



# Corvidane

An Innovative Approach to Treating  
Heart and Liver Diseases



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# INTRODUCTION



Corvidane is developing Corvida™, a safe and effective drug to prevent both...

...the two leading causes of death globally...



...and the #1 cause of liver transplants in the U.S.



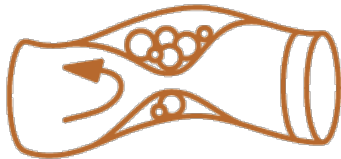
The potential to address these unmet needs makes Corvidane a unique investment opportunity.

# THE PROBLEM



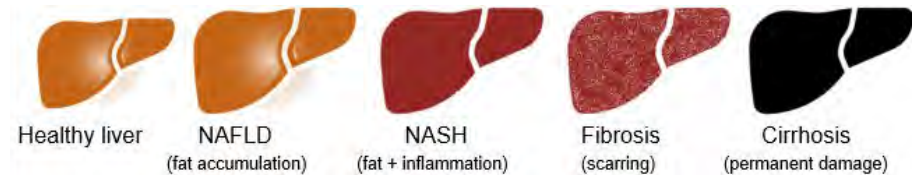
Diseases of lipid metabolism and inflammation

## Atherosclerosis (*ath·er·o·scler·osis*)



The buildup of **fats** and cholesterol (i.e., plaque) in artery walls that, when accompanied by **inflammation**, obstructs blood flow. A major factor in **heart attacks** and **strokes**, the leading causes of death globally.

## Nonalcoholic Steatohepatitis (NASH)



An accumulation of excess liver **fat** accompanied by **inflammation** and cell damage, which can cause fibrosis and lead to cirrhosis and liver cancer. NASH is the leading cause of **liver transplants** in the U.S.

# THE SOLUTION



A drug that is safe and can improve lipid metabolism and reduce inflammation.

Corvida™ contains two fatty acids: an Omega-7 and an Omega-9. Both are Generally Recognized as Safe (GRAS) by the FDA.

Omega-7  
(Palmitoleic acid)

- Associated with preventing atherosclerosis and non-fatal heart attacks. 6,7,8
- Improves metabolic function of the liver and associated with improved insulin sensitivity. 9,10

Omega-9  
(Oleic acid)

- Associated with low blood pressure.
- Has beneficial effects on autoimmune and inflammatory diseases. 11,12

# HOW IT WORKS



Studies have shown that some Omega-7s and Omega-9s can improve lipid metabolism by making the lipids in the body more fluid or easier to metabolize. We selected Omega 7s and Omega 9s that also have anti-inflammatory properties to maximize the health benefit.



**Corvida™ is not an Omega-3 fatty acid medication, which are often used to reduce triglyceride levels in the body.**

Corvida™ uses Omega-7 and Omega-9 fatty acids which are smaller (less carbon atoms) and more capable of entering cells. Omega-3s have multiple double bonds and are more easily oxidized or otherwise damaged.

Fatty Acid	Omega	Size	Double Bonds
Palmitoleic	7	16 Carbon Atoms	1
Oleic	9	18 Carbon Atoms	1
EPA	3	20 Carbon Atoms	5
DHA	3	22 Carbon Atoms	6

# RESEARCH AND PATENTS



Completed studies have demonstrated Corvida™'s potential as a new therapy for cardiovascular and metabolic diseases.

Patents issued in the U.S. and Japan for Atherosclerosis



## The Cleveland Clinic

Corvida™ effective in treating atherosclerosis in ApoE-/- mice



## Case Western Reserve University

Improved metabolic processing of lipids in rodent model



## University of Hawaii

Proved human safety of diet high in monounsaturated fats; Improved lipid profile



## TNO

Active pharmaceutical ingredient sourced from algae superior in ApoE3 mice



U.S. Patent issued for “a composition and method to treat atherosclerosis”.



Japan Patent Granted for “Composition and Use for Treating Atherosclerosis.”

Atherosclerosis patent applications pending in The EU, China, India, Brazil and Canada.

NASH provisional application filed in the U.S.

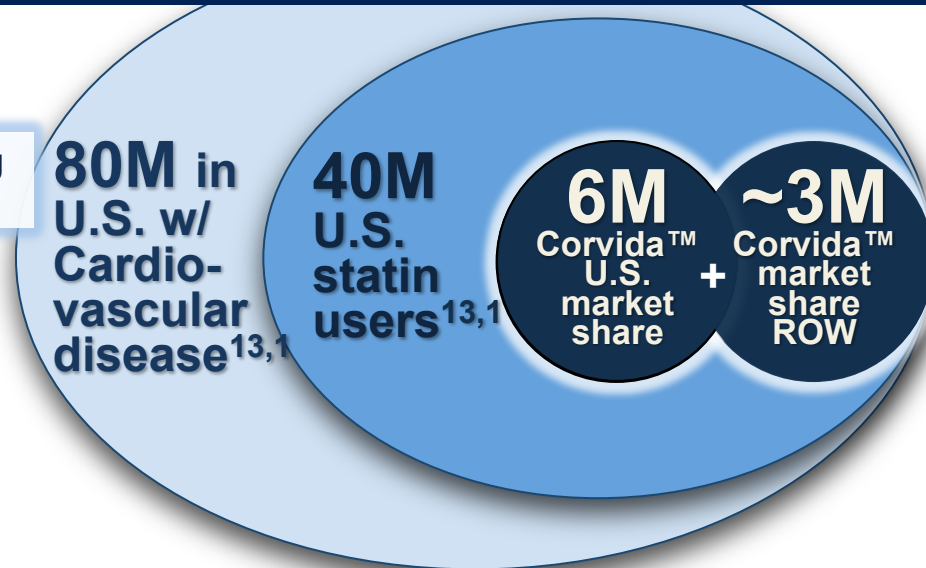


# THE MARKETS



## Atherosclerosis

Targeting at-risk population actively using cholesterol lowering (statin) therapies.

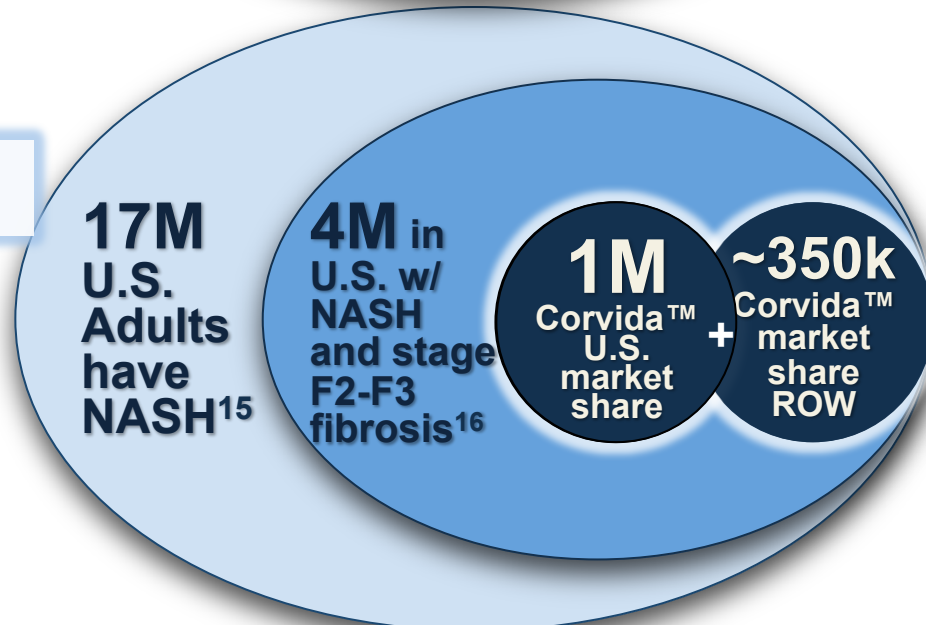


## NASH

Targeting NASH Patients with or without Type 2 Diabetes\*.



Up to 60% of Type 2 Diabetics have NAFLD or NASH<sup>14</sup>





# THE TEAM



**Dr. Paresh Soni, MD, PhD – CEO & Chief Medical Officer**

- 20+ years executive pharmaceutical experience, including **Amarin**, Alexion, Pfizer and Albireo. Led NDA approval of Vascepa®.



**Damion J. Boyer – Co-Founder & COO**

- 6 years as Corvidane CEO. Initiated Corvidane's NASH program and forged strategic alliances in the U.S. and Europe



**Peggy J. Berry – Vice President of Regulatory Affairs**

- 28 years of regulatory experience, incl. 5 years with **Amarin**. Developed and implemented regulatory strategy for **Vascepa®**.



**Patrice Binay, PhD – Vice President of Chemistry and Manufacturing**

- 32 years of pharmaceutical fine chemistry experience.



**Neal Sharpe, PhD – Vice President of PreClinical Services**

- 32 years of pharmaceutical experience that includes Biogen, Merck and Schering-Plough.



**Menno Van Burken, PharmD – Vice President of Commercial Strategies**

- 32 years of pharmaceutical experience, including 17 years with Pfizer.



**John M. Burke - Co-Founder and Inventor of Corvida™**

- 46 years chemical engineering expertise

# THE COMPETITION



Corvida™ has the potential to treat both **Atherosclerosis** and **NASH**.  
Corvida™ targets fat accumulation and inflammation while also reducing triglycerides and cholesterol levels.

## Atherosclerosis



### Amarin – Vascepa® (Icosapent Ethyl)

- Derived from EPA, an Omega-3 fatty acid sourced from fish.
- Originally approved to lower triglycerides.
- Shows the most potential of approved drugs to treat atherosclerosis (EVAPORATE study).



### Affimune – Epaleuton® (15 hydroxy EPA)

- Synthetic derivative of EPA
- Reported to show decreases in Atherosclerotic plaques in the LDLr-/- mouse
- Shown to lower triglycerides and help regulate insulin/glucose in humans

## NASH



### Northsea Therapeutics – Icosabutate

- Derived from EPA, an omega-3 fatty acid sourced from fish
- Currently in Phase 2 human studies targeting NASH patients with F2-F3 fibrosis
- Reduces triglyceride levels, but may increase cholesterol levels

# BUSINESS MODEL



## Return on investment through the sale or license of Corvida™

Major pharmaceutical companies some times innovate through licensing or acquisition of smaller companies when the groundwork is completed and the venture has been de-risked, often after Phase 2 studies.

Promising fatty acid therapeutics have fueled significant business development activity:



Astra Zeneca acquired Omthera for \$343M for their omega-3 fatty acid drug Epanova®.



GSK acquired Reliant Pharmaceuticals for \$1.7B for their omega-3 fatty acid drug Lovaza®.



Northsea Therapeutics licensed Pronova's Omega-3 compound, raised a total of €65M to conduct clinical studies.



Gilead combined Amarin's omega-3 fatty acid drug Vascepa® for inclusion in their NASH combo therapy trials.

Corvidane is well-positioned to take advantage of this model.

# USE OF FUNDS



Corvidane is raising funds to obtain more data and a formal FDA response for Corvida™'s Regulatory path:

Health~  
Holland



\$280k releases ~ \$700k in subsidies for studies with University Medical Center Utrecht:

- Use genetic analysis of Corvida™'s effect on human tissues/cells to predict Corvida™'s efficacy in humans
- Demonstrate Corvida™'s ability to treat both Atherosclerosis and NASH simultaneously in the LDLr-/- mouse

These data will be used for PreIND meetings with the FDA.



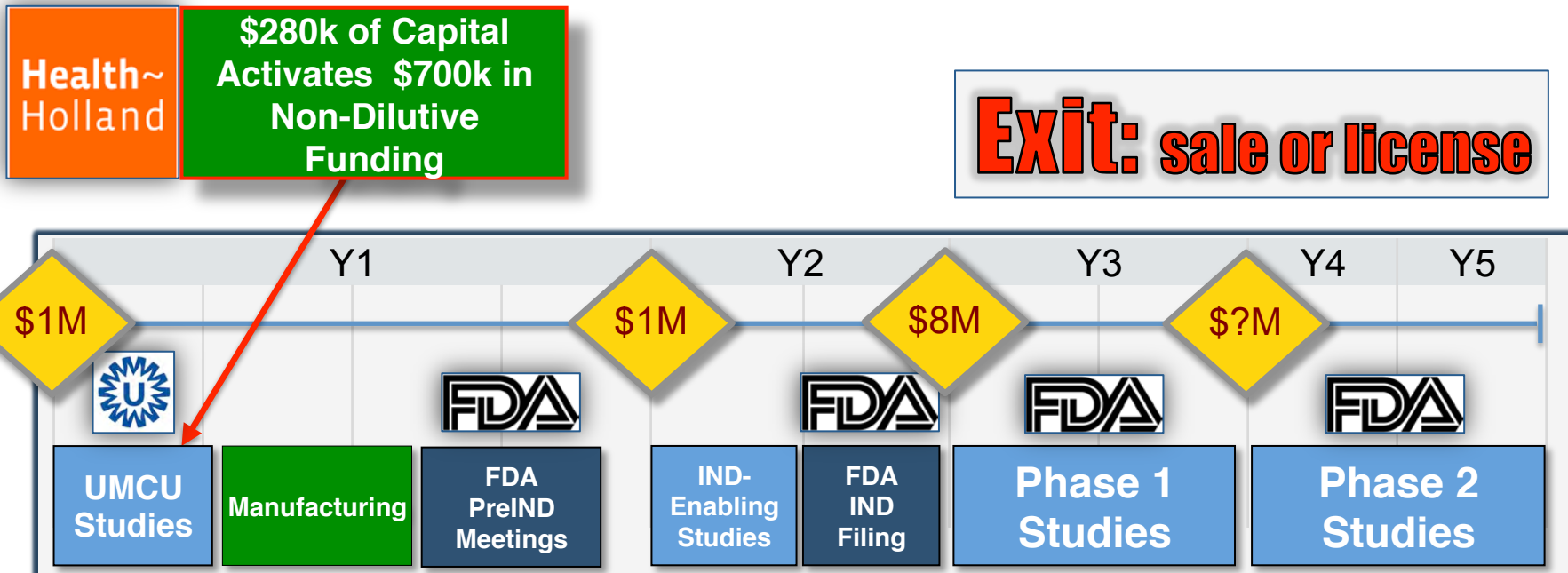
Funds will also be used for:

- Admin/Operations
  - Legal, Accounting, Market Research
- Manufacturing / CMC
- Pharmacokinetic and Toxicology Studies
- Personnel

# RETURN ON INVESTMENT



Our goal is to deliver investors' ROI within 3-5 years. This is most likely to occur after Phase 2 studies, but may occur sooner.



# SUMMARY



**Corvidane is a unique investment opportunity where you can directly improve the lives of millions.**

**Our innovative approach to treat heart and liver diseases is built upon strong Preclinical Science (in-house data and literature studies) and uses molecules with an established safety profile.**

**Our team and partners have the expertise and experience to successfully execute our business strategy and realize a return on your investment.**

**We hope that you will support us in our mission to improve global health.**

# GLOSSARY



## Key Terms and Phrases

**ApoE3 Leiden mouse** – A mouse model developed to study lipid lowering and diabetic drugs

**ApoE-/- mouse** – A mouse model developed to study Atherosclerosis

**Cirrhosis** - Late stage of scarring (Fibrosis) of the liver caused by many forms of liver diseases and conditions

**DHA** - Docosahexaenoic Acid, an Omega-3 fatty acid that contains 22 carbon atoms and 6 double bonds. Often used in combination with EPA

**CMC** – Chemistry, Manufacturing and Controls. Defines the manufacturing process, specifications and stability of the product. Also defines the design, qualification, operation and maintenance of manufacturing facilities and support facilities.

**Double bonds** – A chemical bond between two atoms that share two pairs of electrons. Indicative/Associated with higher oxidation.

**EPA** - EicosaPentaenoic Acid, an Omega-3 fatty acid that contains 20 carbon atoms and 5 double bonds.

**EVAPORATE Study** – A study of Amarin's Vascepa®, a pure form of EPA. This study showed a significant reduction in atherosclerotic plaque levels.

**Fatty Acid** - The building blocks of the fat in our bodies and in the food we eat. During digestion, the body breaks down fats into fatty acids, which can then be absorbed into the blood.

**FDA** – The Food and Drug Administration, a U.S. government agency responsible for assuring the safety of drugs, vaccines and biologics.

**Fibrosis** – The thickening or scarring of tissue. NASH has Fibrosis stages ranging from 0 (None) to 4 (cirrhosis).

**IND Enabling Studies** – Conducted to evaluate potential toxicity risks prior to human studies and to estimate starting doses for clinical trials.

**IND Filing** – Investigational New Drug Application filed for permission to start human clinical trials

**Inflammation** - A localized protective reaction of tissue to irritation, injury, or infection

**Insulin Sensitivity** – Describes how sensitive the body is to insulin. High I.S. allows cells to use blood glucose efficiently, reducing blood sugar.

**LDLr-/- mouse** – Developed for Diabetes, Obesity, Cardiovascular, Metabolism and Lipid Metabolism research. Will develop Atherosclerosis and NASH.

**Lipids** – Fats, waxes, oils, hormones, and certain components of membranes. Function as energy-storage molecules and chemical messengers

**Metabolism** - The breakdown of food and its transformation into energy

**Monounsaturated Fatty Acids** – MUFA have only 1 double bond

**Omega 3, 7, 9** – The Omega number refers to the number of carbon atoms from the terminal end of a fatty acid to the first double bond.

**Oleic Acid** – An Omega-9, monounsaturated fatty acid.

**Oxidize** - Process by which fatty acids are broken down by various tissues to produce energy.

**Palmitoleic Acid** - An Omega 7 Monounsaturated fatty acid

**Pharmacokinetic Study** – Observes how an organism affects a drug (from administration to absorption, distribution, metabolism and excretion from the body).

**Phase 1 Study** – Evaluate a drug's overall safety and determine the safest dose. Usually 20 to 100 healthy volunteers with the disease/condition.

**Phase 2 Study** - Study on a larger group of people (up to several hundred) with the disease/condition, to see if it's safe and effective.

**Phase 3 Study** - Confirm the efficacy of drugs that have successfully completed Phases 1 and 2. Monitor side effects and ensure safe use.

**PreIND Meeting** - A meeting with the FDA to ensure acceptability of a drug development plan and planned human clinical trials.

**Polyunsaturated Fatty Acids** - PUFA that have more than 1 double bond, prone to oxidations, etc.

**ROW** - Rest of the World

**TNO** - The Netherlands Organization for Applied Scientific Research

**Toxicology** – Studies that characterize the toxicity profile of a drug by identifying its impact on organ structure and / or functionality.

**Triglycerides** – A type of fat (lipid) found in your blood. When you eat, your body converts any calories it doesn't need to use right away into triglycerides. The triglycerides are stored in your fat cells. Later, hormones release triglycerides for energy between meals.



# APPENDIX



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Extraordinary Clinical and Commercial success awaits.

“We will meet the challenge.” – Dr. Oheneba Boachie-Adjei

Thank you.

Corvidane

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