LIPOCINE®

ENHANCING HEALTH

Corporate Presentation

Enabling Oral Drug Delivery to
Improve Patient Compliance

September 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")*					**Under FDA Review**
TLANDO XR *(Long Acting Oral Testosterone for Testosterone Replacement Therapy "TRT")*				**Phase 3 Study Protocol Being Finalized with FDA**	
LPCN 1144 *(Oral Testosterone for Non-Cirrhotic NASH)*			***LiFT* Phase 2 Clinical Study Ongoing – Enrollment Complete**		
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

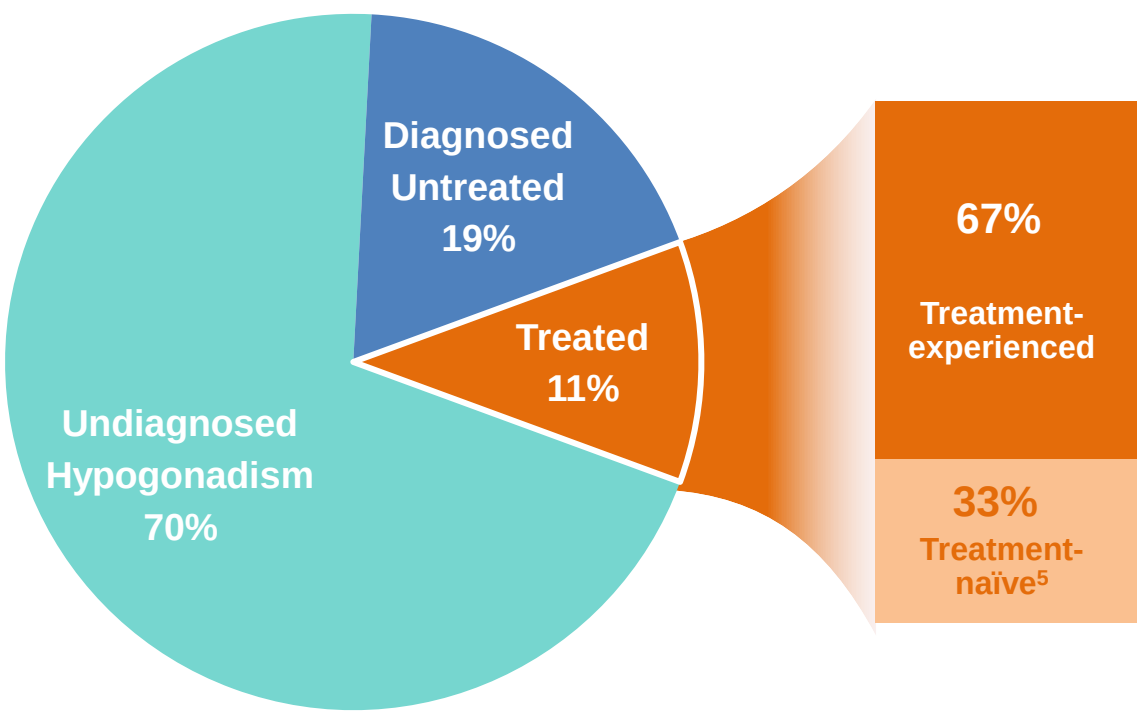
Hypogonadism Affects Up to 20M Men[1, 2]

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

Hypogonadism Under Treatment in US

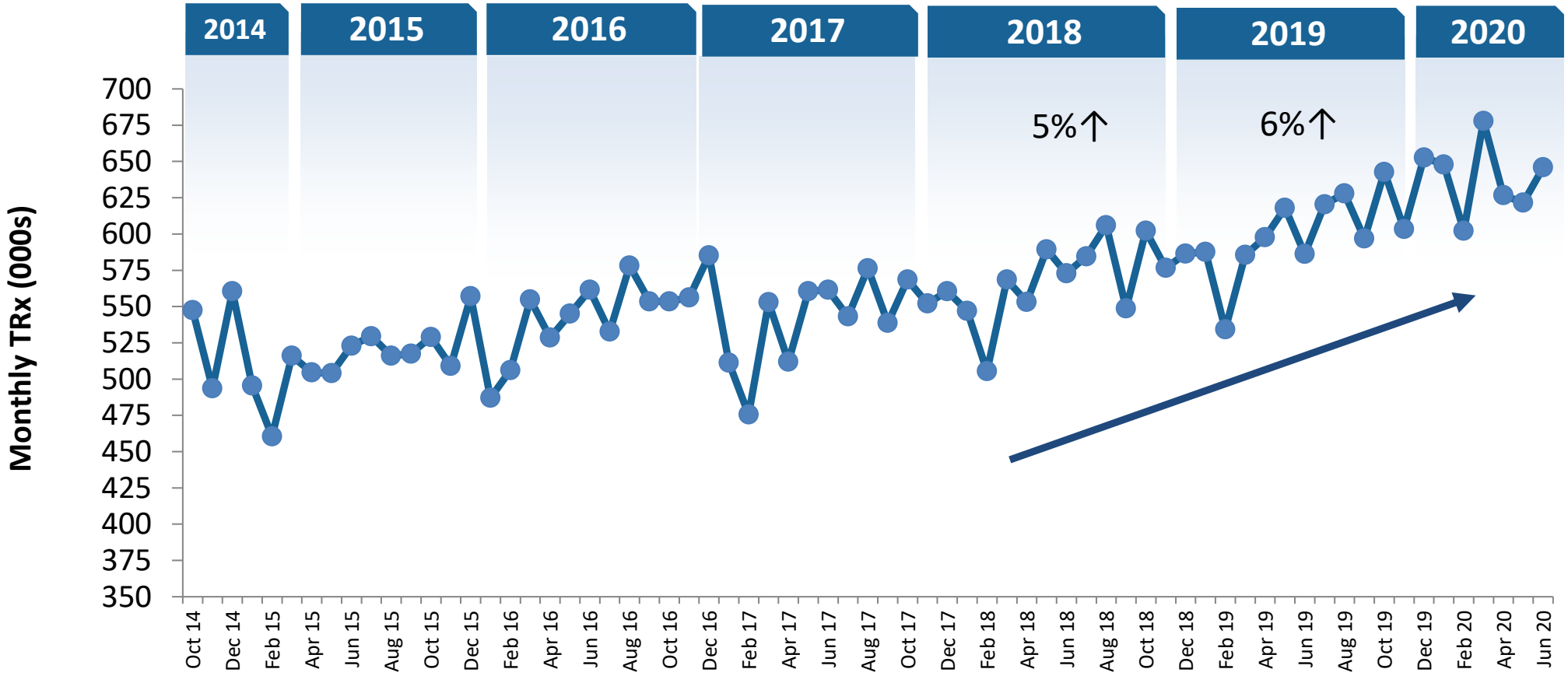
Close to **6M** men with diagnosed hypogonadism[3]

2M men being treated[4]



Monthly TRT TRx Trend

TRT Market is Growing



Last 12 months (July 2019 – June 2020) TRx of 7.5 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 start of therapy is one of the top reasons patients stop using TRT

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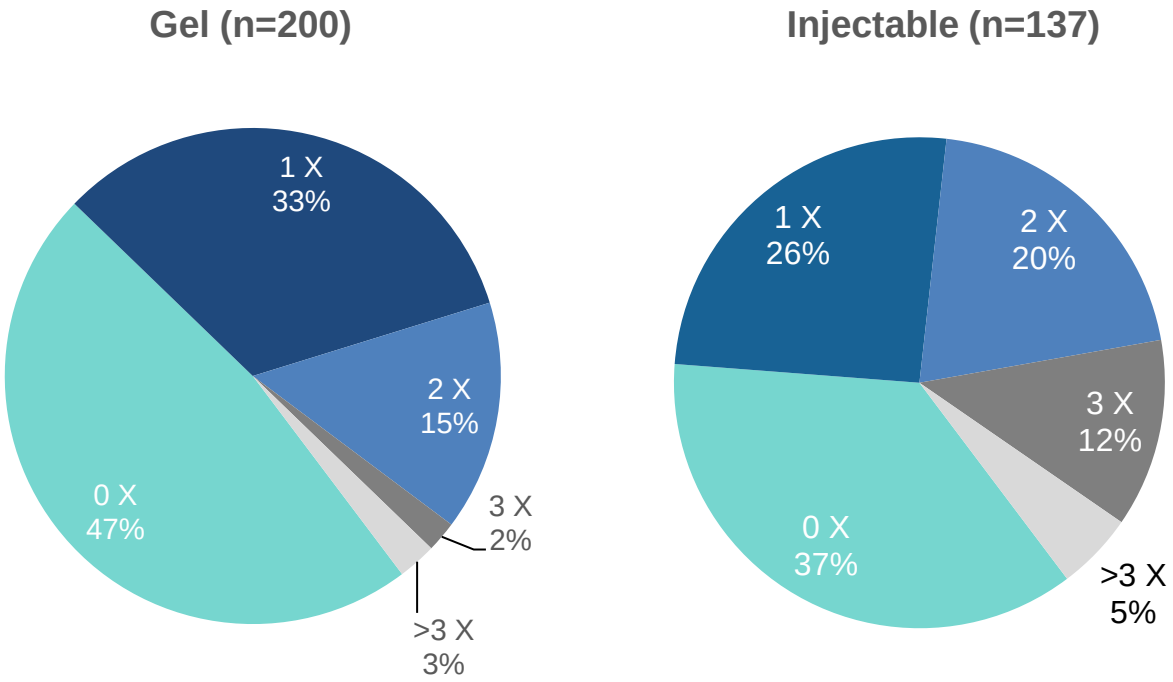
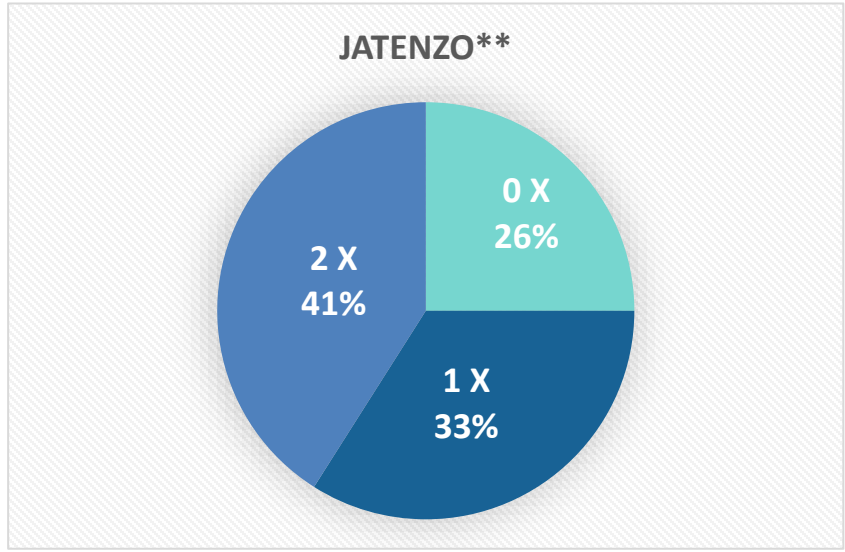
*Pastuszak et al. Sex Med. 2015

Most TRTs Require Dose Titration in Majority of Patients

Majority of Patients are NOT on Efficacious Dose at the Start of Therapy



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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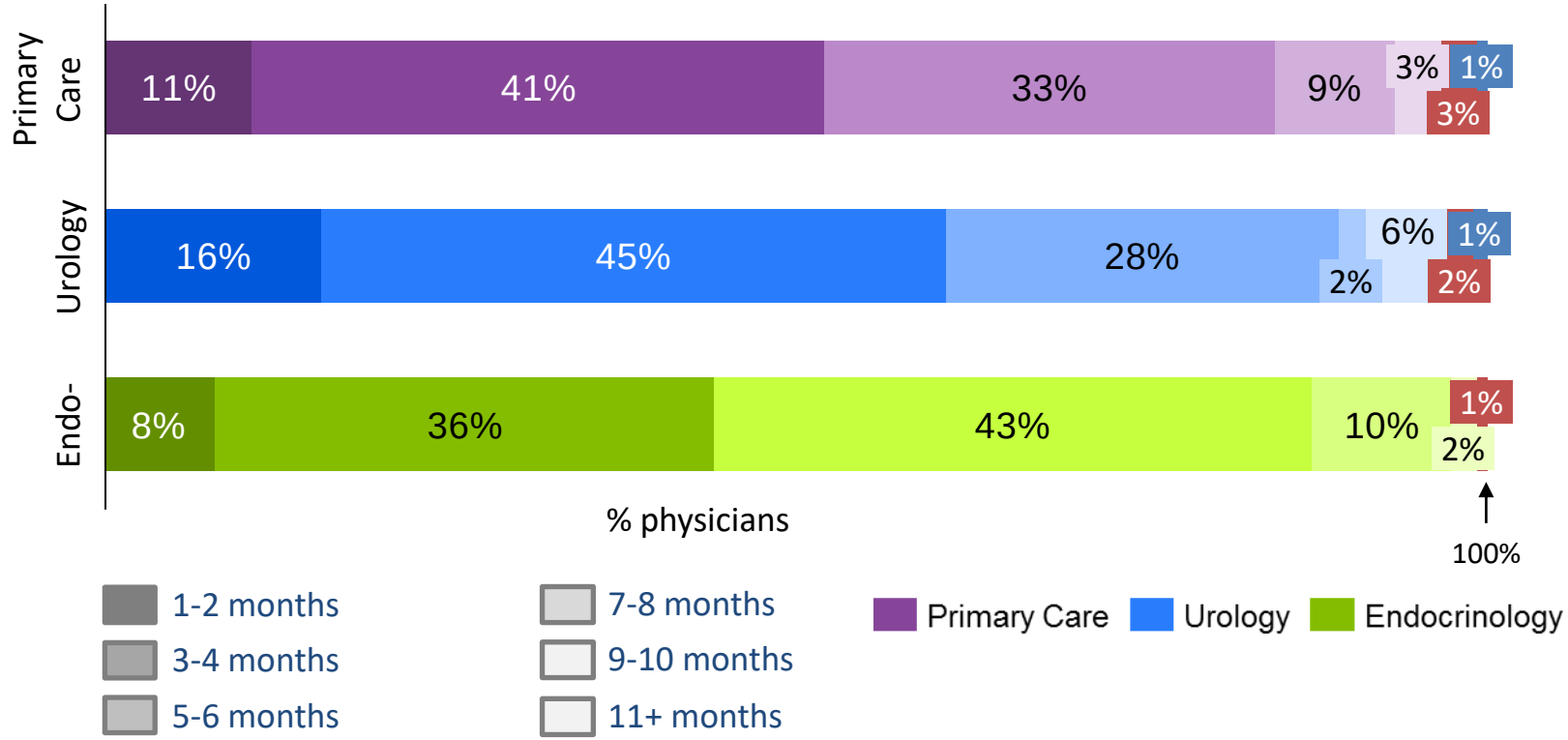
Physician Research Data*

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

- No inadvertent transference or Pulmonary Oil Micro Embolism risks
- Patient and physician preferred
  - Single strength and dose, less confusing

Expected to be Easy to Prescribe and Use

- Enables selection of an effective dose at the start of therapy without delay
- No “efficacy gap” upon switching
  - More conducive to telemedicine switch from other inconvenient TRTs
- No additional pharmacy and clinic co-pays to reach efficacious dose
- No dose adjustment clinic and pharmacy visits
- No dose adjustment invasive samplings
- Bioequivalent exposure in low/med/high fat food
- No titration decision errors
- No concerns about compliance with narrow titration sampling window

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

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*
***Extended by FDA**

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TLANDO XR

(Testosterone Tridecanoate)

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 TLANDO
- ✓ Patients and physicians prefer once a day oral testosterone
- ✓ Strong IP (new molecule & proprietary drug delivery technology)
- ✓ Positive Phase 2b study results

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TLANDO XR: Development Milestones

Historical Activities

Regulatory	Pre-IND Type B meeting held
	IND filed
	Type C meeting held
	FDA in agreement with Phase 3 dose and single pivotal PK study for registration
CMC	Formulation, dose, and dosage form have been identified in Phase 2b
	Analytical methods and specifications for drug product release and stability were established
Nonclinical studies	13-week toxicokinetic study in Beagle dogs
	Androgen Receptor Binding Study
Clinical studies*	Five Phase 1 and two Phase 2
	Met primary and secondary endpoints in Phase 2b (14 days, multiple dose PK study in hypogonadal men)
	Phase 3 dose identified
	No Drug related SAEs and drug related AEs were mild to moderate

*Finalizing Phase 3 protocol with the FDA

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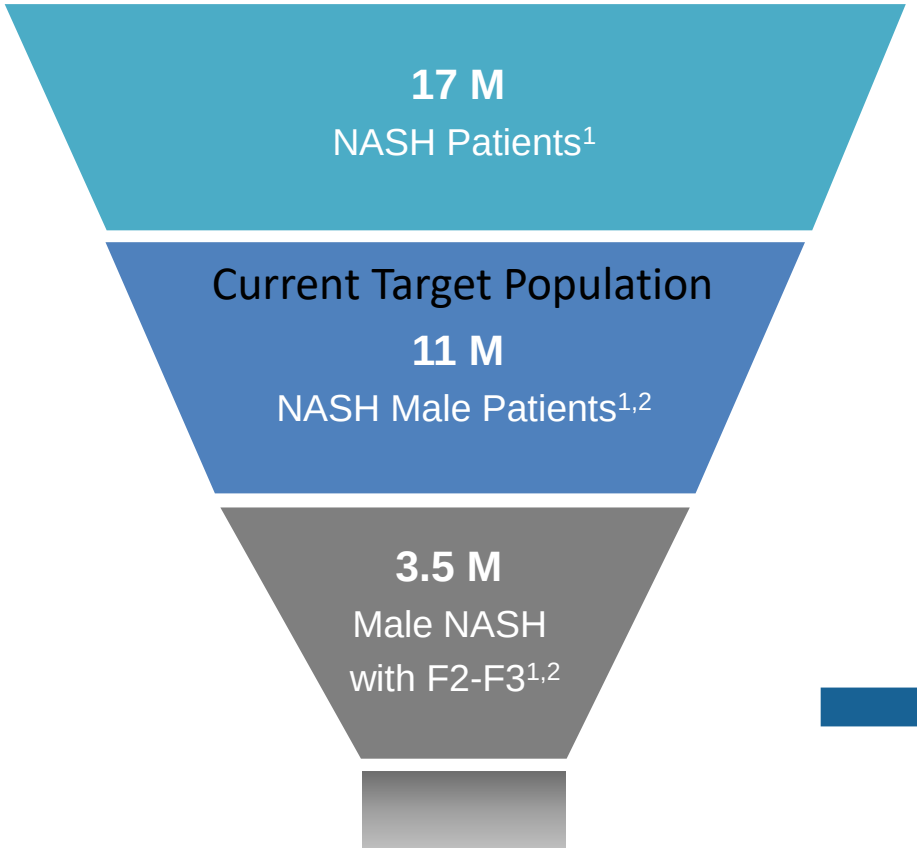
LPCN 1144

for Non-Cirrhotic NASH

LPCN 1144: Rationale to Target Non-Cirrhotic Male NASH Patients

Currently No Approved Treatment



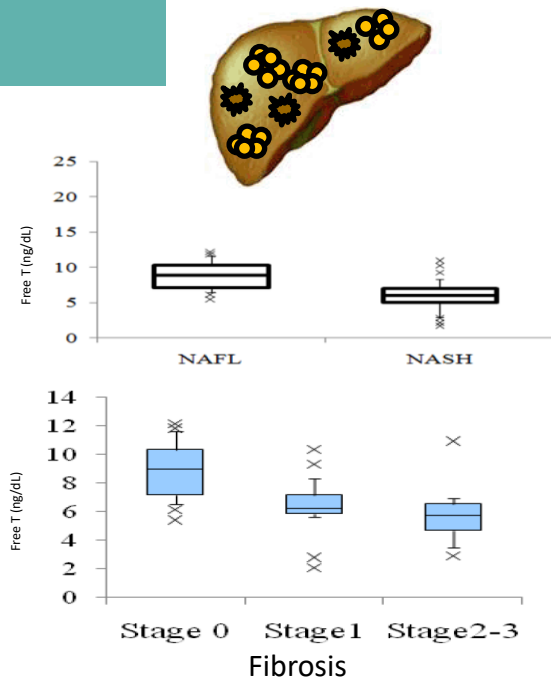
Multi-billion $ Opportunity*

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

Association Between Testosterone and Liver Disease

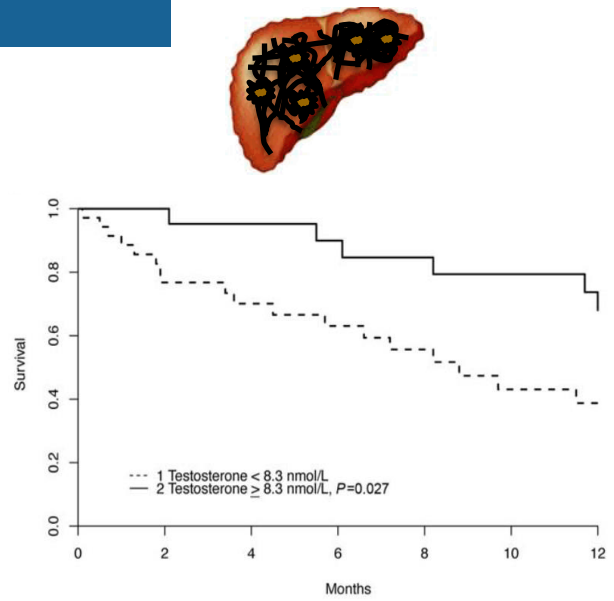
Clinical Evidence

NASH



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

Cirrhosis



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

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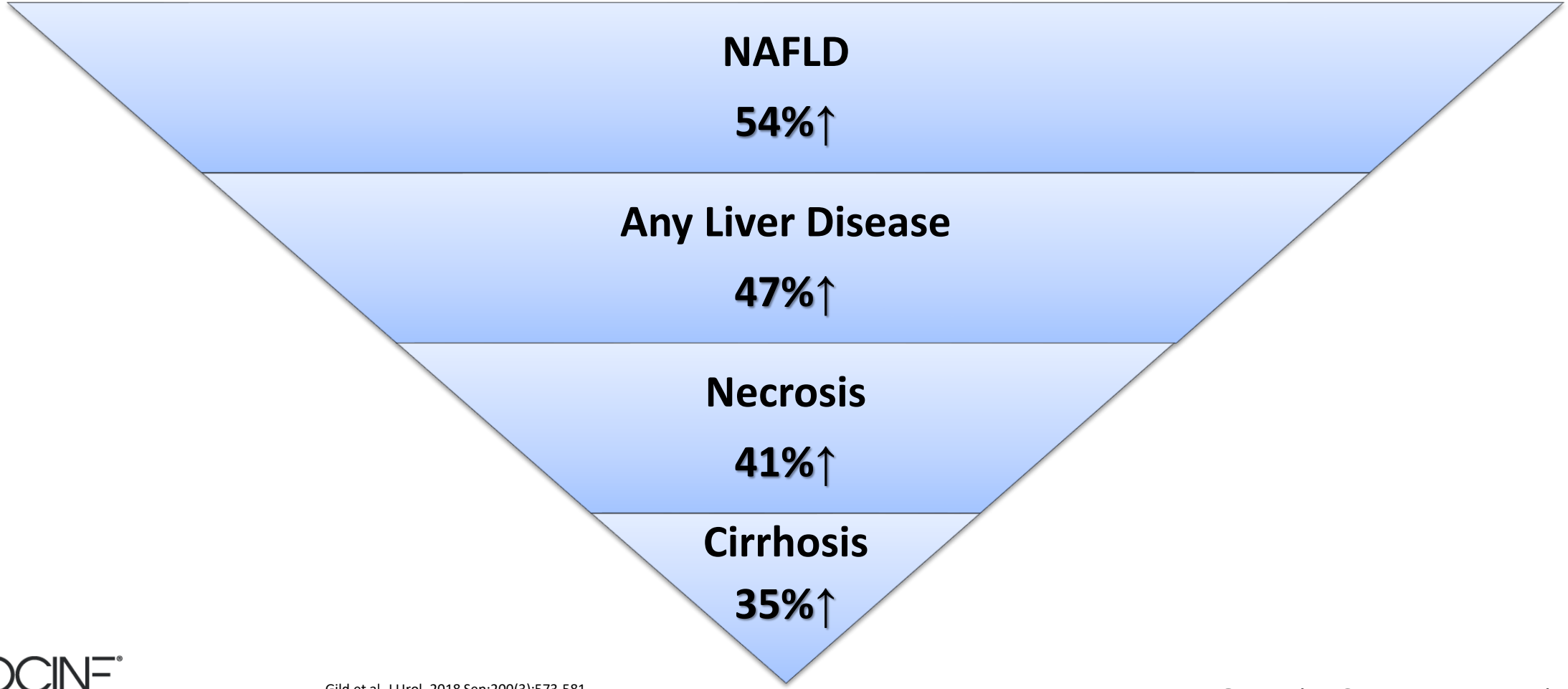
1. Sarkar et al., Gastroenterology 156(6):S-1258 & Poster Sa1623, Digestive Disease Week 2019 2. Sumida et al., Gastroenterol Hepatol 2015; 3. Sinclair et al., Liver Trans 2016; 4. Sinclair M. et al., J. of Gastro and Hepatology, 2015

Association Between Testosterone and Liver Disease – Clinical Evidence

Liver Disease in Men Undergoing Androgen Deprivation Therapy (ADT) for Prostate Cancer

Patients Receiving ADT were Significantly More Likely to Have



Gild et al. J Urol. 2018 Sep;200(3):573-581

LPCN 1144: Androgen Receptor Agonist

Differentiated NASH Treatment Candidate

Targets Unmet Need

Acceptable benefit to risk ratio

- NASH resolution and/or fibrosis improvement
- Tolerability for chronic use

Improvement of sarcopenia

Improvement of sexual/mood dysfunction

Clinical Experience

Non-invasive dosing regimen

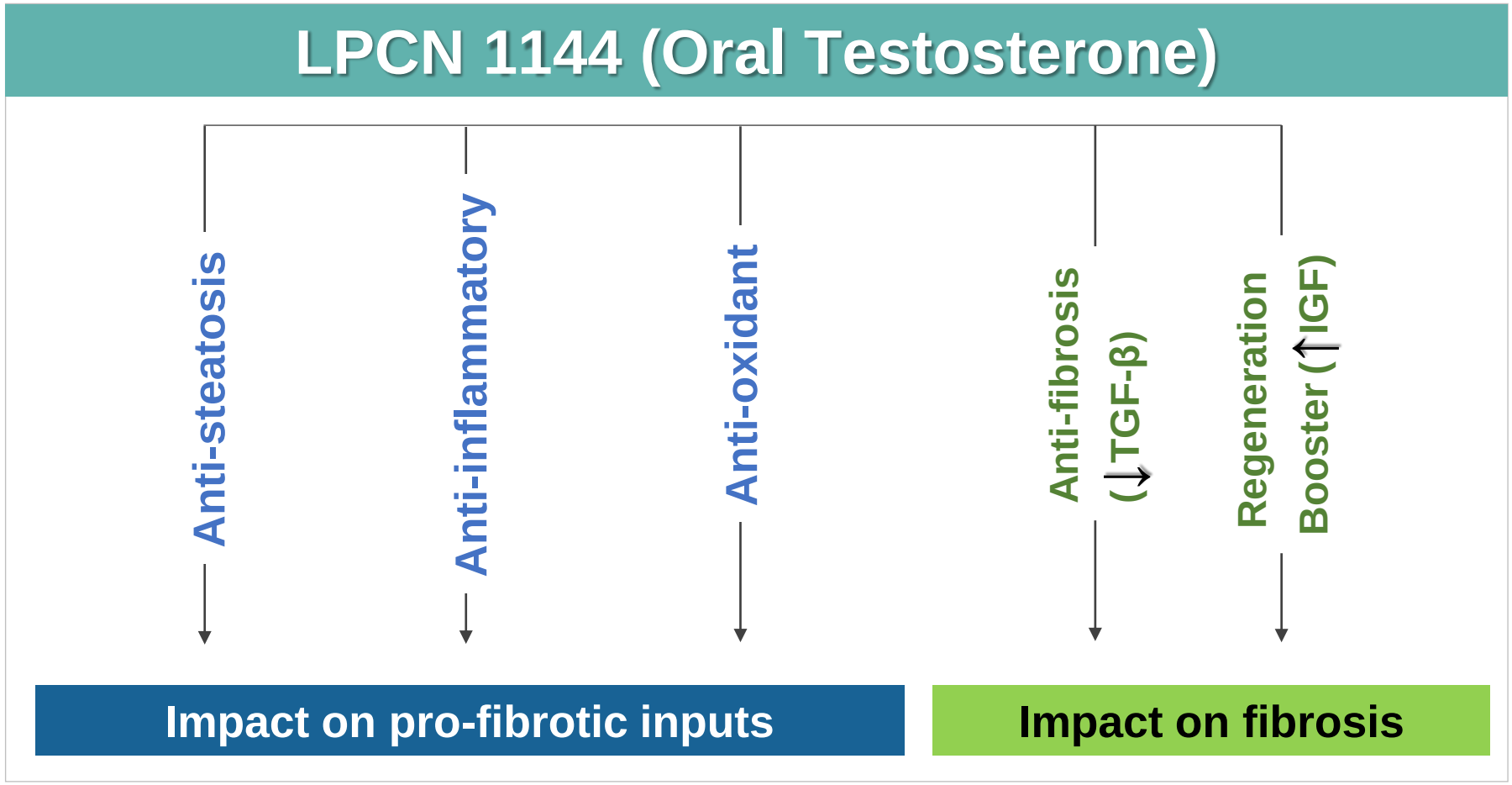
Meaningfully reduced liver fat in POC study

No notable tolerability issues

Improved sexual/mood dysfunction

LPCN 1144: Androgen Receptor Agonist

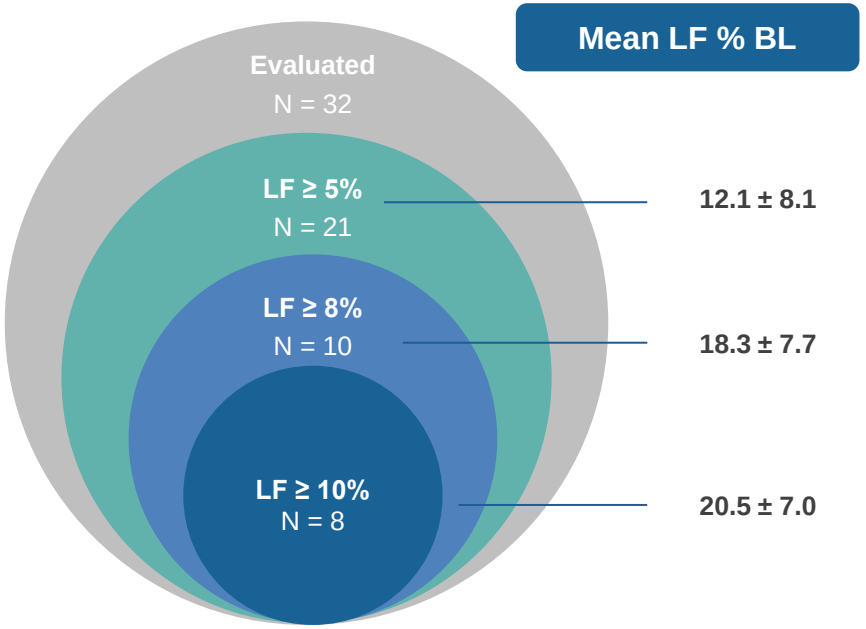
Potential Mode of Action

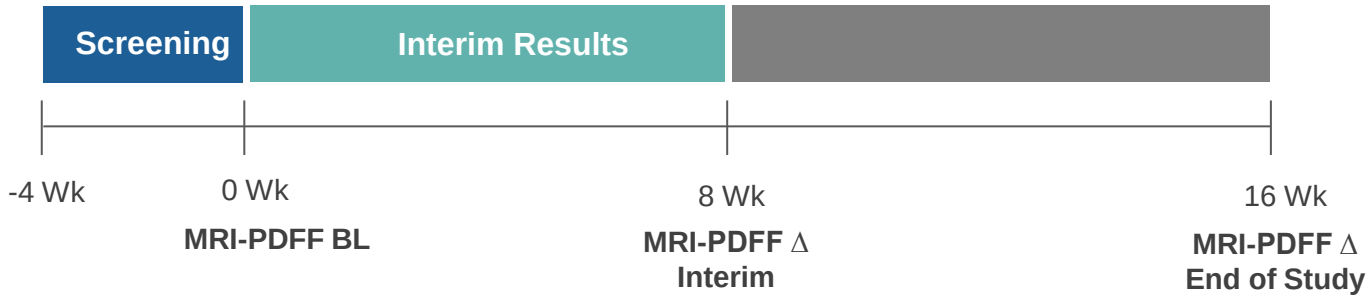


LPCN 1144: Liver Fat Imaging Study ("LFS")

Study Design and Baseline Liver Fat Subject Distribution

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





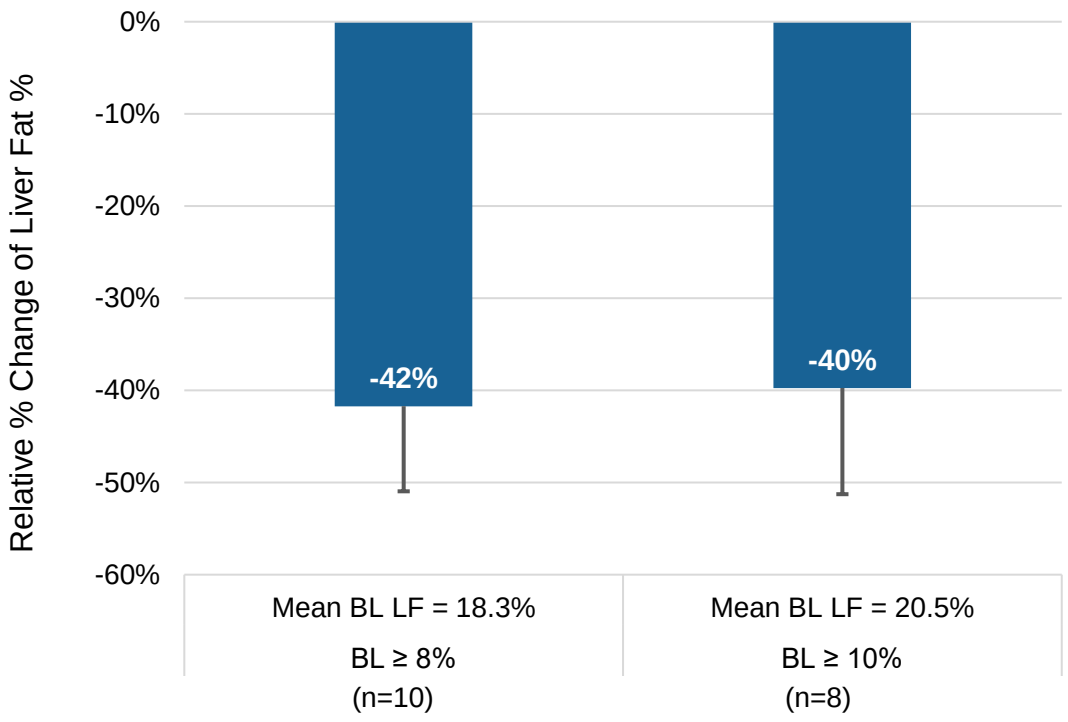
LF = liver fat
BL = baseline

Ref: Albhaisi et al., Hepatology Communications, 2020 https://doi.org/10.1002/hep4.1571

LPCN 1144: Liver Fat Reduction

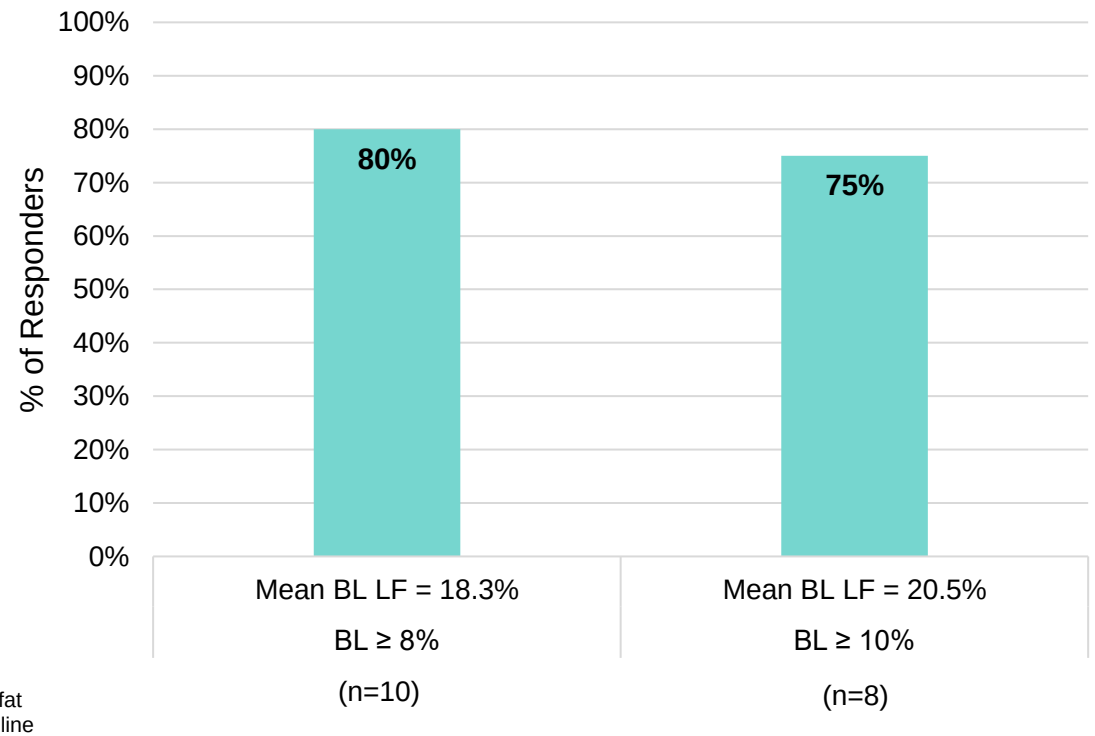
Meaningful Relative Liver Fat % Change and Responder Rate

Mean Relative Liver Fat % Change



LF = liver fat
BL = baseline

Responders with ≥ 30% change for Liver Fat



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Ref: Albhaisi et al., Hepatology Communications, 2020 https://doi.org/10.1002/hep4.1571

LPCN 1144: *LiFT (Liver Fat intervenTion)* Study* Ongoing

Phase 2 Paired-Biopsy Clinical Study in NASH Subjects (NCT04134091)

Study Design

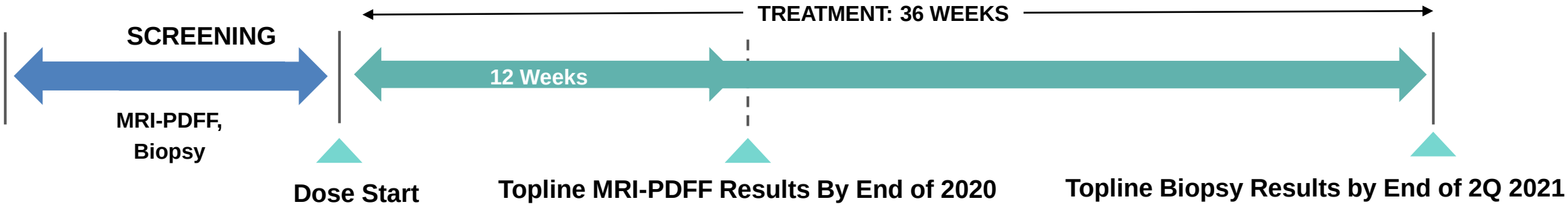
- Three-arm (1:1:1 randomization, two treatments and placebo), multi-center, double-blind
- Targeting 20-25 biopsy confirmed male NASH subjects per arm with NAS ≥ 4, F1-F3
- Treatment duration of 36 weeks

Primary Endpoint

- Change in hepatic fat fraction via MRI-PDFF

Secondary Endpoints

- Change in NASH activity and fibrosis via liver biopsy scoring
- Change in liver markers, anthropomorphic measures (weight, body mass index (BMI), waist to hip ratio, waist circumference), lipids, insulin resistance, inflammatory/fibrosis markers, and labs
- Change in quality-of-life degree (SF-36 and PDQ) and Physical Activity Questionnaire



* Website: www.lift-study.com

LPCN 1148

for Liver Cirrhosis

LPCN 1148: Oral T for Cirrhosis

Background: Prevalence and Common Causes

Transplant Only Cure for Liver Cirrhosis

High Economic Burden of a Liver Transplant[1]

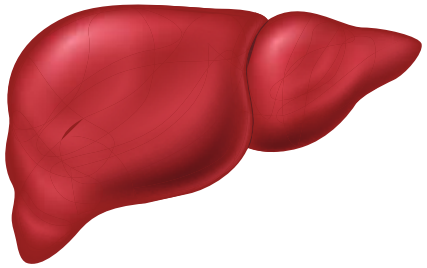
Liver Cirrhosis in US

Over 600K patients with liver cirrhosis[2]

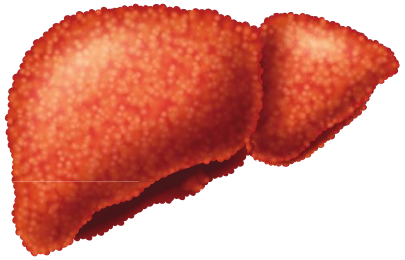
45K deaths in 2017[3]

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**

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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 Addresses

Improvement in quality of life while on waiting list

Stay on transplant list

Sarcopenia is a leading contributory cause of removal from the waitlist

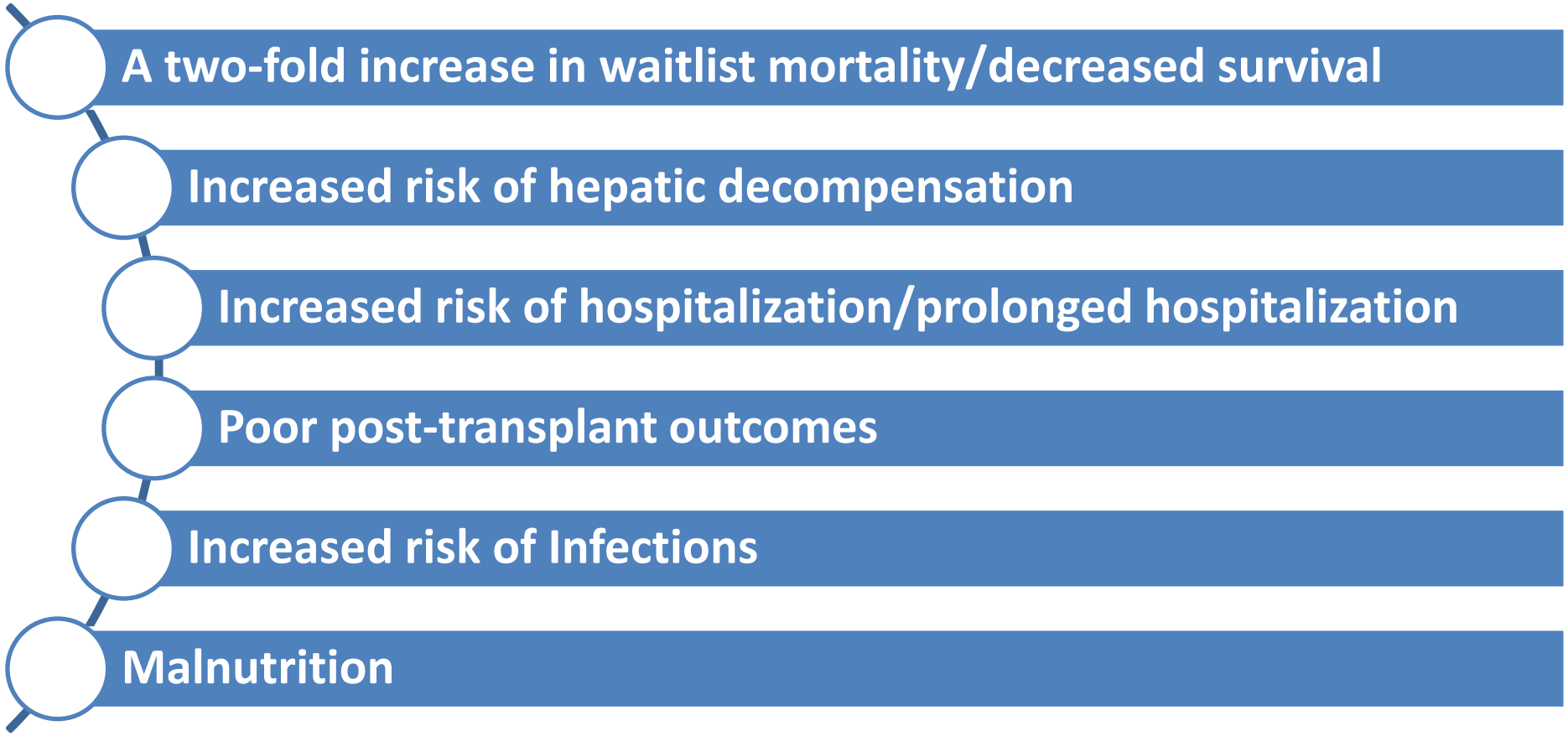
- 40 -70% of cirrhotic patients are sarcopenic

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

Sarcopenia in Liver Cirrhosis

Equivalent to Adding 10 Points to the MELD Score

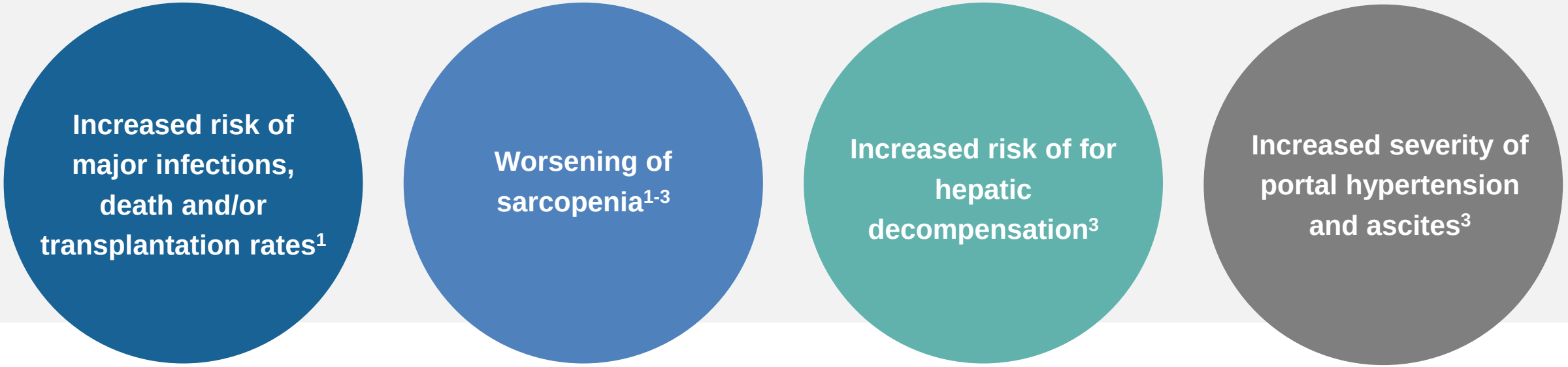


References: Kim and J.W. Jang, World Journal of Gastroenterology, 2015; Sinclair et al., Journal of Gastroenterology and Hepatology (Australia), 2016; Moctezuma-Velazquez et al., Clinical Nutrition, 2018.; Sinclair et al., World Journal of Gastroenterology, 2017. Montano-Loza et al., Clinical and Translational Gastroenterology, 2015; Lai, J.C., et al., Hepatology, 2017; Englesbe et al., J Am Coll Surg, 2010.

MELD Score: Model For End-Stage Liver Disease Score

Progressive Drop in T Level with Increasing Disease Severity[1,3]

Reduced Testosterone Associated with Complications of Cirrhosis

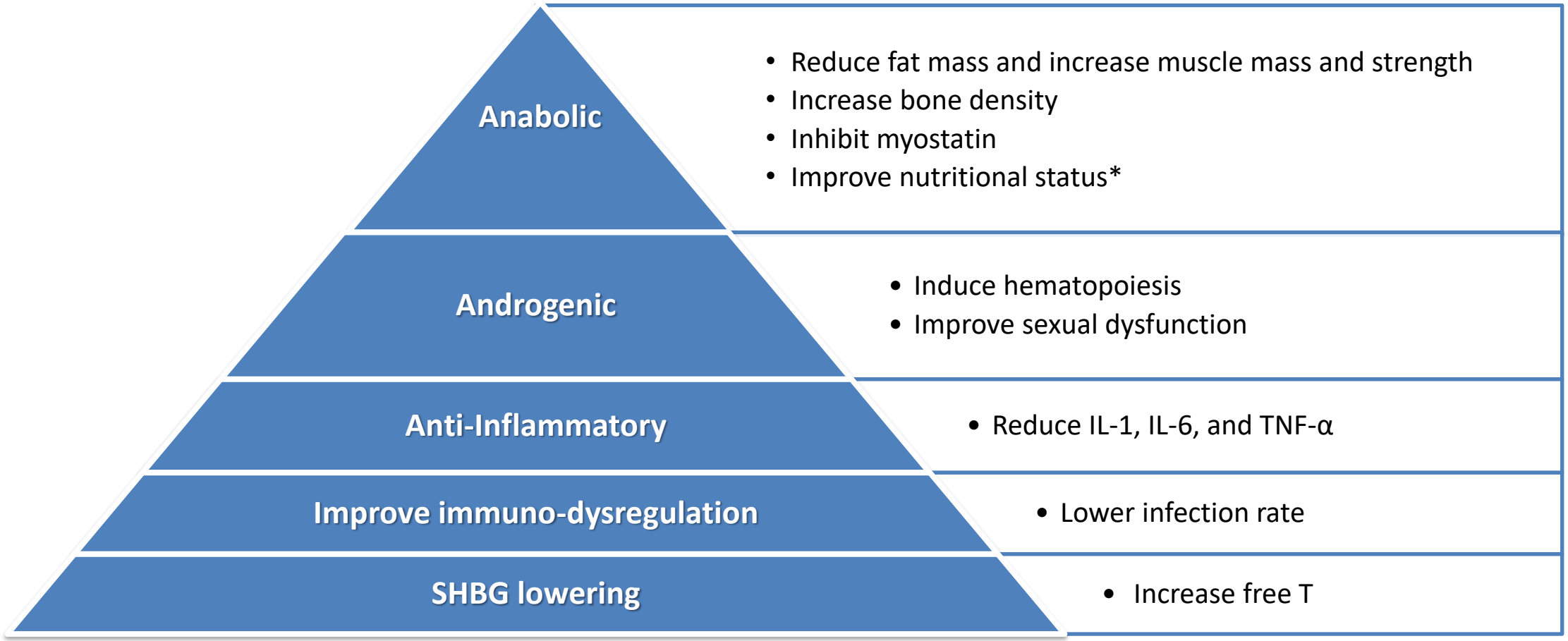


Most cirrhotic male patients have low T[1-3]

1. Sinclair et al., Liver Transplantation, 2016; 2. Sinclair et al., J Gastroenterol Hepatol. 2016; 3. Paternostro et al, Hepatol Res 2019

LPCN 1148 in Cirrhotic Patients

Potential Key Effects



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; Puliyel 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

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Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	PDUFA Date	**August 28, 2020* *Extended by FDA**
LPCN 1144	*LiFT* Primary Endpoint Results	**January 2021**
	LiFT Biopsy Results	**July 2021**
IP Infringement Litigation	Oral Jury Hearing	**February 2021**

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Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	**LPCN (Nasdaq Capital Market)**
Closing Stock Price (9/18/20)	**$1.61/share**
Cash Balance (6/30/20)	**$23.3 million***
Bank Debt (6/30/20)	**$6.3 million**

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* $5M restricted and becomes unrestricted upon TLANDO approval