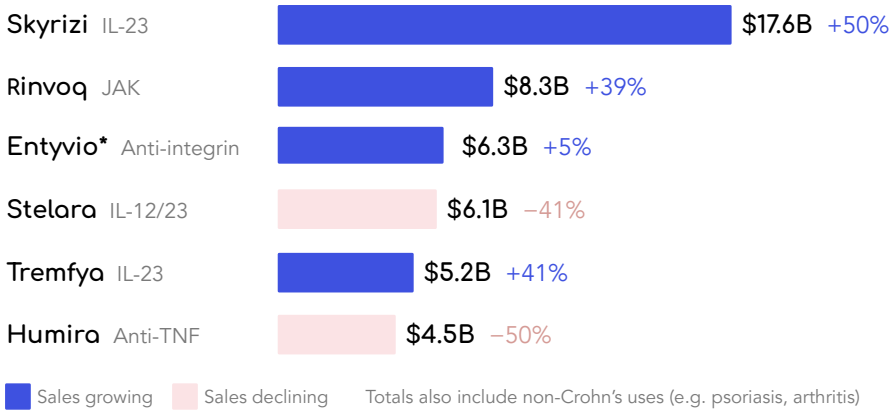
Crohn's Treatment Landscape & Where StemSmart™ Fits

Crohn's alone is a ~US$13B+ market[6] with unmet need for patients that fail biologics

LINE OF THERAPY IN MODERATE–SEVERE CROHN'S

1. **Conventional**
   5-ASA, steroids, immunomodulators
2. **1st advanced therapy**
   Mostly anti-TNF: infliximab, adalimumab[5]
3. **2nd advanced therapy**
   Switch mechanism: IL-23, anti-integrin, JAK
4. **Failed ≥2 mechanisms**
   StemSmart™ target (Phase 2 entry criteria)

LEADING CROHN'S DRUGS · 2025 SALES, US$B, ALL INDICATIONS[4]



For investors: StemSmart™ targets patients after biologics fail: a new line of therapy, not a head-on competitor.

4. AbbVie FY2025 results; J&J FY2025 results; *Takeda FY2025 (to 31 Mar 2026) ¥958.0bn at ~¥152/US$. AER Growth vs prior year.
5. Singh S et al. J Crohns Colitis 2025.
6. ASX Announcement (16 Apr 2025) - "*NeuroScientific to Acquire Leading Stem Cell Technology.*."

Proven Stem Cell Technology

Strong market momentum for approved MSC products

Increased Sales for MSC Products

Mesoblast's (ASX:MSB) recent market announcement[7] highlighted strengthened uptake (+44% vs prior year) of its FDA-approved MSC product for paediatric patients with steroid-refractory acute graft vs host disease

Pathway to Commercialisation in US

The United States FDA's approval of Mesoblast's MSC therapy[8] marked a significant milestone for the commercialisation of this product class, providing a direct roadmap for developers of MSC therapies to commercialise their product candidates and obtain global investment

Significant Opportunity: StemSmart™ is following the established roadmap to penetrate a $13B market in need with a next-generation product

7.Mesoblast Ltd ASX Announcement (29 October 2026) – *"Activity Report for Quarter Ended September 30, 2026 (Appendix 4C)."*
8.Mesoblast Ltd ASX Announcement (19 December 2024) - *"Mesoblast's Ryoncil® is the First U.S. FDA-Approved Mesenchymal Stromal Cell (MSC) Therapy."*

Introducing StemSmart™

Purpose-built Mesenchymal Stem Cell (MSC) therapy for patients with limited options[9]

Designed for severe inflammation	Hunts down inflammation sites and modulate the immune response
Targets treatment-resistant patients	Developed for patients who have failed existing biologic therapies
Proven Safe across multiple clinical trials	Large number of patients treated - no serious adverse events reported
Manufactured to regulatory standards	Produced under TGA accreditation to ensure safety, quality and consistency
Patented platform technology	Proprietary MSC technology enhances safety & efficacy developed at Royal Perth Hospital, WA

Activated MSC
Optimised to enhance therapeutic activity

Differentiated
Proprietary activation process sets StemSmart™ apart

Purpose-built
Designed for high inflammation conditions

9. ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology."*

Prior Clinical Evidence: 80% Response in Refractory Patients

Two independent datasets in Crohn's patients who had run out of approved treatment options

PUBLISHED PHASE 2 · LUMINAL CROHN'S[10]

Open-label, multicentre, n=18 failing anti-TNF therapy; 4 weekly IV infusions, assessed at Day 42

78%	44%	44%
Clinical response (14/18)	Clinical remission (8/18)	Endoscopic improvement (8/18)

- Mean CDAI[17] 366 → 214 (p<0.0001)
- Quality of life (IBDQ) improved (p=0.014)
- Single-arm, no placebo control

SPECIAL ACCESS PROGRAM · FISTULISING[11]

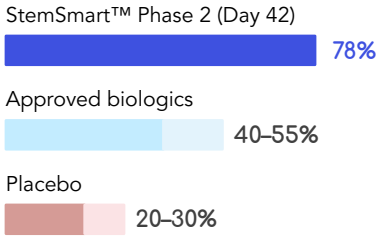
TGA Special Access Scheme (Category B), n=5 adults aged 18–49 resistant to approved therapies

80%	5/5	5/5
Clinical response[13] (4/5)	Reduced fistula discharge	≥1 seton removed

- CDAI, PDAI and IBDQ[14] improved in all 5
- MRI trend toward fistula healing
- No serious adverse events reported

RESPONSE RATES IN CONTEXT[12]

Clinical response (CDAI fall >100) in biologic-refractory Crohn's



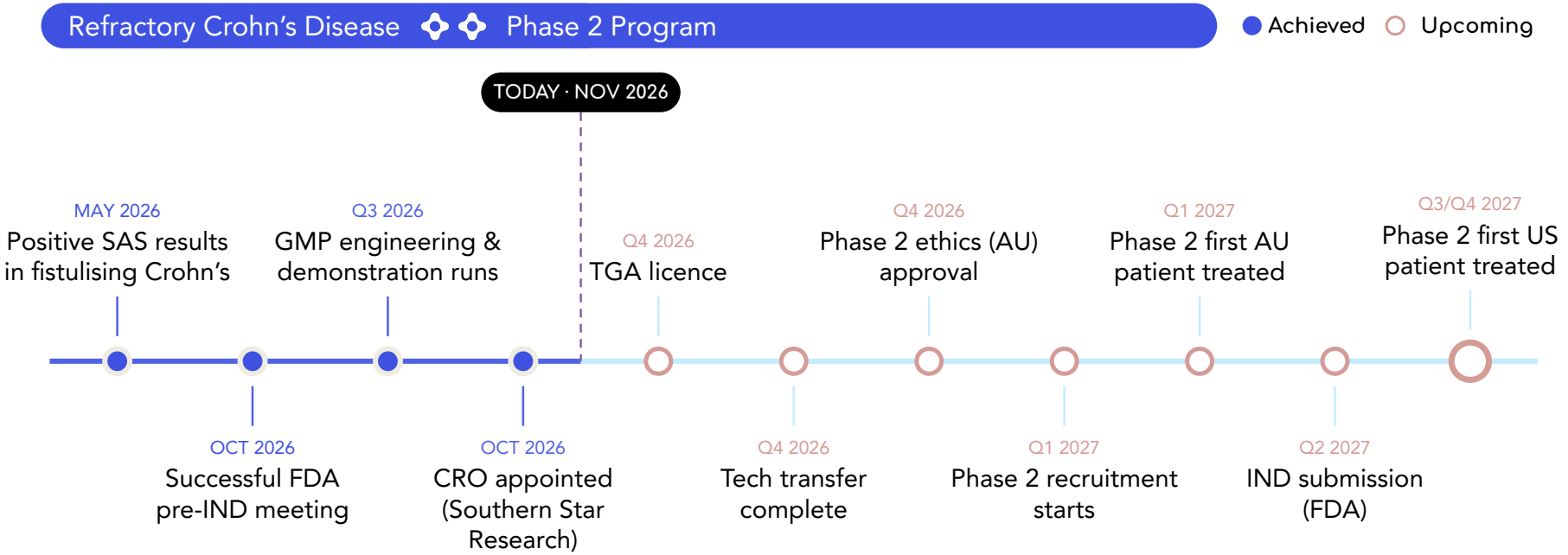
Cross-trial comparison, not head-to-head. StemSmart™ data are open-label; comparator ranges from pivotal biologic trials (UNITI-1/2, GEMINI-II) as cited in the Phase 2 protocol.

Safety: well tolerated; one SAE in Phase unrelated to MSCs[13]

For investors: the Phase 2 trial is designed to confirm this signal against placebo (powered for 55% vs 20%).

10. ASX Announcement (16 April 2025) - *"NeuroScientific to Acquire Leading Stem Cell Technology."*
11. ASX Announcement (26 May 2026) – *"Remarkable Results from Patients treated with StemSmart under Special Access."*.
12. MSX Draft Phase 2 protocol MSC-CDP2-02.
13. SAS clinical response: closure of ≥50% of fistula openings or ≥50% reduction in fistula discharge, assessed by treating physician.
14. CDAI: Crohn's Disease Activity Index, PDAI: Perianal Disease Activity Index, IBDQ: Inflammatory Bowel Disease Questionnaire.

StemSmart™ path to Phase 2 data



Positive FDA Feedback Supports Phase 2 Development

A significant regulatory milestone supporting the proposed US clinical development pathway for StemSmart™.[15]

FDA

6/7

Positive responses to the seven questions submitted to the US FDA

- **Clinical trial design supported:** US FDA agreement with the proposed Phase 2 trial design for refractory Crohn's disease.
- **Existing human evidence accepted:** No additional non-clinical studies required based on the existing human data package reviewed.
- **Product release strategy accepted:** FDA agreed with the proposed StemSmart™ release-testing approach.
- **One outstanding item:** additional virus testing to be added, which is simple to implement and will not impact timelines.

For investors: Positive regulatory alignment provides greater clarity for the planned US IND submission and reduces uncertainty around key clinical and non-clinical development requirements.

15.ASX Announcement (13 October 2026) – *"US FDA Provides Positive Feedback on Planned Phase 2 Crohn's Disease Trial"*

Building Manufacturing Readiness for Clinical Supply at Scale[16,17]

Large patient population, rising burden, limited durable treatment options

FOUR CRITICAL WORKSTREAMS

1

Manufacturing scale-up

Partner with Q-Gen to manufacture StemSmart™ at late stage clinical and commercial scale.

2

Technology transfer

Transferring the proprietary manufacturing process into the clinical manufacturing environment.

3

GMP & quality validation

Conduct activities to demonstrate consistent quality, reproducibility and product release.

4

TGA licensing pathway

Critical regulatory inspection and licensing required for supporting Phase 2 clinical supply.

Target outcome: TGA-licensed manufacturing capability supporting the planned Australian Phase 2 clinical trial.

16.ASX Announcement (31 July 2025) – *"NeuroScientific Partners with Leading Biologic Manufacturer"*
17.ASX Announcement (17 March 2026) - *"StemSmart™ Manufacturing Scale-Up Advances"*

Phase 2 Trial Preparations Advancing Across Key Workstreams[18]

Clinical, operational & regulatory activities are progressing towards the planned initiation of the StemSmart™ Phase 2

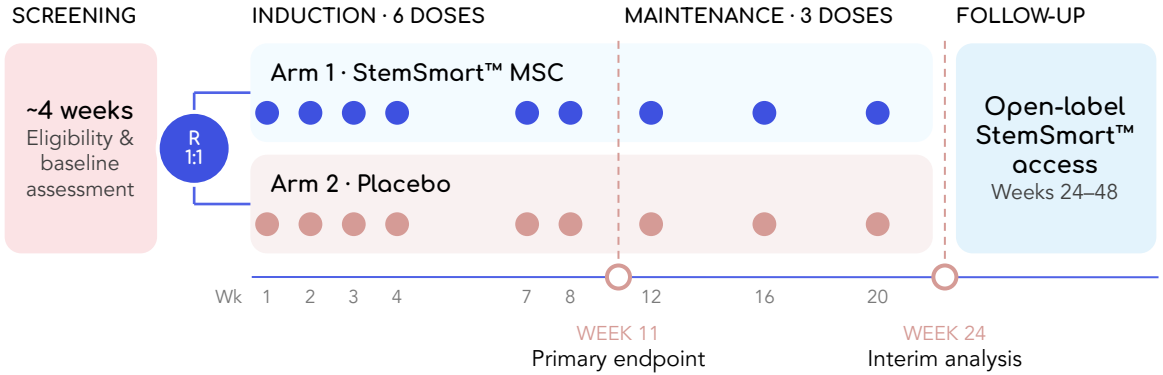
WORKSTREAM	PROGRESS
Clinical research organisation	Southern Star Research appointed
Clinical trial protocol	Finalised
Investigator's Brochure	Being finalised
Clinical site identification	40+ sites throughout Australia being contacted
Trial operations	Site management and treatment logistics responsibilities established
Data and safety management	Specialist service providers being engaged
Regulatory preparation	Australian trial start-up and US IND preparations progressing

Near-term priorities: Complete regulatory and ethics requirements, progress manufacturing readiness, activate clinical sites and initiate patient recruitment.

18.ASX Announcement (1 October 2026) – *"Leading CRO Appointed for Phase 2 Crohn's Trial"*

Phase 2 Study Design[19]: Randomised & Placebo-Controlled

~74 patients (target 66) with refractory Crohn's disease, randomised 1:1 to StemSmart™ or placebo



WEEK 24 RESPONSE DETERMINES THE OPEN-LABEL PATHWAY TO WEEK 48

1. **Responders** — StemSmart™ infusions every 4 weeks
2. **No response / relapse** — Rescue: 4 weekly doses, then every 4 weeks
3. **Endoscopic remission** — Monitored for durability, no further infusions

KEY DESIGN FEATURES

Patients
Aged ≥16; moderate–severe Crohn's (CDAI 220–450, SES-CD ≥6*); failed ≥2 biologic/advanced therapies

Dosing
2×10⁸ cells/kg IV: 6 induction + 3 maintenance infusions over 20 weeks

Primary endpoints
Safety, and clinical response (CDAI fall >100 points) vs placebo at Week 11

Key secondary
Clinical and endoscopic response and remission at Weeks 24/48; steroid-free remission

Statistical power
~80% power to detect 55% vs 20% response rate (66 evaluable)

For investors: Primary readout at Week 11, with an interim analysis once all patients reach Week 24.

19.Source: MSX Draft Phase 2 protocol MSC-CDP2-02; design subject to ethics and regulatory approval. *SES-CD ≥4 for isolated ileal disease. CDAI: Crohn's Disease Activity Index; SES-CD: Simple Endoscopic Score for Crohn's Disease; MSC: mesenchymal stromal cell.

A Clear Path from Phase 2 to Potential Commercialisation

Targeted clinical, regulatory and commercial milestones

TIMING	DEFINITION OF SUCCESS
Q4 2026	Australian Phase 2 trial initiated
Q1 2027	First Australian patient treated
Q2 2027	US IND submitted
2027	FDA Fast Track or RMAT designation sought, subject to eligibility
Q3/Q4 2027	First US patient treated
Q2 2028	Full Phase 2 patient enrolment
Q4 2028	Phase 2 clinical results available
Following Phase 2	Results support the earlier promising clinical findings
Following positive results	Secure a strategic development or commercial partner for Phase 3

Leadership & Advisory Strength[20,21]



Nathan Smith
BSc
Chief Executive Officer
25+ years in biologics and cell & gene therapies



Dr Marian Sturm
FFSc (RCPA), PhD, MSc, BSc Hons
Chief Scientific Officer
40+ years in cellular therapy development



Prof Catherine Cole
MBBS, FRACP, FRCPA
Chief Medical Officer
35 years in paediatric haematology, oncology & clinical trials



Chris Knee
BComm
Chief Financial Officer
20+ years in resources, AI and technology

Board of Directors



Rob McKenzie
LL.B; B.Juris, FAICD, RITF
Non-Executive Chairman
40+ years in corporate governance and M&A



Dr Anton Uvarov
PhD, MBA
Non-Executive Director
Neuroscience and healthcare industry specialist



Paul Fry
BBus
Non-Executive Director
Public markets, capital raisings and governance expert



Clarke Barlow
BCom, MAICD
Non-Executive Director
Capital markets adviser with biotech growth focus

Clinical & Scientific Advisory Board



Dr Ashley Irish
MBBS, FRACP
Advisory Board Member
Renal transplant and kidney disease specialist



Dr Lena Thin
MClinRes, MBBS
Advisory Board Member
IBD clinician & international trial investigator



Dr Michael Musk
MBBS, FRACP
Advisory Board Member
Respiratory physician and lung disease expert



Prof Yuben Moodley
MBBS, FRACP, MD, PhD
Advisory Board Member
Pulmonary fibrosis and respiratory health leader

20. ASX Announcement (6 November 2025) – *"Neuroscientific Appoints Clinical & Scientific Advisory Board"*
21. ASX Announcement (26 October 2026) - *"Appointment of CFO"*

Strong Global IP Position & Protection

Patented manufacturing process with freedom to operate

Active Patents

"Cell Culture Method" for StemSmart™ technology – Dr Marian Sturm

- Granted in 14 Markets including Australia, USA, EU, Japan, UK, China, Canada, et al
- Patent expires in November 2034[22] with potential to apply for extension
- Patented manufacturing process removes non-human proteins from cell products, improving clinical efficacy and safety

Technologies in Development

Provisional Patents Pending

12 Year US Marketing Authorisation Exclusivity Period

22. US Patent – US9868936B2 "Cell Culture Method" (Granted 16 January 2018; Anticipated Expiry 3 November 2034) – https://patents.google.com/patent/US9868936

Four Pillars Supporting the StemSmart™ Investment Opportunity

Key Takeaways

1

Strong Clinical Foundation

Patented StemSmart™ technology supported by strong previous clinical responses[23] and an ironclad safety profile.

2

Consistent Operational Delivery

Key clinical[24], regulatory[25] and manufacturing[26] milestones achieved, supporting progress towards Phase 2.

3

Experienced Team & Partners

Established scientific, clinical, and corporate leadership, supported by experienced partners to deliver the Phase 2 trial.

4

Defined Development Pathway

Clear clinical and regulatory milestones leading towards strategic partnering and commercialisation.

StemSmart™: is progressing towards its next clinical development stage, supported by existing evidence, regulatory engagement and growing operational readiness.

23.ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology."*
24.ASX Announcement (1 October 2026) – *"Leading CRO Appointed for Phase 2 Crohn's Trial"*
25.ASX Announcement (13 October 2026) – *"US FDA Provides Positive Feedback on Planned Phase 2 Crohn's Disease Trial"*
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