LIPOCINE®

ENHANCING HEALTH

CORPORATE PRESENTATION

Enabling Oral Drug Delivery to
Improve Patient Compliance

March 2021

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 and LPCN 1148, 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

Propriety Drug Delivery Platform

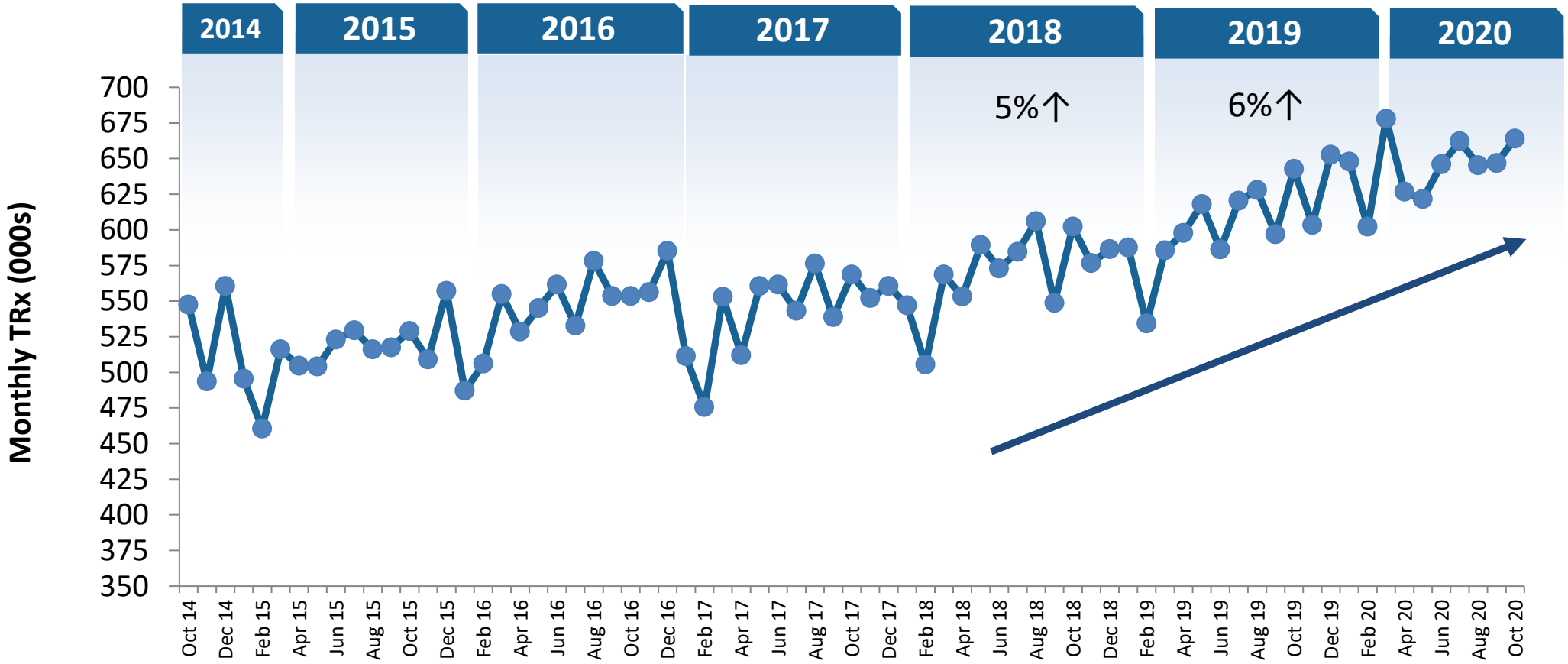
PRODUCT *(Indication)*	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
TLANDO™ *(Oral Testosterone for Testosterone Replacement Therapy "TRT")*					**Tentative Approval**
LPCN 1144 *(Oral Testosterone for Non-Cirrhotic NASH)*			***LiFT* Phase 2 Clinical Study Ongoing**		
TLANDO XR *(Long Acting Oral Testosterone for Testosterone Replacement Therapy "TRT")*				**Next Step: Food Effect Study**	
LPCN 1148 *(Oral Testosterone for Cirrhosis)*			**Next Step: POC Phase 2 Clinical Study**		
LPCN 1107 *(Oral HPC for Prevention of PTB)*				**Next Step: Food Effect Study**	

TLANDO™

The Convenient TRT without Titration Requirement

Monthly TRT TRx Trend

TRT Market is Growing



Last 12 months (Nov 2019 – Oct 2020) TRx of 7.7 million

Source: IMS database
TRx = Total prescriptions

Issues with Current TRT Options

Potential Barriers To Newly Diagnosed and Existing Patients

- **Black box warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylactic shock
- **Inconvenient application or painful injection**
- **High incidence of erythrocytosis was reported in patients on non-oral**
  - 67% on injectable T, 35% on pellets*
- **Most require dose titrations -** Majority of patients are not on efficacious dose at start of therapy and require up titration
  - Avg titration time to reach efficacious dose takes 3-6 months
  - Finding appropriate dose through titration is burdensome for physicians and patients
  - Requires additional clinic/pharmacy visits and invasive samplings
- **Poor persistence with products requiring titration**
  - 50-80% drop off in 3-6 months
  - Insufficient T levels at the beginning of therapy is one of the top reasons patients stop using TRT

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*Pastuszak et al. Sex Med. 2015

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: De-Risked Regulatory Profile

Eligible to Launch After March 27, 2022

Current Status

- Tentative approvals are clearances for drugs to be marketed, but for the existence of patents or market exclusivities
- Initial launch supply manufactured
- Commercialization partnering process ongoing

Opportunities

- Post COVID pandemic launch
- Adequate time for launch preparation/partnering
- Potential exclusivity
- Improves TLANDO XR development prospect

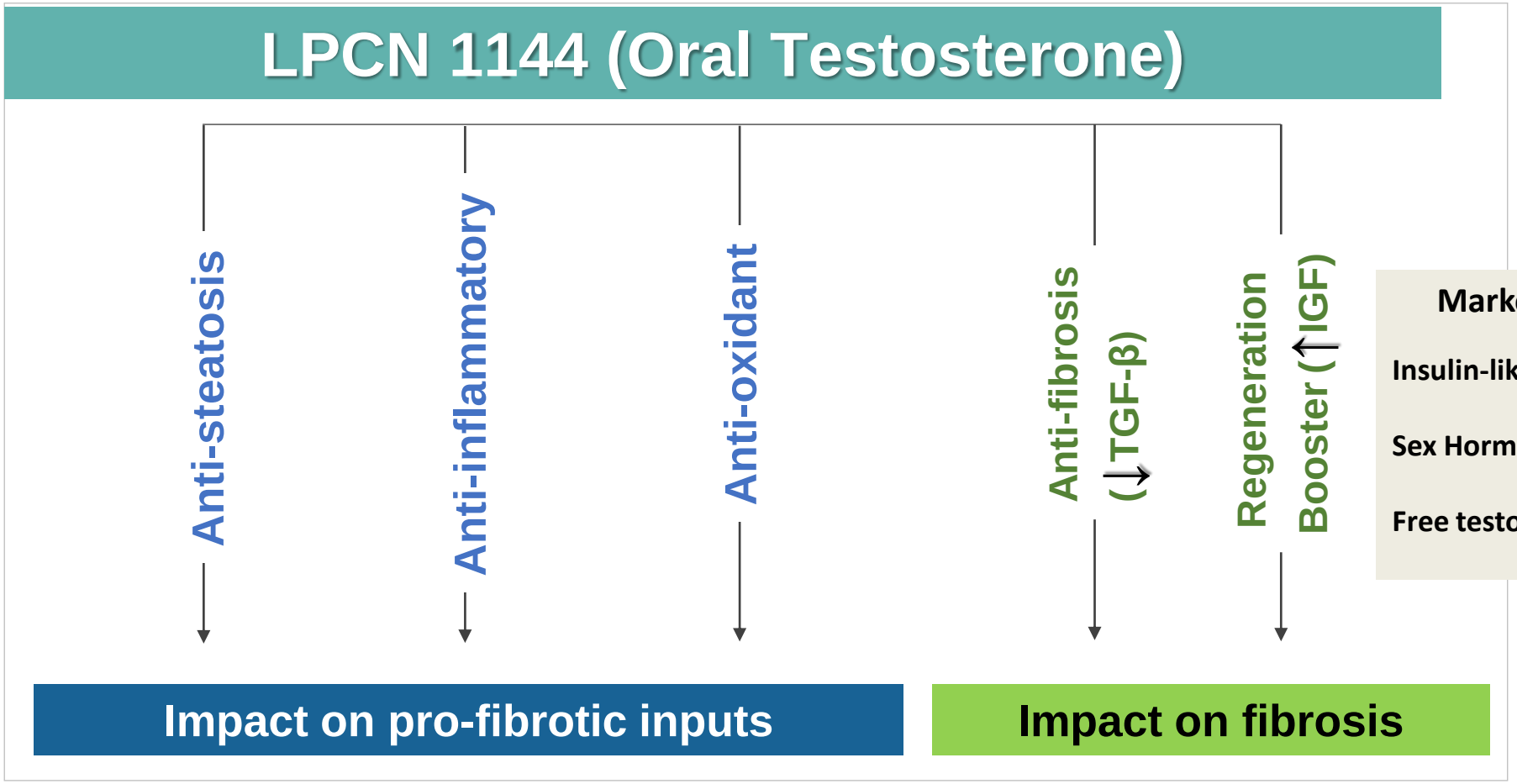
LPCN 1144

for Non-Cirrhotic NASH

Currently No Approved Treatment

LPCN 1144: Androgen Receptor Agonist

Potential Mode of Action



Markers in Advanced Fibrosis*

- Insulin-like Growth Factor (IGF-1) ↓
- Sex Hormone–Binding Globulin (SHBG) ↑
- Free testosterone ↓

*You et al., Hepatology Communications, 2021

LPCN 1144: *LiFT (Liver Fat Intervention with oral Testosterone)**

Phase 2 Paired Biopsy Study in Men with NASH (NCT04134091)

Study Design

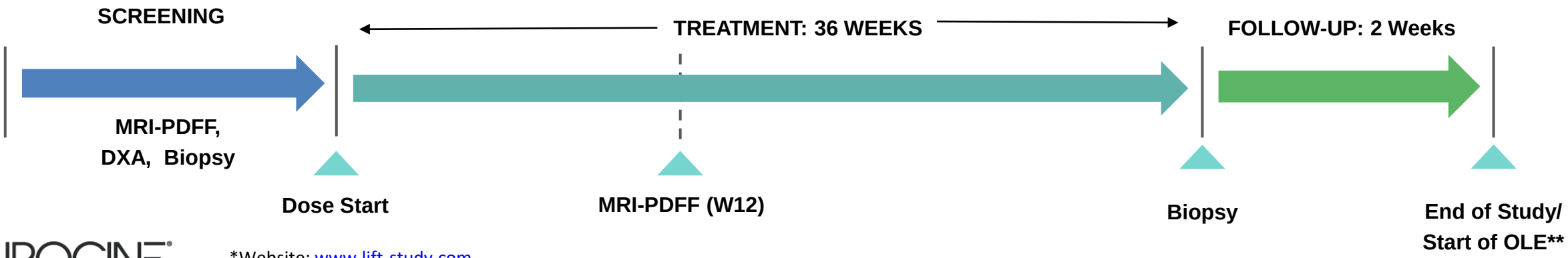
- Biopsy confirmed male NASH subjects with F1-F3 (N=56)
- Three-arm, blinded, placebo-controlled
  - 1:1:1 randomization
    - Treatment A: 142 mg eq. T twice daily
    - Treatment B: 142 mg eq. T + with 217 mg of d-alpha tocopherol equivalent twice daily
    - Placebo twice daily
- Treatment duration of 36 weeks

Primary Endpoint:

- Change in hepatic fat fraction via MRI-PDFF (W12)

Key Secondary Endpoints:

- Change in NASH activity and fibrosis via liver biopsy scoring (W36)
- Change in hepatic fat fraction via MRI-PDFF (W36)
- Change in liver injury markers, anthropomorphic measurements, lipids, insulin resistance, inflammatory/fibrosis markers
- Patient Reported Outcomes (PROs) including quality-of-life and patient global impression scores (PGI)



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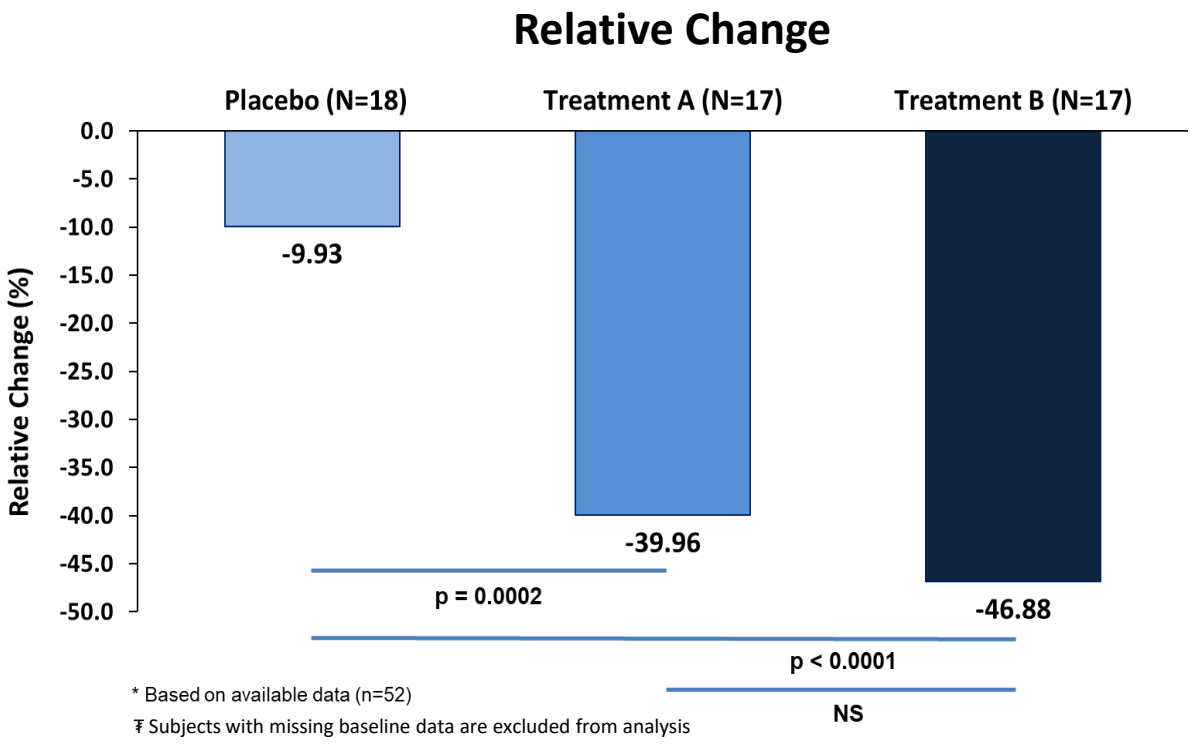
*Website: www.lift-study.com

** Open Label Extension Study

LiFT Study Results: Liver Fat (MRI-PDFF) Changes from Baseline

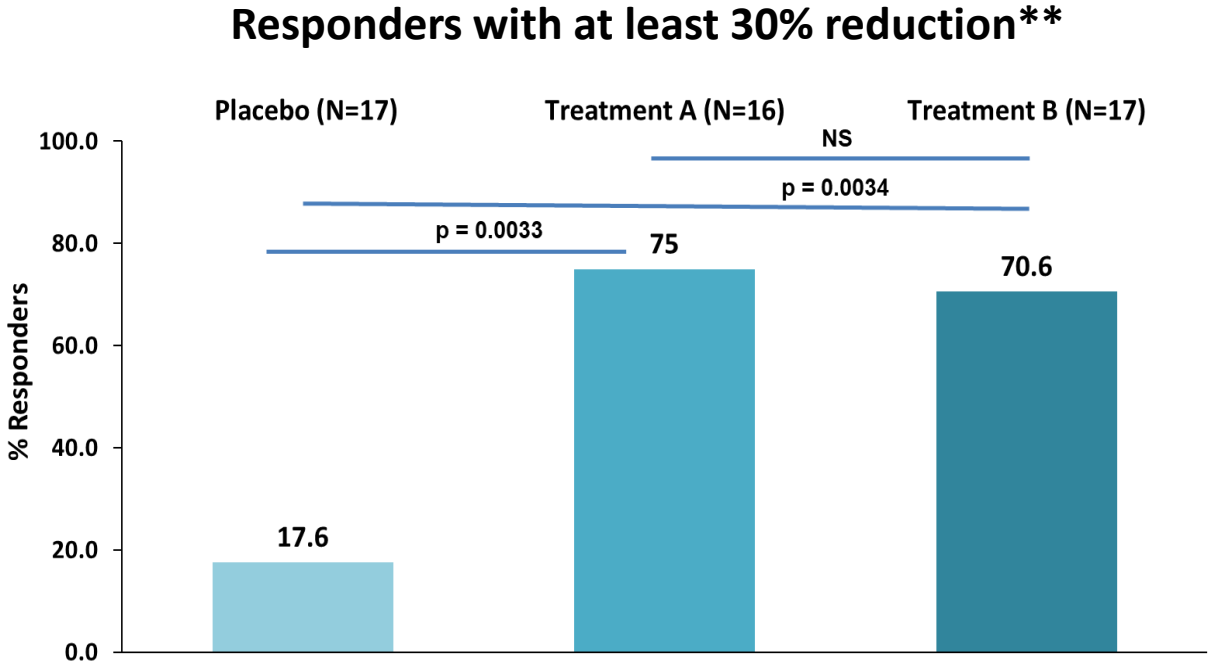
Significant Response in Biopsy Established NASH Subjects with Baseline Liver Fat ≥ 5%

From Baseline to Week 12*₮



* Based on available data (n=52)

₮ Subjects with missing baseline data are excluded from analysis



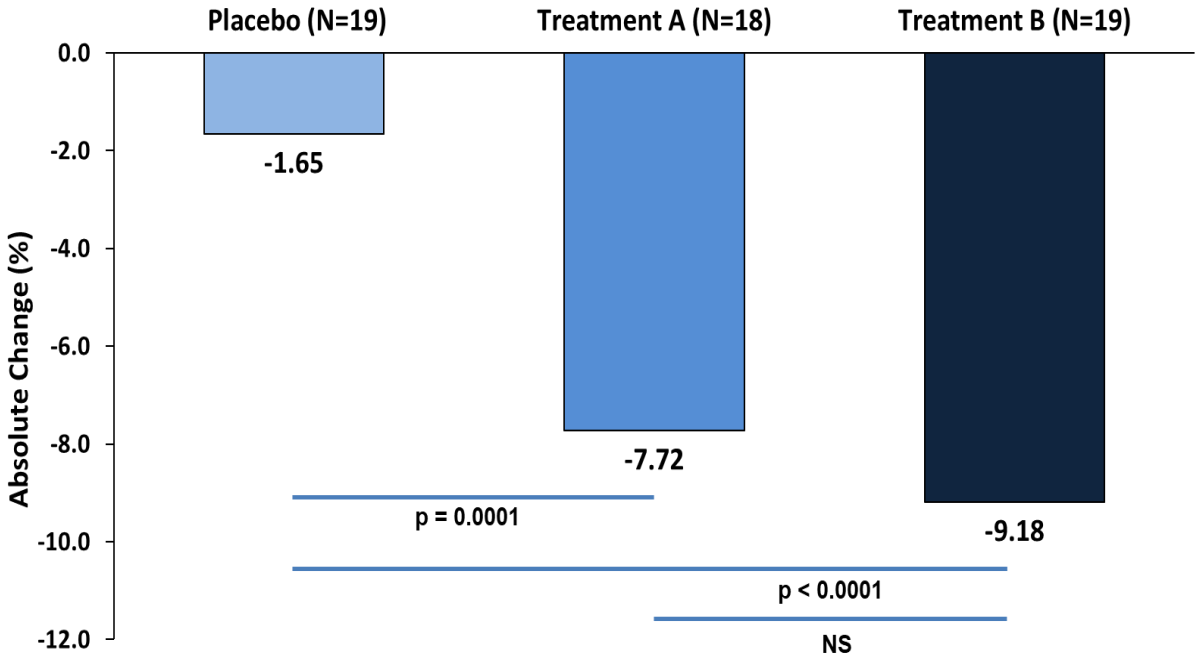
** Subjects with missing MRI data (baseline or Wk12) were excluded from analysis

LiFT Study Results: Absolute Change in Liver Fat (MRI-PDFF)

Significant Reductions Independent of Hypogonadal* Status of Biopsy Established NASH Subjects

From Baseline at Week 12

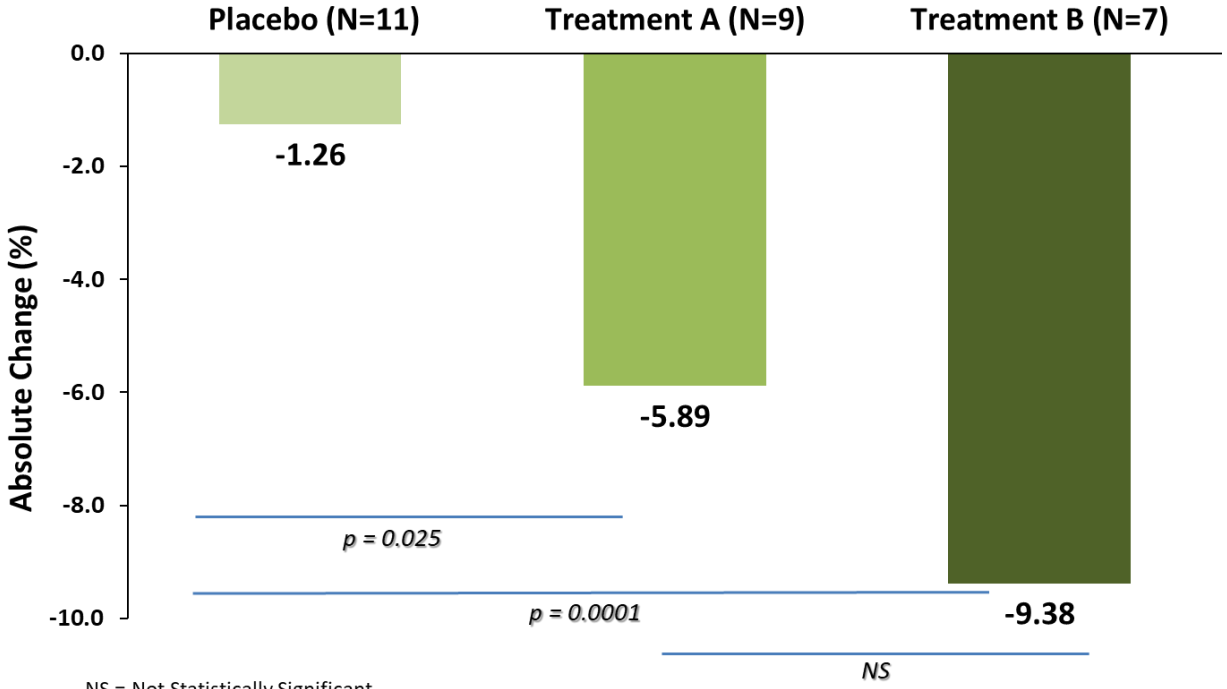
All Subjects



*All Subjects: ITT Dataset, n = 56, missing data imputed using multiple imputation

*Hypogonadal:T< 300 ng/dl, Eugonadal: T ≥ 300 ng/dL

Eugonadal Subjects



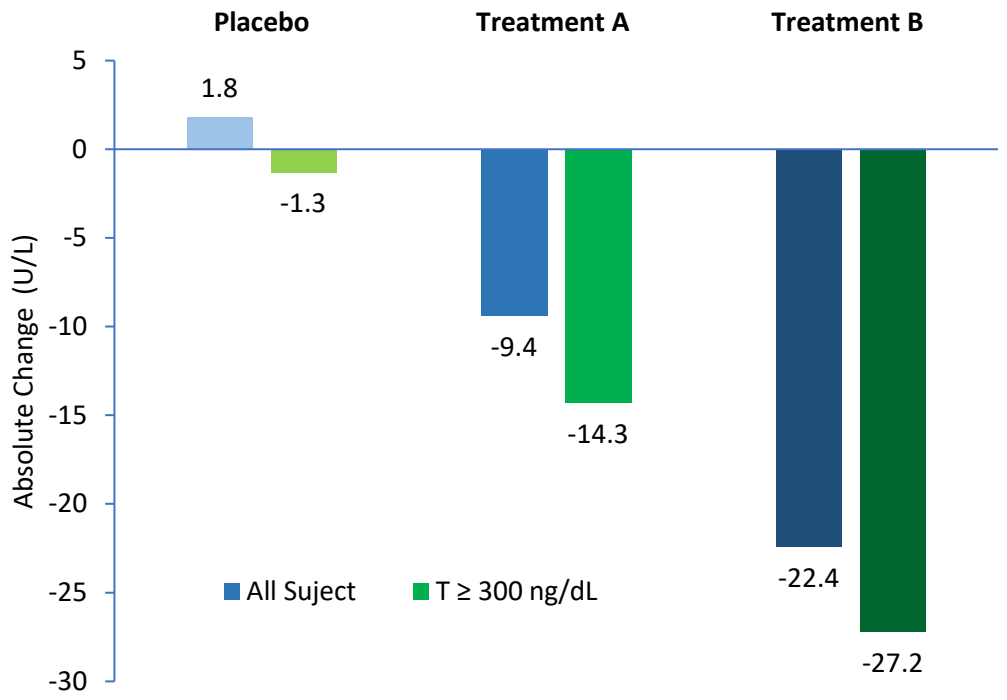
NS = Not Statistically Significant

LiFT Study Results: Key Liver Injury Marker Changes

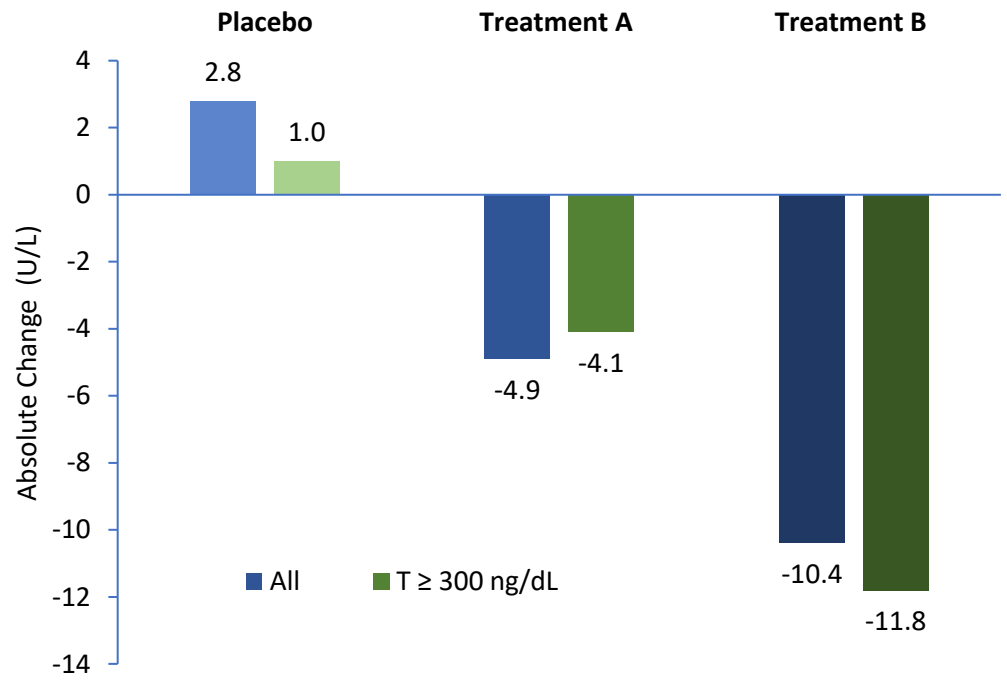
Significant Changes Independent of Subject Hypogonadal Status

From Baseline to Week 12**

Alanine Aminotransferase (ALT)



Aspartate Aminotransferase (AST)



*Hypogonadal:T< 300 ng/dl, Eugonadal: T ≥ 300 ng/dL

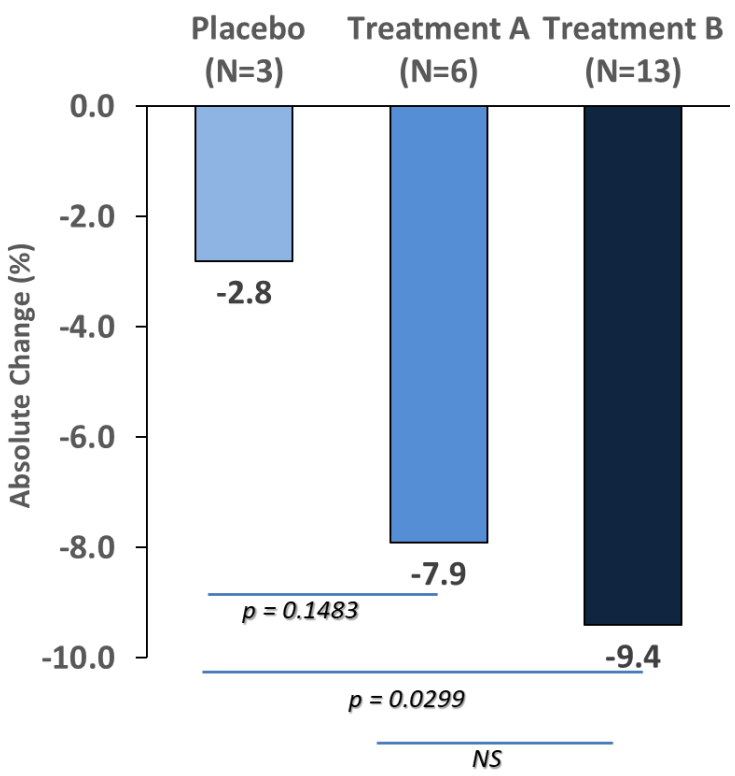
**All Subject: Placebo n= 17, Treatment A n =16, Treatment B n =19; Eugonadal subjects T ≥ 300 ng/dL: Placebo n= 11, Treatment A n =8, Treatment B n =7

LiFT Study Results: Subgroup Analysis

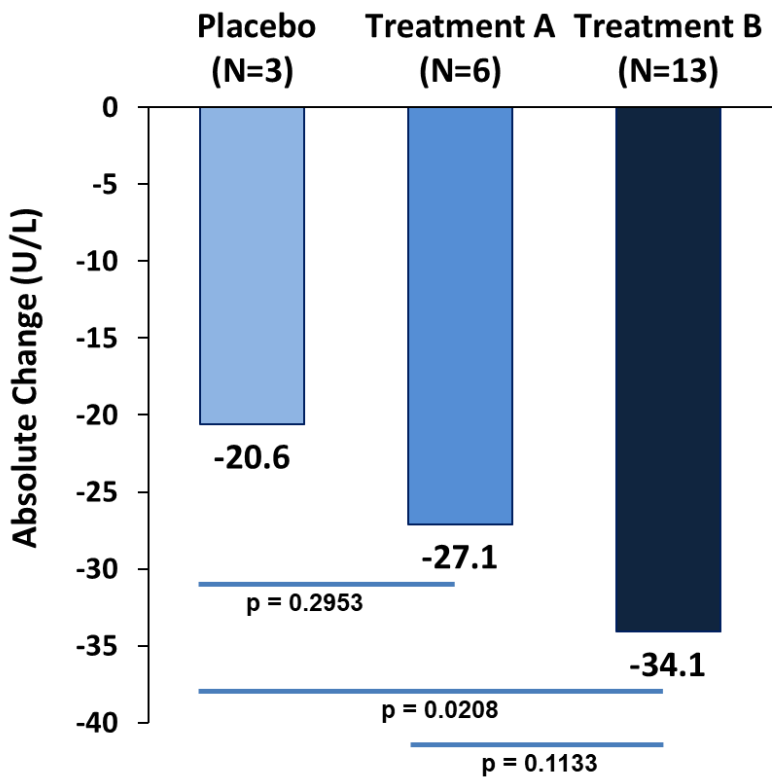
68% Subjects on Treatment B Showed Concurrent Reductions in Liver Fat, ALT and AST

From Baseline to Week 12

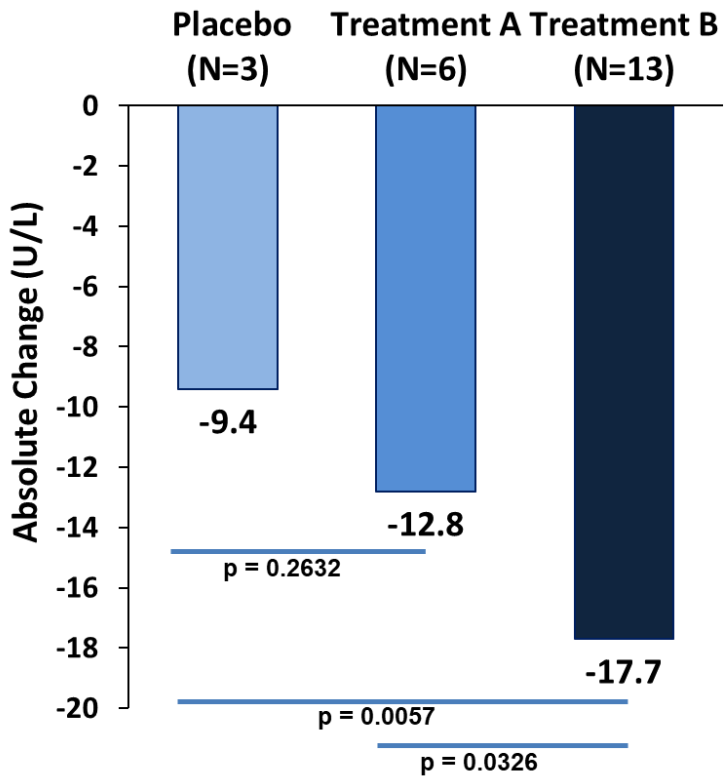
Liver Fat-MRI-PDFF



ALT



AST



NS = Not Statistically Significant

Summary: Positive Topline Results

Both LPCN 1144 Treatment Arms Met the Primary Endpoint with Statistical Significance

- Statistically significant reduction in liver fat was observed compared to placebo independent of hypogonadal status
- Statistically significant reduction in markers of liver injury were observed compared to placebo independent of hypogonadal status
- 68% on Treatment B had concurrent reductions of liver fat, ALT, and AST
- Adverse events in both the treatment arms were comparable to the placebo arm

LiFT Study: Upcoming Data

- Histological change in NASH activity and fibrosis at week 36
- MRI-PDFF liver fat data at week 36
- Body composition data from DXA scan (at 20 weeks and 36 weeks)
- Liver and other markers including (fibrosis and inflammation markers) at week 36
- PROs for periodic visits up to week 36
  - Quality-of-life and patient global impression scores (PGI)

TLANDO XR

Once Daily Oral TRT

TLANDO XR: An Innovative Opportunity

Next Generation TRT Option

- ✓ TLANDO XR is positioned to be the first Oral QD Product
- ✓ TLANDO XR is clinically differentiated from other orals
- ✓ Patients and physicians prefer once a day oral testosterone
- ✓ Strong IP (new molecule & proprietary drug delivery technology)
- ✓ Positive Phase 2b study results

LPCN 1148

for Liver Cirrhosis

LPCN 1148: Oral T for Cirrhosis

Background: Prevalence and Common Causes of Cirrhosis

Transplant Only Cure for Liver Cirrhosis

High Economic Burden of a Liver Transplant[1]

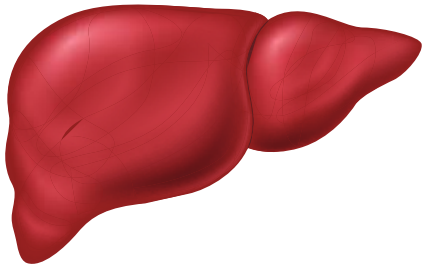
Liver Cirrhosis in US

Over 600K patients with liver cirrhosis[2]

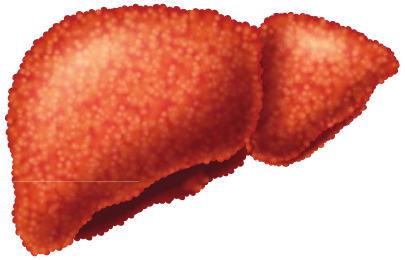
45K deaths in 2017[3]

62% male vs. 38% female on the liver transplant (LT) waitlist[4]

Healthy Liver



Liver with Cirrhosis



Common Causes[5]

- **Alcoholic liver disease**
- **Nonalcoholic Fatty Liver Disease (NAFLD)**
- **Chronic hepatitis B**
- **Chronic hepatitis C**
- **Cryptogenic**

1. Bentley & Phillips, Milliman Research Report 2017
2. Sinclair et al., Liver Transplantation, 2016
3. Sinclair et al., J Gastroenterol Hepatol. 2016;
4. Sarkar et al. J Hepatol. 2015
5. https://www.niddk.nih.gov/health-information/liver-disease/cirrhosis/symptoms-causes

Unmet Needs For Patients with Liver Cirrhosis

Areas that LPCN 1148 Targets

Improvement in quality of life while on waiting list

Stay on transplant list

Sarcopenia is a leading contributory cause of removal from the waitlist

- 40 -70% of cirrhotic patients are sarcopenic

Improvement of post transplant survival/outcomes

Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; Surveillance Report #114, 2019
Scaglione et al., J clin Gastroenterol, 2015; Hart et al., Transplantation, 2016; United Network for Organ Sharing, 2019
Sinclair et al. Aliment Pharmacol Ther, 2016; Lai et al., Am J Transplant, 2014

LPCN 1107

Prevention of Preterm Birth

Unmet Medical Need

Preterm Birth is a Significant Public Health Issue in the U.S

- One Preterm birth (PTB) every minute[1]
- ≥ $26 billion economic impact[2]
- 10% of all US pregnancies[3]
- A leading cause of neonatal mortality and morbidity
- Medical costs for PTB infants are ~10x higher than for full-term infants[4]

1. Pediatric Research (2006) 60, 775–776
2. Institute of Medicine of the National Academies. Jul.200
3. National Vital Statistics Reports, Vol 67, No. 8, Nov 7, 2018: Centers for Disease Control and Prevention (2017)
4. J. Maternal-Fetal and Neonatal Medicine, Dec. 2006, 19(12), 773–782

LPCN 1107: Potential To Be The Standard of Care for Prevention of PTB

Oral Hydroxyprogesterone Caproate (HPC)

- Convenient dosing
- No injection site reactions
- First and only oral enabling technology
- Solid IP coverage
- Orphan drug designated
- Next Step: Food Effect Study

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	Final FDA Approval Decision	**March 2022**
LPCN 1144	*LiFT* Biopsy Results	**July/August 2021**

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	**LPCN (Nasdaq Capital Market)**
Closing Stock Price (1/26/21)	**$1.59/share**
Cash Balance (12/31/20)	**$24.7 million***
Bank Debt (9/30/20)	**$6.4 million**

*Raised an add'l $28.7M gross in January 2021 CMPO