

Global MASH Drug Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global MASH Drug market size is predicted to grow from US\$ 1028 million in 2025 to US\$ 5702 million in 2032; it is expected to grow at a CAGR of 22.2% from 2026 to 2032.

MASH Drug refers to pharmacological therapies developed for metabolic dysfunction-associated steatohepatitis (MASH), the progressive inflammatory and fibrotic form of metabolic dysfunction-associated steatotic liver disease (MASLD), historically referred to as NASH. The research scope focuses on disease-modifying therapies intended to improve steatohepatitis activity, reduce or reverse liver fibrosis, or modify metabolic and fibrotic pathways associated with disease progression. The market covers approved products and investigational candidates across oral, subcutaneous and intravenous administration, and across small-molecule, peptide/protein, RNA or oligonucleotide, carbohydrate-based and other therapeutic modalities.

Key Findings

The average gross profit margin of this product is 72%

Two FDA-approved therapies establish a commercial MASH treatment market

F2-F3 noncirrhotic disease remains the core approved treatment population

Oral small molecules and injectable therapies define current modality competition

F4 cirrhosis remains an important late-stage development opportunity

Pipeline competition spans metabolic antifibrotic and gene-silencing mechanisms

Market Trends

The MASH Drug market is moving from a predominantly clinical-development market toward a multi-mechanism commercial treatment category. The first stage of commercialization has been led by liver-directed THR-? therapy and GLP-1 therapy, while the development pipeline is broadening toward agents that address both hepatic pathology and systemic cardiometabolic dysfunction. This is particularly relevant because MASH commonly overlaps with obesity, type 2 diabetes and other metabolic risk factors. The next competitive phase is therefore likely to emphasize the balance between fibrosis improvement, MASH resolution, weight and metabolic benefits, dosing convenience and long-term safety rather than a single histological endpoint. At the same time, late-stage programs involving FGF21 analogs, GLP-1/glucagon dual agonists, pan-PPAR agonists and other mechanisms are increasing the potential for differentiated treatment selection and future combination strategies. Gene-silencing approaches targeting genetically validated liver pathways further broaden the longer-term technology landscape.

Market Dynamics

Drivers

The primary demand driver is the close relationship between MASH and the expanding cardiometabolic patient population. Obesity, type 2 diabetes and related metabolic abnormalities increase the pool of patients requiring fibrosis assessment and long-term liver disease management, while the emergence of approved pharmacotherapy is giving physicians a clearer reason to identify patients before progression to cirrhosis. The approvals of resmetirom and semaglutide have also validated two distinct therapeutic approaches, strengthening clinical awareness of pharmacological intervention for F2-F3 disease. As treatment options expand, referral pathways between hepatology, gastroenterology, endocrinology and metabolic-care settings are expected to become increasingly important to market development.

Restraints

The major restraint is that commercial treatment depends on accurately identifying patients with clinically meaningful fibrosis from a much broader population with

metabolic liver disease. Current approved indications remain concentrated in noncirrhotic patients with moderate-to-advanced fibrosis, limiting immediate addressability compared with the overall MASLD population. In addition, accelerated or conditional approvals require continued generation of confirmatory clinical evidence, making long-term outcomes, treatment persistence and real-world effectiveness important factors for payer and physician confidence. Chronic treatment duration, medication access and the need to coordinate liver and metabolic management may also constrain penetration even where eligible patients are identified.

Opportunities

The most significant expansion opportunity lies beyond the current F2-F3 treatment core. Compensated MASH cirrhosis represents an important unmet segment, with several development programs evaluating therapies in F4 disease or portal-hypertension-related populations. A second opportunity is combination therapy, in which agents acting on liver fibrosis or de novo lipogenesis could potentially be paired with established or emerging metabolic therapies. In parallel, RNAi programs targeting HSD17B13, PNPLA3 and CIDEA introduce a genetically informed therapeutic strategy that may eventually create new treatment segments beyond conventional receptor agonists and metabolic small molecules. These approaches increase the possibility that future MASH treatment will become stratified by fibrosis stage, metabolic phenotype and molecular mechanism.

Challenges

The main industry challenge is demonstrating durable differentiation in a rapidly expanding pipeline. Future candidates will increasingly be compared not only on MASH resolution or fibrosis improvement, but also on cardiometabolic benefits, safety, tolerability, route of administration and suitability for chronic therapy. Developers must also address the commercial difficulty of translating clinical-trial eligibility into routine diagnosis and treatment, particularly when patients are managed across multiple specialties. For clinical-stage companies, increasingly large late-stage studies and confirmatory requirements raise development costs and financing demands, while the arrival of approved therapies raises the efficacy and convenience benchmarks that new entrants must meet.

Industry Chain Analysis

The MASH Drug industry chain begins with pharmaceutical raw materials, active

pharmaceutical ingredients, specialty intermediates and modality-specific manufacturing technologies. Small-molecule programs depend on chemical synthesis and formulation capabilities, while peptide and protein therapies require biologic or peptide production systems, and RNA/oligonucleotide therapies require sequence design, oligonucleotide synthesis, conjugation and liver-targeted delivery technologies. In the midstream, value creation is concentrated in target validation, candidate selection, clinical development, fibrosis and metabolic endpoint demonstration, regulatory approval, scale-up manufacturing and lifecycle management. Because MASH is a chronic disease with heterogeneous metabolic and fibrotic characteristics, the ability to generate evidence across both liver-specific and cardiometabolic outcomes is becoming increasingly valuable. Downstream commercialization involves hepatology and gastroenterology practices, metabolic and obesity-care networks, specialty pharmacy channels and healthcare systems. Market value therefore depends not only on drug efficacy, but also on patient identification, fibrosis staging, reimbursement access, treatment persistence and the ability to integrate therapy into multidisciplinary chronic-disease management.

Segment Insights

By mechanism, THR- α agonists and GLP-1 receptor agonists currently represent the most commercially advanced MASH Drug segments because each class now has an FDA-approved therapy for moderate-to-advanced fibrosis. Beyond these categories, the pipeline remains highly diversified. FGF21 analogs, GLP-1/glucagon dual receptor agonists and pan-PPAR agonists are positioned around combined liver and metabolic effects, while FASN inhibitors and galectin-3 inhibitors focus more directly on pathways associated with lipid synthesis, fibrogenesis or advanced disease. RNA and oligonucleotide approaches provide an additional mechanism layer through genetically linked targets.

From a product-form perspective, oral therapies have an important convenience advantage for long-term chronic management, while injectable peptide/protein drugs can leverage strong metabolic efficacy and established treatment behavior in obesity and diabetes. From a development-status perspective, approved MASH drugs currently represent a relatively concentrated segment, whereas investigational candidates remain much broader in both mechanism and modality. From a patient perspective, F2-F3 noncirrhotic MASH is the principal commercial treatment segment today, while F4 compensated cirrhosis is becoming one of the most strategically important development areas.

Downstream Market Opportunities

The downstream opportunity is increasingly defined by patient phenotype rather than liver disease alone. Patients with F2-F3 fibrosis remain the core pharmacological treatment population, but MASH patients with obesity or type 2 diabetes create a particularly important overlap between hepatology and metabolic medicine. Therapies capable of addressing liver disease together with weight, glycemic or broader cardiometabolic risk factors may therefore have advantages in multidisciplinary treatment pathways. At the other end of the disease spectrum, patients with compensated cirrhosis represent a high-unmet-need population and an important extension opportunity for antifibrotic, metabolic and combination approaches if ongoing development programs establish sufficient clinical benefit.

Regional Insights

North America is currently the most commercially advanced MASH Drug region. The United States established the first dedicated pharmacological treatment market with FDA approval of Rezdiffra in March 2024 and subsequently broadened mechanism choice through approval of Wegovy for MASH in August 2025. This early regulatory transition has placed the U.S. at the center of initial physician adoption, patient-identification practices and commercial access development.

Europe entered the commercialization stage after Rezdiffra received conditional European Union marketing authorization in August 2025, with rollout occurring on a country-by-country basis. The regional market is therefore moving from clinical development toward commercial access, although reimbursement structures and launch timing can vary across countries. In other regions, future market development will depend more strongly on local regulatory approvals, fibrosis-diagnosis capacity, reimbursement systems and the ability to identify high-risk patients within large obesity and type 2 diabetes populations.

Competitive Landscape Analysis

The competitive landscape is shifting from a single-product market toward a layered structure combining commercial products, late-stage metabolic therapies, liver-targeted small molecules and genetically directed treatments. Madrigal Pharmaceuticals established the first-mover position with Rezdiffra, while Novo Nordisk introduced a GLP-1-based treatment route through Wegovy. Roche is building a late-stage FGF21 position around pegozafermin, and Boehringer Ingelheim, Inventiva and Altimune are advancing survodutide, lanifibranor and pemvidutide through late-stage development.

Viking Therapeutics provides additional THR-? competition through VK2809, while Alnylam Pharmaceuticals and Regeneron Pharmaceuticals are pursuing gene-silencing programs against HSD17B13, PNPLA3 and CIDEA. Galectin Therapeutics is differentiated by its focus on belatacept for MASH cirrhosis and portal hypertension, whereas Sagimet Biosciences is developing the FASN inhibitor denifanstat and exploring combination development with resmetirom. The strategic direction of competition is therefore moving beyond simple entry into MASH toward mechanism differentiation, fibrosis-stage expansion, metabolic benefit and potential combination positioning.

Report Scope

LPI (LP Information)' newest research report, the "MASH Drug Industry Forecast" looks at past sales and reviews total world MASH Drug sales in 2025, providing a comprehensive analysis by region and market sector of projected MASH Drug sales for 2026 through 2032. With MASH Drug sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world MASH Drug industry.

This Insight Report provides a comprehensive analysis of the global MASH Drug landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on MASH Drug portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global MASH Drug market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for MASH Drug and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global MASH Drug.

This report presents a comprehensive overview, market shares, and growth opportunities of MASH Drug market by product type, application, key players and key regions and countries.

Market Segmentation

Segmentation by Type:

THR-? Agonists

GLP-1 Receptor Agonists

Other

Segmentation by Drug Classification:

Small Molecule Drugs

Peptide and Protein Drugs

Segmentation by Route of Administration:

Oral Drugs

Subcutaneous Injectable Drugs

Intravenous Injectable Drugs

Segmentation by Application:

MASH with Compensated Cirrhosis (F4)

MASH with Obesity

MASH with Type 2 Diabetes

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Novo Nordisk

Madrigal Pharmaceuticals

Roche

Boehringer Ingelheim

Inventiva

Viking Therapeutics

Altimune

Alnylam Pharmaceuticals

Regeneron Pharmaceuticals

Galectin Therapeutics

Sagimet Biosciences

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