

LIPOCINE[®]
ENHANCING HEALTH

CORPORATE PRESENTATION
January 2022

**Enabling Oral Drug Delivery to
Improve Patient Compliance**



Forward-Looking Statements

This presentation contains forward-looking statements about Lipocine Inc. (the “Company”). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company’s products and product candidates, FDA’s approval of TLANDO®, the expected timing of Phase 3 trials for TLANDO® XR and LPCN 1107 and Phase 2 studies for LPCN 1144, LPCN 1148 and LPCN 1154, clinical and regulatory processes and objectives, potential benefits of the Company’s product candidates, intellectual property and related matters, all of which involve known and unknown risks and uncertainties. Actual results may differ materially from the forward-looking statements discussed in this presentation.

Accordingly, the Company cautions investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, this presentation. Several factors may affect the initiation and completion of clinical trials and studies, the potential advantages of the Company’s product candidates and the Company’s capital needs. The forward-looking statements contained in this presentation are qualified by the detailed discussion of risks and uncertainties set forth in the Company’s annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission, all of which can be obtained on the Company’s website at www.lipocine.com or on the SEC website at www.sec.gov. The forward-looking statements contained in this document represent the Company’s estimates and assumptions only as of the date of this presentation and the Company undertakes no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company’s expectations.

Clinical Stage Biopharmaceutical Company

Innovative Product Candidates for Metabolic and Endocrine Disorders

PRODUCT (Indication)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
TLANDO® <i>(Oral Testosterone for Testosterone Replacement Therapy)</i>	Partnered				Final Approval Eligibility March 28, 2022
TLANDO® XR <i>(Long-Acting Oral Testosterone for Testosterone Replacement Therapy)</i>	Partner Option to License			Next Step: Food/Phlebotomy Study	
LPCN 1144 <i>(Oral Testosterone for Non-Cirrhotic NASH)</i>				Next Step: FDA meeting for Path Forward	
LPCN 1148 <i>(Oral Testosterone for Cirrhosis Management)</i>				Next Step: Complete Enrollment in Phase 2 Clinical Study	
LPCN 1107 <i>(Oral HPC for Prevention of PTB)</i>				Next Step: Food Effect Study	
Oral Neurosteroid for CNS disorders			Next Step: PK Study Results		

TLANDO[®]

The Convenient Oral TRT
without Titration Requirement

TLANDO[®] XR

Once Daily Oral TRT



TLANDO® Attributes*

Convenient Oral Route

- No inadvertent transference or pulmonary oil micro embolism risks
- Single strength and dose

TRT without titration requirement

- Enables selection of an effective dose at the start of therapy without delay
- No “efficacy gap” upon switching from other TRTs
- No additional pharmacy and clinic copays to reach efficacious dose
- No dose adjustment clinic and pharmacy visits
- No dose adjustment invasive samplings
- No titration decision errors

Bioequivalent exposure in low/med/high fat food

Not known to produce hepatic adverse events associated with 17-methylated testosterone

*Pending final approval



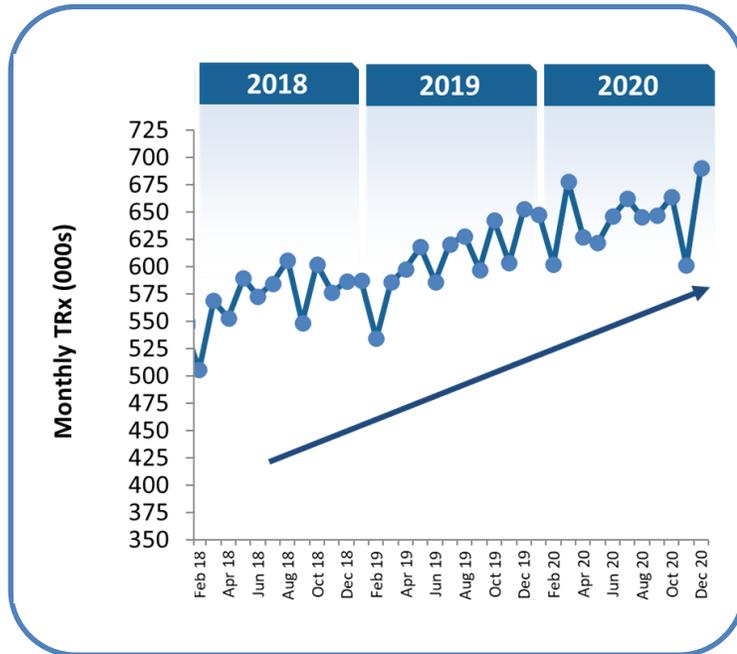
Physician Research: Physicians View No Titration Product as Positive

- Cited “easy/less titration” as an important advantage of TLANDO®
- Finding the adequate TRT dose through titration is burdensome for physicians and patients

TLANDO® Market Potential

Attributes Particularly Attractive for Topical Switch, and Treatment Naive Patients

Overall TRT Market



~7.6M 2020 TRx

Topical Segment

- ~24% of TRT market
- ~1.8M 2020 TRx

Naïve Patient Segment

- 33% of ~2M patients
- ~660K annually

85%
of Physicians

Have a strong interest
in an oral

94%
of TRT Patients

Likelihood to ask
their Doctor about
TLANDO™

TLANDO[®]: Update

Licensed U.S. Rights to Commercialization Partner - Antares Pharma



Economic Interest

Up to \$21.0 million in licensing fees

Commercial sales milestone payments of up to \$160.0 million

Tiered royalties on net sales of TLANDO from mid-teens up to 20%

Licensee to undertake all commercialization, P4 studies, and sourcing



Launch Potential

Targeting 7.6M annual TRx

Unique attributes:

Oral

No titration requirement

Licensee with largest detailing force in TRT space

Licensee with established relationship with payers, KOLs, and physicians



Status

Tentatively approved

Planned resubmission for final approval

Subject to approval - launch planned for 2Q 2022

TLANDO XR: Next Generation TRT Option

Licensee Option Execution Required by March 31, 2022



TLANDO XR is positioned to be the first oral once a day product



TLANDO XR is clinically differentiated



Patients and physicians prefer once a day oral testosterone



Positive Phase 2b study results

Tech transfer/scale up activities on-going

Food/phlebotomy study target dosing 2Q 2022

LPCN 1144

for Non-Cirrhotic NASH

FDA Fast Track Status

Next Step: FDA meeting
on Path Forward

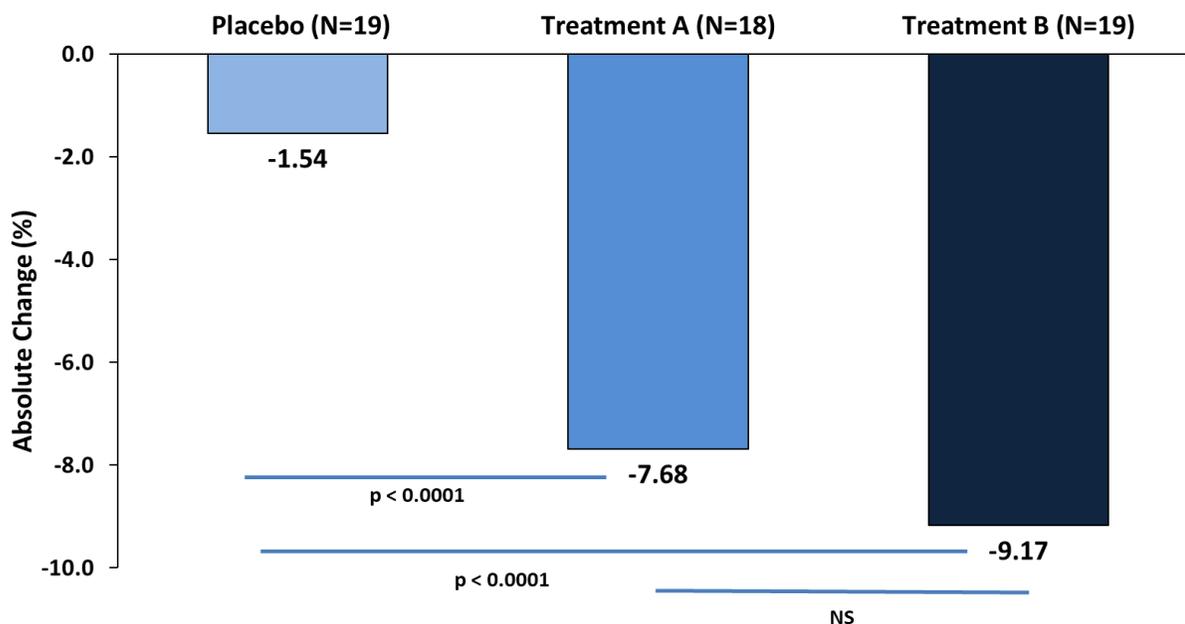
Currently No Approved Treatment For NASH



Key Results from *LiFT* Study

Met NASH Resolution Histology Endpoint and Fat Reductions

Liver Fat Reduction at Week 12 (MRI-PDFF)



All Subjects: ITT Dataset, n = 56, missing data imputed using multiple imputation
 NS = Not Statistically Significant

NASH Resolution with No Worsening of Fibrosis¹

Responders¹, n (%)

	NASH Resolution Set ²	Safety Set ³
Placebo	0 (0%)	0 (0%)
Treatment A	6 (46%)*	6 (33%)**
Treatment B	9 (69%***)	9 (47%***)

* p < 0.05; ** p < 0.01 vs placebo, *** p < 0.001 vs placebo

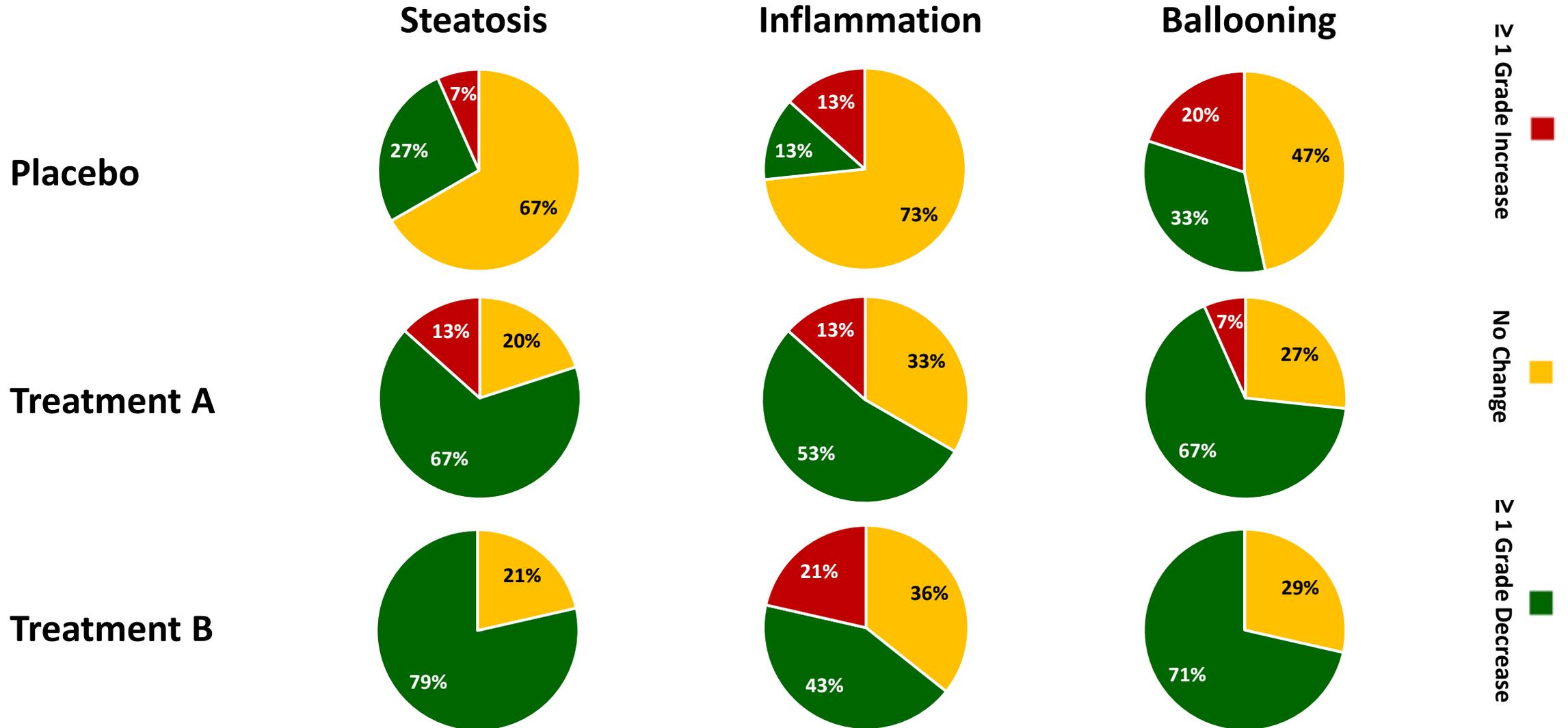
1 NASH resolution is defined per FDA guidance as lobular inflammation score = 0 or 1 and hepatocyte ballooning score = 0

2 NASH Resolution Set includes those subjects with baseline and EOS biopsy and with NASH at baseline (NAS ≥ 4 with lobular inflammation score ≥ 1 and hepatocyte ballooning score ≥ 1) per FDA Phase 3 guidance

3 All randomized subjects (ITT); subjects who were not eligible for NASH resolution evaluation or who were missing EOS biopsies were treated as non-responders

Histological Changes in NASH Components: NASH CRN Scoring

Substantial Improvement in All NASH Components from Baseline



Key Non-Histology Marker Results from *LiFT* Study

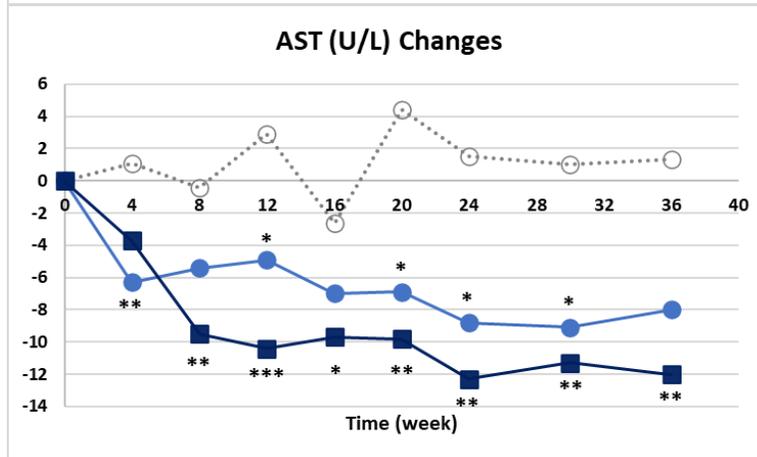
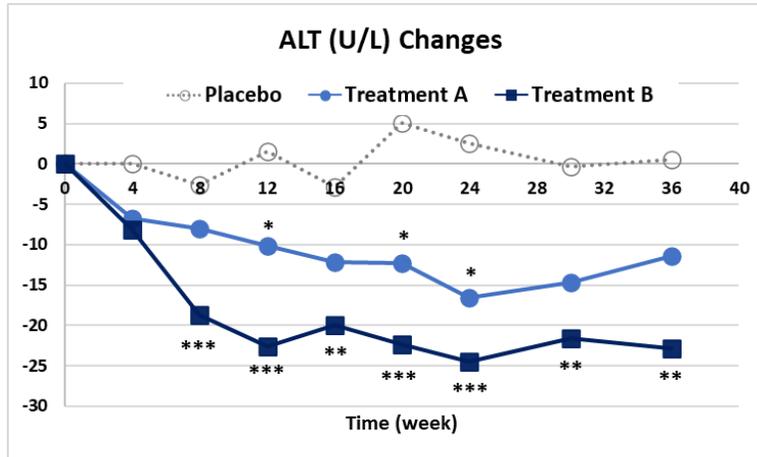
Liver Enzyme# Reductions and Body Composition Changes

Liver Injury Marker Reduction

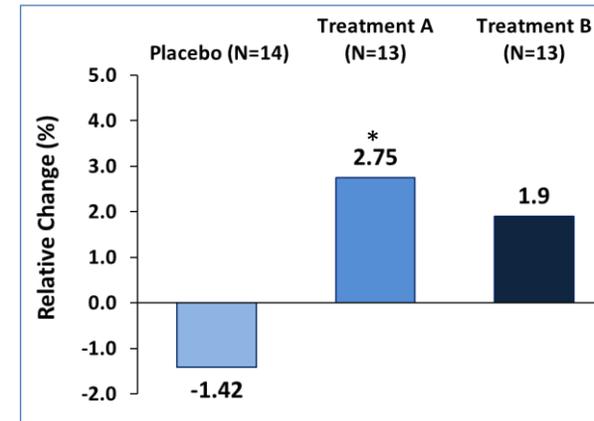
Positive Effects on Body Composition†

Mean Baseline

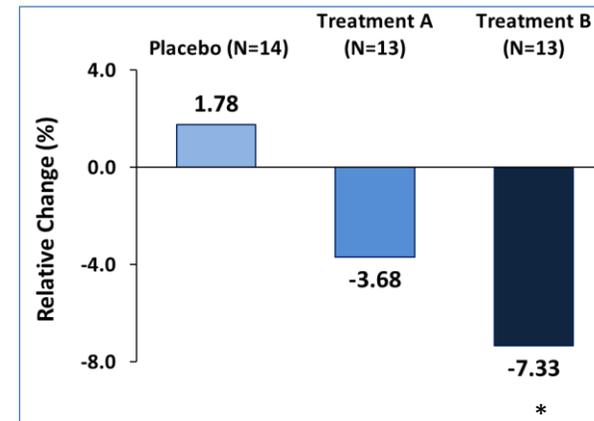
	ALT (U/L)	AST (U/L)
Placebo (N=19)	49.0	35.4
Treatment A (N=18)	53.9	32.4
Treatment B (N=19)	51.5	31.9



Relative Change in Appendicular Lean Mass



Relative Change in Whole Body Fat Mass



† All available data at Week 36 (Last Observation Carry Forward ("LOCF"))
* p < 0.05 vs placebo

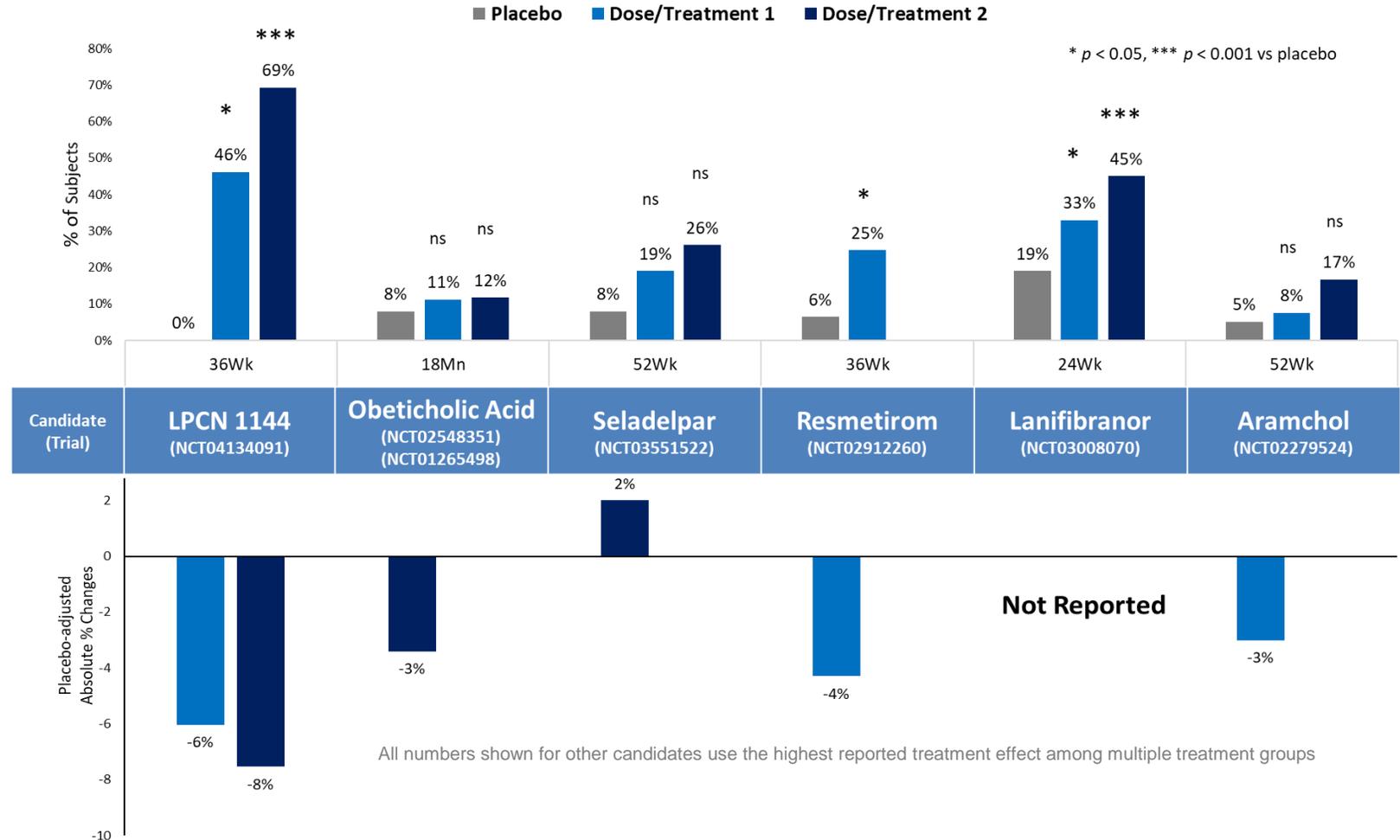
Safety Set with all available data, # ALT: alanine aminotransferase; AST: aspartate aminotransferase
* p < 0.05; ** p < 0.01; *** p < 0.001 vs placebo

Comparison† with Other Oral Drug Candidates

Best in Class in NASH Resolution and Liver Fat Reduction

**NASH Resolution with
No Worsening of Fibrosis**

**Absolute Changes of Liver
Fat from Baseline**



† Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations. No head-to-head clinical trials have been conducted. ‡ Reduction 2-point on NAS or resolution of NASH without worsening of fibrosis with at least a 2-pt reduction in NAS.

Reference: Obeticholic acid (Younossi et al, Lancet 2019), Seladelpar (Cymabay, Apr 2021 Corp deck), Resmetirom (Harrison et al, Lancet 2019; Madrigal, June 2019 Corp deck), Lanifibranor (Inventiva, Jul 2021 Corp deck); Aramchol (Raymond James Life Sciences and MedTech Conference 2019)

Safety Overview of LPCN 1144 Through Week 36

Well-Tolerated with an Overall Safety Profile Comparable to Placebo

- Frequency and severity of TEAEs in both treatment arms were comparable to placebo
- Discontinuance of study drug due to TEAEs: 4 subjects in placebo and 1 subject in treatment arms
- Cardiovascular events were balanced among groups
- No reported cases of hepatocellular carcinoma or Drug Induced Liver Injury (“DILI”)
- Weight change from baseline was comparable among groups
- Changes in lipids comparable to placebo

AEs of Interest, n (%)	Placebo	Treatment A	Treatment B
Diarrhea	2 (10.5%)	1 (5.6%)	0 (0%)
Nausea	1 (5.3%)	1 (5.6%)	0 (0%)
Vomiting	none	none	none
Peripheral Edema	2 (10.5%)	1 (5.6%)	1 (5.3%)
BPH	1 (5.3%)	0 (0%)	0 (0%)
PSA Increased	0 (0%)	1 (5.6%)	0 (0%)
Hypertension [†]	1 (5.3%)	3 (17%)	0 (0%)
Pruritus	1 (5.3%)	1 (5.6%)	0 (0%)

***LiFT* Results Support LPCN 1144 Development for FDA Approval**

Met the Primary and Key Secondary Endpoints with Statistical Significance

01

Statistically significant reduction in liver fat was observed compared to placebo

02

Met with statistical significance the pre-specified histology based regulatory endpoint of NASH resolution with no worsening of fibrosis

03

Changes in key liver enzymes and body composition support beneficial treatment effects

04

Well-tolerated with an overall safety profile comparable to placebo

Potential for Orphan Drug Designation

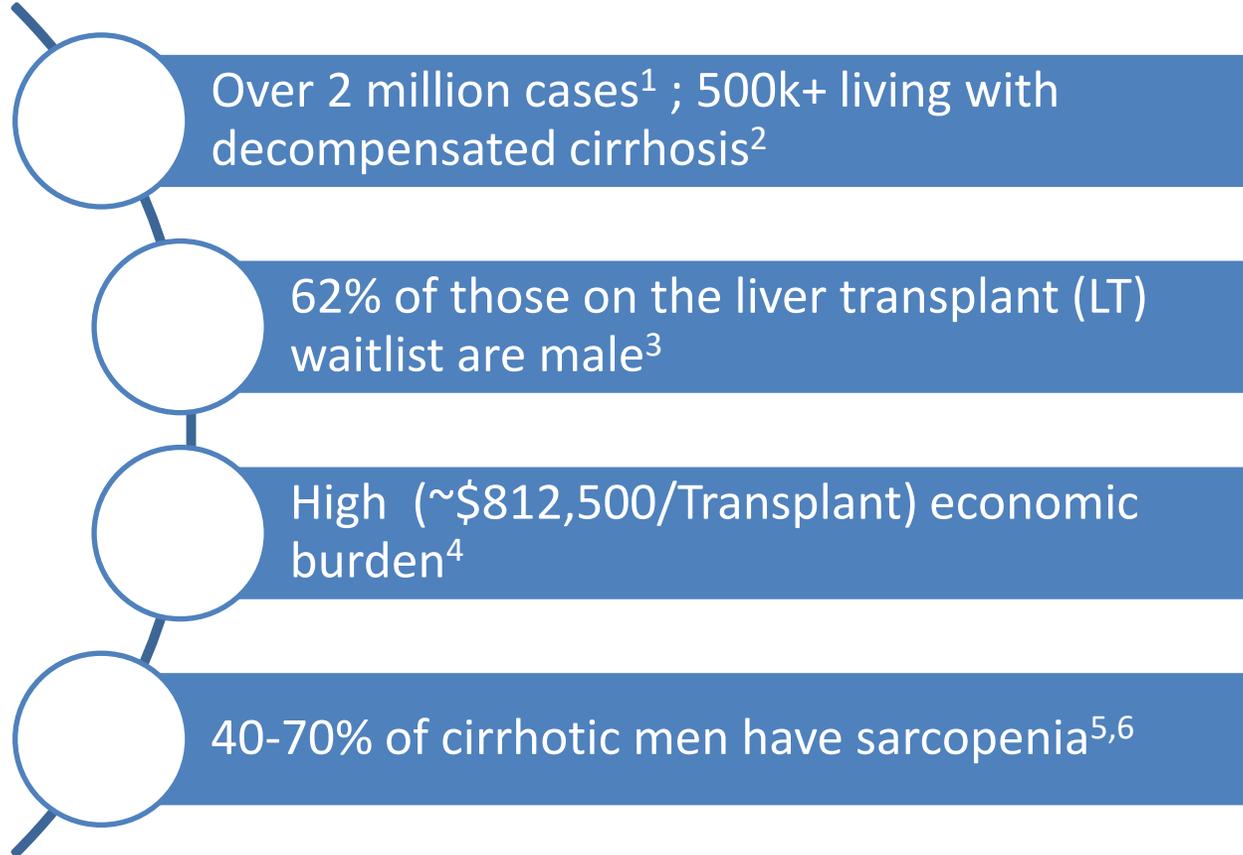
LPCN 1148

for the Management of
Liver Cirrhosis

Next Step: P2 Topline
Primary Endpoint
Results 4Q 2022



Liver Cirrhosis in US



LPCN 1148: Targeting Unmet Need in Cirrhosis

Event free survival/Improve quality of life for transplant patients

- Pre, Post, and the others who optout or are denied being on the waitlist

Improvement of post transplant outcomes/costs

- Decreased hospital readmissions
- Shorter length of hospitalization

1. Moon, Clin Gas and Hep, 2019

2. GBD 2017 Cirrhosis Collaboration, Lancet, 2021

3. Sarkar et al. J Hepatol. 2015

4. Bentley & Phillips, Milliman Research Report 2017

5. Sinclair, Ailment Pharmacol Ther, 2016

6. Lai, Am J Transplant, 2014

7. Younossi, Clin Gastro & Hep, 2021.

Muscle Disorder in Liver Cirrhosis

Sarcopenia Associated with Adverse Outcomes

A two-fold increase in waitlist mortality/decreased survival

Stronger sarcopenia association with waitlist mortality in men

Increased risk of further decompensation; increases overt hepatic encephalopathy risk by 2x

Higher risk of hospitalization

Poor Quality of Life

Including physical, mental, and social wellbeing

Higher Medical Costs at Transplant

Prolonged hospitalizations, time spent in Intensive Care Unit

Poor Post-Transplant Outcomes

Higher mortality rate, higher infection rate

References: Paternostro et al, Hepatol Res 2019 . Kim and J.W. Jang, World Journal of Gastroenterology, 2015; Sinclair et al., Journal of Gastroenterology and Hepatology (Australia), 2016; Moctezuma-Velazquez et al., Clinical Nutrition, 2018.; Sinclair et al., World Journal of Gastroenterology, 2017. Montano-Loza et al., Clinical and Translational Gastroenterology, 2015; Lai, J.C., et al., Hepatology, 2017; Englesbe et al., J Am Coll Surg, 2010. Tandon et al., Hepatology, 2021. Paternostro et al., Liver Int., 2020. Fozouni et al., Clin Transl Gastro, 2019. Ando et al., J Gastro & Hep, 2019.

Potential Mode Of Action of LPCN 1148

Multi-Modal Action

Myo-augmentation (mass, quality, function)

- Inhibit myostatin
- Myo-steotosis reduction
- Increase muscle mass and reduce fat mass
- Anti-catabolic agent
- Slow down muscle autophagy

Hepato-effective

- Improved ALP, ALT, AST, GGT;
- Increased protein synthesis

Immunomodulation

- Improve immuno-dysregulation
 - Lower infection rate

Anti-Inflammatory-antioxidant

- Reduce IL-1, IL-6, and TNF- α
- Improve mitochondrial function

References: Trivedi and Tapper, Gastroenterol Rep (Oxf), 2018; Berzigotti et al., Hepatology, 2017; Chen and Dunn, Clin Liver Dis (Hoboken), 2018; Sinclair et.al, Liver international, 2016; Neff et al., Digestive Diseases and Sciences, 2004; Puliyl et al., Australian and New Zealand Journal of Medicine, 1977; Brown et al., Cleve Clin Q, 1960; Girolami M, Am Geriatr Soc, 1958; Neff et al., Transplant Proc, 2004; Wells R., The Lancet, 1960; Yurci et al., Clinics and Research in Hepatology and Gastroenterology, 2011; Muting D., Verh Dtsch Ges Inn Med, 1969; Gluud C., Liver, 1984.

*individual's health condition as it is influenced by the intake and utilization of nutrients

LPCN 1148: Proof of Concept Study

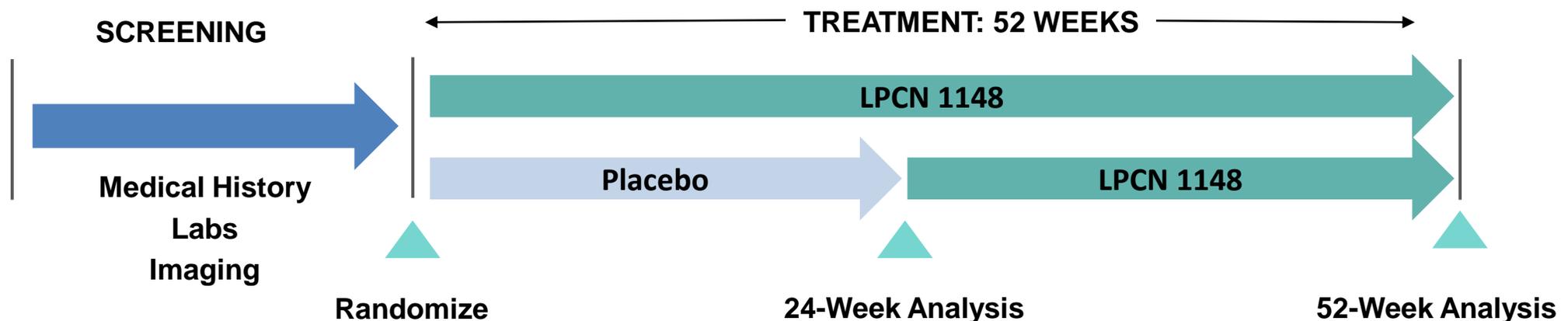
Phase 2, Multicenter, Double-Blinded, Placebo-Controlled Study*

Study Design

- Male subjects with cirrhosis of the liver and sarcopenia
- Stage 1, Weeks 1-24
 - Two-arm (1:1 randomization)
 - Oral LPCN 1148 or Placebo
- Stage 2, Weeks 25-52
 - Single arm – LPCN 1148

Endpoints:

- **Primary:** Change in Skeletal Muscle Index at Week 24
- **Key Secondary:**
 - Change from baseline in Liver Frailty Index
 - Change in number of waitlist events
 - Rates of breakthrough hepatic encephalopathy



LPCN 1148: P2 POC Study: Key Target Outcomes of Interest

Clinical Outcomes

- Overall survival
- New Decompensation Events
 - Hepatic encephalopathy
 - Ascites
- Survive to/through transplant
- Rates of hospitalizations, infections

Muscle/Functionality Changes

- Muscle mass
 - Sarcopenia
- Muscle quality
 - Myosteatorsis
- Functional capacity
 - Liver frailty Index (LFI)
- Body composition by DXA
- PROs

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO®	Final FDA Approval Partner Target Launch	March 2022 2Q 2022
TLANDO® XR	License Option Exercise Food/Phlebotomy Study	by March 31, 2022 2Q 2022
LPCN 1144	FDA Meeting Open Label Extension Results	1Q 2022 Mid 2022
LPCN 1148	Complete Enrollment Topline Primary Endpoint Results	2Q 2022 4Q 2022
LPCN 1107	Food Effect Study Results FDA Meeting on Path Forward	1Q 2022 2Q 2022

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	LPCN
Closing Stock Price (1/3/22)	\$1.09/share
Cash Balance (9/30/21)	\$38.7 million*
Bank Debt (9/30/21)	\$3.1 million

* Doesn't include \$11M received in October 2022 for the out license of TLANDO to Antares Pharma

Appendix



Oral NASH Drug Candidates

Non-Histological Efficacy Comparison†

		LPCN 1144 (Treatment B)	Obeticholic acid (25mg QD)	Seladelpar (50mg QD)	Resmetirom (80±20mg QD)	Lanifibranor (1200mg QD)	Aramchol (600mg QD)
Liver Fat	BL	21%		21%	20%		30%*
	Absolute CBL	-9 %	N/A	-3 %	-7 %	N/A	-3%*
	Relative CBL	-47 %		-13 %	-33 %		-11%
ALT	BL	52 U/L	82 U/L	68 U/L	50 U/L	64 U/L	56 U/L
	Absolute CBL	-23 U/L	-38 U/L	-25 U/L	-15 U/L	-26 U/L	~-13 U/L
	Relative CBL	44%	46%	37%	30%	41%	~-23%
AST	BL	32 U/L	58 U/L	46 U/L	35 U/L	44 U/L	N/A
	Absolute CBL	-12 U/L	-27 U/L	-8 U/L	-7 U/L	-18 U/L	~-10 U/L
	Relative CBL	38%	47%	17%	20%	41%	N/A

† Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations. No head-to-head clinical trials have been conducted.

*Magnetic Resonance Spectroscopy (MRS)

All numbers were the maximum value among the treatment groups

BL = Baseline Level; CBL Change from baseline level