

Stock Data

Share Price:	0.13p
Market Cap.:	£10.26m*
Shares in issue:	7,899.74m*
52 week high/low:	0.40p/0.12p

*Post-Admission numbers

Company Profile

Sector:	Health Care
Ticker:	SVNS
Exchange:	LSE

Activities

Solvonis Therapeutics plc ('Solvonis' 'SVNS', 'the Group') is developing breakthrough therapeutic solutions for high-burden CNS (central nervous system) diseases, across three strategic pillars: addiction, psychiatry and neurology. Its present operational focus centres on a drug pipeline targeting alcohol use disorder ('AUD') and post-traumatic stress disorder ('PTSD').

<https://solvonis.com/>

1-year share price performance



Share price performance since IPO*



*On 6 January 2021 under its former name, Graft Polymer (UK) plc

Source: [LSE](https://www.lse.com/)

Past performance is not an indication of future performance.

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Attention is drawn to the disclaimers and risk warnings at the end of this document.

Solvonis Therapeutics plc

Solvonis has raised £1.30m (gross) new funding through an equity placing priced at 0.12p/share (representing a c.14% discount to Monday's closing). Executed under existing authorities, approximately 19% of the total was raised via direct participation from a new institutional investor. Together with existing cash, this should now provide the Group with an operational runway to H2 2027, during which time its development portfolio is expected to deliver a number of defined clinical and regulatory milestones across addiction and psychiatry. Routinely considered the world's most prevalent and socially significant substance use diagnosis, alcohol use disorder ('AUD') is the lead indication for the Group's two most advanced clinical assets. The new funding will, among other things, be directed toward the addition of selected EU sites for SVN-001's ongoing Phase 3 study (with targeted readout in 2029) in support of prospective European market approval; it will also build on the positive PK bridging data announced in June 2026 for the Group's differentiated SVN-002 candidate in preparation for an IND filing to initiate a US Phase 2 programme during H1 2027. Solvonis' continued leveraging of external UK co-funding, alongside the planned utilisation of a repurposed compound via a US 505(b)(2) pathway, should enable the virtual biotech to maintain exceptional capital efficiency. This sets Solvonis aside from many sector peers, as does its ambition to independently commercialise both its clinical assets, with expected cash flow following SVN-001's 2030 UK filing being directed toward funding the much larger US commercial opportunity presented by SVN-002. The Board considers a future Nasdaq listing will enable it to realise this ambition. While it is true that further modest follow-on equity raises may be required in 2027 and 2028, successful delivery of the Group's near-term value-creating catalysts will serve to highlight its significant and unwarranted discount to its internationally quoted peer group. On this basis, TPI's prudent risk-adjusted NPV_{14%} assessment for Solvonis implies an equity value of almost £38m.

Risk Warning: Potential valuations and price targets are based on financial modelling and there is no guarantee that such valuations, financial forecasts or price targets will ever be realised, therefore please do not base your investment decisions on these alone. Also please note that past performance is not a reliable indicator of future results.

Use of Funds – Clinical/regulatory milestones & working capital

SVN-001 - Support future EU regulatory pathway

- Assess addition of selected EU sites to the ongoing Phase 3 study
- Undertake required feasibility, regulatory and operational work
- Broaden the Phase 3 dataset to support future European regulatory and commercial discussions

SVN-002 – Progress toward US IND and Phase 2 readiness programme

- Build on positive PK bridging data announced in June 2026
- Complete the remaining toxicology and regulatory package
- Seek FDA feedback on the proposed development package
- Prepare an IND-ready US Phase 2 programme

SVN-015 - Maintain externally leveraged progression alongside NIDA

- Advance through further evaluation under the US National Institute on Drug Abuse ('NIDA') programme
- NIDA expected to fund and undertake further confirmatory and in vivo studies

Source: Solvonis, [RNS](https://www.rns.com/) of 25 August 2026

Solvonis Therapeutics - Staged Development Pipeline Across Addiction and Psychiatry

Programme	Indication	Discovery	Lead Optimisation	Phase 1	Phase 2	Phase 3
SVN-001	Severe AUD (UK-FIRST / EU POTENTIAL)					
SVN-002	Moderate-to-severe AUD (U.S. FIRST)					
SVN-114	PTSD					
SVN-015	MDD					
SVN-015	StUD					

Proposed financing supports EU expansion of SVN-001 Phase 3, completion of remaining SVN-002 IND-enabling work and continued SVN-015 progression (subject to NIDA support)

Source: Solvonis, Investor Presentation Q3 2026

Two flagship clinical assets in AUD set to deliver a number of defined milestones

Within an impressive three pillar (addiction, psychiatry and neurology) development pipeline, Solvonis has two clinical stage AUD programmes approaching distinct clinical/regulatory value inflection points. Both programmes are based on repurposed forms of ketamine or its enantiomer combined with specialised therapy. The Group also has a novel dual serotonin and dopamine reuptake inhibitor for substance use disorder ('StUD')/major depressive disorder ('MDD') that is advancing through discovery. Today's funding round will support generation of additional clinical data required to expand SVN-001's Phase 3 trial into the EU ahead of submitting marketing authorisation applications, while also preparing for SVN-002's US Phase 2 programme and maintaining SVN-015's externally leveraged progression as it moves toward IND-enabling studies.

Clinical data from the SVN-001 Phase 2 KARE trial for severe AUD published in January 2022 highlighted a statistically significant increase in abstinent days at six months with favourable tolerability. Having entered a UK Phase 3 trial in August 2024, Solvonis is now undertaking a planned EU expansion in order to capture the much larger market opportunity. The Group's commercial strategy targets a 2029 readout for the expanded programme, with separate filings for the two territories potentially following in 2030 and 2031; realistically, a commercial launch in the UK might then be achieved by late 2031, with the EU coming one year later.

AUD represents a massive, global unmet clinical and social need, with only one in six people receiving treatment despite carrying a high morbidity, mortality and healthcare burden. The UK and EU 'treatment gap', for example, hovers between 78% and 82%, making it one of the Continent's most underserved chronic conditions. Research by [Future Market Insights](#) suggests a 2026 global baseline 'addressable market' valued at c.US\$0.84 billion, which it projects to grow steadily toward US\$1.53 billion over the coming decade, although this almost certainly substantially underestimates the true scale of the opportunity. Approved medications such as naltrexone, acamprosate and disulfiram are said to routinely underperform in real-world settings, while a paper published in *American Family Physician* suggests they are prescribed to only [1% to 3% of eligible patients](#), with most then failing to complete the course. This suggests SVN-001 could ultimately address a global market much larger than is presently being serviced.

SVN 002 is being prepared for a US Phase 2 development programme intended to support a proposed 505(b)(2) regulatory pathway. With FDA agreement, this allows companies to use public safety and efficacy data from existing drugs without the originator's permission; as such it references Johnson & Johnson's (NYSE: JNJ, 'J&J')

approved drug Spravato® (esketamine) for its own proprietary oral thin-film candidate, therein enabling avoidance of higher clinical resource requirements and patient logistics related to IV treatment. Assuming this is successfully established, the Group then plans to promptly seek approval from the FDA for a Phase 2b trial, effectively bypassing the significant costs associated with pre-clinical programmes, Phase 1 and Phase 2a studies. Targeting a broader moderate-to-severe patient US population (estimated to be in excess of 11m) along with expectation that it will be able to achieve a 4x to 6x price premium per patient course over the UK/EU target of £2,000/subject for SVN-001, driven by the structural economics of the US private insurance landscape and specific product advantages, Solvonis sees SVN-002 as its most significant forward opportunity. The Board considers the drug's US registration may be sufficient to support a Nasdaq listing and award a valuation more in line with its obvious sector peers. Under this umbrella, Solvonis' Board is confident that it will be able to independently commercialise the SVN-002.

Business model continues to achieve quite exceptional capital efficiency

The Board's comprehensive understanding of available co-funding routes, ability to utilise repurposed compounds that bypass costly early-stage clinical trials and routes enabling access to early-stage preclinical testing and characterisation for promising compounds targeting CNS disorders, clearly differentiates Solvonis from most other junior biotechs.

SVN-001 uses intravenous ketamine, which of course is a repurposed molecule of an already approved drug and comes with an established safety profile. Therefore, no expensive ground-up chemical synthesis is required and preclinical toxicology requirements are substantially reduced. SVN-001's UK MORE-KARE Phase 3 trial ('the Trial') was co-founded by the UK's Dept. of Health through the Medical Research Council ('MRC') and the National Institute for Health and Care Research ('NIHR') in December 2022. The Trial cost was originally estimated at c.£2.2m, of which NIHR/MRC agreed to pay £1.02m, leaving Solvonis to contribute £0.80m and NHS to pick up the balance through headcount. The Trial start was then put back by 12 months due to delays in site initiation by NHS/NIHR, which required an additional £1m to be committed to fund operational and site management costs. As reflected in the Group's 2025 full year numbers, Solvonis agreed to take responsibility for this additional amount on the basis that it will be offset against any negotiated future amount prospectively claimed by NIHR/MRC when recovering their investment. As it presently stands therefore, the total Trial costs amount to £3.2m of which Solvonis has contributed £1.8m. The Group's decision to expand the Trial into the EU will increase the subject number (perhaps by 100 to 200 additional individuals) and required patient cohort geographical locations. The Board is presently in discussions with UoE with respect administering this and the additional time required. In tandem, it is understood that fruitful exchanges with different EU-based health authorities have also been ongoing and may shortly produce a MOU whose signing could see a Solvonis' financial participation in for the EU part of the Trial adding something as low as €2000/subject (i.e., roughly matching the NHS' costs). Given the expanded market opportunity being offered, such an amount is not considered significant for a highly unmet needs development that has reached Phase 3. Discussions with a suitable EU-based CRO(s) to conduct the proposed work are already underway. Overall, this suggests direct end-to-end development costs in preparation for UK and EU commercialisation will remain exceptionally low.

At this time, Solvonis' stated intention is to commercialise the product itself; this suggests, post-authorisation, it will need to establish local infrastructure (a UK/EU Qualified Person for Pharmacovigilance and supply chains), appoint local agents, secure pricing and reimbursement country-by-country, maintain compliance and service statutory fees, etc, all of which could increase its near-term funding needs to over £5m before achieving its first product sales. Prior to this, however, the Board could possibly find itself tempted by various licensing proposals for this advanced asset. No such negotiations are presently underway, but typically they might take the form of a non-refundable cash payment(s) plus tiered %-based royalty structure from larger external players that possess the regional sales and marketing infrastructure required for rapid regional distribution. Such an agreement would likely include the cost of scaling up compound manufacturing, preparing for post-marketing surveillance, securing reimbursements and maintaining compliance. This would leave Solvonis free to focus its resources on what it considers to be the much larger opportunity presented by SVN-002, which it remains determined to

commercialise independently.

SVN-002 secured early support during a pre-IND meeting with the FDA in December 2024. Following June 2026's release of positive pharmacokinetic ('PK') bridging data and formal submission of SVN-002's proposed 505(b)(2) regulatory pathway, it appears realistic to expect formal FDA alignment on strategy plus remaining requirements by late 2026 or early 2027. This would permit reference to safety and efficacy data from Johnson & Johnson's approved intranasal esketamine product, Spravato®, bypassing traditional Phase 1 and Phase 2a trials, therein adding significant new value for Solvonis shareholders. Subject to funding, launch of its planned Phase 2b clinical trial might then be scheduled to follow two or so years later, which conveniently dovetails with anticipated inflows from SVN-001's proposed UK commercialisation. TPI estimates that the 'out-of-pocket' cost to complete such an independent trial, based on a patient cohort ranging 120 to 160 patients diagnosed with moderate-to-severe AUD in the US, might range between US\$11m and US\$18.5m (£8.5m to £14.3m).

Following review of initial screening results, NIDA has confirmed that SVN-015 will advance into further evaluation under the Addiction Treatment Discovery Program ('ATDP'). This is expected to include confirmatory transporter and *in vivo* studies to characterise the onset and duration of its pharmacological activity. Success here could unlock even deeper, more advanced collaboration opportunities with the Agency; given that stimulant use disorders currently have no FDA-approved medications, it aggressively incentivises promising assets to 'cross the finish line' by expanding support as a candidate drug hits milestones, including Advanced ATDP Efficacy Models, IND-Enabling Toxicology, Interaction Testing and even Transition to Clinical Development Funding. Indeed, success in the ATDP establishes a direct pathway to pitch for NIH clinical development funding via a two-phase, milestone-driven cooperative agreement used by the National Institutes of Health ('NIH'), known as the UG3/UH3 grant mechanism. This offers potential to transition NIDA from a basic preclinical testing provider into a short-term feasibility and planning phase (UG3) or even a full-scale implementation/clinical trial phase (UH3) partner.

Solvonis valuation appears too low given its stages of assets development and unmet need

TPI has based its valuation of Solvonis on forward opportunities presented by SVN-001, SVN-002 and SVN-015. The full details of this DCF_{14%} assessment can be found on pages 18 and 19 of this report. An international peer group comparison has also been tabulated on page 20 to highlight the fact that the Group presently trades at c.7% of the value awarded to other (primarily Nasdaq-listed) mid-stage clinical (Phase 2 and Phase3) average.

The DCF_{14%} assessment assumes SVN-001's UK commercial filing will be achieved in 2030, followed just one year later in the EU. The US filing of the larger opportunity presented by SVN-002 is not expected until 2034, while commencement of first-in-human ('FIH') trials for SVN-015 is targeted by 2029. Assuming patent protection/exclusivity of 9 to 11 years for both clinic assets, with COGS representing 12% of revenues and marketing/SG&A costs ramping up to 28% of sales, after adding estimated (post-raise) net cash a risk-adjusted NPV has been calculated as £37.7m, based on an assumed probability of successes ('PoS') of 55% and 22% for the two drugs respectively.

Although not included in the above valuation, an international peer group comparison (comprising mostly Nasdaq-listed companies) has also been tabulated on Page 20. This highlights a range of valuations across the Addiction & Neuropsychiatry sub-sector, focussing specifically on those with portfolio candidates at similar clinical/near commercial stage to Solvonis. It uncovers the obvious and seemingly unwarranted (except perhaps with respect to equity liquidity) discount Solvonis presently achieves, trading at just c.7% of the average valuation of its obvious mid-stage comparators. Foremost this appears to reflect US investor attitude to such opportunities, while featuring larger pools of specialised capital, a higher risk tolerance and a commercial environment geared toward much higher drug pricing and faster adoption than the UK/EU's constrained systems; the fact that Solvonis' Board has already stated its intention to achieve a future Nasdaq listing suggests it already has this understanding.

Solvonis' two AUD candidates – Differences in geographic strategies and formulations

Solvonis' two clinical candidates use different active drug formulations, different delivery methods, and distinct clinical administration routes tailored to separate market strategies and patient populations. What they do have in common, however, is that both leverage ketamine's glutamatergic mechanism to drive long-term behavioural change. By blocking N-methyl-D-aspartate ('NMDA') receptors on GABAergic inhibitory interneurons, ketamine triggers a transient surge in glutamate release that stimulates AMPA receptors and neuroplastic pathways. This induces a high-plasticity period in the brain, allowing structured psychotherapy to actively target and remodel the maladaptive neural circuits underlying craving and addictive behaviours.

The lead programme, SVN-001 (UK/EU), combines intravenous ('IV') ketamine (dosing perhaps 0.5mg/kg over c.40 minutes) with manualised cognitive behavioural therapy for severe AUD in a clinic-heavy protocol. Ketamine is technically classified as a dissociative anaesthetic, not a classic psychedelic. It is officially approved as an injectable general anaesthetic for humans and animals. Its S-enantiomer derivative, esketamine (brand name Spravato®), is approved as a nasal spray for treatment-resistant depression, while generic racemic ketamine (commonly sold under the brand name Ketelar) is similarly approved by regulatory agencies, although it is widely used off-label for pain and mood disorders for which direct regulatory approval remain narrow due to associated mind-altering effects, changes in perception or detached, dreamlike states that can result.

Recruitment for SVN-001's pivotal UK Phase 3 clinical NHS-based study based on a n=280 two-armed, active placebo-controlled design remains ongoing; it is being conducted in collaboration with the UoE and co-funded by the NIHR, the Medical Research Council ('MRC') and Solvonis. The Group's planned expansion of the programme into the EU is now at an advanced stage in anticipation of substantially broadening the drug's future market opportunity. Given that this implies additional recruitment of EU-based trial participants plus generation of clinical data within the EU regulatory environment, the completed Phase 3 readout target has now shifted to 2029.

SVN-002 (US), Solvonis' proprietary esketamine sublingual (buccal) oral thin film programme, is by contrast being advanced under a planned US FDA 505(b)(2) regulatory pathway referencing Johnson & Johnson's blockbuster esketamine product, Spravato®. It targets a broader moderate-to-severe patient US population in order to avoid higher clinical resource requirements and patient logistics related to IV. In anticipation of a 'scientific bridge' to Spravato® being successfully established the Group plans to promptly seek approval from the FDA for a Phase 2b trial, thereby potentially avoiding the significant costs associated with preclinical programmes and Phase 1 and Phase 2a trials.

AI-supported discovery platform creating a sustainable, capital-efficient pipeline

Solvonis initiated its artificial intelligence-supported central nervous system ('CNS') drug discovery programme on 11 June 2025. Utilising a proprietary CNS library acquired from Awakn Life Sciences and led by the Group's Chief Scientific Officer, Professor David Nutt, initial targeting has focussed on depression and stimulant use disorders.

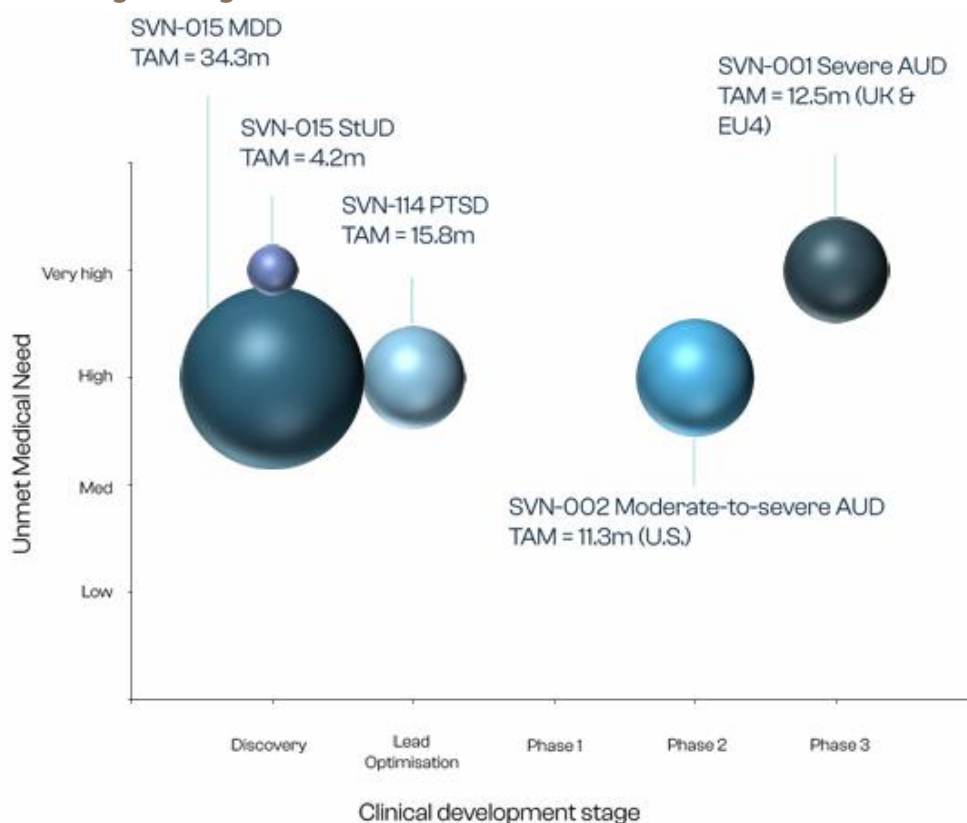
Emerging from this and wholly independent of the Group's flagship AUD assets, on 3 December 2025 SVN-015 made its public debut with announcement of its acceptance into the US National Institute on Drug Abuse's ('NIDA') Addiction Treatment Discovery Program ('ATDP'). On 6 August 2026, Solvonis went on to release encouraging results from the drug's initial *in vitro* cardiac ion-channel and broader off-target screening, following which NIDA confirmed on 6 August 2026 that it will advance into further evaluation under the ATDP. This is expected to include confirmatory transporter and *in vivo* studies to characterise the onset and duration of its pharmacological activity. At this early stage, SVN-015's profile appears materially more favourable than that of GBR-12909, also known as vanoxerine, which was a failed high-affinity, selective dopamine reuptake ('DAT') inhibitor originally developed by Gist-Brocades NV back in the 1970s. With no FDA-approved medications specifically indicated for cocaine use disorder or stimulant addiction, this remains an area of high unmet need; [ResearchandMarkets](#), for example, estimated the former to have a global market valued at US\$1.36 billion in 2025, with high-end estimates

project growth up to USD 2.10 billion by 2032, while the broader stimulant/general substance addiction treatment markets indicates considerably larger valuations.

Having achieved similar external validation on 31 March 2026, SVN-114 was granted a critical US composition-of-matter patent by the US Patent and Trademark Office ('USPTO') covering its compound class for treatment of Post-Traumatic Stress Disorder ('PTSD') and related trauma disorders. Its MoA is to function as a triple monoaminergic modulator targeting serotonin (SERT), dopamine (DAT), and noradrenaline (NET) transporters.

The pipeline's development stage plus extent of unmet medical need is illustrated graphically below:

Pipeline Targets High-Burden CNS Disorders with Substantial Unmet Need



Bubble sizes are illustrative TAM labels show current epidemiological estimates Unmet need positioning reflects Solvonis' assessment. Source: Solvonis, Investor Presentation Q3 2026

Mechanism of Action behind Solvonis' two clinical neuropsychiatric drug candidates

Both SVN-001 and SVN-002 combine NMDA receptor-modulating ketamine compounds with targeted cognitive behavioural therapy ('CBT') to promote neuroplasticity and break compulsive loops as a treatment for AUD.

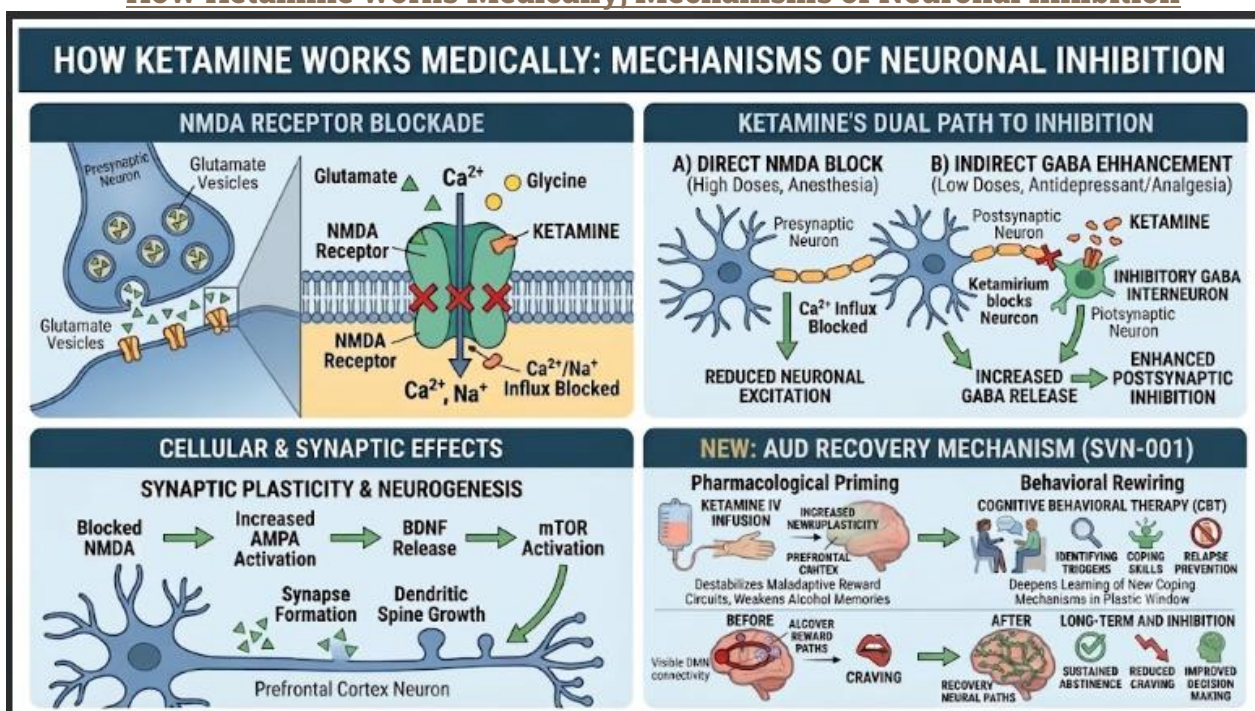
SVN-001 Science and Mechanism

- **Active Agent:** Intravenous ('IV') racemic ketamine (a mix of R- and S-ketamine enantiomers).
- **Psychological Component:** Paired with manualised relapse prevention CBT.
- **Mechanism of Action:** Ketamine acts primarily as an NMDA receptor antagonist, which downstream triggers a surge in glutamate and activates BDNF (brain-derived neurotrophic factor) signalling.
- **Therapeutic Rationale:** This biochemical surge promotes rapid synaptogenesis and neural plasticity in brain circuits damaged by chronic heavy drinking. Opening this temporary "plastic window" allows the concurrent CBT to more effectively reshape entrenched reward pathways and addictive behaviours.

SVN-002 Science and Mechanism

- **Active Agent:** Proprietary esketamine (the S-enantiomer of ketamine) delivered via an oral thin film ('OTF').
- **Psychological Component:** Paired with manualised alcohol education.
- **Mechanism of Action:** Esketamine offers a higher binding affinity for the NMDA receptor than racemic ketamine, yielding potent neuroplasticity and glutamatergic modulation at lower relative doses.
- **Therapeutic Rationale:** The oral thin-film delivery system is designed for controlled, predictable pharmacokinetic absorption. By pairing targeted esketamine administration with structured education, the treatment aims to disrupt cravings and habit loops in moderate-to-severe AUD patients.

How Ketamine works Medically; Mechanisms of Neuronal Inhibition



Source: Solvonis, Online information, TPI

Clear advantage over selective serotonin reuptake inhibitors ('SSRIs') and classic psychedelics

SVN-001 and SVN-002 offer a distinct advantage over SSRIs and classic psychedelics (like psilocybin, LSD and DMT), given that they utilise a completely different MoA (i.e., NMDA receptor modulation via ketamine/esketamine) specifically optimised to treat the root cognitive loops of AUD. SSRIs are generally ineffective at treating addiction, while such psychedelics carry heavy hallucinogenic, regulatory, and drug-interaction burdens that Solvonis' pipeline circumvents. They have also been clinically proven to only gradually increase synaptic serotonin, which manages mood but fails to disrupt the deep-seated reward pathways or compulsions driving substance abuse and so produced a negligible impact on AUD sobriety. By contrast, in Phase 2 clinical trials the protocol behind SVN-001 helped severe AUD patients achieve an 86% abstinence rate at six months post-treatment, compared to just 2% (base case) before the trial. Furthermore, ketamine and esketamine (sold as Spravato® in the form of a prescriptive nasal spray) have a predictable, dose-dependent and significantly shorter psychoactive windows than classical agents like LSD (which lasts 10–12 hours) or psilocybin (which lasts 4–6 hours). Psychedelics also heavily alter sensory perception and can induce hallucinations or acute anxiety, while Solvonis' approach focuses on dissociative and plastic states that are easier to manage clinically.

Irrespective of the US President's Executive Order of 18 April 2026, which established a national policy to accelerate medical research and regulatory reviews in order to increase eventual access to psychedelic drugs for serious

mental illness, LSD, DMT and psilocybin remain heavily restricted Schedule I controlled substances globally, making their clinical rollout logistically difficult. By comparison, Ketamine is already a widely accepted, Schedule III medical anaesthetic with an established clinical infrastructure.

AUD pharmacotherapies that utilise Cognitive Behavioural Therapy relapse prevention

There are no regulatorily approved drug products that legally or structurally combine a specific pharmaceutical regimen with a mandatory 'manualised relapse prevention therapy' into a single regulatory entity. Regulatory agencies (such as the FDA or EMA) approve pharmacological agents and psychological frameworks separately, though clinical guidelines strongly advocate for their integration. Major health organizations (such as SAMHSA in the US or NICE/NHS in the UK), however, outline that while behavioural support is a key pillar of treatment, access to medication should never be withheld simply because a patient cannot (or chooses not to) attend CBT. Details of existing AUD pharmacotherapies that utilise relapse prevention therapy ('RPT') are tabulated below in a commercial matrix highlighting originator and annual sales.

Existing AUD Pharmacotherapies that Utilise Relapse Prevention – Commercial Matrix

Pharmacotherapy & Brand Names	Key Commercialising / Originating Pharmaceutical Companies	RPT Care Type	RPT Protocol Design & Integrated Mechanism	Approvals & Market Context
Naltrexone (Oral & <i>Vivitrol</i>)	• Alkermes (<i>Vivitrol</i>) • Mallinckrodt / Generic Manufacturers (Oral)	Yes (Standard Care)	Extinction & High-Risk Coping: RPT identifies high-risk drinking triggers, social cues, and negative affect states. Because Naltrexone blocks the μ -opioid receptor reward mechanism, RPT leverages continuous blockade so that if a lapse occurs, the patient experiences reduced euphoria, facilitating cognitive re-evaluation and preventing progression to full relapse.	• Oral: 1994 (FDA) • <i>Vivitrol</i>: 2006 (FDA) • <i>Vivitrol</i> net sales: ~\$400M–\$450M/yr
Acamprosate (<i>Campra</i>)	• Merz Pharmaceuticals (Developer) • Forest Laboratories / AbbVie (US Commercialisation) • Generic Manufacturers	Yes (Standard Care)	Protracted Withdrawal & Urge Surfing: RPT is designed around managing baseline distress, anxiety, and somatic cravings associated with post-acute withdrawal. While Acamprosate normalizes hyper-glutamatergic signalling, RPT trains patients in "urge surfing" and cognitive restructuring to navigate internal distress without returning to alcohol.	• 2004 (FDA) / 1989 (EU) • Global market segment: ~\$50M–\$100M/yr
Disulfiram (<i>Antabuse</i>)	• Teva Pharmaceuticals • Odyssey Pharmaceuticals / Generic Manufacturers	Yes (Requires Behavioural Commitment)	Aversive Boundary & Trigger Avoidance: Because disulfiram blocks aldehyde dehydrogenase to produce physical toxicity upon drinking, RPT is designed around behavioural commitment contracts, morning medication routines, and managing immediate impulsive urges by establishing an absolute temporal barrier to drinking.	• 1951 (FDA) • Legacy generic: ~\$10M–\$20M/yr

Source: Online information, TPI

SVN-001 – Combines a defined drug regimen with manualised relapse prevention therapy

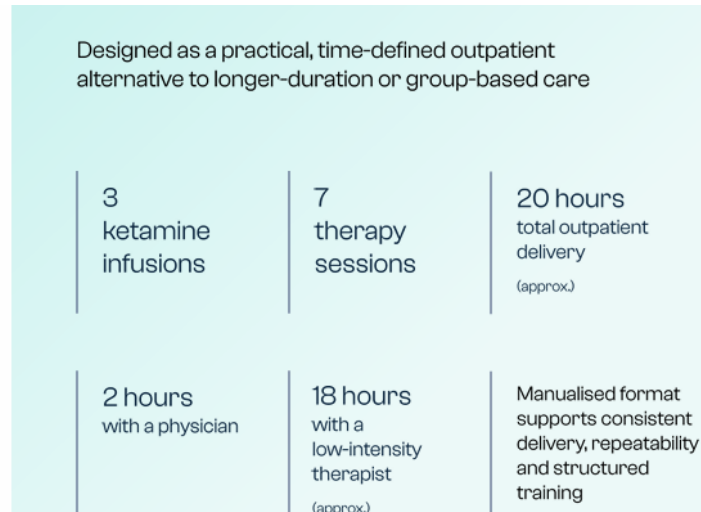
SVN-001 integrates IV ketamine with manualised relapse prevention CBT, targeting both the biological and psychosocial dimensions of severe AUD. The pharmacological agent is intended to create a neuroplastic window, while the CBT is designed to capitalise on the temporarily altered biological state to reshape longer-term behaviour. Regulatory evaluation and clinical trial design for such a combined intervention therefore necessitates evaluation of the therapeutic package as an integrated protocol.

Regulators such as the FDA or EMA are therefore not expected to 'approve' the manualised CBT in the sense used for pharmaceutical substances, but instead validate the standardisation, reproducibility and isolation of variables within the clinical trial design to ensure that the drug's safety and efficacy profile can be accurately measured. Under FDA Finalized Guidance for Psychedelic and Complex Drug Trials (July 2026), sponsors are encouraged to utilise factorial trial designs; this involves separating trial arms to evaluate the drug alone, the therapy alone, and the drug-therapy combination.

SNV-001 Combines Intensive Ketamine-Assisted Treatment Protocol with Manualised CBT

A structured outpatient treatment model designed for consistent delivery

SNV-001 combines a short, intensive ketamine-assisted treatment protocol with manualised relapse-prevention CBT in a format designed for outpatient delivery and repeatable implementation.



Source: Solvonis, Investor Presentation Q3 2026

This allows the FDA's Center for Drug Evaluation and Research ('CDER') (and similarly for the EMA's Committee for Medicinal Products for Human Use ('CHMP')) to mathematically isolate the drug's unique contribution to the clinical outcome. They review the strict treatment guidelines to ensure they contains explicit, non-deviable scripts, session timelines and behavioural exercises. This transforms a highly variable human interaction into a standardised, measurable 'dose'. Sponsors must prove how they will ensure therapist compliance; protocols usually mandate that sessions are audio or video recorded and audited by independent, third-party reviewers to confirm the therapist did not deviate from the approved CBT script.

In response to this, Solvonis has produced and copy-protected a 120-page 'therapy manual' with a label that that specifically ties it to the drug. The intent is the ensure that only people formally recognised by the Group administer the therapy, by building a suite of digital tools capable of training and qualifying suitable medically trained therapists.

KARE trial – Developing a commercial iteration of SVN-001's combination package

The KARE study ('Ketamine for reduction of Alcoholic Relapse') is the foundational, real-world proof of concept for exactly how regulators require a drug-therapy protocol to be structurally evaluated. Led by the University of Exeter and funded by the Medical Research Council ('MRC'), the Phase II KARE trial (and its expanded Phase III successor, MORE-KARE) served as a literal blueprint for isolating the effects of a drug from its psychological counterpart. Its design perfectly mirrors the regulatory framework for combining a manualised therapy with a substance across several distinct dimensions.

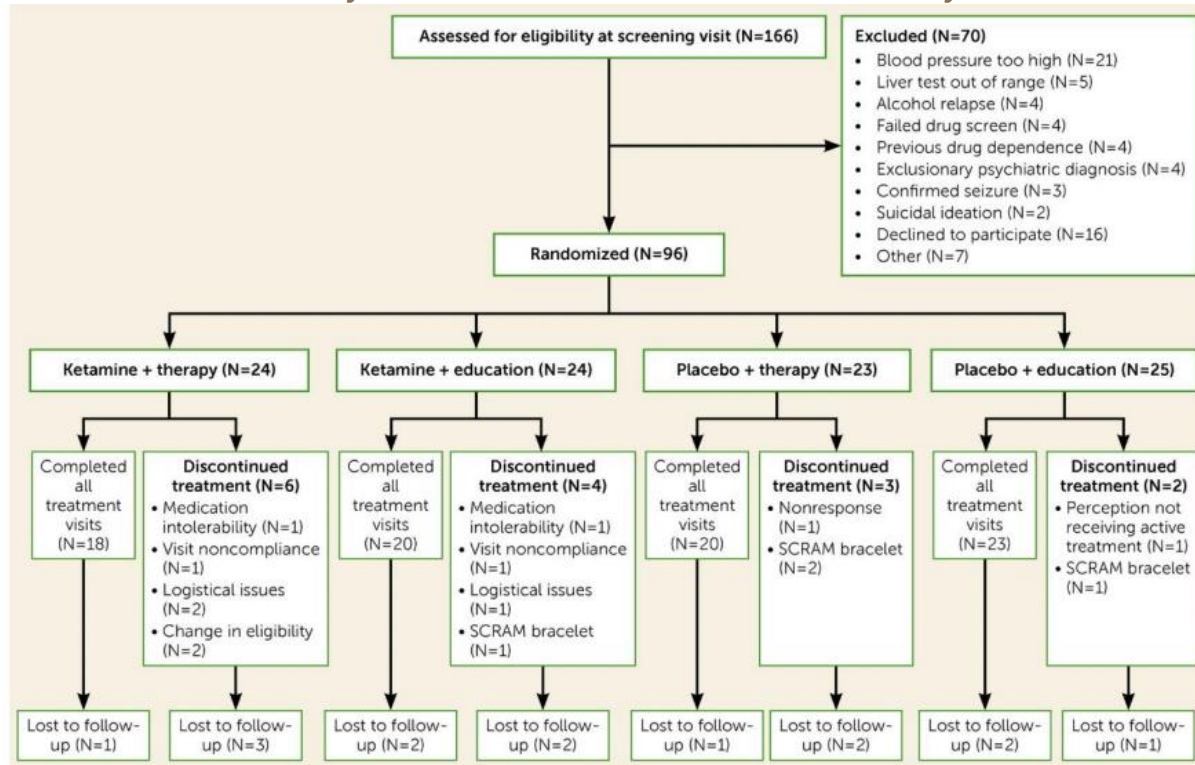
To satisfy regulatory demands that the unique contribution of both the drug and the therapy be explicitly proven, the Phase II KARE trial randomised 96 detoxified patients into four distinct treatment arms. By structuring it this way, researchers provided regulators with the exact data needed to prove that ketamine plus therapy was significantly superior to ketamine alone or therapy alone, establishing a synergistic effect rather than a redundant one:

- **Arm 1:** Ketamine infusions + KARE Psychological Therapy (CBT/Relapse Prevention).
- **Arm 2:** Placebo (Saline) infusions + KARE Psychological Therapy.
- **Arm 3:** Ketamine infusions + Education Control (No active therapy).
- **Arm 4:** Placebo (Saline) infusions + Education Control.

The trial demonstrated that the combined ketamine-therapy arm achieved an impressive 87% complete abstinence rate over a six-month follow-up period, effectively supplying the concrete, un-blinded biological

evidence that modern agencies like the MHRA, EMA, and FDA require before approving a drug-therapy product label.

Patient Distribution by Treatment Arm in Phase 2 NIHR Study for Severe AUD*



*All procedures and patient visits took place at either the National Institute for Health Research (NIHR) Exeter Clinical Research Facility or the NIHR University College London Hospitals Clinical Research Facility. The trial was registered at [ClinicalTrials.gov \(NCT02649231\)](https://clinicaltrials.gov/ct2/show/study/NCT02649231)
Source: [The American Journal of Psychiatry](#)

SVN-001 - Phase 2 results and analysis support a differentiated late-stage opportunity

The published study demonstrated a statistically significant increase in abstinent days at six months and favourable tolerability. Separate exploratory Company analyses of the Phase 2 dataset reported reductions in heavy drinking days (which is believed to be as much as 50% in the active arm against that of Alkermes' Vivitrol drug which is an extended-release injectable naltrexone) and other supportive clinical signals including no drug-related serious adverse events plus positive secondary health outcomes with reduction in depression/lifestyle improvements.

SVN-001 – Phase 2 Results and Analysis



Source: Solvonis, Investor Presentation Q3 2026

SVN-001 - EU Phase 3 expansion is intended to support future EU regulatory pathway

SVN 001 is being advanced through to completion of Phase 3 completion and onward towards expected regulatory submission. Current strategy is for a UK first launch followed by selected EU commercial expansion in order to create longer-term strategic value.

SVN-001 - EU Phase 3 expansion Intended to Support its Future Regulatory Pathway

Current programme and EU Phase 3 expansion Potentially pivotal Phase 3 trial currently operating in the UK using established protocol, clinical infrastructure and data systems. Planned EU expansion would include EU clinical sites and patients, generating EU clinical data intended to support a future marketing authorisation application. UK regulatory pathway supported by MHRA ILAP/Innovation Passport.	Why the asset matters Late-stage severe AUD asset. Strong Phase 2 efficacy and durability. Structured outpatient treatment model. Capital-efficient Phase 3 and regulatory pathway.
UK market opportunity United Kingdom: 2.6 million people aged 15+ with severe AUD ¹ UK provides a clear initial regulatory and commercial reference market Potential application readiness may enhance strategic optionality following Phase 3	Selected EU commercial expansion, potentially starting with Germany Germany 3.2 million people aged 15+ with severe AUD ² EU4: 9.9 million people aged 15+ with severe AUD ³ Germany represents a potential initial EU commercial market opportunity following the UK, with selected country-level expansion offering broader long-term upside.

Source: Solvonis, Investor Presentation Q3 2026

SVN-001 – Projected Timelines to UK and EU Filings

Key milestones				
	2026–28	2029	2030	2031
	Ongoing recruitment	Phase 3 readout	Potential UK filing	Potential EU filing
solvonisTHERAPEUTICS	Sources: HRA MORE-KARE study summary, ISRCTN85955128; European Commission/EMA regulatory-data-protection framework. Planned EU expansion remains subject to final agreements, protocol amendment and applicable regulatory and ethics approvals.			

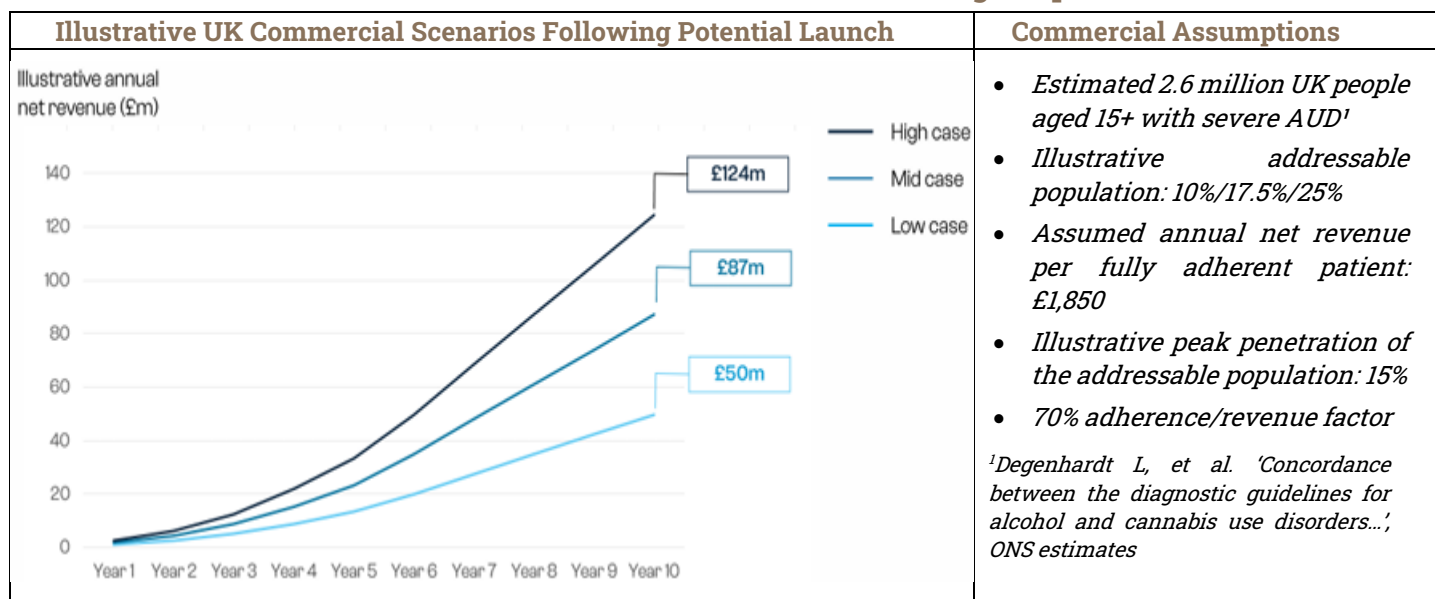
Source: Solvonis, Investor Presentation Q3 2026

UK and German commercial scenarios indicate scale of SVN-001's commercial opportunity

The UK is intended to be the initial launch market for SVN-001 and its commercial scenario provides reference for subsequent commercial expansion.

Solvonis' UK's severe AUD population projection is based on company analysis by WHO Europe (Degenhardt et al. (2019)) and ONS mid-2024 estimates along with prudent peak penetration and adherence estimates, as detailed overleaf. The assumptions are illustrative only and remains subject to timings of regulatory approval and launch, as well as actual pricing, market penetration, etc. which may differ, etc.

SVN-001 -Illustrative Commercial Scenarios Following Proposed UK Launch



Source: Solvonis, Investor Presentation Q3 2026

Having already secured an MHRA's Innovative Licensing and Access Pathway ('ILAP') passport means SVN-001 has already been granted fast-track development and patient access as a medicine targeting severe, life-threatening conditions with significant unmet medical needs. Given that the NHS is expected to control >90% of the UK severe AUD market, following completion of the clinical trials and MHRA approval, the next important step will be to commence discussions with the National Institute for Health and Care Excellence ('NICE') regarding product pricing. Approval can be expected assuming the proposed treatment cost is not considered egregious.

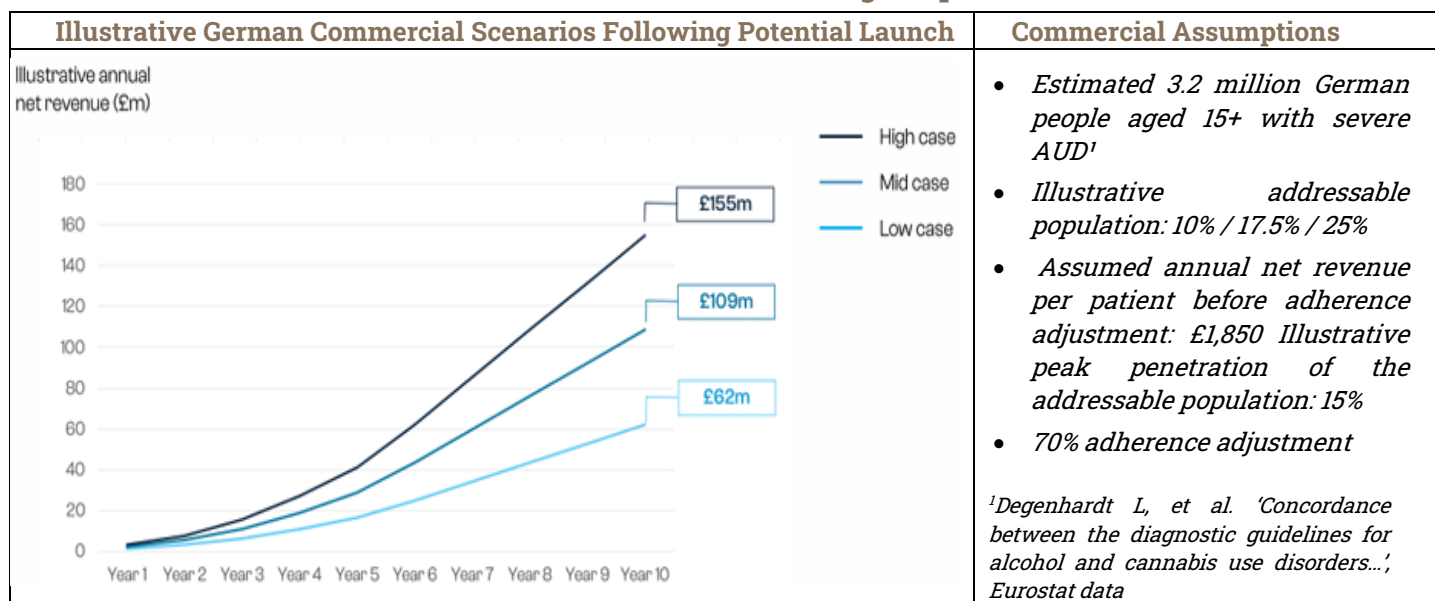
Based on what is expected to be a sub-£100 cost of goods (i.e., the wholesale price of ketamine is around £3/vial, of which there are three per treatment cycle), including secure packaging plus maintenance of associated digital tools (for application, monitoring and medical certification, etc.), should a final, agreed sale price range as low as £1,500 to £2,000 for the subject numbers indicated there remains significant scope to achieve a healthy gross margin. The low projected peak penetration number incorporated into the above modelling is based only on the extent to which sufferers have historically entered traditional treatment and, as such, may be considered prudent. Projected profitability should reflect the fact that the NIHR and MRC are likely to seek some form of a profit share or other participation in order to recoup the c.£1.6m they will have already invested in SVN-001.

Expanding SVN-001's commercial scenario into the EU

Targeting the launch of a severe AUD product across the EU is likely to be focussed initially on nations that formally recognise alcohol abuse as a major problem. This suggests Germany, the Netherlands and Nordic countries which already have necessary infrastructure in place for treatment and support for the disease, compared with Italy, France and Spain which generally do not. The markets available nevertheless are large with Germany, the most likely subsequent launch for example, having an estimated 3.2m individuals aged 15+ with severe AUD. Separate pricing negotiations are required for the EU, although it is realistic to expect a final agreed level similar to that achieved in the UK. Participating drug authorities can similarly be expected to recoup their investments from prospective cash flow.

Further international expansion into other international markets could also follow relatively quickly. Understanding that Australia, Canada, Singapore and Switzerland utilise International Recognition Procedure ('IRP') to fast-track medicine approvals by recognising pre-existing authorisations (such as from the UK), for example, their reviews may be shortened to just 60 days (Route A) or 110 days (Route B) instead of standard 150-day targets by their reference regulators (the TGA, Health Canada, HAS and Swissmedic, resp.)

Illustrative Commercial Scenarios Following Proposed German Launch



Source: Solvonis, Investor Presentation Q3 2026

IP - Targeting regulatory data and market exclusivity alongside defensible protocol

Awakn Life Sciences originally acquired the formulation for SVN-001 plus associated licensing rights for the KARE therapy from the UoE in March 2021 with no registered intellectual property ('IP') at that time. As such, its route forward is to target regulatory data and market exclusivity alongside defensible protocol combinations rather than standalone composition-of-matter patents, given that racemic ketamine is an off-patent generic molecule. In both the UK and EU a 'mixed full application' can be submitted, with success providing 8 to 10 years regulatory data protection plus a further two years for new, internally generated data.

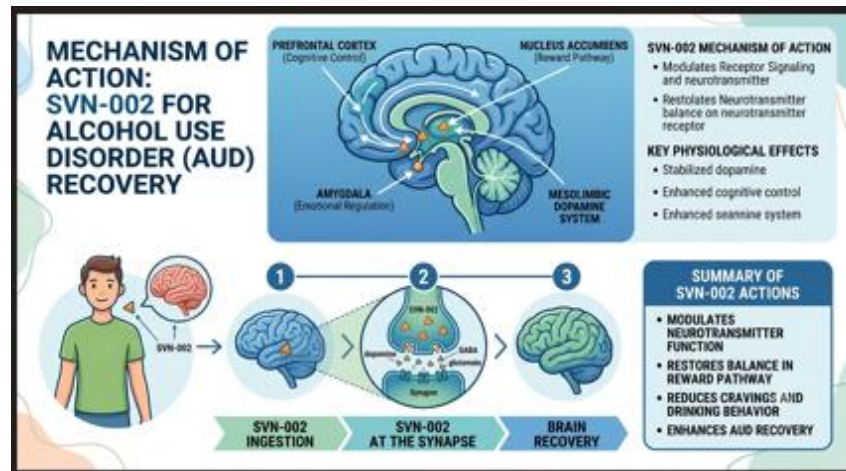
Competitors seeking to emulate Solvonis' success would therefore first need to run their own costly Phase 2 and Phase 3 UK/EU programmes for the same indication. Furthermore, the manualised therapy copyright provides between 40 and 70 years protection with the Group intending to tie the two together as a package under a common label. Altogether this would probably be considered too onerous for any interested party, given the anticipated pricing for what will already be a commercial treatment.

SVN-002 – Addressing the much larger US AUD commercial opportunity

SVN-002 is being developed specifically as a supervised, clinic-administered treatment for moderate-to-severe AUD. An accelerated regulatory pathway has been designed for the drug under which Solvonis utilises the FDA's 505(b)(2) hybrid approach. This enables it to bypass years of safety trials by leveraging historical data taken from J&J's approved drug, Spravato®, for adults with treatment-resistant depression or major depressive disorder. Under this protocol, Solvonis has been granted global exclusivity for addiction, anxiety, PTSD and eating disorders at nil cost.

Importantly, the levels of active esketamine and its principal breakdown product (noresketamine) absorbed into the blood from Solvonis' sublingual film match the levels produced by the approved esketamine nasal spray. This chemical equivalence substantially demonstrates SVN-002's safety profile, although the elevated level of a secondary breakdown product (hydroxynoresketamine), when absorbed under the tongue, requires a further in vivo safety tests (rodents and dogs) to be undertaken, although the team is confident it is safe because recreational and clinical users routinely tolerate much larger total doses of ketamine. Accordingly, they will seek simple type D written (only) feedback from the FDA, given that the exercise is considered largely a regulatory 'box-checking' exercise to verify that the narrow, elevated byproduct does not cause unexpected organ stress or toxicity before securing an IND approval.

Mechanism of Action for SVN-002 to deliver AUD recovery



Source: Solvionis, Online information, TPI

This chemical equivalence demonstrates SVN-002's safety profile. Moreover, while administration of classical psychedelics requires specialised, day-long monitoring, the patent-pending oral thin film (sublingual-buccal delivery) requires just 2-hours in clinic with no IV access, instead simply dissolving under the tongue, while offering bioavailability of up to c.26% for the 50 mg film (compared with typically 10%-20% in oral form). This creates a far more scalable delivery model for outpatient behavioural clinics paired with structured manualised, digitally delivered psychosocial support. Filed method-of-use patents are expected to be recognised in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations), that lists approved small-molecule drug products, their therapeutic equivalence codes (such as A or B ratings) and related patent and market exclusivity details. This should then secure 5.5 years US data protection for the programme, which incidentally is exactly the same level J&J went to market with esketamine for depression that eventually turned into a global run-rate of c.US\$1.7 billion/year. 90% of this comes from the US due to the fact that it has access to 14,000 substance use disorder treatment facilities.

Moderate to severe AUD has high relapse and produces a substantial economic burden in the US; there are c.11.3m people aged 12+ in the US with the condition which is 4x the estimated 2.8 million US Treatment Resistant Depression ('TRD') comparator population. The cost of excessive alcohol use across the US was estimated to be US\$249 billion in 2010). Solvionis is presently designing a 10-film treatment dosing cycle that will be supervised in clinic; an AUD reimbursement pathway (allocating necessary CPT codes) for SVS-220 is to be established based on this and psychosocial workflows. An FDA-aligned, IND-ready US Phase 2 programme is expected to be approved in H1 2027.

SVS-002 – Commercial Opportunity and Catalysts



Source: Solvionis, Investor Presentation Q3 2026

Although US pricing has yet to be established, it is likely to be between 4x and 6x that seen in UK/EU. The US

comparator is Vivitrol, which is a repurposed generic of naltrexone. Naltrexone blocks the opioid receptor to reduce inebriation; it costs c.\$0.50 for a once-a-day pill, but there's adherence issues because individuals specifically sought a state of drunkenness. Alkermes accordingly repurposed the drug from a daily pill into a monthly subcutaneous (slow release) injection. The charge is for up to US\$2000/injection over a 12 to 24 month treatment cycle. This indicates the totally cost of treatment payers are willing to accept; the product presently generates c.US\$500m/ year revenue and delivers around a 40% operating margin.

SVN-002 – Development Steps

Progress		
Phase 1 complete (favourable safety/PK)	FDA pre-IND interaction completed in December 2024, providing initial guidance on the proposed 505(b)(2) development pathway	Patent applications filed covering formulation and method of use; potential Orange Book listing subject to patent grant, NDA approval and applicable eligibility requirements
solvonisTHERAPEUTICS 1- Sacks JJ, Gonzales KR, Bouchery EE, Tornelli LE, Brewer RD. 2010 national and state costs of excessive alcohol consumption. <i>Am J Prev Med</i> 2015;49(5):e73-e79.		

Source: Solvonis, Investor Presentation Q3 2026

Based on establishment of SVN-002's 505(b)(2) bridge being established by the end of 2026, followed by preparation of a regulatory package in the opening months of the New Year, Solvonis hopes to then secure FDA alignment along with approval for a Phase 2 trial. It will endeavour to limit this specifically to a Phase 2b only, focussed specifically on dose finding and proving robust effectiveness before entering larger Phase 3 tests. Should it have access to the necessary capital, the Group plans to conduct these itself in the US. As indicated previously, this dovetails quite conveniently with anticipated UK and EU cash generation from the newly filed SVN-001. It is also worth highlighting the additional value that can be generated through raised US investor interest; Definium Therapeutics Inc. (Nasdaq: DFTX), for example, which has enjoyed as much as a four-fold price appreciation over the past year, taking its market capitalisation to almost US\$6 billion, having seen its repurposed LSD-based experimental pill significantly reduce anxiety symptoms in late-stage studies. Given that moderate to severe AUD represents a much larger prospective market for Solvonis, the Board remains determined to advance SVN-002 itself.

Discovery programmes – SVN-015 and SVN-114

Solvonis discovered its development candidates SVN-015 and SVN-114 using proprietary AI-enabled CNS discovery platforms and its proprietary CNS compound library that was originally acquired from Awakn Life Sciences. Launched in June 2025 and championed by the Group's CSO, Professor David Nutt, four distinct procedural goals were outlined (ranging through Data-Driven Asset Prioritisation, Structure-Activity Relationship Analysis, Translational Hypothesis Generation and Candidate Optimisation) to incorporate AI into its research workflow. Initial focus was on pipeline expansion through shared neural pathways to treat overlapping psychiatric conditions. This computational route was selected to efficiently screen and design small molecules that precisely rebalance complex, multi-transporter brain circuits while avoiding cardiac toxicities that historically hindered older medications. This computational discovery plus externally secure validation was designed by the Board as a quick, efficient and low-cost route to expand early-stage pipelines with minimal shareholder dilution.

SVN-015 - A selective serotonin and dopamine reuptake inhibitor

As a selective serotonin and dopamine reuptake inhibitor ('SDRI'), the candidate was selected following encouraging initial cardiac ion-channel/broader off-target screening results and identified through screening targeting the transporters that recycle dopamine and serotonin. Solvonis' lead focus is on Stimulant Use Disorder ('StUD'), which has a c.4.0–4.5 million addressable patients across the US, EU5, and Japan (focusing on cocaine and methamphetamine dependence). Secondary expansion into Major Depressive Disorder ('MDD') provides a market as large as c.21m US adults annually and c.30–40m across major global markets (US, UK, EU4, Japan). These were selected as its initial indications due to the compound's pharmacological profile directly targeting the brain circuits hijacked by addictive substances/mood disorders. Given that there are no FDA-approved medications available to treat StUD, meaning treatment relies almost entirely on behavioural and psychosocial interventions, this clearly

identifies significant unmet need. While there are numerous conventional treatments for MDD, such as selective serotonin reuptake inhibitors ('SSRIs'), these only target the serotonergic system and frequently fail to provide adequate symptom control for a significant portion of patients. By engaging both serotonin and dopamine channels, SDRIs offer a mechanistically broader approach. Positive preclinical data showing repeatable antidepressant-like activity, which successfully benchmarked against standard fluoxetine (Prozac), provides empirical justification to expand development scope into this indication.

SVN-015 - A Novel Dual Serotonin and Dopamine Reuptake Inhibitor

A novel dual serotonin and dopamine reuptake inhibitor for StUD and MDD

Indication & Need

StUD:

~4.2 million combined cocaine and amphetamine-type use-disorder cases across U.S., UK, EU4, and Japan¹. High unmet need for treatments.

Major Depressive Disorder:

~34.3 million in the estimated epidemiological population across U.S., UK, EU4, and Japan². High unmet need for treatments.



SOLVONIS THERAPEUTICS

1-2 Sources: Slide 25

Mechanism of action

Novel serotonin and dopamine reuptake inhibitor targeting SERT and DAT transporters

Designed to modulate pathways central to mood, motivation and reward processing

Progress to date

Composition of matter patents filed

Selected for evaluation within the U.S. National Institute on Drug Abuse ("NIDA") Addiction Treatment Discovery Program ("ATDP") for StUD.

Demonstrated antidepressant-like activity in direct preclinical evaluation.

Status & pathway

Q3 2026 (f) Data from NIDA ATDP initial work package

Q4 2026 (f) Data from NIDA ATDP final work package

2027 (f): Potential application to NIDA for UG3/UH3 grant support of up to \$3m per year for 5 years, subject to successful completion of ATDP

¹Our World in Data. Number with a drug use disorder by substance. Source: IHME, Global Burden of Disease (2025), with OWID processing; 2023 central estimates; accessed 22 July 2026. SAMHSA. Key Substance Use and Mental Health Indicators in the United States: Results from the 2024 NSDUH. 2025; Table A.37B and pp.30–32. NHS England. Adult Psychiatric Morbidity Survey 2023/24. Chapter 1: Common mental health conditions. ²Bromet E, et al. "Cross-national epidemiology of DSM-IV major depressive episode." BMC Medicine. 2011;9:90. doi:10.1186/1741-7015-9-90, Table 2. Source: Solvonis, Investor Presentation Q3 2026

Having demonstrated favourable initial in vitro cardiac ion-channel and off-target screening results superior to older analogues like GBR-12909. SVN-015 was independently selected and advanced into further non-dilutive preclinical evaluation under the NIDA ADTP. Following review of the initial screening results, on 6 August 2026 NIDA confirmed that the candidate will advance into further evaluation under the ATDP. This is expected to include confirmatory transporter studies and *in vivo* studies to characterise the onset and duration of its pharmacological activity. Upcoming Preclinical Studies are expected to include:

- **Dopamine Transporter ('DAT') Binding:** Run confirmatory tests on how the compound binds to and affects the dopamine transporter.
- **5-HT_{2B} Receptor Activity:** Conduct a closer assessment of interaction and activity levels at the serotonin 5-HT_{2B} receptor.
- ***In Vivo* Mouse Studies:** Perform in vivo testing in mice to measure the onset speed and duration of the drug's effects.

Solvonis' ambition is to build a comprehensive profile of SVN-015 to guide future clinical development strategies for the two indications. Realistically, this could be achieved over the coming 9 to 18 months, following which it will use positive results to support applications for further non-dilutive NIH and/or NIDA funding. Note that NIDA's support does not constitute a cash grant to the Group, meaning it retains ownership of SVN-015 and its intellectual property.

SVN-114 - Lead candidate for Solvonis' Post-Traumatic Stress Disorder ('PTSD') discovery program

SVN-114 is a novel monoaminergic modulator. It targets serotonin, dopamine, and noradrenaline transporters to affect social behaviour without being structurally derived from the substituted amphetamine series of MDMA.

MDMA (commonly known as ecstasy), it is globally classified as an illegal Schedule I or Class A controlled substance, with very rare, restricted exceptions for authorised psychiatric research or prescription (such as in Australia). Although Solvonis has largely paused development for the drug due to its high cost versus that of its lead candidates, it intends to progress it through preclinical evaluation with IND-enabling studies planned for 2028, backed by international composition-of-matter patents. Unlike traditional psychiatric medications that target only one or two neurotransmitters, the molecule simultaneously modulates all three primary monoamine systems in the brain to create a unique therapeutic window for PTSD. It binds to and inhibits the transporter proteins responsible for cleaning up neurotransmitters from the synaptic cleft (the space between brain cells).

SVN-114 – A Novel Compound to Modulate Serotonin, Dopamine and Noradrenaline Signalling

A novel compound identified through an AI-enabled discovery programme, designed to modulate serotonin, dopamine and noradrenaline signalling.

Indication & need

Post-Traumatic Stress Disorder (PTSD):
~15.8 million estimated
epidemiological population
across U.S./UK/EU4/Japan¹



Mechanism of action

Novel monoaminergic modulator
targeting SERT, DAT, and NET
transporters

Designed to rebalance
dysregulated neurotransmission
in PTSD-relevant circuits

Progress to date

SVN-114 selected as lead candidate from
discovery programme

Composition of matter patents filed

Preclinical activity observed in vitro and in
vivo

Status & pathway

2027 (subject to funding):
Lead optimisation

2028 (subject to funding):
IND-enabling studies

2029 (subject to funding):
IND submission

¹Koenen KC, et al. "posttraumatic stress disorder in the World Mental Health Surveys." *Psychological Medicine* 2017;47:2260–2274. doi:10.1017/S0033291717000708. Table 1. NHS England. *Adult Psychiatric Morbidity Survey 2023/24*. Chapter 3: Post-traumatic stress disorder. Census Bureau, *Vintage 2024 Population Estimates*; ONS mid-2024 population estimates; Eurostat demo_pjan, 2024; Statistics Bureau of Japan, *population by age at 1 October 2024*
Source: Solvonis, Investor Presentation Q3 2026

By blocking these transporters, the drug is able to keep chemicals active in the brain for longer. The core scientific hypothesis behind SVN-114 is that a specific, finely balanced ratio of these three chemicals can induce pro-social behaviour. In patients with severe trauma, defensive barriers and emotional blocks make it almost impossible to process such memories; by safely elevating dopamine and serotonin simultaneously, SVN-114 mimics aspects of empathy-enhancing compounds, as follows:

- **Serotonin Transporter (SERT):** Elevating serotonin levels helps stabilize mood, reduce underlying anxiety, and mitigate the hyperarousal and panic states common in PTSD.
- **Noradrenaline Transporter (NET):** Noradrenaline governs the body's fight-or-flight response. While traditional antidepressants can sometimes spike this and increase anxiety, SVN-114's balanced design aims to stabilize noradrenaline transmission, improving focus, emotional regulation, and resilience to stress triggers.
- **Dopamine Transporter (DAT):** Modulating dopamine directly addresses **anhedonia** (the inability to feel pleasure) and emotional numbing. It restores motivation, reward processing, and cognitive clarity, which are heavily suppressed in chronic PTSD sufferers.

Solvonis does not view SVN-114 as a simple daily 'chemical band-aid.' Instead, the science is optimised to act as a catalyst for trauma-focused psychotherapy. By lowering the brain's fear response (via serotonin/noradrenaline balance) and increasing engagement and trust (via dopamine), the compound creates an ideal neurological state for patients to revisit and process deep-seated trauma with a therapist without being re-traumatized by overwhelming panic.

The US is estimated to have c.13m people suffer from PTSD, which expands to >20m when also factoring in other major western markets. There are currently no modern, highly targeted licensed medicines specifically engineered to alter the neurobiology of trauma processing. Because existing options routinely introduce side effects (such as

weight gain, sexual dysfunction and emotional blunting) and often fail or merely suppress symptoms rather than treat the root trauma, the market is actively searching for novel drug classes. Traditional antidepressants (specifically SSRIs) are said to make up almost half of the current market that is presently valued at c.US\$20 billion.

Forecasts vary but indicate this will expand to reach [US\\$25.64 billion by 2031](#) and up to [US\\$30.2 billion by 2035](#) based on projected CAGR in the range of 5.0% to 10.7% based on accelerating mental health awareness, proactive trauma screening and expanded veteran/first-responder healthcare. Against this background, it is not surprising that larger pharmaceutical companies are willing to pay a substantial premiums to enter this space; one major industry benchmark, for example, was when Japanese drugmaker Otsuka Pharmaceutical Co., Ltd. (TSE: 4578) agreed to acquire Transcend Therapeutics in March 2026 for up to US\$1.23 billion in order to capture its clinically advanced neuropsychiatric pipeline focussed on PTSD.

Valuation – Solvonis trades at unwarranted discount to its international peer group

Solvonis' commercial thesis relies on its development of protected drugs addressing high-burden neuropsychiatric conditions with low patient satisfaction and few FDA/EMA-approved modern therapies. TPI's valuation has been based on the Group's two clinical candidates plus one that remains in discovery.

Risk-adjusted Net Present Value (rNPV) valuation key model assumptions:

- **Discount Rate (WACC): 14.0%** (reflects clinical-stage equity risk premium and cost of capital).
- **Tax Rate: 25%** (UK/US/EU weighted average).
- **Patent / Exclusivity Life: 10–12 years** post-launch prior to generic erosion.
- **COGS & SG&A:** COGS at 12% of revenue; Commercial/SG&A ramping up to 28% of revenue.

TPI's modelling of SVN-001's opportunity anticipates UK commercial filing in 2030, followed by the EU in 2031. It assumes UK and EU severe AUD epidemiology and addressable population to be 12.5m adults, of which less than 10% receive medical therapy due to poor compliance, side effects of existing options (e.g., naltrexone, acamprosate, disulfiram), and social stigma. Assuming prudent peak market penetration of 4.5% (suggesting prudent 500,000/year peak market penetration along with an estimated annual average net price/patient for the two zones of €2000 each, a risked DCF based on a 14% WACC and a cumulative POS of 55% (due to existing safety profile/ bridging clinical data) has been calculated:

SVN-001 (Phase 3 – UK/EU severe AUD) commercialisation assumptions:

- **Estimated Launch: 2030 (UK)/2031 (EU)**
- **Peak Market Penetration: 4.5% of treated severe AUD population (~22,500 patients/year)**
- **Peak Sales: £38.5 Million (€45.0m)**
- **Cumulative PoS: 55% (higher due to existing safety profile / bridging clinical data)**
- **Risk-Adjusted Peak Sales: £21.2m**
- **Risk-adjusted NPV: £19.3m**

For SVN-002, targeting moderate-to-severe AUD in the lucrative US market (of c.2.25 million addressable treated patients). The model anticipates entrance to a Phase 2b clinical trial in 2027 as the next step toward a 2024 US launch. The opportunity has been awarded a POS of 22% (based on standard biotech benchmark) and assume a peak market penetration of 90,000 patients/year generating annual net price per patient modelled at US\$9,000 (c.£6,640).

SVN-002 (Phase 2b – UK/EU moderate-to-severe AUD) model assumptions:

- **Estimated Launch: 2034**
- **Peak Market Penetration: 4.0% of treated US AUD population (~90,000 patients/year)**
- **Peak Sales: US\$810 Million (£597.6m)**
- **Cumulative PoS: 22% (Phase 2b to FDA approval standard biotech benchmark)**
- **Risk-Adjusted Peak Sales: £131.5m**
- **Risk-Adjusted NPV: £41.9m**

GBP= 1.17€ = 1.36US\$

For SVN-015, there are currently no FDA/EMA-approved pharmacological treatments, hence Solvonis' ambition establish a 'first-in-class' medical treatment model for stimulant addiction; for the larger MDD market, 30–40% of patients experience an inadequate response or residual symptoms under standard SSRI/SNRI regimens (which frequently fail to resolve anhedonia (inability to feel pleasure) and reduced motivation. Before filing an Investigational New Drug (IND) application with the FDA, the compound must undergo formal GLP toxicology, safety pharmacology in whole animals and process chemistry/formulation development. Assuming positive readouts from NIDA's in vivo work and successful IND-enabling toxicology, an IND application could be submitted to the FDA in 2028, enabling Phase 1 First-in-Human ('FIH') trials to commence by 2029.

SVN-015 (Discovery phase – StUD, MDD) model assumptions:

- **Early-Stage Valuation:** Option value estimated at £2.8 Million (rNPV accounting for <10% PoS).

rNPV VALUATION SUMMARY

Asset / Component	Assumed Peak Sales	Unrisked NPV (£M)	Overall PoS	WACC (Discount Rate)	rNPV Contribution	% of Gross Pipeline Value
SVN-001 (Phase 3 - UK/EU AUD)	£38.5m (£45.0m)	£35.1m	55%	14.0%	£19.3m	30.2%
SVN-002 (Phase 2b - US AUD)	US\$810.0m (£597.6m)	£190.5m	22%	14.0%	£41.9m	65.5%
PTSD / AI Platform	£120.0m	£35.0m	8%	14.0%	£2.8m	4.3%
Gross Pipeline Total	—	£260.6m	—	14.0%	£64.0m	100.0%
Less: Operating Burn/Overhead (5 yrs)	—	—	—	14.0%	-£28.0m	—
Plus: Net Cash	—	—	—	—	+£1.7m	—
Total Implied Equity Value	—	—	—	14.0%	£37.7m	—

Source: TPI estimates

Peer Group Comparison & Market Multiples

A peer group comparison tabulated overleaf comprises addiction medicine leaders, CNS platforms and neuropsychiatry/psychedelic developers.

Within this, note that those with Phase 2b/Phase 3 CNS or addiction assets typically command market caps between US\$180m and US\$1 billion. Solvonis presently trades at c.7% of its mid-stage international peer average. This highlights the fact that it does not yet have a US (Nasdaq or NYSE) listing, something that the Board hopes to achieve prior of its proposed commercialisation of SVN-002.

Note also that Indivior's premium valuation appears to demonstrate the long-term cash flow potential in addiction therapy when an asset achieves dominant adoption in specialty addiction clinics, while sector operators like Solvonis that leveraging reformulation technologies (e.g., oral thin films or sublingual formulations under the FDA 505(b)(2) pathway) within their portfolios typically carry lower development risk than new chemical entities.

Benchmarking against BioXcel and Orexo highlights that even commercial-stage reformulation biotechs trade at enterprise values between US\$50M and US\$150M, reinforces the view that Solvonis suffers from a deep UK-market liquidity discount. MindMed, for example, demonstrates the premium US capital markets place on late-stage clinical programs targeting severe anxiety, PTSD and social function. Despite its significantly unmet need, there are a limited number of listed pure-play AUD developers quoted on western markets (such as Clearmind, Orexo and Indivior), highlighting potential for Solvonis to become a M&A target for mid-tier specialty pharma seeking addiction medicine exposure. Note also that Adial Pharmaceuticals seemingly valuation reflects its failure to meet the primary endpoint of its July 2022 Phase 3 trials, having fallen from its 2021 peak market cap of c.US\$120m.

Solvonis – International Peer Group Comparison*

Company	Ticker	Market Capitalisation*	Enterprise Value (EV)*	Strategic Rationale for Inclusion, Comparison to Solvonis & Status
Indivior	NASDAQ: INDV	US\$4.60B	US\$4.42B	Commercial Addiction Leader (Commercial Peer): Commercialized addiction treatment model (<i>Sublocade</i>) with robust cash flows. Demonstrates the scale and top-line commercial potential for Solvonis if SVN-001/002 achieve specialty clinic adoption.
GH Research	NASDAQ: GHRS	US\$2.03B	US\$1.78B	Ultra-Short-Acting CNS Benchmark (Clinical Peer): Phase 2b ultra-short-acting 5-MeO-DMT platform, highlighting institutional capital appetite for rapid-acting, short-duration neuropsychiatric interventions.
COMPASS Pathways	NASDAQ: CMPS	US\$1.89B	US\$1.66B	Phase 3 Trauma/CNS Peer (Clinical Peer): Active Phase 3 execution in neuropsychiatry (<i>COMP360</i>). Receives strong institutional support on NASDAQ relative to Solvonis's London listing.
MindMed	NASDAQ: MNMD	US\$1.46B	US\$1.22B	Next-Gen Neuropsychiatry Peer (Clinical Peer): Late-stage clinical overlap in social/trauma disorders (<i>MM120/MM402</i>). Illustrates the significant valuation premium US capital markets assign to late-stage CNS platforms compared to Solvonis.
Cybin	NYSE American: CYBN	US\$743M	US\$685M	Novel Delivery CNS Peer (Clinical Peer): Developing deuterated psilocybin (<i>CYB003</i>) with expedited clinical timelines. Shares a similar mid-to-late stage development profile to Solvonis's Phase 2b/3 portfolio.
Altimimmune	NASDAQ: ALT	US\$595M	US\$424M	Substance Abuse Pipeline Benchmark (Clinical Peer): Dual GLP-1/Glucagon agonist (<i>Femvidutide</i>) in Phase 2 for obesity and alcohol-related liver disease. Serves as a mid-cap clinical benchmark for addiction assets.
Orexo	STO: ORX	US\$82M	US\$39M	European SUD Specialty Pharma (Commercial Peer): Stockholm-listed peer with commercialized sublingual formulations for addiction (<i>Zubsolv</i>). Proves the commercial viability of sublingual/reformulation delivery models in European markets.
BioXcel Therapeutics	NASDAQ: BTAI	US\$28.0M	US\$21.5M	505(b)(2) Reformulation Benchmark (Commercial/Clinical Peer): Uses sublingual film delivery (<i>JGALM</i>) via the lower-risk FDA 505(b)(2) pathway, directly mirroring Solvonis's US clinical pathway for SVN-002.
Adial Pharmaceuticals	NASDAQ: ADIL	US\$9.4M	US\$4.6M	Direct Phase 3 AUD Micro-Cap Peer (Clinical Peer - Phase 3 AUD): The only other public micro-cap with an active Phase 3 AUD asset (<i>ADD4</i>). Highlights how public market valuations for standalone AUD assets remain severely depressed prior to commercial partnership.
Clearmind Medicine	NASDAQ: CMND	US\$2.4M	-US\$11.1M	Pure-Play AUD Early Peer (Micro-Cap Clinical Peer): Developing MEAI-based compounds (<i>CMND-100</i>) for heavy drinking. Demonstrates the extreme scarcity of clinical-stage AUD competitors in Western markets.
Solvonis	LSE: SVNS	US\$13.8M (£10.2M)	US\$11.5M (£8.5M)	Potential Target Company: Holds a Phase 3 European asset (SVN-001) and Phase 2b US asset (SVN-002), yet trades at a severe micro-cap valuation due to UK market illiquidity and capital constraints.

*19 August 2026, GBP= 1.36US\$

Source: Market information, TPI estimates

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