
CLINICAL-STAGE BIOTECHNOLOGY

TREXAPHARM

TREXAVIVE® — a patented and proprietary rapid, non-sedating outpatient therapy for treatment-resistant depression

Targeting a major unmet need in the rapidly evolving global depression market.



Trexapharm Corporate Overview

Trexapharm is an Australian clinical-stage biotechnology company developing TREXAVIVE®, a patented and proprietary microdose combination therapy targeting treatment-resistant depression — one of the largest unmet needs in mental health.

TREXAVIVE® has already generated encouraging human proof-of-concept evidence and is continuing to build real-world clinical experience through Australia's Special Access Scheme. The therapy is being developed around a differentiated rapid, non-sedating outpatient profile with the potential for sustained benefit.



Large Unmet Need

Millions of patients with treatment-resistant depression remain inadequately treated despite existing antidepressants and newer rapid-acting therapies.



Differentiated TREXAVIVE® Profile

Patented and proprietary therapy targeting a rapid, non-sedating outpatient treatment model with the potential for sustained benefit.



Human + Real-World Clinical Evidence

Encouraging human proof-of-concept study completed, including an early signal in suicidal ideation, with ongoing prescribing and clinical experience through Australia's Special Access Scheme.



Global Commercial & Partnering Opportunity

A differentiated treatment profile and growing human evidence base support the potential for pharmaceutical partnering and global development.

The Changing Landscape of Depression Treatment

Many patients with treatment-resistant depression do not respond adequately to conventional antidepressants, which may also take weeks to produce benefit.

Rapid-acting therapies have changed expectations, but current options such as Spravato® require repeated supervised administration and monitoring.

The next opportunity in depression treatment is to combine rapid symptom improvement with a practical, non-sedating outpatient treatment model.

EVOLUTION OF TREATMENT EXPECTATIONS



Trexavive® is being developed to evaluate rapid, non-sedating outpatient treatment and the potential for sustained benefit.

Why this matters

Millions of patients remain inadequately treated

Demand for faster relief is increasing

Major pharmaceutical companies are increasing investment in next-generation mental health treatments

Healthcare systems need scalable outpatient solutions

The next generation of value in depression treatment may combine rapid onset, practical outpatient delivery and the potential for sustained benefit.

STRATEGIC DIFFERENTIATION

The Next Challenge Isn't Discovering Rapid Therapies. It's Delivering Them.

Many rapid-acting treatments can involve supervised administration, monitoring requirements, specialised treatment settings and operational complexity — limiting practical access and scalability.

TREXAVIVE® is being developed to combine the advantages of rapid-acting treatment with a potentially simpler outpatient model.

DELIVERY MODEL DIFFERENTIATION



Rapid-Treatment Burden

- Supervised administration
- Monitoring requirements
- Specialised settings + operational complexity



Practical Innovation

- Non-sedating outpatient treatment
- Reduced treatment burden
- Routine psychiatric care + scalable implementation

Rapid-Acting Potential + Practical Outpatient Model

= Differentiated Treatment Model

Why This Matters

Commercial differentiation depends not only on rapid treatment, but on whether delivery can be practical, repeatable and scalable.

Rapid + Non-Sedating + Outpatient

TREXAVIVE® is being developed to combine rapid-acting treatment advantages with a potentially simpler, scalable outpatient model.

Why TREXAVIVE®?

TREXAVIVE®: rapid, non-sedating microdose combination therapy for treatment-resistant depression.

TREXAVIVE® combines a patented and proprietary treatment approach, encouraging human evidence, ongoing real-world clinical experience and a differentiated rapid, non-sedating outpatient profile.

FIVE REINFORCING PILLARS



A patented clinical-stage asset addressing a large unmet need with human evidence already generated.

LEAD CLINICAL PROGRAM

Introducing TREXAVIVE®

Rapid, non-sedating microdose combination therapy for treatment-resistant depression.

TREXAVIVE® is Trexapharm's patented and proprietary lead clinical-stage therapy for treatment-resistant depression. It combines microdoses of flumazenil and naltrexone through complementary mechanisms and is being developed as a rapid, non-sedating outpatient treatment.

GABAergic + Opioid / Reward + Neuroimmune

↓ **Mood · Stress · Reward & Pleasure**

Different mechanisms. One integrated approach to mood, stress, reward and inflammatory pathways.

FOUR KEY ATTRIBUTES



Rapid

Encouraging improvement observed from Day 4.



Non-Sedating

Designed to avoid significant sedation and associated recovery burden.



Outpatient

Designed for potential integration into outpatient psychiatric care.



Potential Sustained Benefit

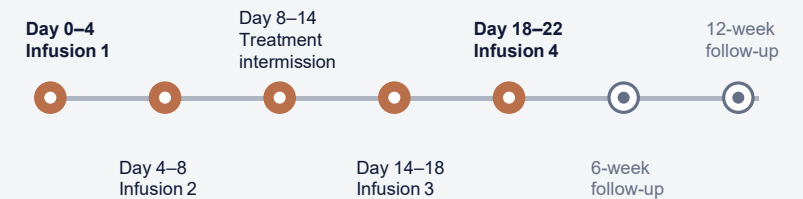
Benefit remained visible through Week 12 in the initial proof-of-concept study.

MAC-D PROOF-OF-CONCEPT STUDY

COMPLETED
HUMAN STUDY

TREATMENT

Subcutaneous microdoses of flumazenil and naltrexone



HISTORICAL REGIMEN

Historical proof-of-concept study regimen. Future clinical formulation, dosing and delivery may be further optimised.

Completed in patients with treatment-resistant depression

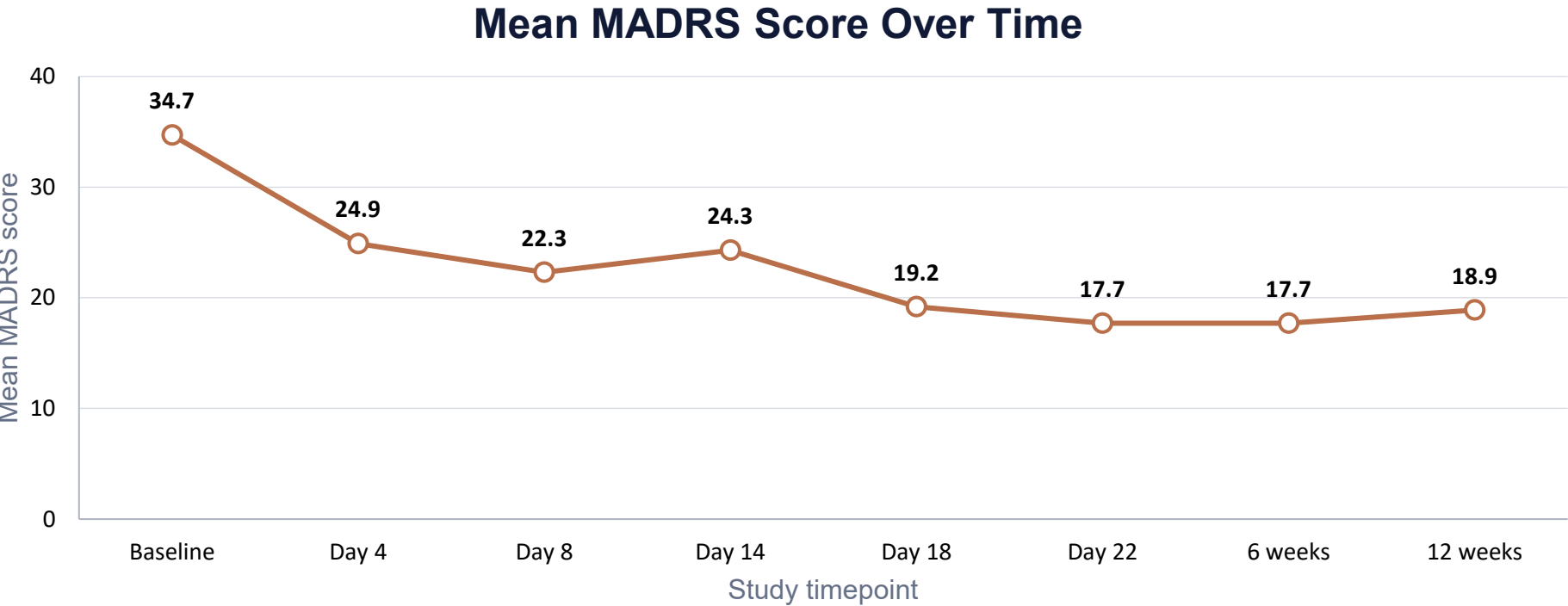
Lead Clinical Program

INDICATION	Treatment-resistant depression (TRD)
SETTING	Designed for outpatient psychiatric care
DEVELOPMENT	Clinical-stage; completed human study
VISION	Expand access through outpatient delivery

TREXAVIVE® integrates complementary mechanisms in a patented, rapid, non-sedating outpatient clinical-stage asset.

Human Proof-of-Concept: Improvement from Day 4 Through Week 12

Mean MADRS scores improved from Day 4, with the observed reduction remaining visible through Week 12.



Lower MADRS scores indicate lower depressive symptom severity.

Observed mean scores · N=10

DAY 4

-9.8 point mean change

Early improvement observed
p<0.001

DAY 22

-17.3 point observed mean change

Largest observed mean improvement
p<0.001

WEEK 12

-15.8 point mean change

Benefit remained visible
p<0.001

SUICIDAL IDEATION

7/10 Lower suicidal-thought scores observed

STUDY SUMMARY

Open-label proof-of-concept study | N=10 | treatment-resistant major depressive disorder | four subcutaneous infusions | 22-day treatment phase | 12-week follow-up | 10/10 completed treatment

Open-label, single-centre, uncontrolled proof-of-concept study; N=10. Controlled confirmation required.

Evidence Beyond the Formal Trial

Special Access Scheme experience provides an ongoing clinical evidence stream and practical insight into real-world outpatient care.

Human Proof-of-Concept



Ongoing Real-World Clinical Experience



Controlled Clinical Development

FORMAL EVIDENCE

Formal Proof-of-Concept Study

- Completed in 10 adults with treatment-resistant major depressive disorder. Improvements were observed across clinician-rated depression, patient-reported depression and social and occupational functioning.
- All participants completed treatment. No serious adverse events or treatment discontinuations due to adverse events were reported.
- Lower suicidal-thought scores were observed in 7 of 10 participants.

ONGOING EVIDENCE STREAM

Ongoing Real-World Clinical Experience

- Ongoing patient access through Australia's Special Access Scheme is building real-world prescriber and patient experience.
- Experience can inform tolerability and durability, as well as how TREXAVIVE® may fit into real-world outpatient implementation.
- Practical learnings can inform future clinical development and commercialisation while controlled studies progress.



FORMAL CLINICAL VALIDATION PATHWAY

Controlled Phase IIa development is intended to provide formal validation of efficacy, safety, tolerability and durability.
Final protocol remains subject to regulatory, statistical, clinical and CMC review.

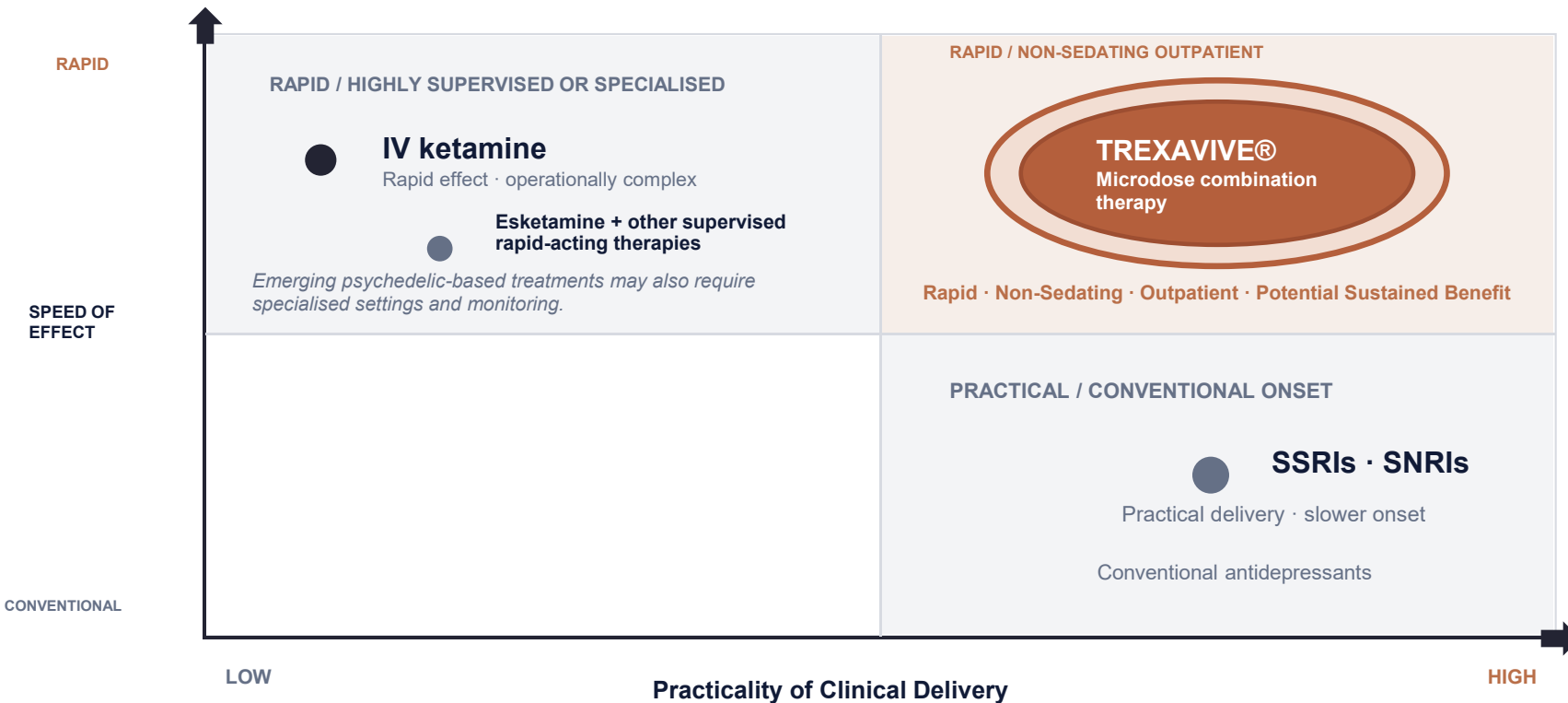
EVIDENCE + IMPLEMENTATION

TREXAVIVE® is continuing to generate real-world clinical and implementation experience while formal controlled development progresses.

Positioned for the Next Generation of Depression Care

TREXAVIVE® is positioned between conventional antidepressants and highly supervised rapid-acting therapies, with a development profile centred on rapid, non-sedating outpatient delivery and potential sustained benefit.

CONCEPTUAL POSITIONING OF DEPRESSION THERAPIES



Why the Position Matters

TREXAVIVE® is being developed to combine rapid treatment with a practical outpatient model and without the sedation or dissociation associated with many highly supervised rapid-acting therapies.

TREXAVIVE® occupies a differentiated position between conventional antidepressants and highly supervised rapid-acting therapies.

A Significant Global Market Opportunity

Market scale is increasingly matched by major-pharma strategic interest.

Treatment-resistant depression represents a substantial global healthcare and commercial opportunity. The combination of a large, growing market and recent major-pharma investment highlights strategic interest in differentiated next-generation depression assets.

MARKET OPPORTUNITY AT A GLANCE

280M+

People living with depression globally

~80M

Estimated people potentially living with treatment-resistant depression*

US\$2.7B

Estimated global treatment-resistant depression treatment market (2026)

US\$6.1B

Projected global market by 2034

11%

CAGR 2026–2034

*Illustrative estimate based on published global depression prevalence and commonly cited treatment-resistant depression prevalence estimates. Market forecast adapted from Fortune Business Insights (2026).

MAJOR PHARMA VALIDATING THE OPPORTUNITY

Eli Lilly → AtaiBeckley | July 2026

US\$2.8B upfront + up to US\$1.0B in milestone payments

AtaiBeckley's lead asset, BPL-003, is a late-stage rapid-acting treatment being developed for treatment-resistant depression. The transaction highlights increasing strategic pharmaceutical interest in differentiated next-generation depression assets.

The Lilly/AtaiBeckley transaction is presented as evidence of strategic interest in the TRD category.

A large, growing TRD market and major-pharma transaction activity reinforce strategic interest in differentiated depression assets.

A Capital-Efficient Phase IIa Value-Inflection Strategy

A focused controlled milestone designed to de-risk TREXAVIVE® and strengthen partnering potential.

Trexapharm's development strategy is designed to build on existing human proof-of-concept and real-world Australian experience through a focused controlled clinical milestone that can materially de-risk TREXAVIVE® and strengthen pharmaceutical partnering potential.

PHASE IIa VALUE-CREATION PATHWAY

EXISTING EVIDENCE BASE

- ✓ Human proof-of-concept
- ✓ International patent development

ONGOING

Australian Special Access Scheme clinical experience
Real-world evidence generation

CURRENT DEVELOPMENT

Phase IIa Preparation

Protocol and statistical planning

Regulatory and CMC development

Clinical and development planning

VALUE-INFLECTION CATALYST

Randomised Phase IIa Clinical Trial

The proposed Phase IIa program is planned as an approximately 50-patient, multicentre Australian, randomised, double-blind, placebo-controlled study with four arms: TREXAVIVE®, flumazenil, naltrexone and placebo.

VALUE CREATION

First controlled efficacy signal

Component contribution

Safety and tolerability

Rapid onset

Potential sustained benefit

Stronger pharmaceutical partnering position

FOLLOWING SUCCESSFUL READOUT

Regulatory / FDA engagement → Strategic pharmaceutical partnering → Phase IIb and/or comparative development → Potential future benchmarking against Spravato®

QUALIFICATION

Final protocol, endpoints, timing and development requirements remain subject to CRO, regulatory, statistical, clinical, CMC and operating planning.

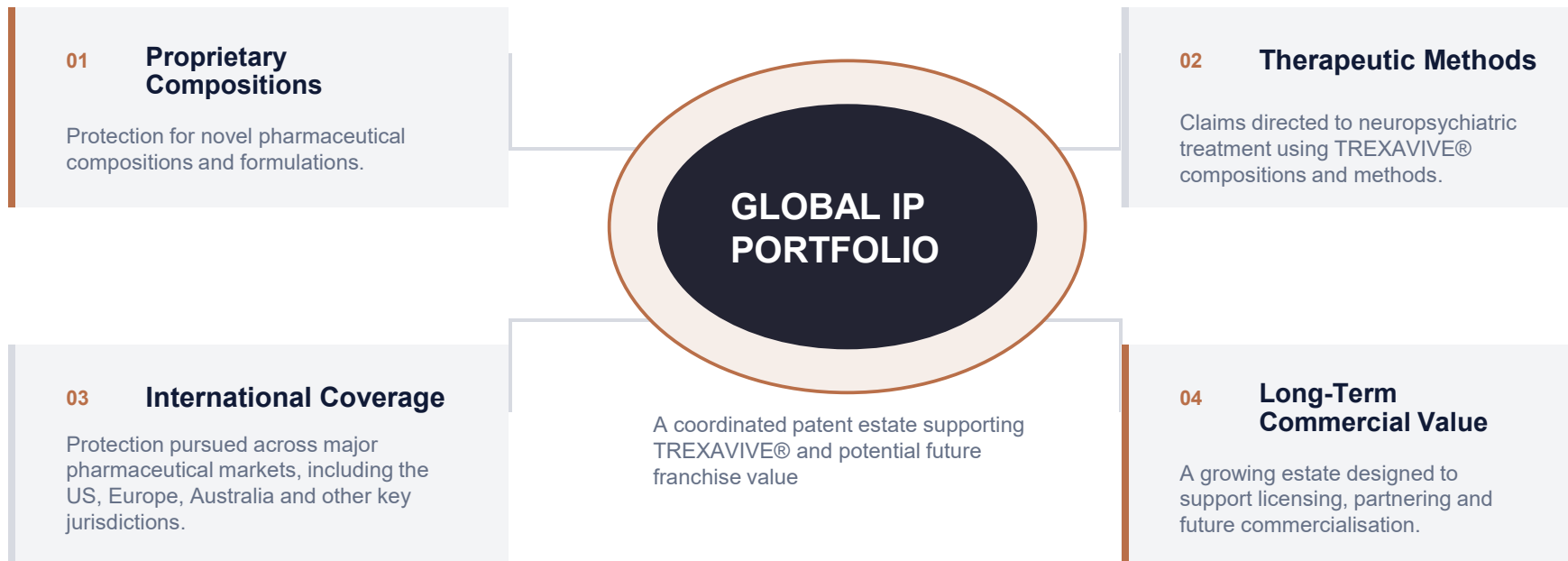
Phase IIa is designed as a focused value-creating catalyst, while ongoing Special Access Scheme experience continues to build real-world evidence in parallel.

Building a Defensible TREXAVIVE® Franchise

Intellectual property designed to support long-term commercial value.

Trexapharm has developed an international intellectual property strategy intended to protect TREXAVIVE® pharmaceutical compositions and methods of use in major commercial markets. The portfolio may support long-term commercialisation and future partnering opportunities, subject to the current international portfolio and individual jurisdictions.

A MULTI-LAYERED INTELLECTUAL PROPERTY STRATEGY



Why IP Matters

Strong intellectual property may:

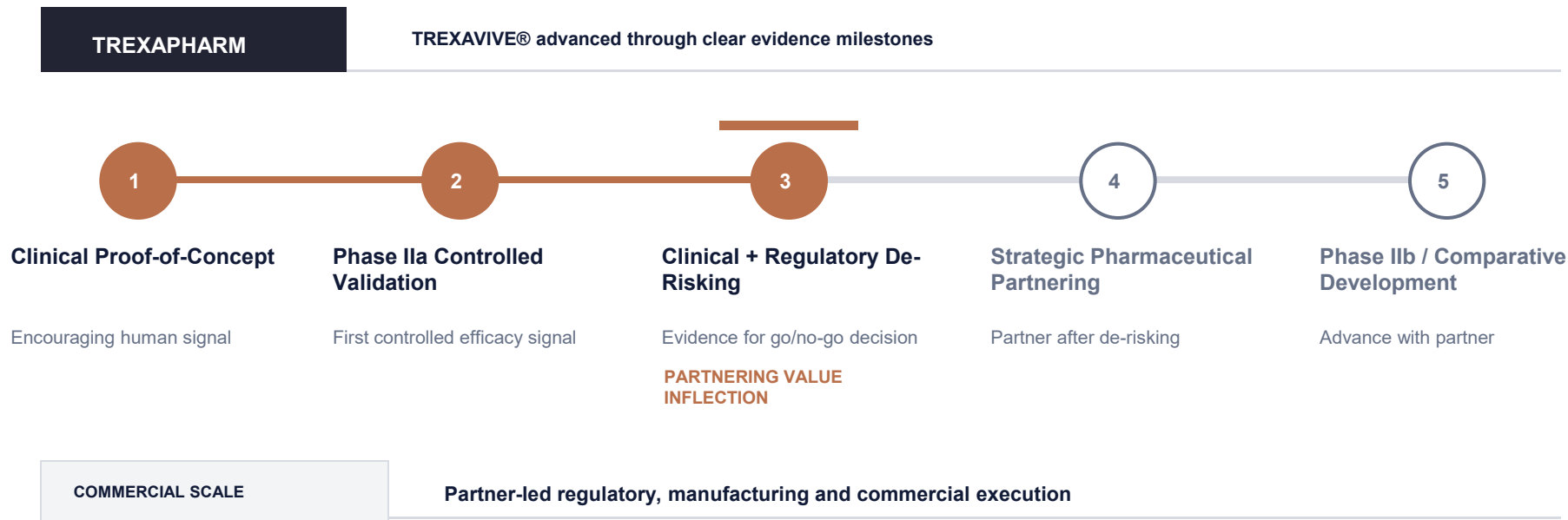
- ✓ Support potential commercial exclusivity
- ✓ Increase partnering value
- ✓ Support licensing opportunities
- ✓ Strengthen long-term enterprise value

Commercialisation Strategy

Building value through global pharmaceutical partnerships.

Trexapharm's strategy is to advance TREXAVIVE® through clear clinical value inflection points. The proposed Phase IIa is intended to provide the next major formal controlled clinical validation milestone, while Australian Special Access Scheme experience continues to generate real-world clinical evidence in parallel.

VALUE CREATION THROUGH EVIDENCE + PARTNERSHIPS



FOUR STRATEGIC PILLARS

- 01 Focused Development**
Advance TREXAVIVE® through key clinical milestones.
- 02 Strategic Partnerships**
Collaborate with regional and global pharmaceutical companies.
- 03 Value Milestones**
Prioritise milestones that strengthen evidence and partnering value.
- 04 Global Opportunity**
Pursue multiple geographic partnerships to maximise value.

TREXAVIVE® is designed to advance through focused clinical value inflection points toward strategic pharmaceutical partnering.

External Validation & Strategic Momentum

Trexapharm-specific clinical, commercial and strategic milestones continue to build alongside broader pharmaceutical interest in differentiated TRD assets.

SIX VALIDATION MILESTONES



01

Completed Human Proof-of-Concept Study

Completed human proof-of-concept study showing encouraging early improvements in mood and daily functioning.



02

BEDA MedTech Accelerator Program

Selected for the BEDA MedTech Accelerator Program delivered with Life Science Nation.



03

Strategic Commercial Collaboration

Heads of Agreement executed with ASX-listed BLS Pharmaceutical Ltd to evaluate Australian commercialisation, manufacturing and supply of TREXAVIVE®, subject to definitive agreements.



04

International Patent Estate

Growing international patent portfolio supporting long-term commercial protection.



05

Global Regulatory Strategy

Development strategy supported by specialist international regulatory advisers.



06

Australian Clinical Experience

Ongoing Australian Special Access Scheme clinical experience helping inform development and outpatient implementation.

SECTOR MOMENTUM

Major pharmaceutical companies are increasing investment in differentiated mental-health assets, including Eli Lilly's July 2026 agreement to acquire AtaiBeckley for up to US\$3.8 billion, whose lead late-stage asset targets treatment-resistant depression.

This transaction is shown as evidence of sector and strategic interest, not as a Trexapharm valuation comparable.

Trexapharm at a Glance

Trexapharm is developing TREXAVIVE®, a patented and proprietary clinical-stage therapy targeting one of the largest unmet needs in mental health, with encouraging human proof-of-concept evidence, ongoing real-world Australian clinical experience and a differentiated rapid, non-sedating outpatient profile.

SIX CORE ATTRIBUTES



01

Large Global Unmet Need

Millions of treatment-resistant depression patients remain inadequately treated.



02

Patented & Proprietary TREXAVIVE®

Differentiated microdose combination therapy supported by international intellectual property.



03

Human Evidence Already Generated

Improvement observed from Day 4 with benefit remaining visible through Week 12 in the initial proof-of-concept study, together with an encouraging early signal in suicidal ideation.



04

Real-World Australian Experience

Ongoing patient access and clinical experience through the Special Access Scheme.



05

Clear Value-Creation Pathway

Controlled clinical development designed to further de-risk TREXAVIVE®.



06

Global Pharmaceutical Partnering Potential

Growing evidence and a differentiated outpatient profile support future strategic partnering.

Patented asset. Human proof-of-concept. Real-world clinical experience. Large global unmet need. Growing pharmaceutical interest in next-generation TRD treatments.

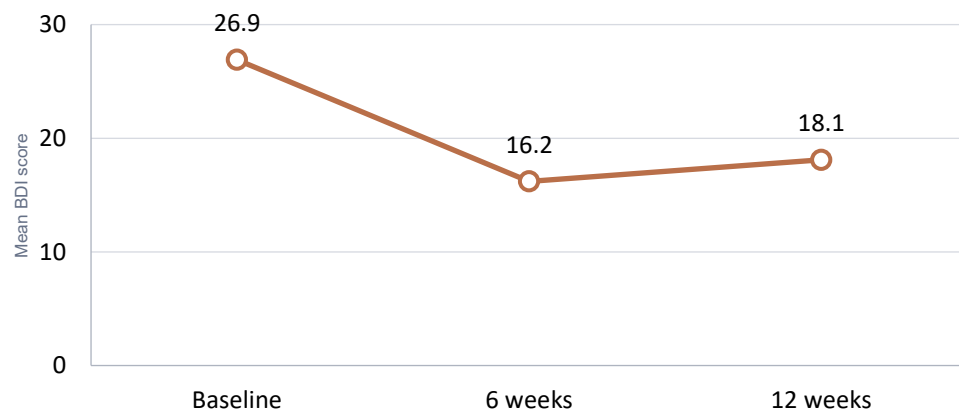
TREXAVIVE® combines a differentiated clinical-stage asset, human and real-world evidence, a large unmet need and global partnering potential.

Supporting Clinical Outcomes

Patient-reported depression and social and occupational functioning improved during follow-up.

PATIENT-REPORTED DEPRESSION SYMPTOMS

Mean Beck Depression Inventory Score



-10.7

mean change at 6 weeks

p<0.001

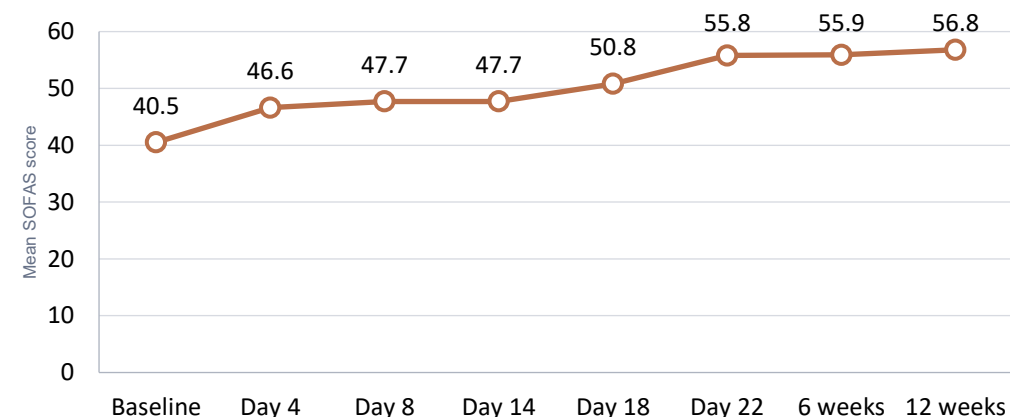
-8.8

mean change at 12 weeks

p=0.004

SOCIAL AND OCCUPATIONAL FUNCTIONING

Mean SOFAS Score



+16.3

point mean improvement at 12 weeks

40.5 baseline → 56.8 at 12 weeks



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