

PharmaSynapse Report — metformin

AI Executive Summary

Metformin, an established generic drug for Type 2 Diabetes, shows promising repurposing potential in Non-Alcoholic Fatty Liver Disease (NAFLD). While the core molecule is off-patent, a robust ecosystem of new patents for derivatives, combinations, and novel uses exists. The US market for metformin is stable at approximately \$850.5 million with a modest 3.2% CAGR, driven by shifts towards fixed-dose combinations and use in prediabetes/insulin resistance. A key Phase 2 trial for Metformin in NAFLD is actively recruiting, supported by internal strategy focused on leveraging NAFLD trial signals for market access and emphasizing metabolic comorbidities with HCPs. Supply chain is heavily reliant on India and China, necessitating diversification strategies. Overcoming the off-label perception and demonstrating compelling Real-World Evidence (RWE) are critical for market penetration in NAFLD.

Strategic Recommendations

- Accelerate clinical development for Metformin in NAFLD, prioritizing the active Phase 2 trial and planning for subsequent phases
- Develop a comprehensive HEOR (Health Economics and Outcomes Research) and RWE strategy specifically for Metformin
- Explore strategic partnerships or licensing opportunities with companies holding patents for novel Metformin formulations (e.g., extended-release)
- Implement an aggressive market access strategy targeting top US payers with outcomes-based contracts, emphasizing the clinical benefits for NAFLD
- Diversify the Metformin API supply chain by identifying alternative sourcing options beyond India and China, or explore near-shore manufacturing
- Invest in targeted physician education and communication programs to address the off-label perception of Metformin in NAFLD

Market (IQVIA mock)

US | \$850.5M | 3.2% CAGR | 3 comps

Patent Landscape

- Total: 20 | Active: 20 | Expired: 0
- Patent landscape for metformin: 20 relevant patents identified (20 active, 0 expired, 0 pending). This view is based on live PatentsView data.

Clinical Trials

- NCT00011111 | Phase 2 | Recruiting | Non-alcoholic fatty liver disease
NCT00022222 | Phase 3 | Active, not recruiting | Obesity with insulin resistance
NCT00033333 | Phase 4 | Completed | Prediabetes

Web Intelligence (guidelines/RWE/news)

- Comprehensive web intelligence for metformin in NAFLD: 18 sources across 6 regulatory updates, 6 scientific publications, and 1 news article.

EXIM Trade

- EXIM trends for Metformin: exports \$89.5M, imports \$29.5M. Top exporter: India; top importer: US.

Internal Documents

- Metformin NAFLD Strategy Deck (Q1) | strategy_deck | 2024
Field Insights â€“ Metformin (Nov) | field_report | 2024