LIPOCINE®

ENHANCING HEALTH

Corporate Presentation

Enabling Oral Drug Delivery to
Improve Patient Compliance

July 2020

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 product candidates, FDA review process related to our resubmitted NDA for 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")*					PDUFA Date August 28, 2020
TLANDO XR *(Long Acting Oral Testosterone for Testosterone Replacement Therapy "TRT")*				Phase 3 Dose Identified	
LPCN 1144 *(Oral Testosterone for Non-Cirrhotic NASH)*			*LiFT* Phase 2 Clinical Study - Top Line Results End of 2020		
LPCN 1148 *(Oral Testosterone for Cirrhosis)*			Next Step: POC Phase 2 Clinical Study		
LPCN 1107 *(Oral HPC for Prevention of PTB)*				Phase 3 Dose Identified	

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TLANDO™

The First Oral TRT Without Titration Requirement

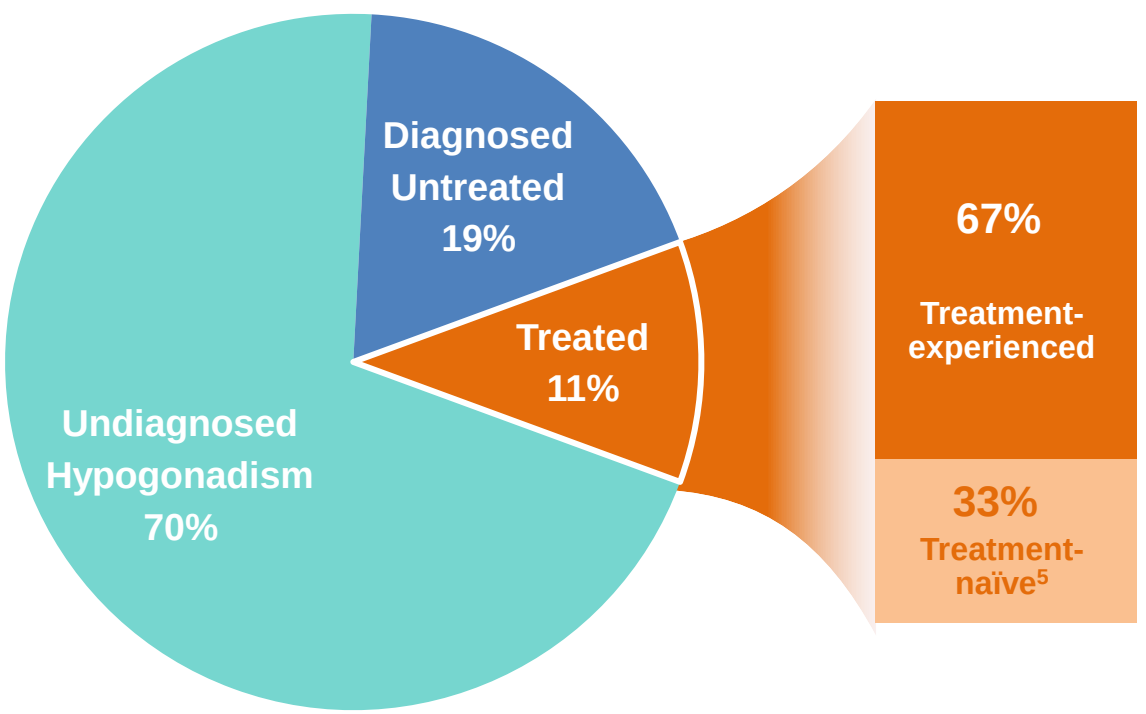
Hypogonadism Affects Up to 20M Men[1, 2]

TLANDO Franchise has the Potential to Drive Market Expansion[1,2]

Hypogonadism Under Treatment in US

Close to **6M** men with diagnosed hypogonadism[3]

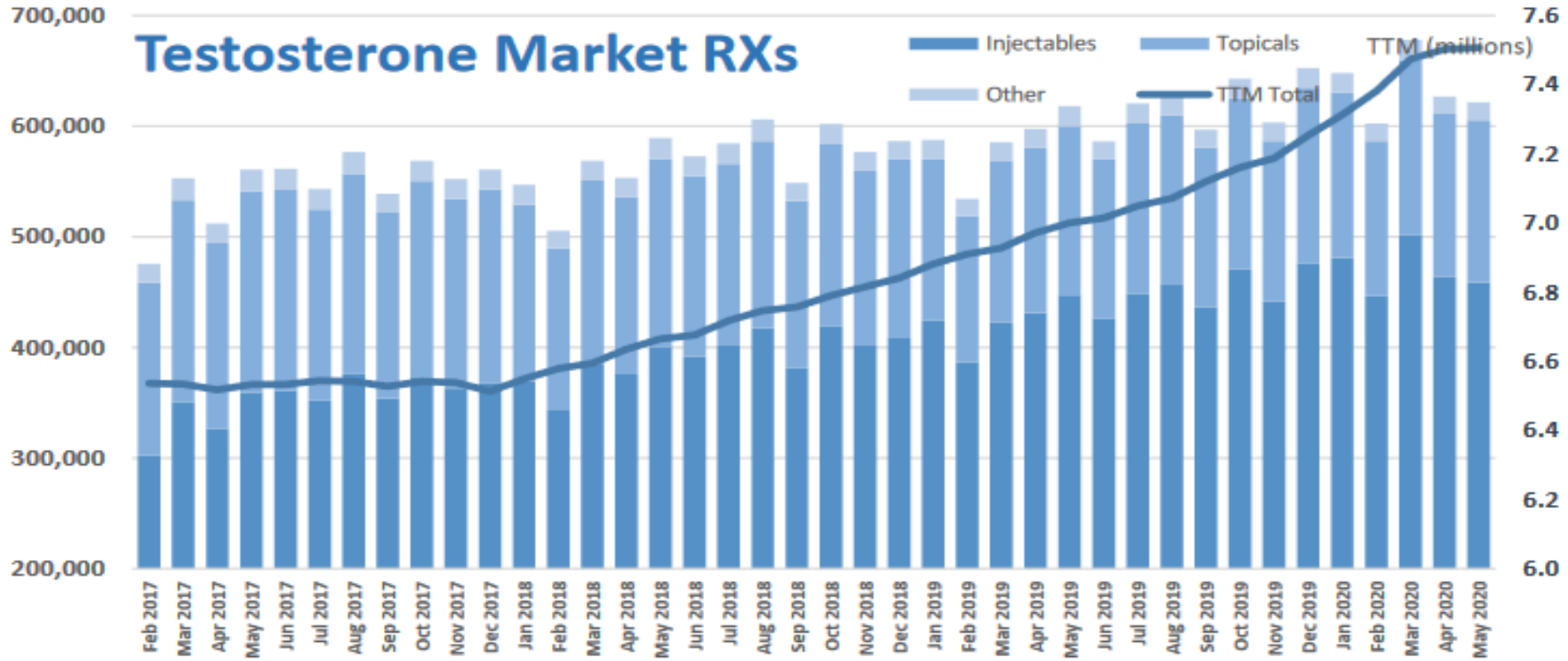
2M men being treated[4]



1. US Census data. http://www.infoplease.com/us/census/data/demographic.html. 2. Mulligan T, et al. *Int J Clin Pract.* 2006 Jul;60(7):762-9.
3. Araujo, et al. *J Clin Endo* Metabol 2007. 92(11):4241-7. 4. Symphony Healthcare 2014 for FDA Advisory Meeting. 5. IMS Health Sept 2015.

Monthly TRT TRx Trend

TRT Market is Growing



Source: IQVIA, Raymond James research.

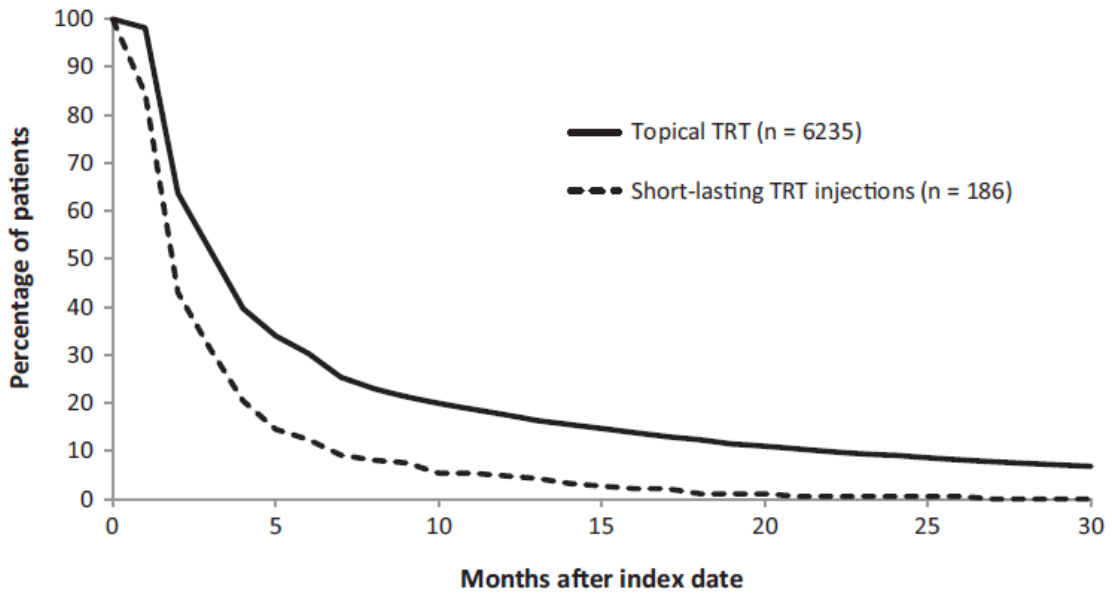
Issues with Current TRT Options

Potential Barrier To Newly Diagnosed and Existing Patients

- **Black Box Warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylaxis shock
- **Inconvenient application or painful injection**
- **Most require dose titrations (up titrations)**
  - More than 50% of patients need dosage adjustment
  - Typical titration takes 3-6 Months to reach efficacious dose
  - Finding appropriate dose through titration is burdensome for physicians and patients
  - Requires additional clinic/pharmacy visits
- **Poor persistence with products requiring titration**
  - 50-80% drop off in 3-6 months
  - Insufficient T levels at the start of therapy is one of the top reasons patients stop using TRT

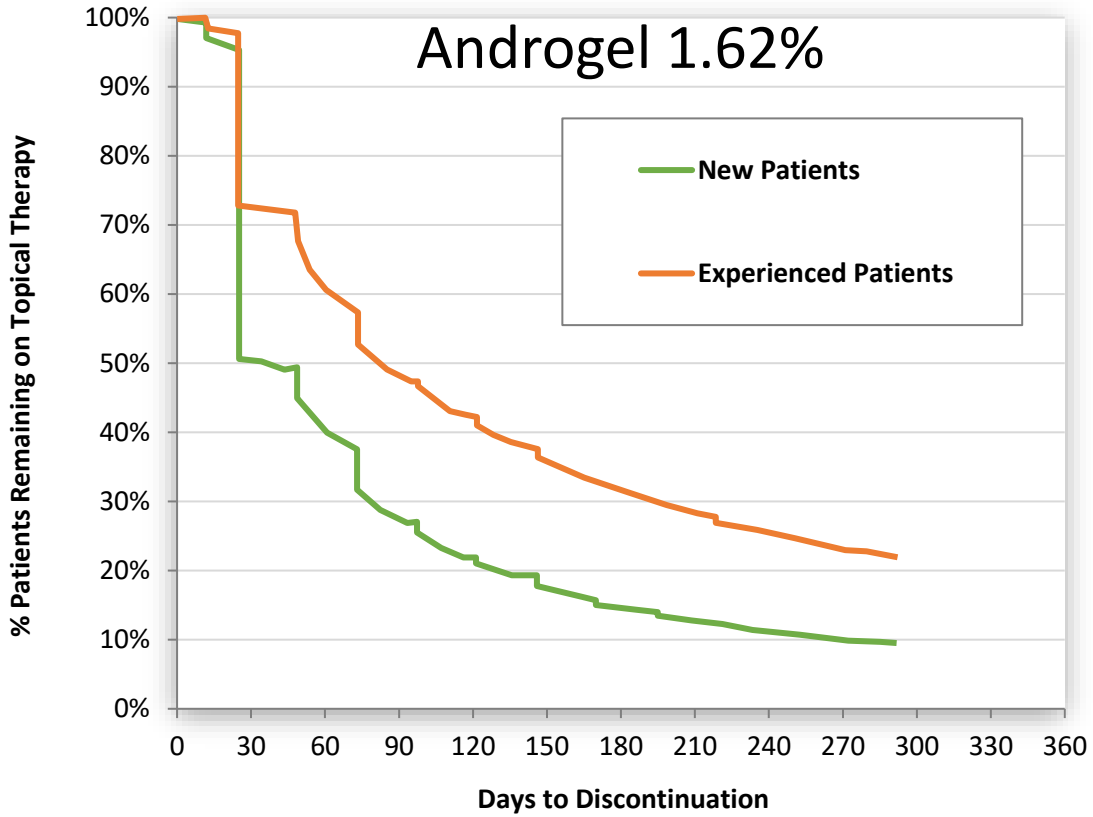
Persistence Issue with TRTs

High Discontinuation Rates with Products Requiring Titration



Y-axis represents percentage of patients in the discontinued group who were receiving treatment with topical TRT or short-lasting TRT injections during the follow-up period. P < 0.0001.

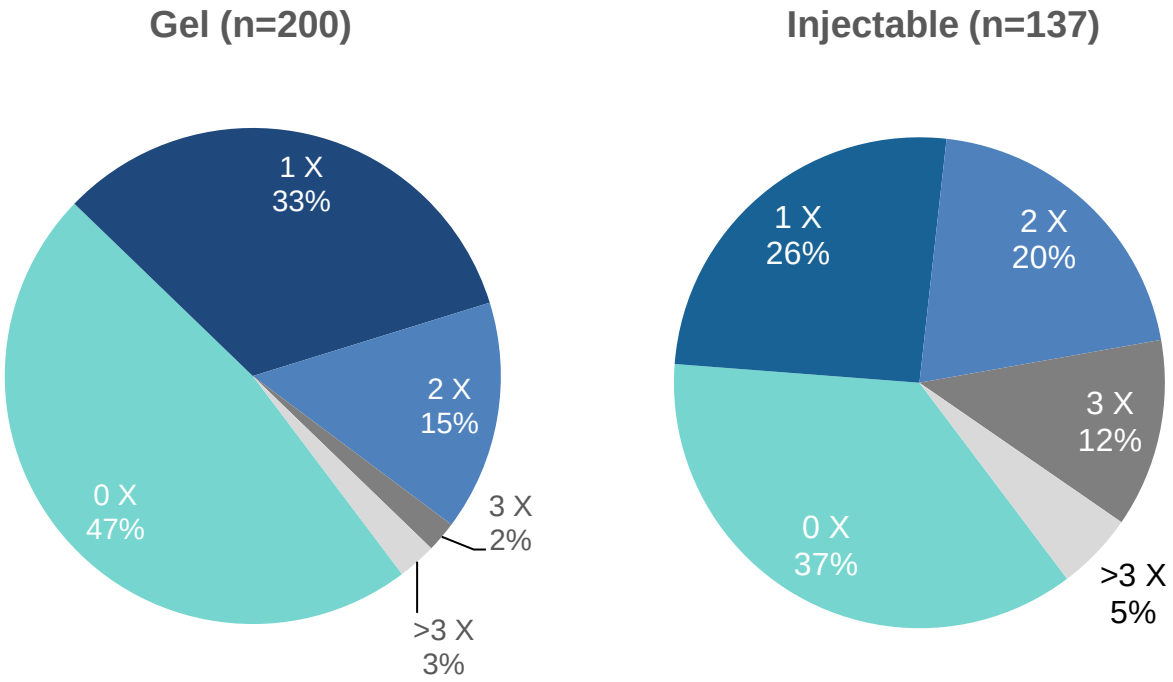
*Donatucci C, et al. J Sex Med. 2014



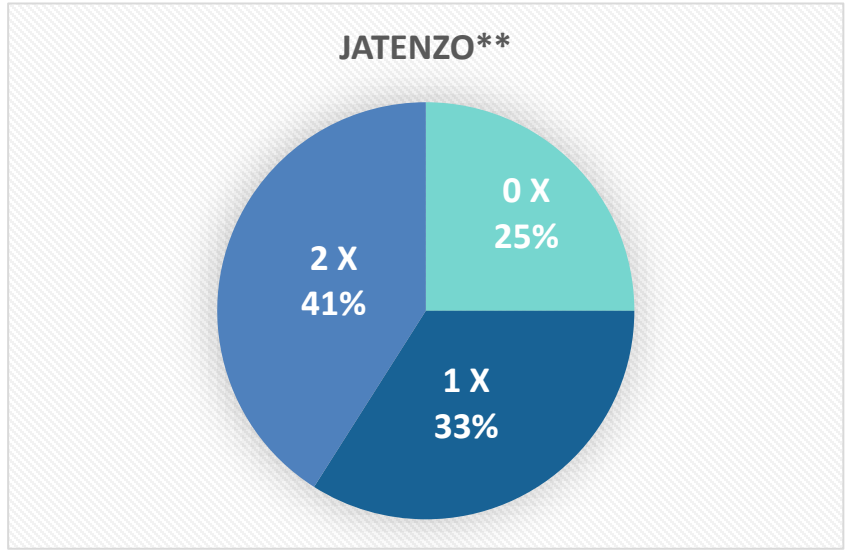
Source: Adheris Health 2017
Cohort Period: February 2016 – January 2017
Analysis Period: 12 Months

Titration Requirements of Current TRTs

Majority of Patients Need Dose Adjustment



Number of Current TRT Dose Adjustments by Form*



- 74% of patients required dose adjustments
- 97% of dose adjusted patients required up titration

* Current TRT n=412
Q16. Since you started using your current testosterone medication, how many times was the dose adjusted up or down until you reached your current dose level?

**Jatenzo CLAR-15012 clinical study results

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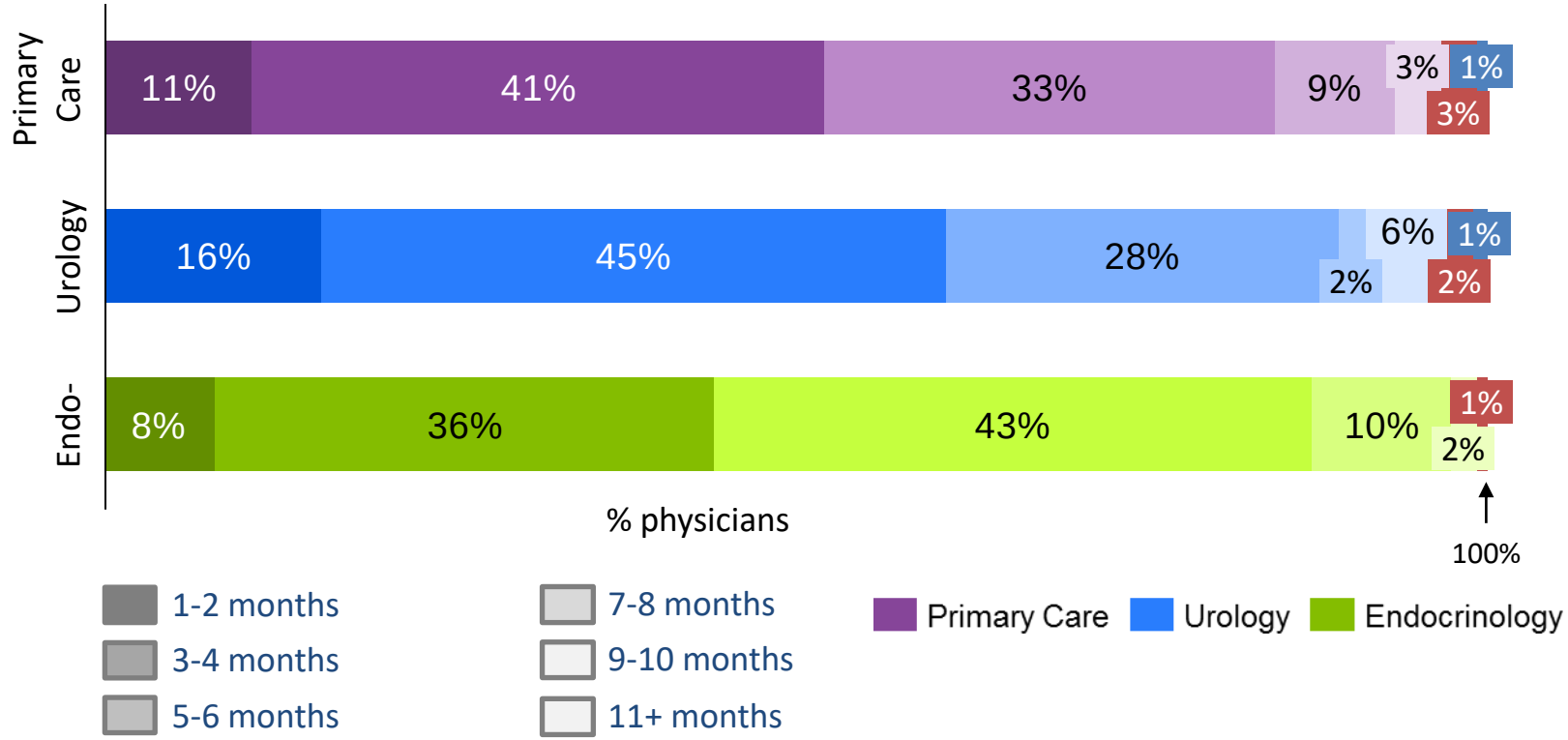
Physician Research Data*

Typical Titration for TRT Takes 3-6 Months to Reach Efficacious Dose for Majority of Patients

Average titration time to steady state dose

N = 402 physicians; 150 primary care, 102 urology, 150 endocrinology



1.18: How long, typically, does it take to titrate a patient to their steady state dose?

*QuintilesIMS-Lipocine, Physician Quantitative Survey, Nov 2017

TLANDO™ Attributes

TRT without Titration Requirement

Convenient Oral Route

- Patient and physician preferred

Easy to Prescribe and Use

- Enables selection of an effective dose at the start of therapy
- Potential for higher persistence/adherence
- No burden of additional dose adjustment visits
- Not prone to titration decision errors

Differentiated Hypertension (“HTN”) and Hematocrit Profile

- ~ 1% new anti-HTN starts or increase in anti-HTN dose
- Low incidence of hematocrit increase (erythrocytosis)

Consistent Inter-Day Restoration of T Levels

Demonstrated Paradigm Shifting Liver Benefits

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 Regulatory Update

Near Term PDUFA Date

CRL received
November 9, 2019

One deficiency:
Did not meet the three secondary endpoints for maximal testosterone concentrations (Cmax)

Post Action Meeting
January 16, 2020

The FDA indicated approach to addressing the deficiency through reanalysis in accordance with FDA feedback appears to be a reasonable path forward

NDA Filed
February 28, 2020

The NDA incorporates the reanalysis of existing data to address the deficiency discussed in the Post Action Meeting with the FDA

PDUFA Date
August 28, 2020

TLANDO XR

(Testosterone Tridecanoate)

Once Daily Oral TRT

Phase 2b Study: Result Summary

Met Primary and Secondary Endpoints

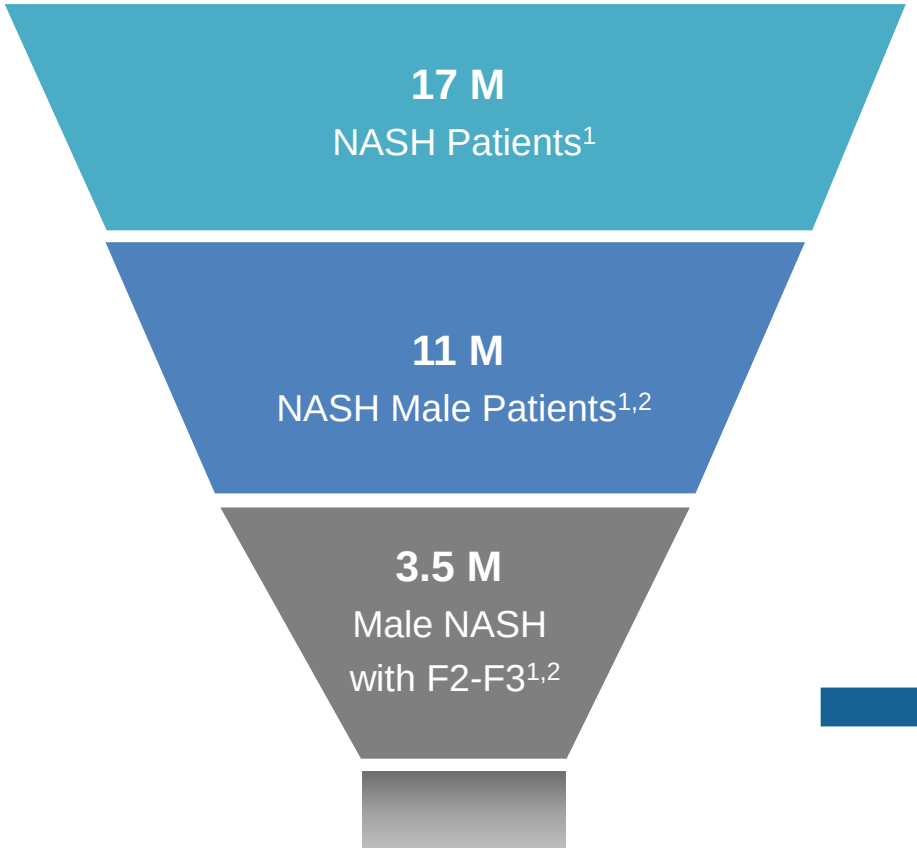
- Once daily dose for 14 days in an open label, multiple dose PK study in hypogonadal men (n=36 subjects)
  - ✓ Phase 3 dose identified
  - ✓ No Drug related SAEs
  - ✓ Drug Related AEs are Mild to Moderate
- Next step: Pivotal study protocol submission to FDA

LPCN 1144

for Non-Cirrhotic NASH

LPCN 1144: Rationale to Target Non-Cirrhotic NASH

Currently No Approved Treatment



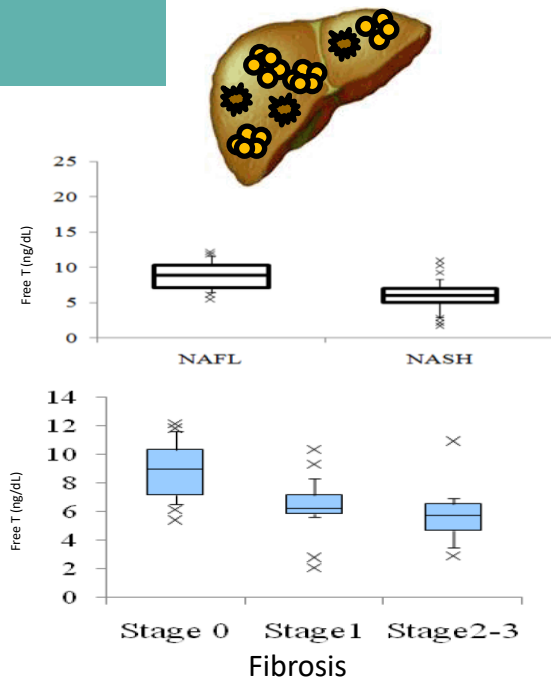
Multi-billion $ Opportunity*

1. Estes et al., Hepatol 2018. 2. Williams et al., Gastroenterology 2011. *2015 data

Association Between Testosterone and Liver Disease

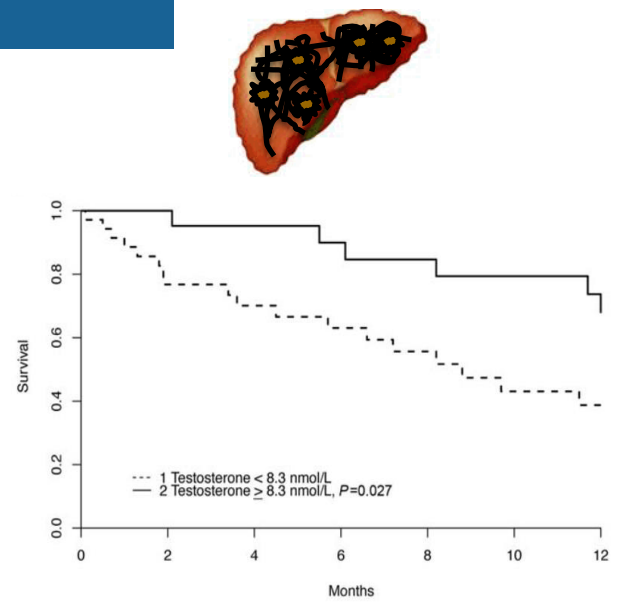
Clinical Evidence

NASH



- ~75% of biopsy-confirmed NASH male patients have testosterone < 372 ng/dL[1]
- Levels of free T decreased significantly with the increased incidence of fibrosis[2]

Cirrhosis



"Low T reported in up to 90% of cirrhosis patients[3] and is a predictor of mortality."[4]

1. Sarkar et al., Gastroenterology 156(6):S-1258 & Poster Sa1623, Digestive Disease Week 2019 2. Sumida et al., Gastroenterol Hepatol 2015; 3. Sinclair et al., Liver Trans 2016; 4. Sinclair M. et al., J. of Gastro and Hepatology, 2015

LPCN 1144: Oral Testosterone Therapy

Differentiated NASH Treatment Candidate

Targets Unmet Need

NASH resolution and/or fibrosis improvement

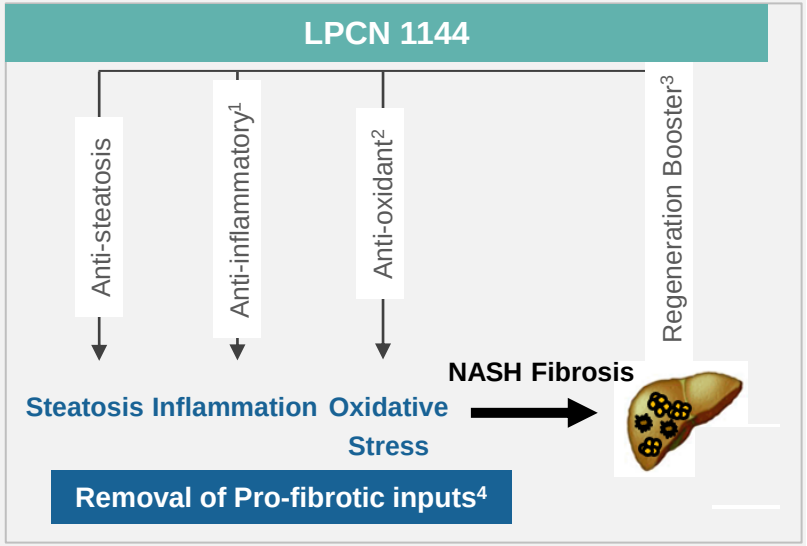
Acceptable tolerability for chronic use

Improvement of sarcopenia

Improvement of sexual dysfunction

Improvement of mental health

Potential Mode of Action



Clinical Experience

Meaningfully reduced liver fat in POC study

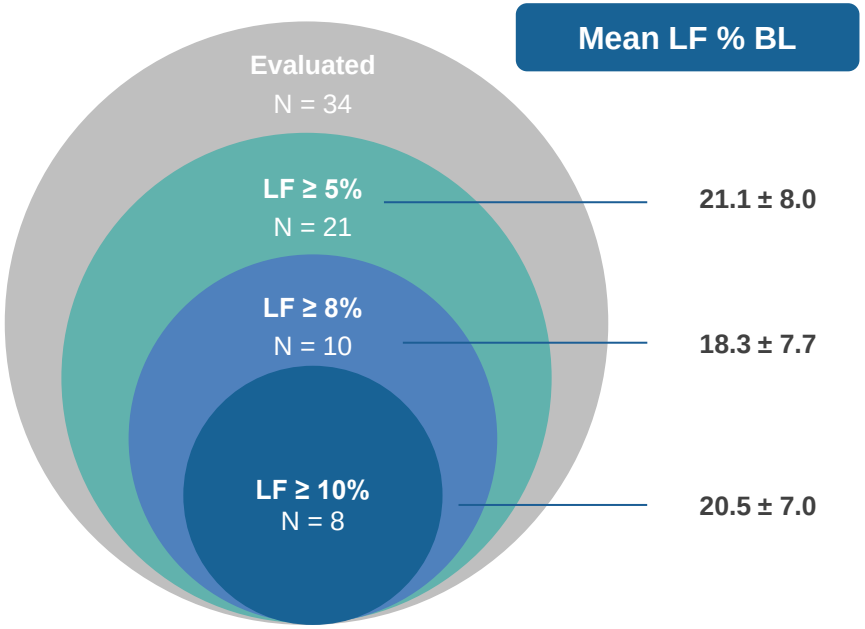
Well tolerated in 700+ subjects with up to 52-week exposure

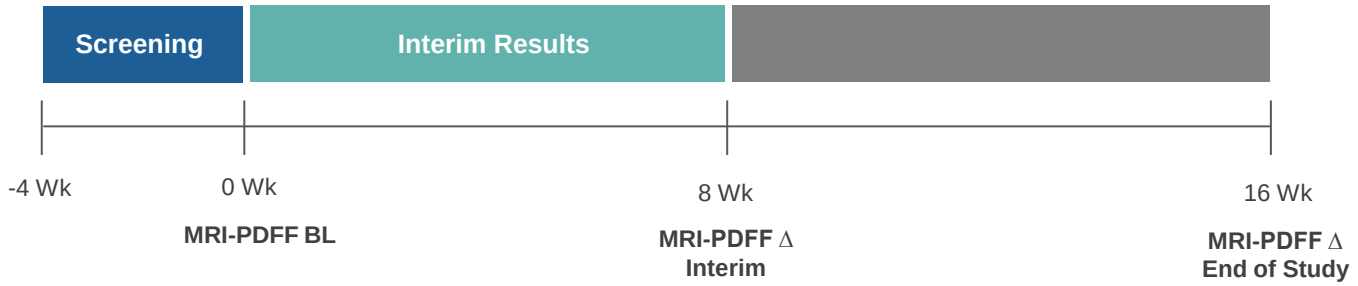
Improved sexual and mood dysfunction

LPCN 1144: Liver Fat Imaging Study (“LFS”)

Study Design and Baseline Liver Fat Subject Distribution

LFS was an open-label, multi-center single-arm 16-week study (N=36) with 225 mg BID LPCN 1144 in hypogonadal males



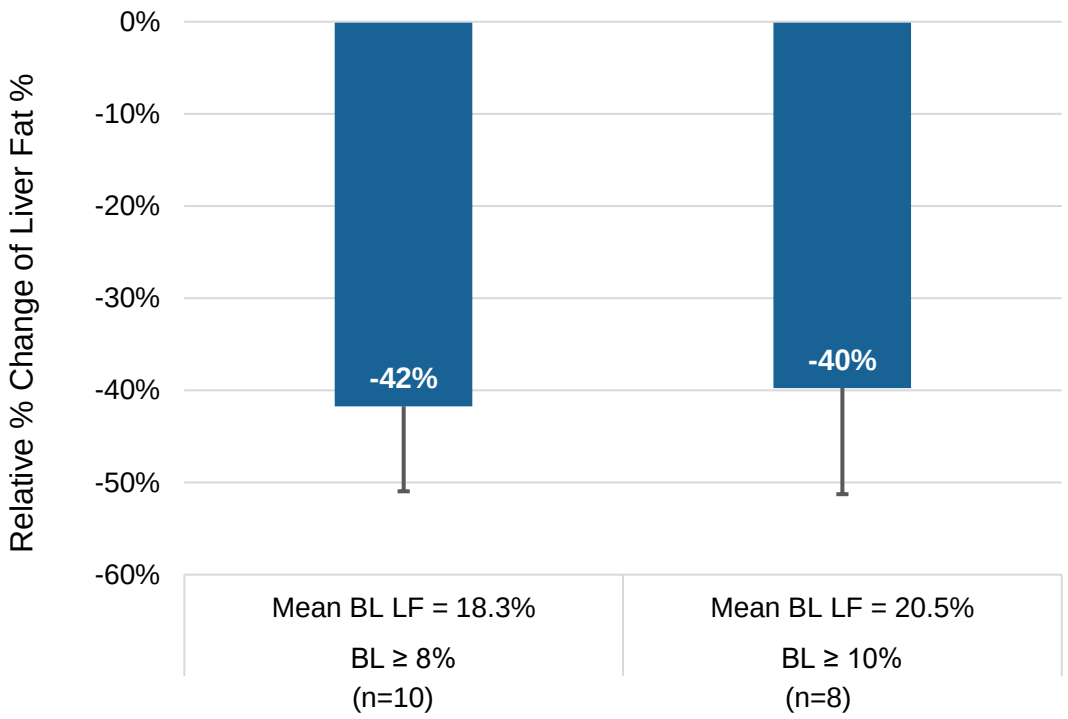


LF = liver fat
BL = baseline

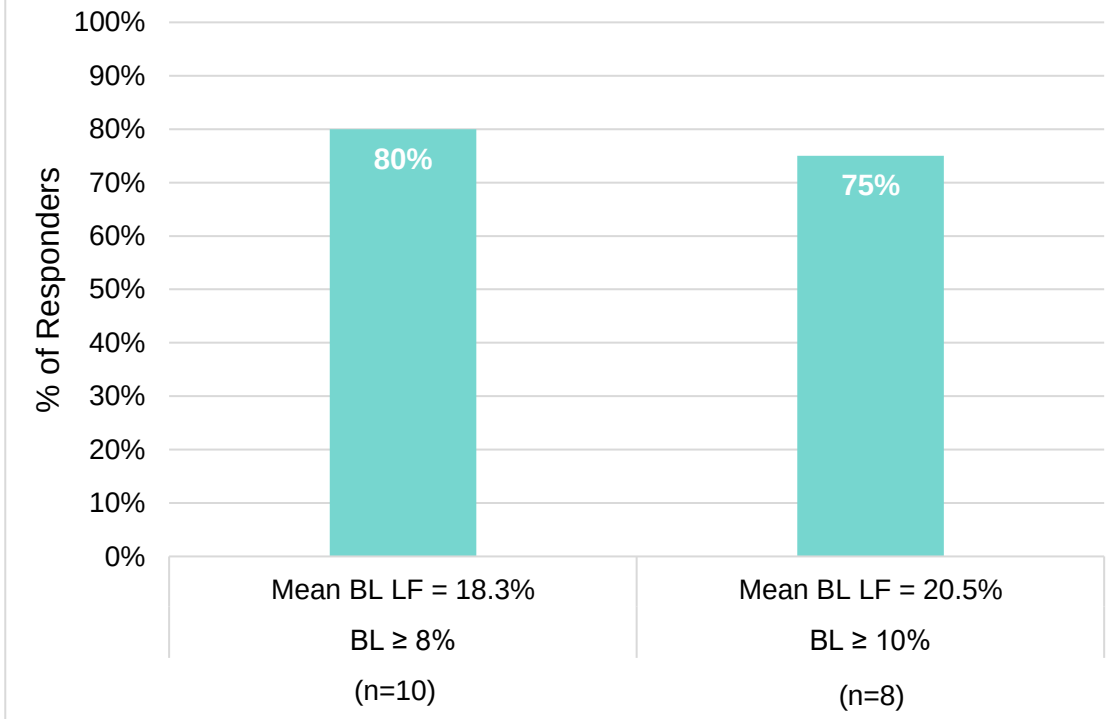
LPCN 1144: Liver Fat Reduction

Meaningful Relative Liver Fat % Change and Responder Rate

Mean Relative Liver Fat % Change



Responders with 30% change for Liver Fat

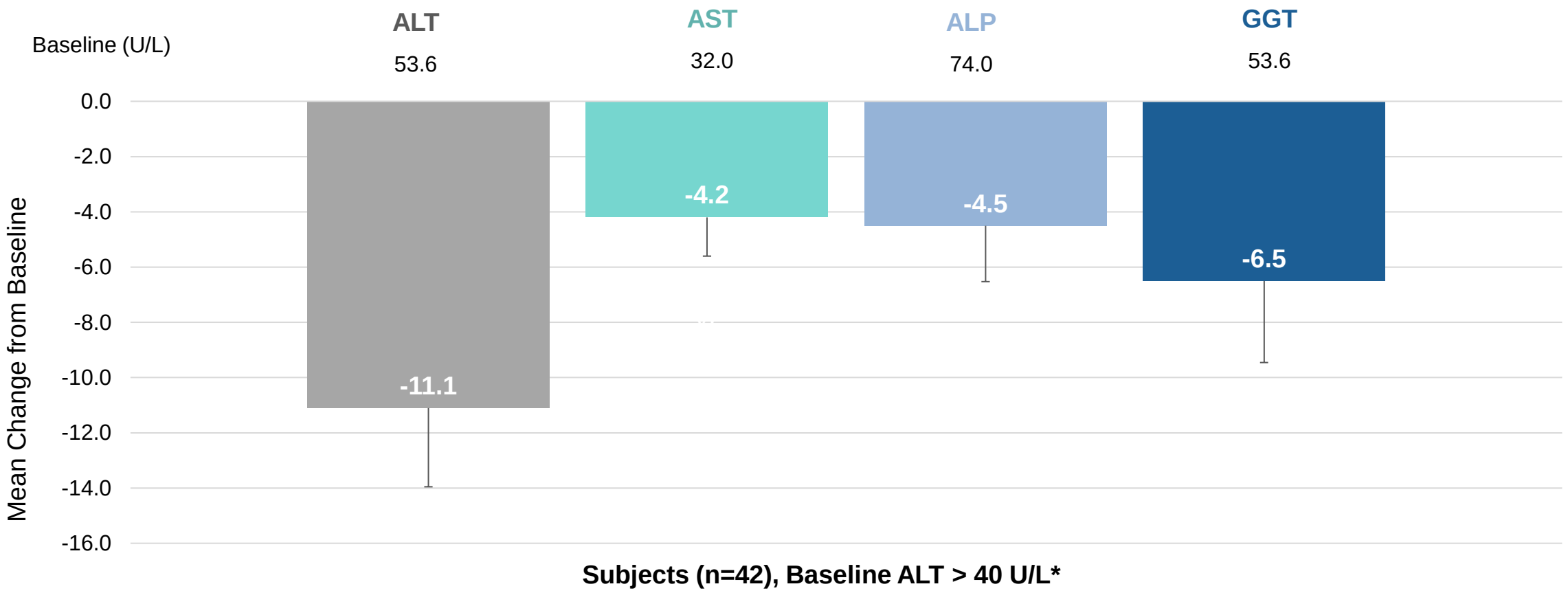


LF = liver fat
BL = baseline

LPCN 1144: Reduction of Liver Injury Markers

In Patients with Elevated ALT at Baseline

Liver enzymes mean change from baseline to end of study (1-Yr), NCT02081300



Alanine amino transferase (ALT), Aspartate amino transferase (AST), Alkaline phosphatase (ALP), Gamma-glutamyl transpeptidase (GGT)

* Sanyal et al, Hepatol, 2015

LPCN 1144: *LiFT* Study* Ongoing

Liver Fat Intervention with Oral Testosterone Study

Phase 2 paired-biopsy clinical study in NASH subjects (NCT04134091)

Study Design

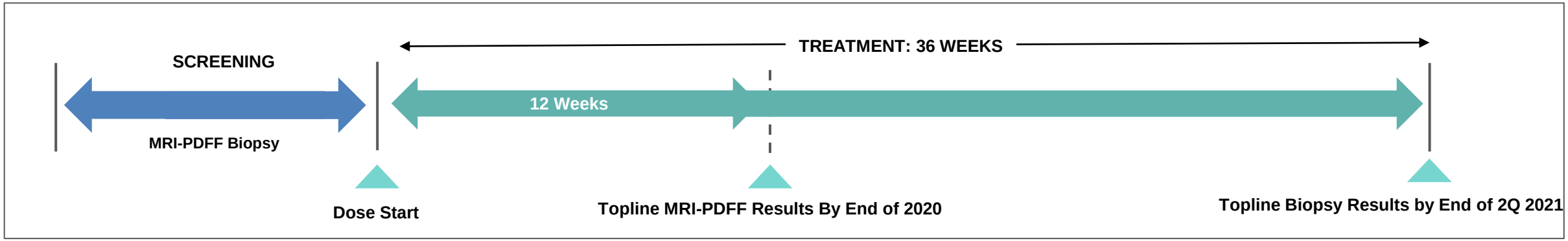
- Three-arm (1:1:1 randomization, two treatments and placebo), multi-center, double-blind
- 225mg twice daily (450mg Daily)
- 20-25 biopsy confirmed NASH male subjects per arm with NAS ≥ 4, F1-F3
- Treatment duration of 36 weeks

Primary Endpoint

- Change in hepatic fat fraction via MRI-PDFF measure

Secondary Endpoints

- Change in NASH activity and fibrosis via liver biopsy scoring
- Change in liver enzymes, anthropometric measure, lipids, insulin resistance, inflammatory/fibrosis markers, and labs
- Change in quality-of-life degree (SF-36 and PDQ), weight, BMI, waist circumference, waist to hip ratio, and PAQ activity



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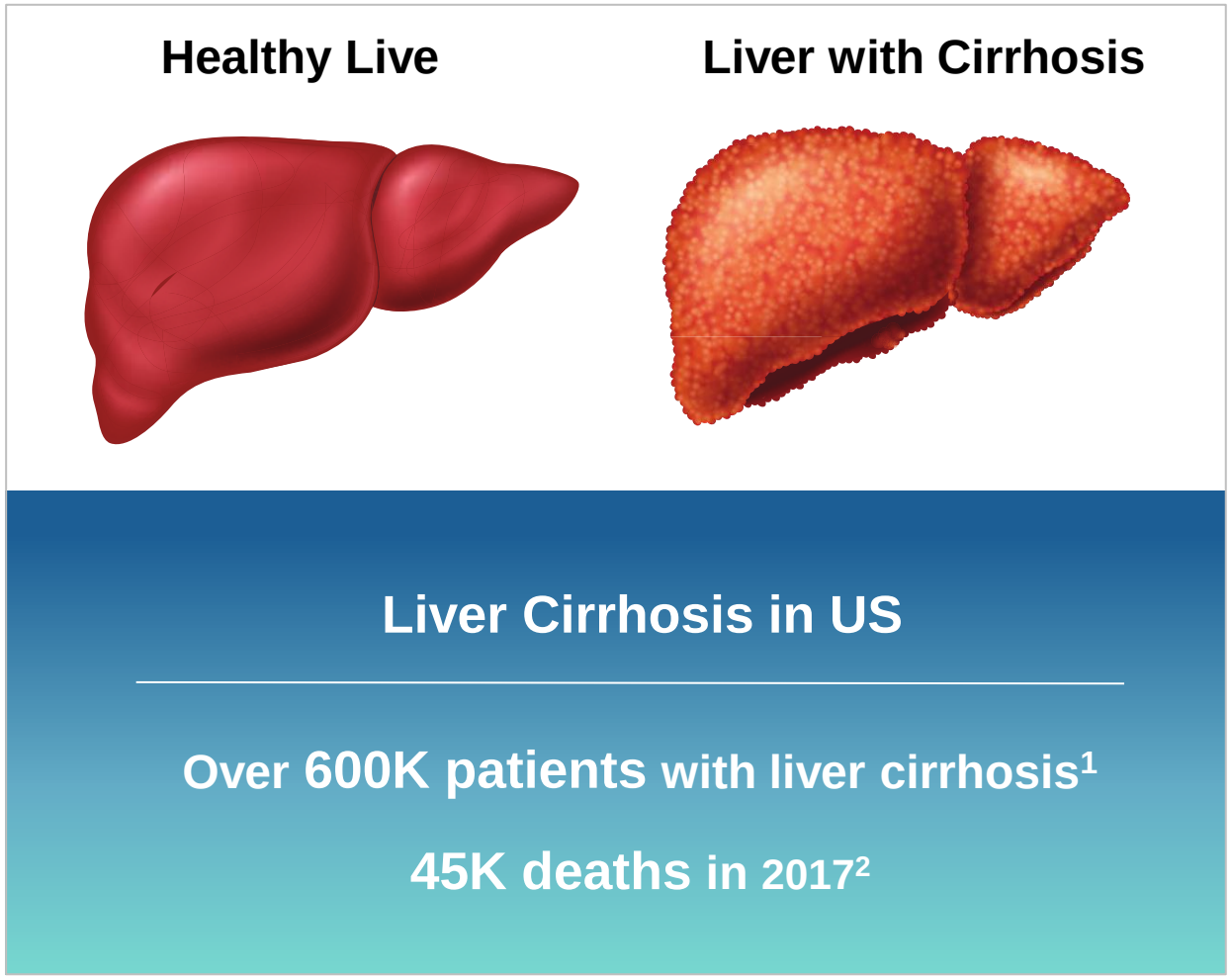
* Website: www.lift-study.com

LPCN 1148

for Liver Cirrhosis

LPCN 1148: Oral T for Cirrhosis

Background: Prevalence and Common Causes



Common Causes[3]

Alcoholic liver disease

Nonalcoholic Fatty Liver Disease (NAFLD)

Chronic hepatitis B

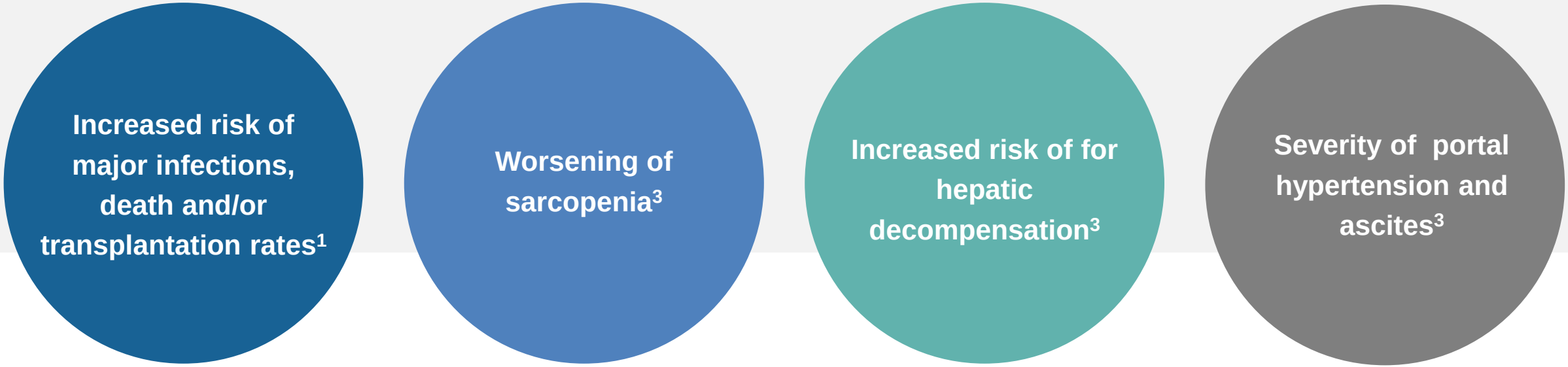
Chronic hepatitis C

Cryptogenic

1. Sinclair et al., Liver Transplantation, 2016; 2. Sinclair et al., J Gastroenterol Hepatol. 2016; 3.. Paternostro et al, Hepatol Res 2019
MELD Score: Model For End-Stage Liver Disease Score; Child-Pugh Score for Cirrhosis Mortality

Reduced Testosterone* – Cirrhosis Association

Progressive Drop in T Level with Increasing Disease Severity[1]



1. Sinclair et al., Liver Transplantation, 2016; 2. Sinclair et al., J Gastroenterol Hepatol. 2016; 3. Paternostro et al, Hepatol Res 2019
MELD Score: Model For End-Stage Liver Disease Score; Child-Pugh Score for Cirrhosis Mortality. *Most cirrhotic male patients have low T2

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	PDUFA Date	**August 28, 2020**
LPCN 1144	*LiFT* Primary Endpoint Results	**By End of 2020**
	LiFT Biopsy Results	**By End of 2Q 2021**
IP Infringement Litigation	**Oral Jury Hearing**	**February 2021**

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	**LPCN (Nasdaq Capital Market)**
Closing Stock Price (7/16/20)	**$1.33/share**
Cash Balance (3/31/20)	**$20.6 million***
Bank Debt (3/31/20)	**$6.4 million**

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* $5M restricted and becomes unrestricted upon TLANDO approval

Lipocine Investment Highlights

Near Term TLANDO PDUFA with a Promising Pipeline

Potential to be a TRT Market Leader

TLANDO™: Differentiated product profile with potential for market expansion

TLANDO XR: Unique long acting oral with potential to maintain leadership

- ~$2B+ opportunity in an established and growing market with favorable market dynamics

Oral Testosterone Targeted for Non-Cirrhotic NASH/Cirrhosis

LPCN 1144: A differentiated modality with potential for mono/combo non-cirrhotic NASH therapy

LPCN 1148: Targeting cirrhosis