

Substance Use Disorder Therapeutics Global Market Insights 2025, Analysis and Forecast to 2030, by Market Participants, Regions, Technology, Product Type

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Abstracts

Introduction

The substance use disorder therapeutics market encompasses pharmaceutical interventions and medication-assisted treatments designed to address the compulsive and harmful use of psychoactive substances, including opioids, alcohol, tobacco, stimulants, and cannabis. Substance use disorder represents a significant mental health condition affecting millions globally, characterized by physical dependence, behavioral changes, and profound health, social, and economic consequences. The market comprises synthetic opioid receptor agonists such as buprenorphine and methadone, opioid antagonists including naltrexone and naloxone, and various non-opioid medications for alcohol and tobacco cessation. These therapeutic interventions work through diverse mechanisms including receptor modulation, craving reduction, and relapse prevention.

The industry serves addiction treatment centers, hospitals, outpatient clinics, and community-based programs, addressing multiple substance dependencies through evidence-based medication-assisted treatment protocols. The market benefits from increasing global prevalence of substance use disorders, expanding government funding for treatment programs, regulatory reforms enabling wider prescriber access, growing recognition of addiction as a medical condition rather than moral failing, and advances in digital therapeutics and telehealth delivery models. International organizations including the World Health Organization and United Nations Office on Drugs and Crime report that over 39.5 million people worldwide suffer from drug use

disorders, while approximately 2.6 million deaths annually are attributed to alcohol consumption and 600,000 deaths to psychoactive substance use, underscoring the urgent need for effective therapeutic interventions.

Market Size and Growth Forecast

The global substance use disorder therapeutics market is projected to reach 11.5-12.5 billion USD by 2025, with estimated compound annual growth rates ranging from 7.0% to 9.0% through 2030. This growth trajectory reflects expanding treatment access driven by regulatory reforms, increasing public sector funding for behavioral health programs, rising adoption of medication-assisted treatment protocols, and growing awareness that reduces stigma associated with seeking treatment. The removal of prescribing restrictions for buprenorphine in late 2024 and enforcement of mental health parity laws in 2025 have significantly expanded treatment accessibility across developed markets.

Regional Analysis

North America dominates the substance use disorder therapeutics market with estimated growth rates of 6.5%-8.0%, driven primarily by the ongoing opioid crisis and substantial government investment in treatment infrastructure. The United States represents the largest single market, supported by mature insurance coverage systems, robust prescribing capacity following regulatory reforms eliminating waiver requirements for buprenorphine prescribing, and significant federal funding through programs including State Opioid Response grants totaling 1.48 billion USD. The Mental Health Parity Act enforcement in January 2025 has compelled commercial insurance plans covering 175 million Americans to eliminate prior authorization barriers for addiction treatment, immediately expanding treatment utilization. Canada continues developing safe-supply programs and expanding telehealth-based medication-assisted treatment, while Mexico is enhancing cross-border tele-MAT partnerships to reach underserved populations.

Asia Pacific demonstrates the fastest growth rates of 7.0%-8.5%, fueled by rapid industrialization, expanding healthcare infrastructure, and shifting policy approaches from punitive to medical treatment models. China has deployed 191 detoxification centers serving 1.7 million patients, exemplifying state-driven infrastructure scaling. India and Southeast Asian nations are expanding treatment programs through public-private partnerships, while Japan and South Korea are enhancing community-based intervention systems. The region benefits from increasing healthcare investments and growing recognition of substance use disorders as public health priorities requiring

medical intervention rather than criminal justice approaches.

Europe exhibits growth rates of 6.0%-7.5%, characterized by comprehensive healthcare systems, stringent regulatory frameworks, and advanced harm reduction strategies. Major markets including Germany, France, and the United Kingdom maintain established treatment infrastructure with strong public funding support. The region emphasizes integrated care models combining medication-assisted treatment with behavioral therapies and social support services. European countries have implemented extensive naloxone distribution programs and are pioneering supervised consumption sites, reflecting comprehensive public health approaches to substance use disorders.

South America shows growth potential of 5.5%-6.5%, with Brazil and Mexico leading regional development. The region faces challenges including limited treatment infrastructure, variable insurance coverage, and persistent stigma affecting treatment-seeking behavior. However, increasing government awareness, international organization support, and growing middle-class access to healthcare services are gradually expanding treatment availability. Regional governments are implementing national drug strategies emphasizing prevention and treatment over criminalization.

The Middle East and Africa region demonstrates growth rates of 5.0%-6.0%, driven by expanding healthcare systems in Gulf states and growing recognition of substance use disorders as medical conditions. South Africa maintains relatively advanced treatment infrastructure, while North African and Middle Eastern countries are developing programs addressing prescription opioid misuse and stimulant use. The region faces significant challenges including limited resources, cultural stigma, and underdeveloped healthcare infrastructure, but international partnerships and WHO technical assistance are supporting capacity building.

Type Analysis

Synthetic Opioid Receptor Agonists: This segment demonstrates projected growth of 7.5%-9.0%, dominated by buprenorphine and methadone formulations. Buprenorphine, available in sublingual tablets, film strips, extended-release injections, and implantable formulations, represents the fastest-growing segment driven by regulatory reforms eliminating prescribing restrictions and expanding telehealth initiation protocols. Extended-release formulations including monthly injectable buprenorphine have gained FDA approval and demonstrate superior adherence compared to daily dosing. Methadone remains essential for severe opioid use disorder treatment through

specialized clinic-based programs, though growth is constrained by regulatory requirements mandating daily observed dosing in certified facilities. The segment benefits from expanding recognition that opioid agonist maintenance represents the evidence-based standard of care, reducing overdose mortality by approximately 50% compared to abstinence-only approaches.

Opioid Antagonists: Expected to grow at 6.5%-8.0%, encompassing naltrexone for relapse prevention and naloxone for overdose reversal. Naltrexone, available as daily oral tablets and monthly extended-release injections, serves patients who have completed detoxification and seek abstinence-based approaches. The extended-release injectable formulation demonstrates improved adherence and outcomes compared to daily oral dosing. Naloxone, formulated as nasal sprays, auto-injectors, and injectable solutions, has experienced explosive demand growth driven by widespread community distribution programs, standing orders enabling pharmacy dispensing without prescriptions, and public health initiatives distributing take-home naloxone kits. State and federal harm reduction programs have distributed millions of naloxone units, contributing to stabilization or modest declines in opioid overdose deaths in some jurisdictions despite continued high potency fentanyl prevalence.

Key Market Players

BioXcel: This biopharmaceutical company focuses on neuroscience and immunoncology, developing innovative treatments for acute agitation and substance use disorders. BioXcel's lead candidate utilizes sublingual dexmedetomidine for acute treatment of agitation associated with psychiatric disorders, representing novel approaches to managing behavioral crises commonly encountered in addiction treatment settings. The company maintains strong clinical development capabilities and strategic partnerships supporting regulatory advancement.

Opiant: A specialty pharmaceutical company dedicated to developing treatments for opioid overdose and addiction, Opiant focuses on novel delivery systems and formulations addressing critical unmet needs in opioid use disorder. The company has developed intranasal naloxone formulations and is advancing pipeline candidates targeting opioid withdrawal management and relapse prevention, contributing to harm reduction and treatment retention strategies.

Intra-Cellular Therapies: This biopharmaceutical company develops therapies for central nervous system disorders, including substance use disorders. The company's research focuses on neurobiological mechanisms underlying addiction, developing

compounds that modulate dopaminergic and glutamatergic neurotransmission. Intra-Cellular maintains robust research and development capabilities and is advancing multiple clinical programs targeting various substance dependencies.

ATAI Life Sciences: A clinical-stage biopharmaceutical company exploring psychedelic compounds and other novel mechanisms for treating mental health disorders and addiction. ATAI's pipeline includes investigational therapies targeting stimulant use disorder, alcohol use disorder, and opioid use disorder through mechanisms distinct from traditional treatments. The company represents the emerging frontier of psychedelic-assisted therapy research, with multiple compounds in clinical development addressing treatment-resistant substance use disorders.

Kona Gold Beverage: This company focuses on functional beverages and wellness products, including cannabidiol-based formulations being investigated for potential applications in addiction treatment and recovery support. The company represents the emerging integration of cannabis-derived compounds into therapeutic frameworks, though regulatory pathways and clinical evidence requirements remain evolving.

Industry Value Chain Analysis

The substance use disorder therapeutics industry value chain extends from pharmaceutical research and development through clinical implementation in diverse treatment settings. Upstream activities include drug discovery and development, clinical trials establishing safety and efficacy, and regulatory approval processes through agencies including the FDA, EMA, and other national authorities. Pharmaceutical manufacturers produce active pharmaceutical ingredients and finished dosage forms through certified facilities meeting stringent quality standards.

Distribution channels encompass pharmaceutical wholesalers, specialty distributors serving addiction treatment facilities, and retail pharmacies dispensing medications under various regulatory frameworks. For controlled substances including buprenorphine and methadone, distribution follows additional security and tracking requirements under international drug control treaties and national controlled substance regulations. Digital health platforms are increasingly integrating medication management with telehealth consultations, enabling remote prescribing and monitoring where regulations permit.

Healthcare delivery occurs through multiple channels including specialized addiction treatment centers offering residential and outpatient programs, office-based practices

where physicians prescribe medication-assisted treatment, hospital emergency departments initiating treatment for overdose patients, and correctional facilities providing continuity of care for incarcerated populations. Treatment models increasingly emphasize integrated care combining pharmacotherapy with behavioral interventions, peer support, and social services addressing co-occurring mental health conditions and social determinants of health.

Professional societies, clinical guidelines, and quality improvement initiatives support evidence-based treatment delivery. Organizations including the American Society of Addiction Medicine provide clinical practice guidelines, continuing education, and advocacy supporting expanded treatment access. Peer recovery support specialists, many with lived experience of addiction and recovery, increasingly integrate into treatment teams, enhancing engagement and retention.

Market Opportunities and Challenges

Opportunities

Expanding Treatment Access Through Regulatory Reform: Recent regulatory changes eliminating prescriber training requirements and waiver systems for buprenorphine prescribing have dramatically expanded the potential prescriber pool, creating opportunities for pharmaceutical companies to reach previously underserved markets. Continued advocacy for evidence-based regulations reducing unnecessary barriers while maintaining patient safety represents significant growth opportunities.

Digital Therapeutics and Telehealth Integration: FDA approval of prescription digital therapeutics for substance use disorder treatment, combined with telehealth prescribing allowances, creates opportunities for innovative care delivery models. Digital platforms enabling remote monitoring, medication management, virtual counseling, and contingency management demonstrate improved access, particularly in rural areas lacking specialized addiction treatment infrastructure. Companies developing integrated digital health solutions positioned at the intersection of pharmacotherapy and technology represent high-growth market segments.

Novel Therapeutic Mechanisms: Emerging research into alternative pharmacological targets including glutamatergic modulation, immunotherapy approaches, and psychedelic-assisted therapy represents potential paradigm

shifts in addiction treatment. Clinical trials investigating psilocybin for alcohol use disorder, ketamine for treatment-resistant depression and substance use disorders, and MDMA-assisted therapy demonstrate promising preliminary results. Companies advancing novel mechanisms through rigorous clinical development could capture significant market share if approved.

Harm Reduction and Overdose Prevention: Expanding recognition of harm reduction as a critical public health strategy creates opportunities for products including long-acting naloxone formulations, safer drug supply programs, and overdose prevention centers. Development of longer-acting naloxone products addressing high-potency synthetic opioids like fentanyl represents an urgent unmet need, as current formulations may have insufficient duration of action for emerging ultra-potent opioids.

Challenges

Persistent Stigma and Treatment Gap: Despite growing recognition of addiction as a medical condition, persistent stigma continues limiting treatment-seeking behavior. International data indicates only one in seven people with substance use disorders receives treatment annually, representing a massive treatment gap constraining market growth. Addressing stigma requires sustained public education, advocacy, and healthcare system transformation normalizing addiction treatment within general medical care.

Regulatory and Reimbursement Complexity: International variation in regulatory frameworks for controlled substances creates market access challenges for manufacturers. Reimbursement systems frequently impose administrative barriers including prior authorization requirements, limited coverage of certain formulations, and inadequate payment rates that discourage provider participation. While recent parity law enforcement has improved coverage in some markets, inconsistent implementation and ongoing disputes regarding treatment necessity continue limiting access.

Cost and Affordability Barriers: High treatment costs, particularly for extended-release formulations and specialized therapies, create affordability challenges for uninsured and underinsured populations. Generic competition has reduced costs for some medications, but newer formulations command premium pricing. Public sector funding through grants and subsidies partially addresses

affordability gaps, but sustainable financing models remain elusive in many jurisdictions.

Trump Administration Tariff Policy Uncertainty and Global Supply Chain Impacts: Current trade policy uncertainties, including potential tariff implementations on pharmaceutical ingredients and finished products, create cost pressures and supply chain risks for manufacturers. Many active pharmaceutical ingredients are sourced from China and India, and tariff policies could increase production costs, necessitate supply chain diversification, and potentially disrupt medication availability. Global supply chain restructuring to reduce dependence on single-source suppliers and geographies represents both a challenge and an opportunity for companies with diversified manufacturing footprints. Trade policies favoring domestic pharmaceutical production could incentivize reshoring investments but might increase costs in the short term.

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