



Somnus Therapeutics, Inc. (Bedminster, NJ) is a private specialty pharmaceutical company that is developing SKP-1041, a bedtime oral therapeutic to address a major unmet need of insomnia patients: preventing early awakening without next-day residual effects.

Insomnia Market Opportunity

Although insomnia affects up to 40% of the population, only 20% of insomniacs pursue pharmaceutical treatments, in part because available therapeutics do not meet most patients' needs for sleep improvement. The majority of insomnia patients have difficulty staying asleep, a problem increasing in prevalence as people age. SKP-1041 addresses the needs of the 29% of insomniacs who have no problem falling asleep but awake during their sleep periods.

Somnus sees a greater than \$500 million market for a new sleep maintenance treatment that delivers improved satisfaction to patients and an improved risk/reward profile to investors. The company has licensed from SkyePharma PLC (LSE: SKP) a novel delayed-release formulation of zaleplon, a short half-life non-benzodiazepine agent, suitable for bedtime dosing.

Risk Mitigating Clinical Strategy

By leveraging the development of a chemical entity from the most successful class of current insomnia drugs, taking advantage of the 505(b)(2) regulatory pathway and, through technical advances in formulation, delayed-release, and clinical testing, we have so far speeded development and reduced clinical costs to increase return on investment.

Key Differentiators:

- SKP-1041 addresses the top need of insomnia patients: preventing middle-of-the-night awakenings while avoiding next-day hangover and providing restorative sleep without residual cognitive effects.
- A bedtime pill is preferred by >80% of prescribers, has less risk of errors of dose and timing than drugs taken in the middle of the night, does not reinforce poor sleep habits (waking for a pill), and produces a lower risk of falls at night, especially among elderly patients.
- SKP-1041 releases no drug in the first 2 hours, thus avoiding interference with early deep delta wave sleep. Once released, effects last 4 hours so as to be gone by the time of awakening.
- Our clinical strategy leverages advances in sleep research and clinical testing to evaluate SKP-1041 taken day or night in young and old subjects, as well as to test them for next-day cognitive and driving impairments.
- Our virtual, single-product business model reduces costs and accelerates development by leveraging a small core development team with successful experience in IND and NDA submissions through efficient use of outsourcing.

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