# solvonis THERAPEUTICS

Innovative therapeutics for high-burden CNS disorders

December 2025

Corporate Deck

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Solvonis is an emerging biopharmaceutical company developing innovative small-molecule therapeutics for high-burden CNS disorders.

# **Strategy:** Building a Diversified CNS Portfolio Across Addiction, Psychiatry, and Neurology

Executing in AUD, SUD and PTSD today

Expanding deeper into Psychiatry and evaluating entry into Neurology.

## Addiction

Alcohol Use Disorder (AUD)

Stimulant Use Disorder (SUD)

## Psychiatry

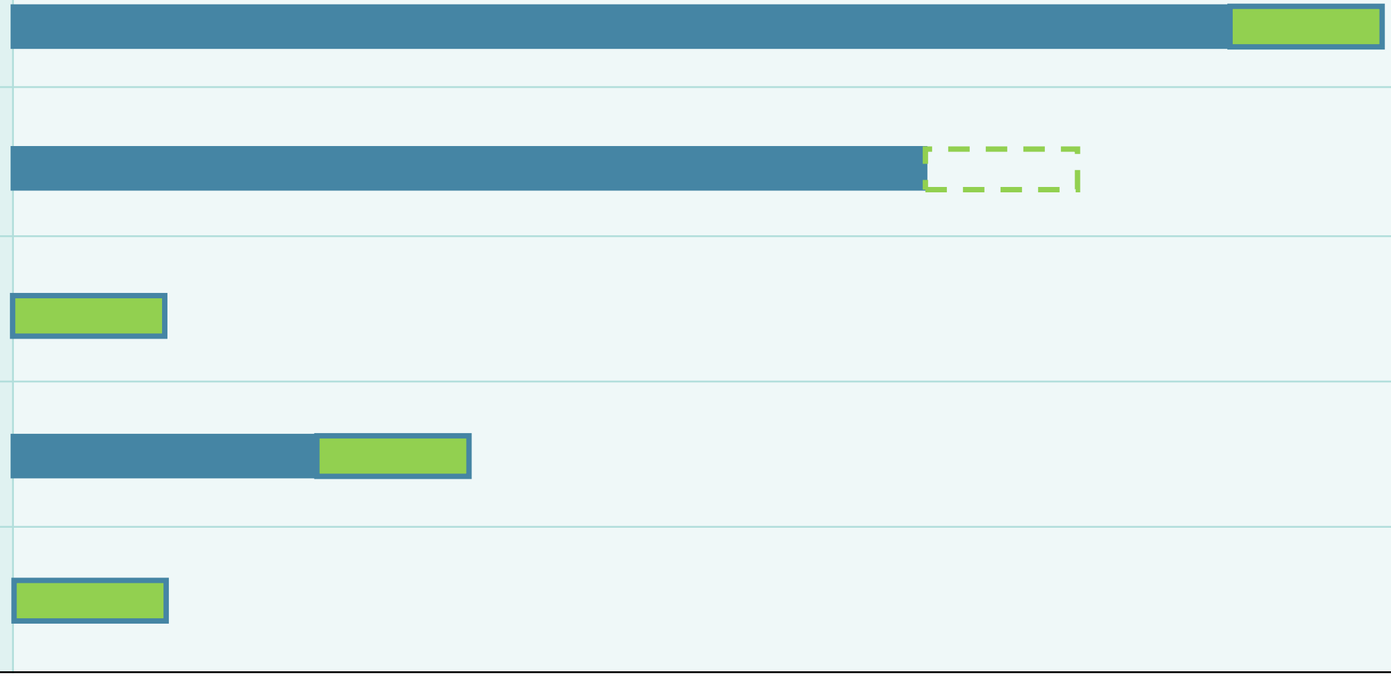
Post-Traumatic Stress Disorder (PTSD)

## Neurology

Exploratory Entry via Discovery Programme

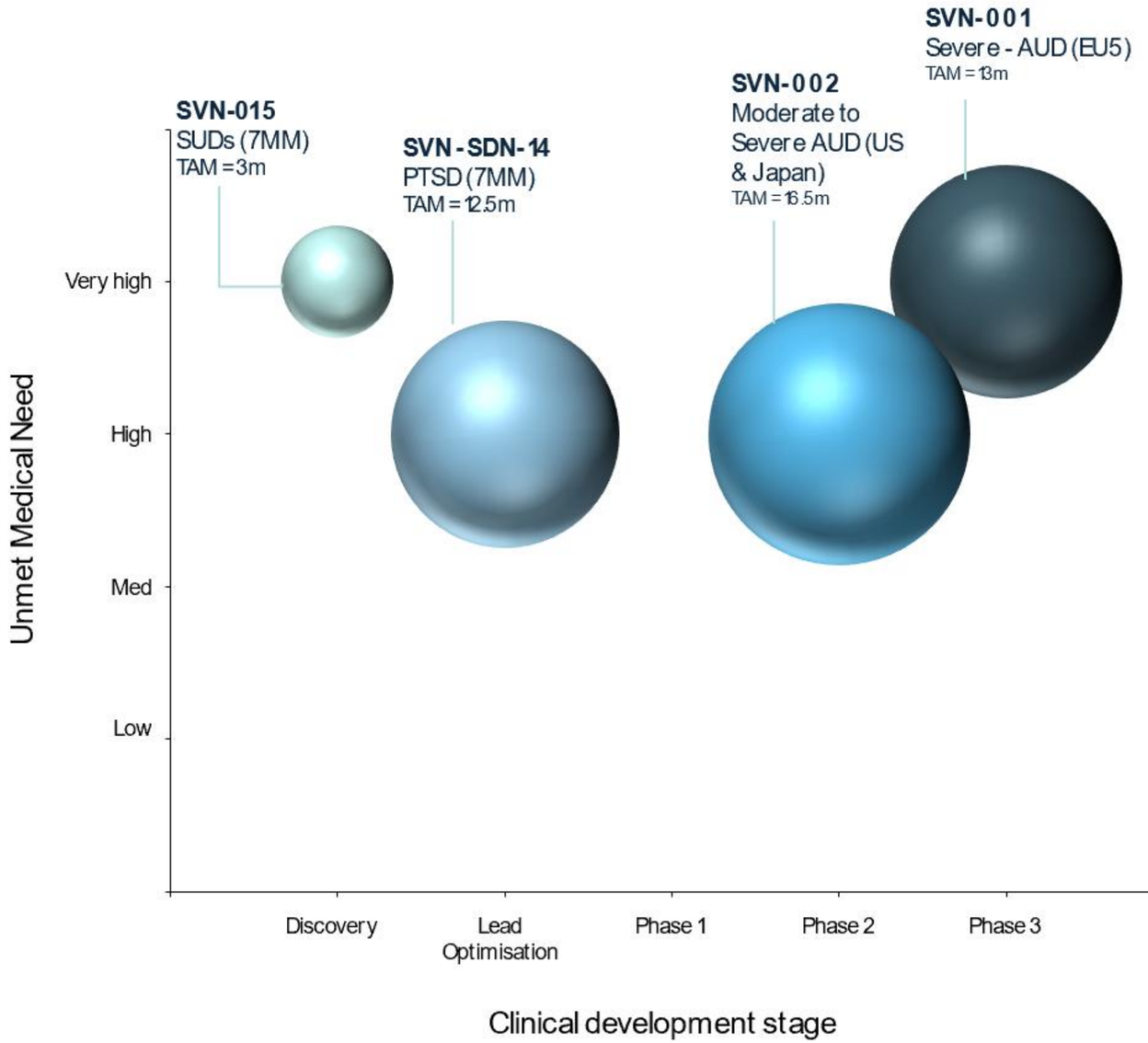
# **Pipeline**: A diversified pipeline across Addiction and Psychiatry

| Pillar | Programme | Indication | Discovery | Lead Optimisation | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|---|---|---|
| Addiction | SVN-001 | Severe AUD (UK & EU) | | | | | |
| | SVN-002 | Moderate–Severe AUD (ex-UK & EU) | | | | | |
| | SVN-015 | Stimulant Use Disorder | | | | | |
| Psychiatry | SVN-SDN-14 | PTSD | | | | | |
| AI Drug Discovery Programme for Psychiatry, and Neurolgy | | | | | | | |



# Pipeline Focused on High-Burden CNS Disorders with Major Unmet Need

- AUD relapse >75% on SoC
- No FDA-approved PTSD drug
- No approved therapeutics for SUDs




7MM = 7 major markets
(US, Japan, UK, Germany, Italy, France, Spain)

**ALCOHOL USE DISORDER:** ~280m people worldwide meet criteria for AUD

(WHO/GBD; ~5% of adults)

# Responsible for ~3M deaths annually and a top-five contributor to global disability and premature mortality

# **ALCOHOL USE DISORDER:** A Massive Global Crisis and a 30M+ Patient Market in the 7MM

**~29.6M**
patients with clinically significant AUD

(moderate–severe/severe), 25% with Severe AUD and 50% with Moderate to Severe AUD

**75%**
relapse within 12 months on existing therapies
(acamprosate, naltrexone, disulfiram + psychosocial care)

**<10%**
treatment uptake

— stigma, access, poor efficacy

**>$250bn**
Direct medical costs annually in US

**>$90bn**
Direct medical costs annually in EU

A huge, under-addressed global crisis, with Solvonis initially targeting the ~30M moderate–severe/severe patients in the 7MM:

**SVN-001**
For Severe AUD for the UK & EU, 13 million total addressable market in EU5

**SVN-002**
For Moderate to Severe AUD for RoW ex EU5, 16.6 million total addressable market in US 7 Japan (7mm ex EU5)

# SVN-001:

## Novel Combination Therapy for Severe AUD for the UK & EU Markets

### THE APPROACH

SVN-001 is a first-of-its-kind combination therapy combining IV ketamine (an NMDA receptor antagonist) with copyrighted manualized relapse prevention cognitive behavioural therapy (CBT) targeting both the biological and psychosocial aspects of Severe AUD

### THE NEED

- Severe AUD: ~13M patients in EU5
- Current treatments relapse >75% within 12 months
- Severe AUD associated with highest morbidity, mortality, and healthcare burden within AUD

### INTEGRATED APPROACH:

IV ketamine (NMDA antagonist) + copyrighted relapse-prevention CBT

### TREATMENT CYCLE

3 IV sessions + structured CBT across 12 weeks; practical for outpatient delivery

### WEEK 1

- Initial medical assessment hour long initial assessment (IMA)
- Prep session with client & therapist 90 mins
- Ketamine 1
- Integration 1

### WEEK 2

- Prep session 2
- Ket session 2
- integration session 2

### WEEK 3

- Prep 3
- Ket 3
- Int 3
- Close out session - with Dr. Therapist & Patient

# SVN-001:

## Novel Combination Therapy for Severe AUD for the UK & EU Markets

Phase 2a/b: a successful UK, Medical Research Counsel funded, and University of Exeter run phase 2ab trail :

86%
abstinent at 6 months

**vs**

2%
pre-trail

~50%
reduction in heavy drinking days

**vs**

placebo

Improvements in:

- Liver function
- Depression
- Quality of life

No drug-related SAEs

(Am J Psychiatry, 2022)

Durability:

Efficacy maintained through 6-month follow-up

Strongest dataset yet generated in Severe AUD; demonstrates both practicality and durability.

# SVN-001:

## Phase 3, Regulatory & Partnering

## Pivotal trial launched Jul 2024

(280 patients, 8 NHS sites)

## Late-stage, low-cost pivotal programme with clear upcoming catalysts and strong licensing potential.

**FUNDING:**
Majority UK government-funded; Total trial cost ~£2.5 - £3.5m vs £25–35m typical cost for similar trial

**REGULATORY:**
Targeting EU/UK “mixed-full” MAA; 8–10 years data protection;

**CATALYSTS:**

| | |
|---|---|
| 2026–27: | Interim recruitment/engagement updates (non-price sensitive) |
| 2028: | Phase 3 readout |
| 2028–29: | EU/UK filing |

# SVN-002:

## Commercial Opportunity & Catalysts

**CURRENT GAP**
No reimbursable therapies; high relapse and healthcare costs (>US$250bn annually in US)

**INNOVATION**
Sublingual/buccal esketamine OTF + digital psychosocial support

**TREATMENT CYCLE**
Supervised in-clinic dosing, aligned to Spravato® CPT/J-codes

**REGULATORY:**
505(b)(2) pathway referencing Spravato® — leverages established efficacy/safety precedent

**INDICATION:**
Moderate–Severe AUD (~16.6M patients in US & Japan)

**PROGRESS:**

- Phase 1 complete (favourable safety/PK)
- FDA pre-IND (Dec 2025): no additional human data required before Phase 2b
- Patent applications filed (formulation + method-of-use); Orange Book listable if granted

# SVN-002:

## Commercial Opportunity & Catalysts

**MARKET SCALE:**

- Moderate–Severe AUD: ~16.6M patients in US/Japan
- 2× TRD patient population (Spravato® target indication)
- Commercial analogue: Spravato® (esketamine nasal spray, J&J) surpassed US $1 billion in annual global sales in 2024* from a patient population of ~7 million with treatment-resistant depression (TRD) — SVN-002 targets a >2× larger population with moderate-to-severe Alcohol Use Disorder (AUD)
- Delivery infrastructure: ~15,000 US addiction clinics suitable for supervised administration

**CATALYSTS:**

- 2026: Phase 2 initiation
- 2027-28: Phase 2b data readout
- 2028+: Licensing opportunity (Phase 2b CNS deal benchmarks >$150m total economics)

* Source: J&J Investor Relations – Q4 2024 Earnings Transcript, s203.q4cdn.com

# SVN-AI-Enabled Discovery Programme:

## Creating Novel Monoaminergic Modulators for CNS Pipeline Expansion and Future Partnerships

### MODALITY & MECHANISM

Multiple novel chemical series generated via AI-enabled discovery

Targeting serotonin (SERT), dopamine (DAT), and noradrenaline (NET) transporters

Integrated modulation of monoaminergic systems to rebalance dysregulated CNS signalling

Differentiated from traditional single-transporter approaches

### PROGRESS TO DATE

Patents filed covering novel CNS-active chemical matter

Several compound series advancing to Hit-to-Lead

First output: SVN-SDN-014 (PTSD) emerging from this discovery engine

### STRATEGIC ROLE

Core engine for Solvonis' preclinical pipeline

Expands CNS pipeline depth across addiction, neuropsychiatry, and possible entry to neurology

Provides a renewable source of proprietary IP to underpin future partnerships

# SVN-SDN-14:

## First Programme from the SVN-AI-Enabled Discovery Engine

### INDICATION & NEED

Post-Traumatic Stress Disorder (PTSD): ~13M patients across US/EU5/Japan

No FDA-approved pharmacotherapies specifically indicated for PTSD

High unmet need: current treatments often inadequate or off-label

### MECHANISM OF ACTION

Novel monoaminergic modulator targeting SERT, DAT, and NET transporters

Designed to rebalance dysregulated neurotransmission in PTSD-relevant circuits

### PROGRESS TO DATE

Patents filed covering novel chemical matter

Hit-to-Lead completed with multiple compounds advanced

In vitro and in vivo efficacy signals demonstrated

### STATUS & PATHWAY

2025(f): Lead optimisation begins

2028(f): IND-enabling studies

2029(f): IND submission

# SVN-015:

a novel selective serotonin and dopamine re-uptake inhibitor for Stimulant (cocaine and methamphetamine) Use Disorder

AI-Discovered Candidate for SUDs

Accepted into NIDA's Addiction Treatment Discovery Program (ATDP).

NIDA to fund and conduct preclinical safety and efficacy studies.

Strategic Significance

Expands pipeline beyond AUD/PTSD into stimulant addictions — major unmet need with no approved drug treatments

Creates a clear, non-dilutive pathway: fully funded preclinical evaluation → potential NIH clinical development grants (up to US$3m/year for 5 years)

Market Opportunity

~3.0–3.2 million patients with SUDs across US, EU5, and Japan

No approved pharmacological treatments; psychosocial interventions only, with limited outcomes

# Leadership Team with Deep CNS and Capital Markets Expertise

**Experts in:**

- Addiction, psychiatry, and neurology
- Biopharma capital markets and M&A
- Drug development & commercialisation

## MANAGEMENT

Chief Executive Officer
Anthony Tennyson

Awakn Life Sciences Corp · AON · Merrill Lynch

Chief Scientific Officer
Prof. David Nutt

Imperial College London

Chief Financial Officer
Ryan Neates

HeLIX EXPLORATION

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# **Peer Comparables:** Material valuation gap to peers

| solvonis THERAPEUTICS | MindMed | atai LIFE SCIENCES | GH Research | GILGAMESH |
|---|---|---|---|---|
| Addiction & Psychiatry | Psychiatry | Psychiatry & Addiction | Psychiatry | Psychiatry & Addiction |
| Phase 3 | Phase 3 | Phase 2 | Phase 2 | Phase 2a |
| LSE | Nasdaq | Nasdaq | Nasdaq | Private |
| SVNS | MNM | ATAI | GHRS | N/A |
| £20-25m | £750m – £1b | £1b – £1.25b | £750m – £1b | Bought by AbbVie for £1b |

# Investment summary

- Significant unmet need in the space - addressing AUD and PTSD which are both underserved markets with few or no approved therapies
- Targeting >30m AUD patients across major markets and >$250 billion in annual healthcare costs, with the potential to address 280m individuals who meet the criteria for AUD
- Dual approach tackling both biological and psychological aspects of addiction
- High impact, low risk diversified pipeline & efficient and de-risked business model
- Strong upside vs. others in the sector - Innovating disease classes, that have lacked innovation for decades
- Vast industry experience in leadership team

# **2026 Catalysts:** Building the next generation CNS Biopharma

**SVN-001:** Targeted out-licensing agreement for the Phase 3 severe AUD programme.

**SVN-002:** Completion of scientific bridging work to J&J's Spravato® under the 505(b)(2) pathway and IND submission to enable a Phase 2b trial in moderate-to-severe AUD.

**SVN-SDN-14:** Lead candidate for PTSD identified, declared, and advanced into preclinical development.

**AI Drug Discovery Programme:** Preclinical readouts across additional addiction and psychiatric indications, with exploratory opportunities in neurology.

# Capital Structure

| | |
|---|---|
| Common shares | 6,806,403,493 |
| Warrants | 989,798,765 |
| Options | 298,000,000 |
| Fully Diluted Capital Structure | 8,094,202,258 |

# Thank you

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