

# Nonalcoholic Steatohepatitis - Pipeline Insight, 2021

<https://marketpublishers.com/r/N1F5F26C9BDEN.html>

Date: May 2021

Pages: 230

Price: US\$ 3,000.00 (Single User License)

ID: N1F5F26C9BDEN

## Abstracts

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DelveInsight's, "Nonalcoholic Steatohepatitis - Pipeline Insight, 2021," report provides comprehensive insights about 140+ companies and 140+ pipeline drugs in Nonalcoholic Steatohepatitis pipeline landscape. It covers the pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

### Geography Covered

Global coverage

### Nonalcoholic Steatohepatitis Understanding

#### Nonalcoholic Steatohepatitis: Overview

Nonalcoholic steatohepatitis (NASH) is liver inflammation and damage caused by a fat buildup in the liver. It is part of a group of conditions called nonalcoholic fatty liver disease. Nonalcoholic fatty liver disease can be divided into the isolated fatty liver in which there is only accumulation of fat, and nonalcoholic steatohepatitis (NASH), in which there is fat, inflammation, and damage to liver cells. In NASH, there is an abnormal amount of fat in the liver cells, but, in addition, in NASH, there is inflammation within the liver, and, as a result, the liver cells are damaged, they die, and are replaced by scar tissue. NASH usually does not cause symptoms. Most people who have NASH feel fine and do not know that they have it. As NASH progresses and liver damage gets worse, a patient may start to have symptoms such as Fatigue, Weight loss, General

weakness, and acne in the upper right part of the belly.

'Nonalcoholic Steatohepatitis - Pipeline Insight, 2021' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Nonalcoholic Steatohepatitis pipeline landscape is provided which includes the disease overview and Nonalcoholic Steatohepatitis treatment guidelines. The assessment part of the report embraces, in depth Nonalcoholic Steatohepatitis commercial assessment and clinical assessment of the pipeline products under development. In the report, detailed description of the drug is given which includes mechanism of action of the drug, clinical studies, NDA approvals (if any), and product development activities comprising the technology, Nonalcoholic Steatohepatitis collaborations, licensing, mergers and acquisition, funding, designations and other product related details.

## Report Highlights

The companies and academics are working to assess challenges and seek opportunities that could influence Nonalcoholic Steatohepatitis R&D. The therapies under development are focused on novel approaches to treat/improve Nonalcoholic Steatohepatitis.

## Nonalcoholic Steatohepatitis Emerging Drugs Chapters

This segment of the Nonalcoholic Steatohepatitis report encloses its detailed analysis of various drugs in different stages of clinical development, including phase II, I, preclinical and Discovery. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press releases.

## Nonalcoholic Steatohepatitis Emerging Drugs

### Semaglutide: Novo Nordisk

Semaglutide is a long-acting GLP-1 analog intended as a once-daily treatment for Nonalcoholic fatty liver disease (NASH). It is currently in the phase III stage of development for NASH and is being developed by Novo Nordisk.

### Resmetirom: Madrigal Pharmaceuticals

Resmetirom (MGL-3196) is a first-in-class, orally-administered, small-molecule, liver-directed thyroid hormone receptor (THR)  $\alpha$ -selective agonist. Preclinical, toxicology, Phase 1, and Phase 2 clinical data suggest resmetirom has an attractive, differentiated profile as a potential treatment for Nonalcoholic steatohepatitis (NASH), Nonalcoholic fatty liver disease (NAFLD) and associated dyslipidemias. THR- $\alpha$  selectivity also enhances the safety profile of resmetirom, compared to non-selective agents. Resmetirom has shown neither suppression of the central thyroid axis nor THR- $\alpha$  effects on heart rate or bone, reducing elevated liver enzymes in NASH patients. It is currently in the Phase III stage of development for Nonalcoholic steatohepatitis and is being developed by Madrigal Pharmaceuticals.

### Oltipraz: PharmaKing

Oltipraz is currently in the Phase III stage of development for nonalcoholic steatohepatitis (NASH). It is being developed by Pharmaking and acts as Glutathione transferase stimulants, Liver X receptor antagonists, NQO1 stimulants, and Ribosomal protein S6 kinase modulators.

### ALS-L1023: AngioLab

ALS L1023 is a dried extract of ethyl acetate, prepared by activity-guided fractionation from Melissa leaf (lemon balm). The Angiogenesis Inhibitor ALS-L1023 from Lemon-Balm Leaves Attenuates High-Fat Diet-Induced Nonalcoholic Fatty Liver Disease through Regulating the Visceral Adipose-Tissue Function. The drug is currently being investigated in Phase II clinical trials for the treatment of patients with Nonalcoholic Steatohepatitis.

### ORMD-0801: Oramed

Oramed's oral insulin (ORMD-0801) has the potential to create a new paradigm in the treatment of diabetes and Nonalcoholic Steatohepatitis by oral delivery of insulin at an earlier stage of treatment, potentially slowing disease progression and delaying or even eliminating late-stage complications. A Phase II clinical trial is currently being evaluated

for ORMD-801 in the patients with Nonalcoholic Steatohepatitis.

### CB4211: CohBar

CB4211 is our novel, refined analog of MOTS-c, a naturally occurring mitochondrial peptide. MOTS-c plays a significant role in the regulation of metabolism. CB4211 also inhibits adipocyte lipolysis, a process that is foundational in the development of liver steatosis, through an insulin-dependent mechanism. The drug is being developed and investigated by CohBar in Phase I for the treatment of Nonalcoholic Steatohepatitis.

Further product details are provided in the report

### Nonalcoholic Steatohepatitis: Therapeutic Assessment

This segment of the report provides insights about the different Nonalcoholic Steatohepatitis drugs segregated based on following parameters that define the scope of the report, such as:

#### Major Players in Nonalcoholic Steatohepatitis

There are approx. 140+ key companies which are developing the therapies for Nonalcoholic Steatohepatitis. The companies which have their Nonalcoholic Steatohepatitis drug candidates in the most advanced stage, i.e. phase III include, Madrigal Pharmaceuticals.

#### Phases

DelveInsight's report covers around 140+ products under different phases of clinical development like

Late stage products (Phase III)

Mid-stage products (Phase II)

Early-stage product (Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Nonalcoholic Steatohepatitis pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Oral

Parenteral

Intravenous

Subcutaneous

Topical

Molecule Type

Products have been categorized under various Molecule types such as

Monoclonal Antibody

Peptides

Hepatoprotectant

Small molecule

Cell therapy

Antisense oligonucleotides

Recombinant proteins

Small interfering RNA

Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

Nonalcoholic Steatohepatitis: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Nonalcoholic Steatohepatitis therapeutic drugs key players involved in developing key drugs.

Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging Nonalcoholic Steatohepatitis drugs.

Nonalcoholic Steatohepatitis Report Insights

Nonalcoholic Steatohepatitis Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

Nonalcoholic Steatohepatitis Report Assessment

Pipeline Product Profiles

Therapeutic Assessment

Pipeline Assessment

Inactive drugs assessment

Unmet Needs

## Key Questions

### Current Treatment Scenario and Emerging Therapies:

How many companies are developing Nonalcoholic Steatohepatitis drugs?

How many Nonalcoholic Steatohepatitis drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Nonalcoholic Steatohepatitis?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Nonalcoholic Steatohepatitis therapeutics?

What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for Nonalcoholic Steatohepatitis and their status?

What are the key designations that have been granted to the emerging drugs?

## Key Players

Novo Nordisk

Madrigal Pharmaceuticals

PharmaKing

Cirius Therapeutics

Inventiva Pharma

Galmed Pharmaceuticals

AbbVie

Galectin Therapeutics

Viking Therapeutics

Sagimet Biosciences

Novartis

Hepion Pharmaceuticals

Celgene

Boston Pharmaceuticals

Bristol-Myers Squibb

NGM Biopharmaceuticals

Boehringer Ingelheim

Axcella Health

Corcept Therapeutics

TaiwanJ Pharmaceuticals

AngioLab

Oramed

Can-Fite Biopharma



Mitsubishi Tanabe Pharma

MediciNova

Merck Sharp & Dohme

Metacrine

MedImmune

Lipocine

Chemomab Therapeutics

Afimmune

NorthSea Therapeutics

Rivus Pharmaceuticals

HighTide Biopharma

Hanmi Pharmaceutical

ENYO Pharma

Histogen

Akero Therapeutics

Enanta Pharmaceuticals

Gilead Sciences

Ionis Pharmaceuticals

Eli Lilly and Company

Terns Pharmaceuticals

Sinew Pharma

Poxel

CytoDyn

Future Medicine

89bio Ltd.

HK inno.N

Arrowhead Pharmaceuticals

Promethera Biosciences

Enanta Pharmaceuticals

## Key Products

Semaglutide

Resmetirom

Oltipraz

MSDC-0602K

Lanifibranor

Aramchol

Cenicriviroc

Belapectin

VK2809

TVB-2640

Tropifexor (LJN452)

CRV431

CC-90001

BOS-580

BMS-986263

Aldafermin

BI 456906

AXA1125

Miricorilant

JKB-122

ALS-L1023

ORMD-0801

Namodenoson

MN-001

MT-3995

MK-3655

MET642

MEDI 0382

LYS006

LPCN 1144

CM101

Epeleuton

Icosabutate

HU6

HTD1801

HM15211

EPY001a

Emricasan

Efruxifermin (EFX)

EDP-305

Firsocostat

ION224

Tirzepatide

TERN-101

SNP-610

PXL770

Leronlimab

FM101

BIO89-100

IN-A010

ARO-HSD

HepaStem

EDP-297

## Contents

- Introduction
- Executive Summary
- Nonalcoholic Steatohepatitis: Overview
  - Causes
  - Mechanism of Action
  - Signs and Symptoms
  - Diagnosis
  - Disease Management
- Pipeline Therapeutics
  - Comparative Analysis
- Therapeutic Assessment
  - Assessment by Product Type
  - Assessment by Stage and Product Type
  - Assessment by Route of Administration
  - Assessment by Stage and Route of Administration
  - Assessment by Molecule Type
  - Assessment by Stage and Molecule Type
- Nonalcoholic Steatohepatitis – DelveInsight's Analytical Perspective
- In-depth Commercial Assessment
  - Nonalcoholic Steatohepatitis companies' collaborations, Licensing, Acquisition -Deal
- Value Trends
- Nonalcoholic Steatohepatitis Collaboration Deals
  - Company-Company Collaborations (Licensing / Partnering) Analysis
  - Company-University Collaborations (Licensing / Partnering) Analysis
- Late Stage Products (Phase III)
  - Comparative Analysis
- Resmetirom: Madrigal Pharmaceuticals
  - Product Description
  - Research and Development
  - Product Development Activities
- Drug profiles in the detailed report.....
- Mid Stage Products (Phase II)
  - Comparative Analysis
- ALS-L1023: AngioLab
  - Product Description
  - Research and Development
  - Product Development Activities

Drug profiles in the detailed report.....

Early Stage Products (Phase I)

Comparative Analysis

CB4211: CohBar

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Preclinical and Discovery Stage Products

Comparative Analysis

ALG-055009: Aligos Therapeutics

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Inactive Products

Comparative Analysis

Nonalcoholic Steatohepatitis Key Companies

Nonalcoholic Steatohepatitis Key Products

Nonalcoholic Steatohepatitis- Unmet Needs

Nonalcoholic Steatohepatitis- Market Drivers and Barriers

Nonalcoholic Steatohepatitis- Future Perspectives and Conclusion

Nonalcoholic Steatohepatitis Analyst Views

Nonalcoholic Steatohepatitis Key Companies

Appendix

## List Of Tables

### LIST OF TABLES

- Table 1 Total Products for Nonalcoholic Steatohepatitis
- Table 2 Late Stage Products
- Table 3 Mid Stage Products
- Table 4 Early Stage Products
- Table 5 Pre-clinical & Discovery Stage Products
- Table 6 Assessment by Product Type
- Table 7 Assessment by Stage and Product Type
- Table 8 Assessment by Route of Administration
- Table 9 Assessment by Stage and Route of Administration
- Table 10 Assessment by Molecule Type
- Table 11 Assessment by Stage and Molecule Type
- Table 12 Inactive Products



## List Of Figures

### LIST OF FIGURES

- Figure 1 Total Products for Nonalcoholic Steatohepatitis
- Figure 2 Late Stage Products
- Figure 3 Mid Stage Products
- Figure 4 Early Stage Products
- Figure 5 Preclinical and Discovery Stage Products
- Figure 6 Assessment by Product Type
- Figure 7 Assessment by Stage and Product Type
- Figure 8 Assessment by Route of Administration
- Figure 9 Assessment by Stage and Route of Administration
- Figure 10 Assessment by Molecule Type
- Figure 11 Assessment by Stage and Molecule Type
- Figure 12 Inactive Products

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