

Global Fatty Liver Disease Drugs Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global Fatty Liver Disease Drugs market size is predicted to grow from US\$ 1227 million in 2025 to US\$ 4418 million in 2032; it is expected to grow at a CAGR of 17.8% from 2026 to 2032.

Fatty Liver Disease Drugs are pharmacological products developed to treat steatotic liver diseases characterized by abnormal hepatic fat accumulation, metabolic dysfunction, inflammation and progressive fibrosis. The research scope focuses on approved and investigational therapies for metabolic dysfunction-associated steatotic liver disease (MASLD), metabolic dysfunction-associated steatohepatitis (MASH), noncirrhotic MASH with moderate-to-advanced fibrosis, compensated MASH cirrhosis, alcohol-associated steatotic liver disease, and fatty liver disease associated with obesity or type 2 diabetes. Major product modalities include small-molecule drugs, peptide and protein therapeutics, RNA-based medicines and combination regimens, delivered primarily through oral tablets or subcutaneous injection. Principal mechanisms include thyroid hormone receptor beta activation, GLP-1 and multi-receptor metabolic agonism, PPAR modulation, FGF21 analog activity, fatty acid synthase inhibition, RNA interference and other metabolic or antifibrotic pathways. The market therefore covers both liver-directed therapies that act on hepatic lipid metabolism and fibrosis and systemic metabolic therapies that improve weight, insulin resistance and associated cardiometabolic risk.

Key Findings

The average gross profit margin of this product is 35%

Two targeted MASH therapies are approved across the United States and Europe

Rezdiffra treated more than 36,250 patients by year-end 2025

F2–F3 noncirrhotic MASH remains the core commercial treatment population

Phase III pipelines span PPAR, FGF21 and dual receptor agonists

Oral and injectable mechanisms are progressing toward combination treatment

Market Trends

The Fatty Liver Disease Drugs market is transitioning from symptom management and control of associated metabolic conditions toward disease-modifying pharmacotherapy supported by histological, imaging and biomarker evidence. The approval of an oral liver-directed thyroid hormone receptor beta agonist established a targeted treatment pathway, while the subsequent approval of injectable semaglutide demonstrated that systemic metabolic intervention can also improve MASH and fibrosis. Development strategies are consequently moving toward a dual approach: reducing hepatic fat, inflammation and fibrosis directly while simultaneously addressing obesity, insulin resistance, dyslipidaemia and cardiovascular risk. Pipeline activity is broadening from single-pathway small molecules to long-acting FGF21 analogs, PPAR agonists, GLP-1/glucagon or other multi-receptor peptides, fatty acid synthase inhibitors and RNA-based therapies. Non-invasive tests are also becoming increasingly important for patient identification, fibrosis staging and treatment monitoring, reducing reliance on liver biopsy in routine clinical pathways. Over the longer term, treatment is likely to become more stratified by fibrosis stage, metabolic phenotype and response profile, with combination regimens used to address the multiple biological drivers of disease progression.

Market Dynamics

Drivers

Growth in Fatty Liver Disease Drugs is primarily supported by the increasing clinical overlap between fatty liver disease, obesity, type 2 diabetes, dyslipidaemia and cardiovascular risk. The availability of the first approved MASH therapies has created a defined pharmaceutical treatment market and is encouraging healthcare systems to establish clearer diagnosis, referral and reimbursement pathways. Improved awareness among hepatologists, endocrinologists and primary-care physicians is expanding the

identifiable treatment population, while advances in elastography, blood-based fibrosis tests and imaging-based liver-fat assessment are making high-risk patients easier to detect. Positive regulatory precedents in the United States and Europe also reduce development uncertainty for candidates capable of demonstrating MASH resolution, fibrosis improvement or reduced liver-related clinical events.

Restraints

Commercial expansion remains constrained by underdiagnosis, as early MASLD and MASH frequently progress without specific symptoms and many patients are identified only after substantial fibrosis has developed. Liver biopsy remains an important clinical-trial endpoint but is invasive, costly and unsuitable for broad population screening, while non-invasive diagnostic thresholds are not yet applied uniformly across healthcare systems. Treatment affordability and reimbursement assessment may also limit early uptake, particularly where payers require evidence of advanced fibrosis or specialist confirmation. In addition, approved therapies require continued verification of long-term clinical benefit, and tolerability, drug interactions, treatment duration and adherence can influence real-world adoption. These factors create a substantial gap between the total disease population and the population that is formally diagnosed, eligible and treated.

Opportunities

The most important opportunity lies in expanding treatment beyond noncirrhotic F2–F3 MASH into earlier-stage high-risk disease, compensated MASH cirrhosis and other steatotic liver disorders. Multiple programs are evaluating therapies in advanced fibrosis or cirrhosis, where clinical need remains high and available pharmacological options are limited. Combination treatment represents another major opportunity, particularly regimens pairing a liver-directed antifibrotic agent with a metabolic drug that produces weight loss and glycaemic improvement. Additional potential exists in alcohol-associated steatotic liver disease, obesity- and diabetes-associated fatty liver, and treatment models based on non-invasive patient selection. Markets in which metabolic disease prevalence is high but specialist diagnosis and drug penetration remain relatively low also provide substantial room for future commercial development.

Challenges

Fatty liver disease is biologically heterogeneous, and improvements in liver fat or inflammatory activity do not always translate directly into durable fibrosis regression or fewer clinical events. Developers must therefore conduct long, complex and costly trials

that often require histological endpoints followed by confirmatory outcomes studies. Competitive differentiation will become more difficult as therapies with different mechanisms target overlapping F2–F3 populations, requiring evidence not only of efficacy but also of safety, dosing convenience, weight and cardiometabolic benefits, compatibility with combination treatment and sustained real-world adherence. Regulatory standards may continue to evolve as more drugs enter the market, while differences in diagnostic practice and reimbursement policy could produce uneven adoption across regions.

Industry Chain Analysis

The upstream chain for Fatty Liver Disease Drugs includes medicinal chemistry platforms, peptide and protein engineering, RNA synthesis, active pharmaceutical ingredients, excipients, delivery devices, analytical reagents and contract development and manufacturing services. Small-molecule products depend on scalable chemical synthesis and formulation capabilities, while peptide, protein and RNA therapies require more specialized production, purification, cold-chain and quality-control systems. Diagnostic companies and clinical laboratories also play an increasingly important upstream-enabling role by providing fibrosis biomarkers, imaging support and companion patient-selection tools.

The midstream segment covers target discovery, preclinical development, clinical trials, regulatory registration, commercial manufacturing and lifecycle management. The main value is created through intellectual property, differentiated mechanisms, histological and outcomes evidence, manufacturing reliability and access to specialist treatment networks rather than through raw-material inputs alone. Downstream demand is generated by hospitals, hepatology and endocrinology departments, obesity and diabetes clinics, specialty pharmacies and integrated metabolic-care programs. Commercial performance depends on connecting non-invasive screening with specialist confirmation, payer authorization and long-term treatment monitoring, making diagnosis infrastructure and market access integral parts of the pharmaceutical value chain.

Segment Insights

By product modality, the commercial market is currently anchored by oral small-molecule therapy and subcutaneous peptide therapy. Oral thyroid hormone receptor beta agonists provide a liver-directed approach with convenient daily administration, while GLP-1 receptor agonists address MASH through weight reduction and broader metabolic improvement. Within the investigational pipeline, peptide and protein

therapies are gaining strategic importance because FGF21 analogs and dual or triple metabolic receptor agonists may influence liver fat, inflammation, fibrosis and systemic metabolic risk simultaneously. Small molecules nevertheless remain important because of their manufacturing scalability, oral dosing potential and suitability for combination regimens.

By mechanism, thyroid hormone receptor beta agonists and GLP-1 receptor agonists represent the first established commercial classes. PPAR agonists, FGF21 analogs and dual incretin or glucagon receptor agonists form the most advanced competitive group behind them, while fatty acid synthase inhibitors, RNA interference therapeutics and other antifibrotic agents provide differentiated development routes. By development status, approved and marketed drugs account for a narrow set of mechanisms, whereas Phase II and Phase III pipelines remain substantially more diverse. This structure indicates that future growth will depend less on expansion of a single drug class and more on clinical differentiation across disease stage, metabolic profile, dosing format and combination potential.

Downstream Market Opportunities

The principal downstream opportunity is the treatment of adults with noncirrhotic MASH and moderate-to-advanced fibrosis, where the first regulatory approvals have established a clinically defined and commercially addressable population. Further demand can emerge from patients with compensated cirrhosis, high-risk MASLD identified through non-invasive testing, and fatty liver associated with obesity or type 2 diabetes. Integrated care involving hepatology, endocrinology, cardiology and weight-management services is particularly relevant because many eligible patients have multiple metabolic comorbidities. Alcohol-associated steatotic liver disease may become an additional development area as therapies capable of reducing inflammation and fibrosis are evaluated across broader liver-disease populations. The largest downstream value will be created by treatment pathways that identify patients earlier, match therapy to fibrosis and metabolic risk, and maintain long-term adherence.

Regional Insights

North America is currently the most developed commercial region for Fatty Liver Disease Drugs. The United States established the first dedicated MASH approval in March 2024, followed by approval of semaglutide for MASH in August 2025. Early prescribing experience, specialist liver networks and the expansion of payer coverage have given the region a leading position in treated-patient volume and commercial

adoption. By year-end 2025, Madrigal reported that more than 36,250 patients were receiving Rezdiffra, illustrating the speed with which a previously untreated pharmaceutical category began to form.

Europe entered a broader commercialization phase after conditional authorizations for Rezdiffra in August 2025 and Kayshild in March 2026. Uptake is expected to vary by country because health-technology assessment, specialist referral pathways and reimbursement decisions remain decentralized. Asia-Pacific represents a significant long-term expansion opportunity, supported by the development of regional PPAR, FGF21, fatty acid synthase and metabolic agonist programs. China and India have active domestic development or commercialization platforms, but differences in diagnosis rates, regulatory status, affordability and reimbursement will continue to shape market access.

Report Scope

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

This Insight Report provides a comprehensive analysis of the global Fatty Liver Disease Drugs 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 Fatty Liver Disease Drugs portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Fatty Liver Disease Drugs market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Fatty Liver Disease Drugs 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 Fatty Liver Disease Drugs.

This report presents a comprehensive overview, market shares, and growth

opportunities of Fatty Liver Disease Drugs market by product type, application, key players and key regions and countries.

Market Segmentation

Segmentation by Type:

Small-Molecule Drugs

Peptide and Protein Drugs

RNA-Based Therapeutics

Other

Segmentation by Route of Administration:

Oral Drugs

Subcutaneous Injectable Drugs

Other Injectable Drugs

Segmentation by Disease:

Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

MASH with Moderate-to-Advanced Fibrosis

Compensated MASH Cirrhosis

Other

Segmentation by Application:

Hospitals

Retail Pharmacies

Others

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.

Madrigal Pharmaceuticals

Novo Nordisk

Zydus Lifescience

Inventiva

Chia Tai Tianqing Pharmaceutical

Boehringer Ingelheim

Zealand Pharma

Roche

GSK

Eli Lilly

Viking Therapeutics

Amylam Pharmaceutical

Regeneron Pharmaceuticals

Sagimet Biosciences

Contents

1 SCOPE OF THE REPORT

- 1.1 Market Introduction
- 1.2 Years Considered
- 1.3 Research Objectives
- 1.4 Market Research Methodology
- 1.5 Research Process and Data Source
- 1.6 Economic Indicators
- 1.7 Currency Considered
- 1.8 Market Estimation Caveats

2 EXECUTIVE SUMMARY

- 2.1 World Market Overview
 - 2.1.1 Global Fatty Liver Disease Drugs Market Size (2021-2032)
 - 2.1.2 Fatty Liver Disease Drugs Market Size CAGR by Region (2021 VS 2025 VS 2032)
 - 2.1.3 World Current & Future Analysis for Fatty Liver Disease Drugs by Country/Region (2021, 2025 & 2032)
- 2.2 Fatty Liver Disease Drugs Segment by Type
 - 2.2.1 Small-Molecule Drugs
 - 2.2.2 Peptide and Protein Drugs
 - 2.2.3 RNA-Based Therapeutics
 - 2.2.4 Other
 - 2.2.5 Fatty Liver Disease Drugs Market Size by Type
 - 2.2.5.1 Fatty Liver Disease Drugs Market Size CAGR by Type (2021 VS 2025 VS 2032)
 - 2.2.5.2 Global Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)
- 2.3 Fatty Liver Disease Drugs Segment by Route of Administration
 - 2.3.1 Oral Drugs
 - 2.3.2 Subcutaneous Injectable Drugs
 - 2.3.3 Other Injectable Drugs
 - 2.3.4 Fatty Liver Disease Drugs Market Size by Route of Administration
 - 2.3.4.1 Fatty Liver Disease Drugs Market Size CAGR by Route of Administration (2021 VS 2025 VS 2032)
 - 2.3.4.2 Global Fatty Liver Disease Drugs Market Size Market Share by Route of

Administration (2021-2026)

2.4 Fatty Liver Disease Drugs Segment by Disease

2.4.1 Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)

2.4.2 Metabolic Dysfunction-Associated Steatohepatitis (MASH)

2.4.3 MASH with Moderate-to-Advanced Fibrosis

2.4.4 Compensated MASH Cirrhosis

2.4.5 Other

2.4.6 Fatty Liver Disease Drugs Market Size by Disease

2.4.6.1 Fatty Liver Disease Drugs Market Size CAGR by Disease (2021 VS 2025 VS 2032)

2.4.6.2 Global Fatty Liver Disease Drugs Market Size Market Share by Disease (2021-2026)

2.5 Fatty Liver Disease Drugs Segment by Application

2.5.1 Hospitals

2.5.2 Retail Pharmacies

2.5.3 Others

2.5.4 Fatty Liver Disease Drugs Market Size by Application

2.5.4.1 Fatty Liver Disease Drugs Market Size CAGR by Application (2021 VS 2025 VS 2032)

2.5.4.2 Global Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

3 FATTY LIVER DISEASE DRUGS MARKET SIZE BY PLAYER

3.1 Fatty Liver Disease Drugs Market Size Market Share by Player

3.1.1 Global Fatty Liver Disease Drugs Revenue by Player (2021-2026)

3.1.2 Global Fatty Liver Disease Drugs Revenue Market Share by Player (2021-2026)

3.2 Global Fatty Liver Disease Drugs Key Players Head office and Products Offered

3.3 Market Concentration Rate Analysis

3.3.1 Competition Landscape Analysis

3.3.2 Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

3.4 New Products and Potential Entrants

3.5 Mergers & Acquisitions, Expansion

4 FATTY LIVER DISEASE DRUGS BY REGION

4.1 Fatty Liver Disease Drugs Market Size by Region (2021-2026)

4.2 Global Fatty Liver Disease Drugs Annual Revenue by Country/Region (2021-2026)

4.3 Americas Fatty Liver Disease Drugs Market Size Growth (2021-2026)

4.4 APAC Fatty Liver Disease Drugs Market Size Growth (2021-2026)

4.5 Europe Fatty Liver Disease Drugs Market Size Growth (2021-2026)

4.6 Middle East & Africa Fatty Liver Disease Drugs Market Size Growth (2021-2026)

5 AMERICAS

5.1 Americas Fatty Liver Disease Drugs Market Size by Country (2021-2026)

5.2 Americas Fatty Liver Disease Drugs Market Size by Type (2021-2026)

5.3 Americas Fatty Liver Disease Drugs Market Size by Application (2021-2026)

5.4 United States

5.5 Canada

5.6 Mexico

5.7 Brazil

6 APAC

6.1 APAC Fatty Liver Disease Drugs Market Size by Region (2021-2026)

6.2 APAC Fatty Liver Disease Drugs Market Size by Type (2021-2026)

6.3 APAC Fatty Liver Disease Drugs Market Size by Application (2021-2026)

6.4 China

6.5 Japan

6.6 South Korea

6.7 Southeast Asia

6.8 India

6.9 Australia

7 EUROPE

7.1 Europe Fatty Liver Disease Drugs Market Size by Country (2021-2026)

7.2 Europe Fatty Liver Disease Drugs Market Size by Type (2021-2026)

7.3 Europe Fatty Liver Disease Drugs Market Size by Application (2021-2026)

7.4 Germany

7.5 France

7.6 UK

7.7 Italy

7.8 Russia

8 MIDDLE EAST & AFRICA

- 8.1 Middle East & Africa Fatty Liver Disease Drugs by Region (2021-2026)
- 8.2 Middle East & Africa Fatty Liver Disease Drugs Market Size by Type (2021-2026)
- 8.3 Middle East & Africa Fatty Liver Disease Drugs Market Size by Application (2021-2026)
- 8.4 Egypt
- 8.5 South Africa
- 8.6 Israel
- 8.7 Turkey
- 8.8 GCC Countries

9 MARKET DRIVERS, CHALLENGES AND TRENDS

- 9.1 Market Drivers & Growth Opportunities
- 9.2 Market Challenges & Risks
- 9.3 Industry Trends

10 GLOBAL FATTY LIVER DISEASE DRUGS MARKET FORECAST

- 10.1 Global Fatty Liver Disease Drugs Forecast by Region (2027-2032)
 - 10.1.1 Global Fatty Liver Disease Drugs Forecast by Region (2027-2032)
 - 10.1.2 Americas Fatty Liver Disease Drugs Forecast
 - 10.1.3 APAC Fatty Liver Disease Drugs Forecast
 - 10.1.4 Europe Fatty Liver Disease Drugs Forecast
 - 10.1.5 Middle East & Africa Fatty Liver Disease Drugs Forecast
- 10.2 Americas Fatty Liver Disease Drugs Forecast by Country (2027-2032)
 - 10.2.1 United States Market Fatty Liver Disease Drugs Forecast
 - 10.2.2 Canada Market Fatty Liver Disease Drugs Forecast
 - 10.2.3 Mexico Market Fatty Liver Disease Drugs Forecast
 - 10.2.4 Brazil Market Fatty Liver Disease Drugs Forecast
- 10.3 APAC Fatty Liver Disease Drugs Forecast by Region (2027-2032)
 - 10.3.1 China Fatty Liver Disease Drugs Market Forecast
 - 10.3.2 Japan Market Fatty Liver Disease Drugs Forecast
 - 10.3.3 Korea Market Fatty Liver Disease Drugs Forecast
 - 10.3.4 Southeast Asia Market Fatty Liver Disease Drugs Forecast
 - 10.3.5 India Market Fatty Liver Disease Drugs Forecast
 - 10.3.6 Australia Market Fatty Liver Disease Drugs Forecast
- 10.4 Europe Fatty Liver Disease Drugs Forecast by Country (2027-2032)
 - 10.4.1 Germany Market Fatty Liver Disease Drugs Forecast
 - 10.4.2 France Market Fatty Liver Disease Drugs Forecast

- 10.4.3 UK Market Fatty Liver Disease Drugs Forecast
- 10.4.4 Italy Market Fatty Liver Disease Drugs Forecast
- 10.4.5 Russia Market Fatty Liver Disease Drugs Forecast
- 10.5 Middle East & Africa Fatty Liver Disease Drugs Forecast by Region (2027-2032)
 - 10.5.1 Egypt Market Fatty Liver Disease Drugs Forecast
 - 10.5.2 South Africa Market Fatty Liver Disease Drugs Forecast
 - 10.5.3 Israel Market Fatty Liver Disease Drugs Forecast
 - 10.5.4 Turkey Market Fatty Liver Disease Drugs Forecast
- 10.6 Global Fatty Liver Disease Drugs Forecast by Type (2027-2032)
- 10.7 Global Fatty Liver Disease Drugs Forecast by Application (2027-2032)
 - 10.7.1 GCC Countries Market Fatty Liver Disease Drugs Forecast

11 KEY PLAYERS ANALYSIS

11.1 Madrigal Pharmaceuticals

- 11.1.1 Madrigal Pharmaceuticals Company Information
- 11.1.2 Madrigal Pharmaceuticals Fatty Liver Disease Drugs Product Offered
- 11.1.3 Madrigal Pharmaceuticals Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
- 11.1.4 Madrigal Pharmaceuticals Main Business Overview
- 11.1.5 Madrigal Pharmaceuticals Latest Developments

11.2 Novo Nordisk

- 11.2.1 Novo Nordisk Company Information
- 11.2.2 Novo Nordisk Fatty Liver Disease Drugs Product Offered
- 11.2.3 Novo Nordisk Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
- 11.2.4 Novo Nordisk Main Business Overview
- 11.2.5 Novo Nordisk Latest Developments

11.3 Zydus Lifescience

- 11.3.1 Zydus Lifescience Company Information
- 11.3.2 Zydus Lifescience Fatty Liver Disease Drugs Product Offered
- 11.3.3 Zydus Lifescience Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
- 11.3.4 Zydus Lifescience Main Business Overview
- 11.3.5 Zydus Lifescience Latest Developments

11.4 Inventiva

- 11.4.1 Inventiva Company Information
- 11.4.2 Inventiva Fatty Liver Disease Drugs Product Offered
- 11.4.3 Inventiva Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share

(2021-2026)

11.4.4 Inventiva Main Business Overview

11.4.5 Inventiva Latest Developments

11.5 Chia Tai Tianqing Pharmaceutical

11.5.1 Chia Tai Tianqing Pharmaceutical Company Information

11.5.2 Chia Tai Tianqing Pharmaceutical Fatty Liver Disease Drugs Product Offered

11.5.3 Chia Tai Tianqing Pharmaceutical Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)

11.5.4 Chia Tai Tianqing Pharmaceutical Main Business Overview

11.5.5 Chia Tai Tianqing Pharmaceutical Latest Developments

11.6 Boehringer Ingelheim

11.6.1 Boehringer Ingelheim Company Information

11.6.2 Boehringer Ingelheim Fatty Liver Disease Drugs Product Offered

11.6.3 Boehringer Ingelheim Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)

11.6.4 Boehringer Ingelheim Main Business Overview

11.6.5 Boehringer Ingelheim Latest Developments

11.7 Zealand Pharma

11.7.1 Zealand Pharma Company Information

11.7.2 Zealand Pharma Fatty Liver Disease Drugs Product Offered

11.7.3 Zealand Pharma Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)

11.7.4 Zealand Pharma Main Business Overview

11.7.5 Zealand Pharma Latest Developments

11.8 Roche

11.8.1 Roche Company Information

11.8.2 Roche Fatty Liver Disease Drugs Product Offered

11.8.3 Roche Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)

11.8.4 Roche Main Business Overview

11.8.5 Roche Latest Developments

11.9 GSK

11.9.1 GSK Company Information

11.9.2 GSK Fatty Liver Disease Drugs Product Offered

11.9.3 GSK Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)

11.9.4 GSK Main Business Overview

11.9.5 GSK Latest Developments

11.10 Eli Lilly

- 11.10.1 Eli Lilly Company Information
- 11.10.2 Eli Lilly Fatty Liver Disease Drugs Product Offered
- 11.10.3 Eli Lilly Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
- 11.10.4 Eli Lilly Main Business Overview
- 11.10.5 Eli Lilly Latest Developments
- 11.11 Viking Therapeutics
 - 11.11.1 Viking Therapeutics Company Information
 - 11.11.2 Viking Therapeutics Fatty Liver Disease Drugs Product Offered
 - 11.11.3 Viking Therapeutics Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
 - 11.11.4 Viking Therapeutics Main Business Overview
 - 11.11.5 Viking Therapeutics Latest Developments
- 11.12 Alnylam Pharmaceutical
 - 11.12.1 Alnylam Pharmaceutical Company Information
 - 11.12.2 Alnylam Pharmaceutical Fatty Liver Disease Drugs Product Offered
 - 11.12.3 Alnylam Pharmaceutical Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
 - 11.12.4 Alnylam Pharmaceutical Main Business Overview
 - 11.12.5 Alnylam Pharmaceutical Latest Developments
- 11.13 Regeneron Pharmaceuticals
 - 11.13.1 Regeneron Pharmaceuticals Company Information
 - 11.13.2 Regeneron Pharmaceuticals Fatty Liver Disease Drugs Product Offered
 - 11.13.3 Regeneron Pharmaceuticals Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
 - 11.13.4 Regeneron Pharmaceuticals Main Business Overview
 - 11.13.5 Regeneron Pharmaceuticals Latest Developments
- 11.14 Sagimet Biosciences
 - 11.14.1 Sagimet Biosciences Company Information
 - 11.14.2 Sagimet Biosciences Fatty Liver Disease Drugs Product Offered
 - 11.14.3 Sagimet Biosciences Fatty Liver Disease Drugs Revenue, Gross Margin and Market Share (2021-2026)
 - 11.14.4 Sagimet Biosciences Main Business Overview
 - 11.14.5 Sagimet Biosciences Latest Developments

12 RESEARCH FINDINGS AND CONCLUSION

List Of Tables

LIST OF TABLES

Table 1. Fatty Liver Disease Drugs Market Size CAGR by Region (2021 VS 2025 VS 2032) & (\$ millions)

Table 2. Fatty Liver Disease Drugs Annual Sales CAGR by Country/Region (2021, 2025 & 2032) & (\$ millions)

Table 3. Major Players of Small-Molecule Drugs

Table 4. Major Players of Peptide and Protein Drugs

Table 5. Major Players of RNA-Based Therapeutics

Table 6. Major Players of Other

Table 7. Fatty Liver Disease Drugs Market Size CAGR by Type (2021 VS 2025 VS 2032) & (\$ millions)

Table 8. Global Fatty Liver Disease Drugs Market Size by Type (2021-2026) & (\$ millions)

Table 9. Global Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)

Table 10. Major Players of Oral Drugs

Table 11. Major Players of Subcutaneous Injectable Drugs

Table 12. Major Players of Other Injectable Drugs

Table 13. Fatty Liver Disease Drugs Market Size CAGR by Route of Administration (2021 VS 2025 VS 2032) & (\$ millions)

Table 14. Global Fatty Liver Disease Drugs Market Size by Route of Administration (2021-2026) & (\$ millions)

Table 15. Global Fatty Liver Disease Drugs Market Size Market Share by Route of Administration (2021-2026)

Table 16. Major Players of Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)

Table 17. Major Players of Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Table 18. Major Players of MASH with Moderate-to-Advanced Fibrosis

Table 19. Major Players of Compensated MASH Cirrhosis

Table 20. Major Players of Other

Table 21. Fatty Liver Disease Drugs Market Size CAGR by Disease (2021 VS 2025 VS 2032) & (\$ millions)

Table 22. Global Fatty Liver Disease Drugs Market Size by Disease (2021-2026) & (\$ millions)

Table 23. Global Fatty Liver Disease Drugs Market Size Market Share by Disease (2021-2026)

Table 24. Fatty Liver Disease Drugs Market Size CAGR by Application (2021 VS 2025 VS 2032) & (\$ millions)

Table 25. Global Fatty Liver Disease Drugs Market Size by Application (2021-2026) & (\$ millions)

Table 26. Global Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

Table 27. Global Fatty Liver Disease Drugs Revenue by Player (2021-2026) & (\$ millions)

Table 28. Global Fatty Liver Disease Drugs Revenue Market Share by Player (2021-2026)

Table 29. Fatty Liver Disease Drugs Key Players Head office and Products Offered

Table 30. Fatty Liver Disease Drugs Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

Table 31. New Products and Potential Entrants

Table 32. Mergers & Acquisitions, Expansion

Table 33. Global Fatty Liver Disease Drugs Market Size by Region (2021-2026) & (\$ millions)

Table 34. Global Fatty Liver Disease Drugs Market Size Market Share by Region (2021-2026)

Table 35. Global Fatty Liver Disease Drugs Revenue by Country/Region (2021-2026) & (\$ millions)

Table 36. Global Fatty Liver Disease Drugs Revenue Market Share by Country/Region (2021-2026)

Table 37. Americas Fatty Liver Disease Drugs Market Size by Country (2021-2026) & (\$ millions)

Table 38. Americas Fatty Liver Disease Drugs Market Size Market Share by Country (2021-2026)

Table 39. Americas Fatty Liver Disease Drugs Market Size by Type (2021-2026) & (\$ millions)

Table 40. Americas Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)

Table 41. Americas Fatty Liver Disease Drugs Market Size by Application (2021-2026) & (\$ millions)

Table 42. Americas Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

Table 43. APAC Fatty Liver Disease Drugs Market Size by Region (2021-2026) & (\$ millions)

Table 44. APAC Fatty Liver Disease Drugs Market Size Market Share by Region (2021-2026)

Table 45. APAC Fatty Liver Disease Drugs Market Size by Type (2021-2026) & (\$ millions)

Table 46. APAC Fatty Liver Disease Drugs Market Size by Application (2021-2026) & (\$ millions)

Table 47. Europe Fatty Liver Disease Drugs Market Size by Country (2021-2026) & (\$ millions)

Table 48. Europe Fatty Liver Disease Drugs Market Size Market Share by Country (2021-2026)

Table 49. Europe Fatty Liver Disease Drugs Market Size by Type (2021-2026) & (\$ millions)

Table 50. Europe Fatty Liver Disease Drugs Market Size by Application (2021-2026) & (\$ millions)

Table 51. Middle East & Africa Fatty Liver Disease Drugs Market Size by Region (2021-2026) & (\$ millions)

Table 52. Middle East & Africa Fatty Liver Disease Drugs Market Size by Type (2021-2026) & (\$ millions)

Table 53. Middle East & Africa Fatty Liver Disease Drugs Market Size by Application (2021-2026) & (\$ millions)

Table 54. Key Market Drivers & Growth Opportunities of Fatty Liver Disease Drugs

Table 55. Key Market Challenges & Risks of Fatty Liver Disease Drugs

Table 56. Key Industry Trends of Fatty Liver Disease Drugs

Table 57. Global Fatty Liver Disease Drugs Market Size Forecast by Region (2027-2032) & (\$ millions)

Table 58. Global Fatty Liver Disease Drugs Market Size Market Share Forecast by Region (2027-2032)

Table 59. Global Fatty Liver Disease Drugs Market Size Forecast by Type (2027-2032) & (\$ millions)

Table 60. Global Fatty Liver Disease Drugs Market Size Forecast by Application (2027-2032) & (\$ millions)

Table 61. Madrigal Pharmaceuticals Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 62. Madrigal Pharmaceuticals Fatty Liver Disease Drugs Product Offered

Table 63. Madrigal Pharmaceuticals Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 64. Madrigal Pharmaceuticals Main Business

Table 65. Madrigal Pharmaceuticals Latest Developments

Table 66. Novo Nordisk Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 67. Novo Nordisk Fatty Liver Disease Drugs Product Offered

Table 68. Novo Nordisk Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 69. Novo Nordisk Main Business

Table 70. Novo Nordisk Latest Developments

Table 71. Zydus Lifescience Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 72. Zydus Lifescience Fatty Liver Disease Drugs Product Offered

Table 73. Zydus Lifescience Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 74. Zydus Lifescience Main Business

Table 75. Zydus Lifescience Latest Developments

Table 76. Inventiva Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 77. Inventiva Fatty Liver Disease Drugs Product Offered

Table 78. Inventiva Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 79. Inventiva Main Business

Table 80. Inventiva Latest Developments

Table 81. Chia Tai Tianqing Pharmaceutical Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 82. Chia Tai Tianqing Pharmaceutical Fatty Liver Disease Drugs Product Offered

Table 83. Chia Tai Tianqing Pharmaceutical Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 84. Chia Tai Tianqing Pharmaceutical Main Business

Table 85. Chia Tai Tianqing Pharmaceutical Latest Developments

Table 86. Boehringer Ingelheim Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 87. Boehringer Ingelheim Fatty Liver Disease Drugs Product Offered

Table 88. Boehringer Ingelheim Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 89. Boehringer Ingelheim Main Business

Table 90. Boehringer Ingelheim Latest Developments

Table 91. Zealand Pharma Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 92. Zealand Pharma Fatty Liver Disease Drugs Product Offered

Table 93. Zealand Pharma Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 94. Zealand Pharma Main Business

Table 95. Zealand Pharma Latest Developments

Table 96. Roche Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 97. Roche Fatty Liver Disease Drugs Product Offered

Table 98. Roche Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 99. Roche Main Business

Table 100. Roche Latest Developments

Table 101. GSK Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 102. GSK Fatty Liver Disease Drugs Product Offered

Table 103. GSK Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 104. GSK Main Business

Table 105. GSK Latest Developments

Table 106. Eli Lilly Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 107. Eli Lilly Fatty Liver Disease Drugs Product Offered

Table 108. Eli Lilly Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 109. Eli Lilly Main Business

Table 110. Eli Lilly Latest Developments

Table 111. Viking Therapeutics Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 112. Viking Therapeutics Fatty Liver Disease Drugs Product Offered

Table 113. Viking Therapeutics Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 114. Viking Therapeutics Main Business

Table 115. Viking Therapeutics Latest Developments

Table 116. Alnylam Pharmaceutical Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 117. Alnylam Pharmaceutical Fatty Liver Disease Drugs Product Offered

Table 118. Alnylam Pharmaceutical Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 119. Alnylam Pharmaceutical Main Business

Table 120. Alnylam Pharmaceutical Latest Developments

Table 121. Regeneron Pharmaceuticals Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 122. Regeneron Pharmaceuticals Fatty Liver Disease Drugs Product Offered

Table 123. Regeneron Pharmaceuticals Fatty Liver Disease Drugs Revenue (\$ million),

Gross Margin and Market Share (2021-2026)

Table 124. Regeneron Pharmaceuticals Main Business

Table 125. Regeneron Pharmaceuticals Latest Developments

Table 126. Sagimet Biosciences Details, Company Type, Fatty Liver Disease Drugs Area Served and Its Competitors

Table 127. Sagimet Biosciences Fatty Liver Disease Drugs Product Offered

Table 128. Sagimet Biosciences Fatty Liver Disease Drugs Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 129. Sagimet Biosciences Main Business

Table 130. Sagimet Biosciences Latest Developments

List Of Figures

LIST OF FIGURES

- Figure 1. Fatty Liver Disease Drugs Report Years Considered
- Figure 2. Research Objectives
- Figure 3. Research Methodology
- Figure 4. Research Process and Data Source
- Figure 5. Global Fatty Liver Disease Drugs Market Size Growth Rate (2021-2032) (\$ millions)
- Figure 6. Fatty Liver Disease Drugs Sales by Geographic Region (2021, 2025 & 2032) & (\$ millions)
- Figure 7. Fatty Liver Disease Drugs Sales Market Share by Country/Region (2025)
- Figure 8. Fatty Liver Disease Drugs Sales Market Share by Country/Region (2021, 2025 & 2032)
- Figure 9. Global Fatty Liver Disease Drugs Market Size Market Share by Type in 2025
- Figure 10. Global Fatty Liver Disease Drugs Market Size Market Share by Route of Administration in 2025
- Figure 11. Global Fatty Liver Disease Drugs Market Size Market Share by Disease in 2025
- Figure 12. Fatty Liver Disease Drugs in Hospitals
- Figure 13. Global Fatty Liver Disease Drugs Market: Hospitals (2021-2026) & (\$ millions)
- Figure 14. Fatty Liver Disease Drugs in Retail Pharmacies
- Figure 15. Global Fatty Liver Disease Drugs Market: Retail Pharmacies (2021-2026) & (\$ millions)
- Figure 16. Fatty Liver Disease Drugs in Others
- Figure 17. Global Fatty Liver Disease Drugs Market: Others (2021-2026) & (\$ millions)
- Figure 18. Global Fatty Liver Disease Drugs Market Size Market Share by Application in 2025
- Figure 19. Global Fatty Liver Disease Drugs Revenue Market Share by Player in 2025
- Figure 20. Global Fatty Liver Disease Drugs Market Size Market Share by Region (2021-2026)
- Figure 21. Americas Fatty Liver Disease Drugs Market Size 2021-2026 (\$ millions)
- Figure 22. APAC Fatty Liver Disease Drugs Market Size 2021-2026 (\$ millions)
- Figure 23. Europe Fatty Liver Disease Drugs Market Size 2021-2026 (\$ millions)
- Figure 24. Middle East & Africa Fatty Liver Disease Drugs Market Size 2021-2026 (\$ millions)
- Figure 25. Americas Fatty Liver Disease Drugs Value Market Share by Country in 2025

Figure 26. United States Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 27. Canada Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 28. Mexico Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 29. Brazil Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 30. APAC Fatty Liver Disease Drugs Market Size Market Share by Region in 2025

Figure 31. APAC Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)

Figure 32. APAC Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

Figure 33. China Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 34. Japan Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 35. South Korea Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 36. Southeast Asia Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 37. India Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 38. Australia Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 39. Europe Fatty Liver Disease Drugs Market Size Market Share by Country in 2025

Figure 40. Europe Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)

Figure 41. Europe Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

Figure 42. Germany Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 43. France Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 44. UK Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 45. Italy Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 46. Russia Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)

Figure 47. Middle East & Africa Fatty Liver Disease Drugs Market Size Market Share by Region (2021-2026)

Figure 48. Middle East & Africa Fatty Liver Disease Drugs Market Size Market Share by Type (2021-2026)

Figure 49. Middle East & Africa Fatty Liver Disease Drugs Market Size Market Share by Application (2021-2026)

- Figure 50. Egypt Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)
- Figure 51. South Africa Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)
- Figure 52. Israel Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)
- Figure 53. Turkey Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)
- Figure 54. GCC Countries Fatty Liver Disease Drugs Market Size Growth 2021-2026 (\$ millions)
- Figure 55. Americas Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 56. APAC Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 57. Europe Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 58. Middle East & Africa Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 59. United States Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 60. Canada Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 61. Mexico Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 62. Brazil Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 63. China Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 64. Japan Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 65. Korea Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 66. Southeast Asia Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 67. India Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 68. Australia Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 69. Germany Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 70. France Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 71. UK Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 72. Italy Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 73. Russia Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 74. Egypt Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 75. South Africa Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 76. Israel Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 77. Turkey Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)
- Figure 78. Global Fatty Liver Disease Drugs Market Size Market Share Forecast by Type (2027-2032)
- Figure 79. Global Fatty Liver Disease Drugs Market Size Market Share Forecast by Application (2027-2032)
- Figure 80. GCC Countries Fatty Liver Disease Drugs Market Size 2027-2032 (\$ millions)

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