# Corvidane

September 15<sup>th</sup>, 2023

A novel approach to treating Cardiovascular and Liver diseases



# Corvidane is using a patented scientific discovery to target TWO multibillion dollar markets.

Our unique approach to address unmet medical needs has created a compelling investment opportunity.

# INTRODUCTION

Corvidane is developing Corvida<sup>™</sup>, a drug to prevent Heart Attacks, Stroke and NASH, the leading cause of liver transplants.



(*ath*·*er*·*o*·*scle*·*ro*·*sis*) The main factor in Heart attack and Stroke, the leading causes of death globally.

NASH (NonAlcoholic Steatohepatitis) is the leading cause of liver transplants in the U.S. and there are <u>NO FDA approved drugs</u>.

1) American Heart Association 2) World Heath Organization 3) America Stroke Association 4) "Nonalcoholic Fatty Liver Disease 2020: The State of the Disease", T.G. Cotter, M. Rinella, Gastroenterology, 2020 May;158(7):1851-1864 5) "Global epidemiology of nonalcoholic fatty liver disease-Meta-analytic assessment of prevalence, incidence, and outcomes", Younossi ZM, Koenig AB, Hepatology 2016;64:73-84



### Diseases of lipid metabolism + inflammation

#### Atherosclerosis





The buildup of fats and cholesterol (plaque) in artery walls that, when accompanied by inflammation, obstructs blood flow.

An accumulation of excess liver fat accompanied by inflammation and cell damage, which can cause fibrosis and lead to cirrhosis and liver cancer.

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SOLUTION

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

Corvida<sup>™</sup> 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 heart attacks.
- Improves metabolic function of the liver and associated with improved insulin sensitivity.

#### OMEGA-9 (oleic acid)

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

Corvida<sup>™</sup> is <u>not</u> an Omega-3 fatty acid drug, which are often used to reduce triglyceride levels in the body





# SOLUTION

We selected Omega-7s and Omega-9s that improve lipid metabolism and have anti-inflammatory properties to maximize the health benefit via multiple pathways.

Omega	Size	Double Bonds
7	16 Carbon Atoms	1
9	18 Carbon Atoms	1
3	20 Carbon Atoms	5
3	22 Carbon Atoms	6
	Omega 7 9 3 3	OmegaSize716 Carbon Atoms918 Carbon Atoms320 Carbon Atoms322 Carbon Atoms

Omega-7 and Omega-9 fatty acids are smaller and more capable of entering cells than Omega-3s.

Corvida<sup>™</sup> is <u>not</u> an Omega-3 fatty acid drug, which are often used to reduce triglyceride levels in the body Omega-7 and Omega-9 fatty acids have fewer double bonds (**Monounsaturated**) and are less easily oxidized or otherwise damaged.



#### ATHEROSCLEROSIS

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

1. "National Trends in Statin Use and Expenditures in the US Adult Population From 2002 to 2013", JAMA Cardiology 2017



MARKETS



#### NASH

Targeting NASH patients with or without Type 2 Diabetes.

UP TO 60% OF TYPE 2 DIABETICS HAVE NAFLD OR NASH.

2. "Non-Alcoholic Steatohepatitis (NASH) – Opportunity Analysis and Forecasts to 2029", GlobalData 2020

### FATTY ACID DRUG M&A ACTIVITY

#### Corvida<sup>™</sup>: SELL, LICENSE OR IPO

Promising fatty acid therapeutics have fueled significant business development activity:

AstraZeneca

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

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

mthera

northsea

PRONOVA

Northsea Therapeutics licensed Pronova's omega-3 compound (Icosabutate), raised ~ €140M since 2017

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

**≢**MARIN

HLS Therapeutics Inc. Pfizer enters into promotional agreement with HLS Therapeutics for Vascepa® in Canada

**Pfizer** 

GILEAD

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# OFFERING

Corvidane is offering Equity to Investors as part of a \$5M Raise. These funds will be used to achieve a significant drug development milestone: Submission of an Investigation New Drug (IND) Application with the FDA to initiate Human Clinical Trials.



Corvidane is actively pursuing a non-dilutive NIH STTR Grant to offset CMC costs (\$1M+). To-date Corvidane has raised \$360k USD with RegCF and a €650k Subsidy for collaboration with University Medical Center Utrecht. Future Investments are intended to only be through institutional investors.



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

An expert in **NASH** with 20+ years executive pharmaceutical experience, including **Amarin**, Alexion, Pfizer and Albireo. Led NDA approval of Vascepa®.



Damion J. Boyer – Co-Founder & COO

Former Corvidane CEO. Initiated Corvidane's NASH program and forged strategic alliances in Europe.

Patrice Binay, PhD – Vice President of Chemistry and Manufacturing

34 years of pharmaceutical fine chemistry experience.



Menno Van Burken, PharmD – Vice President of Commercial Strategy

33 years of pharmaceutical experience, including 17 years with Pfizer.



John M. Burke - Co-Founder and Inventor of Corvida<sup>™</sup>

47 years of Chemical Engineering experience.





HEROSCLEROSIS

# **MARIN**

#### Vascepa® (Icosapent Ethyl)

- Purified Eicosapentaenoic Acid (EPA), an omega-3 fatty acid, not Monounsaturated
- Originally approved to lower triglycerides
- Shows most potential of approved drugs to
  treat atherosclerosis (EVAPORATE study)
- Does not provide benefit in NASH



#### Icosabutate

- Modified Eicosapentaenoic Acid (EPA), an omega-3 fatty acid, not Monounsaturated
- Currently in Phase 2 human studies targeting NASH patients with F2-F3 fibrosis
- Reduces triglyceride levels, but may increase
  LDL cholesterol levels

## INTELLECTUAL PROPERTY

#### Intellectual Property

特許广• Japan

PROPRIEDADE • Brazil

Patents to treat Atherosclerosis Issued:

**USPto** • The United States



NASH patent applications filed in the U.S., Japan and Canada.



#### Corvida<sup>™</sup> studies have shown promising results



Reduction in Atherosclerotic Plaque in the ApoE-/- mouse model



Improved metabolic processing of lipids in rodent model



Effects on Atherogenic Lipids in Humans



Effects on Atherogenic Lipids in ApoE3 mouse model



Ability to treat Atherosclerosis and NASH simultaneously in the LDLr-/- mouse model (awaiting results)



#### Palmitoleic Acid (Omega-7)

#### Oleic Acid (Omega-9)







#### Proof of Concept: Effects on Atherosclerosis in Rodents The Cleveland Clinic Mouse Atherosclerosis Progression Study

•Examined the effects Corvida<sup>™</sup> (CCO) diet vs. Western Diet in ApoE-/- mice; a well- established model for atherosclerotic progression

•Corvida<sup>™</sup> diet replaced 20% standard Western diet fat with Corvida<sup>™</sup>:

- Increased HDL cholesterol by 77% compared to the control group
- •Reduced triglycerides by 11% compared to control group

•Produced significant reductions in atherosclerosis

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Table 2. Aor	Aortic sinus lesion size (mm <sup>2</sup> )		
	Control	Treatment	
Corvida™	$0.33 \pm 0.09$	0.18 ± 0.07**	
Table 3.	Aortic lesion (%)		
	Control	Treatment	
Corvida™	9.63 ± 2.8	3.17 ± 1.6**	
†Rosuvastatin (20mg/kg/c	$day^2$ 21.9 ± 2.9	11.9 ± 1.9*	

Compared to the Control group, \*P<0.05, \*\*P<0.001

+ Enomoto S, Sata M, Fukuda D, et al., "Rosuvastatin prevents endothelial cell death and reduces atherosclerotic lesion formation in ApoE-deficient mice.", Biome Pharmacotherapy. 2007





#### Improved Metabolic Processing of Lipids

#### **Case Western Reserve University**

#### Study of Corvida<sup>™</sup> in an Animal Model

Double blind, 8-week study of 18 Sprague Dawley rats receiving 50% of calories from fat to resemble typical American diet (40%-45% of calories from fat). Three arms of 6 rats each:

- 1. Corvida<sup>™</sup> Diet
- 2. Saturated Fat Diet Lauric acid (C12:0) and Myristic acid (C14:0)
- 3. Oleic acid (C18:1)

Lead Investigator: Dr. Charles Hoppel, M.D.

#### **Results/Conclusions:**

- Corvida<sup>™</sup>'s constituents absorbed into the blood and heart, liver and adipose tissue
- Corvida<sup>™</sup> improves metabolic processing of lipids and glucose resulting in reduced liver fat accumulation and sustained liver function.





#### Improved Metabolic Processing of Lipids

#### Case Western Reserve University

#### Study of Corvida<sup>™</sup> in an Animal Model

Analysis reveals the statistical and physical evidence of Corvida<sup>™</sup>'s ability to improve metabolic function:







#### Proof of Concept: Proof of Concept Effects on Atherogenic Lipids in Humans

#### The University of Hawaii Human Dietary Study

•Used macadamia nuts (high in oleic and palmitoleic acids) compared to typical Western diet

•Subjects were relatively healthy volunteers with well-controlled lipids at baseline (mean baseline LDL-C levels of 130 mg/dl; mean baseline TGs of 80 mg/dl)

•With macadamia nut diet:

•LDL-C was 5.9 mg/dl lower than American diet (p<0.05)

•TGs were 7.1 mg/dl lower than American diet (p<0.05)

•Non-HDL-C is calculated to be 7.4 mg/dl lower than American diet

•Macadamia nut diet was safe and well-tolerated





# Proof of Concept: Effects on Atherogenic Lipids in Rodents TNO

#### **ApoE3\* Leiden Mouse Model Lipids Study**

•ApoE3\*Leiden mouse model is a well-established and validated model for human dyslipidemia and progression of atherosclerosis

•Martek algae oil was tested to western diet. Specifically, 6% Martek algae oil replaced 6% of cacao butter in the Western diet (which is 15% cacao butter).

•Martek algae oil is highly enriched in palmitoleic acid and palmitic acid

•As compared to Western diet, Martek algae oil at 4 weeks

•Reduced total cholesterol by 37%

•Reduced TGs by 44%



# THANK YOU

"We will meet the challenge." - Dr. Oheneba Boachie-Adjei

paresh@Corvidane.com damion@Corvidane.com