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Solvonis Therapeutics PLC
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Solvonis Therapeutics plc
("Solvonis" or the "Company")

Research and Development Update - Q4 2025
Pipeline advancing across addiction and psychiatry with multiple 2026 catalysts

Solvonis Therapeutics plc (LSE: SVNS), an emerging biopharmaceutical company developing novel medicines for high-burden central nervous system ("CNS") disorders, provides an update on progress across its development pipeline and discovery programmes as the Company concludes 2025 and enters a catalyst-rich period in 2026.

Pipeline development advancing across addiction and psychiatry

SVN-001 | Severe Alcohol Use Disorder (AUD) - UK & EU

The Company's lead programme, SVN-001, continues to advance through a potentially pivotal Phase 3 clinical trial for severe AUD in the United Kingdom, addressing a large and underserved patient population across the UK and EU. In parallel, the Company continues to progress licensing and commercial-partnership discussions.

Recruitment remains ongoing in this **NHS**-based study, conducted in collaboration with the University of Exeter ("**UoE**") and co-funded by the National Institute for Health and Care Research ("**NIHR**"), the Medical Research Council ("**MRC**"), and Solvonis. Top-line results are anticipated in late 2027 / early 2028. In parallel, with potential partners in UK and internationally.

SVN-002 | Moderate-to-Severe AUD - Global (ex-UK & EU) | Initial focus: United States

SVN-002, Solvonis' proprietary esketamine oral thin-film programme, is being advanced under a planned U.S. FDA 505(b)(2) regulatory pathway referencing Johnson & Johnson's blockbuster esketamine product, Spravato®.

During Q4 2025, preparatory work continued with WuXi AppTec on a pharmacokinetic bridging programme to support regulatory alignment. Initial data are expected in Q1 2026, with further progress through Q2 2026.

If the scientific bridge to Spravato® is successfully established the Company plans to promptly seek approval from the US Food and Drug Administration ("**FDA**") for a Phase 2b trial, thereby potentially avoiding the significant costs associated with pre-clinical programmes and Phase1 and Phase 2a trials.

The programme targets approximately 15 million adults in the United States living with moderate-to-severe AUD and represents a differentiated, clinic-based therapeutic approach within a large and underserved market.

SVN-015 | Stimulant (Methamphetamine and Cocaine) Use Disorder

In December 2025, Solvonis announced that SVN-015, a novel compound emerging from its AI-enabled discovery programme, was accepted into the U.S. National Institute on Drug Abuse's ("**NIDA**") Addiction Treatment Discovery Program ("**ATDP**").

Under the programme, NIDA - part of the U.S. National Institutes of Health ("**NIH**") - will fund and conduct a standard package of preclinical safety and pharmacology studies, including cardiovascular risk assessment. Initial results are expected in Q1 2026. Subject to supportive outcomes, SVN-015 may progress into further NIDA-funded efficacy testing in validated models of methamphetamine and cocaine addiction.

Acceptance into ATDP represents an important external validation of Solvonis' proprietary discovery platform and expands the Company's pipeline beyond alcohol use disorder into stimulant addictions, which remain among the most severe psychiatric conditions with no approved pharmacological treatments.

Successful completion of the ATDP programme would position Solvonis to compete for subsequent NIH development funding, including potential UG3/UH3 awards, providing a non-dilutive pathway from preclinical validation toward clinical development.

SVN-SDN-14 | Post-Traumatic Stress Disorder (PTSD)

Following the announcement of positive preclinical data in August 2025, Solvonis' proprietary serotonin-dopamine-noradrenalin modulator programme continues to progress through final in-vivo studies designed to support lead-candidate selection.

Four compounds are currently being evaluated in rat brain microdialysis studies to confirm central pharmacokinetics and target engagement across relevant monoaminergic pathways. Lead-candidate selection is expected in Q1 2026, after which the Company intends to advance the selected compound into IND-enabling studies.

AI-enabled CNS discovery platform

Beyond SVN-015 and SVN-SDN-14, Solvonis continues to advance its AI-enabled discovery programme, generating

novel small-molecule candidates targeting key neurotransmitter systems relevant to addiction and psychiatry. Exploratory work is also underway to assess potential applications in neurology.

Further updates on discovery-stage progress are expected during H1 2026 as compound evaluation and prioritisation continue.

Anthony Tennyson, Chief Executive Officer of Solvonis Therapeutics plc, commented: "*2025 has been a transformative year for Solvonis. The completion of the acquisition of Awakn Life Sciences in May materially reshaped the Company, establishing a differentiated CNS platform spanning late-stage clinical development, earlier-stage discovery, and multiple regulatory pathways.*

"Over the course of the year, we have advanced our clinical programmes with discipline, strengthened our balance sheet, and progressed our proprietary discovery capability, including securing external validation through the acceptance of SVN-015 into the U.S. National Institute on Drug Abuse's Addiction Treatment Discovery Program.

"As we look ahead to 2026, the Company is entering a period with multiple clearly defined catalysts across regulatory, preclinical, and discovery activities. Our strategy remains centred on capital efficiency, clear regulatory pathways, and partnering optionality, which we believe provides near, medium, and long-term shareholder value creation opportunities."

Outlook
Solvonis enters 2026 with a diversified CNS pipeline spanning late-stage clinical development, near-term regulatory catalysts, and early-stage discovery programmes supported by external validation and non-dilutive funding pathways.

The Company remains focused on disciplined execution across its addiction and psychiatry programmes while continuing to selectively expand its proprietary discovery platform.

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About Solvonis Therapeutics plc

Solvonis Therapeutics plc (LSE: SVNS) is an emerging biopharmaceutical company developing novel small-molecule therapeutics for high-burden central nervous system (CNS) disorders. Headquartered in London and listed on the main market of the London Stock Exchange, Solvonis is advancing a differentiated pipeline of repurposed and novel compounds across addiction, psychiatry, and neurology.

The Company's lead programmes address Alcohol Use Disorder (AUD) and Post-Traumatic Stress Disorder (PTSD), with additional discovery work supporting expansion into broader CNS indications. Its lead asset, SVN-001, is currently in Phase 3 for severe AUD in the UK, while SVN-002 is preparing for a Phase 2b trial in the US targeting moderate-to-severe AUD. The preclinical PTSD programme (SVN-SDN-14) leverages novel serotonin-dopamine modulators designed to enhance pro-social behaviour and long-term outcomes.

In parallel, Solvonis is advancing proprietary CNS discovery programmes built on a dedicated compound library to identify new small-molecule modulators of key neurotransmitter systems. This platform enables efficient early-stage innovation and supports the Company's integrated approach to developing therapies across its three strategic pillars.

With a capital-efficient model, dual development strategy, and near-term partnering opportunities, Solvonis is positioned to deliver sustained value through innovation in CNS therapeutics.
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