

LIPOCINE[®]

ENHANCING HEALTH

Enabling Oral Drug Delivery to Improve Patient Compliance

Corporate Presentation

August 7, 2019



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 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.

Lipocine Investment Highlights

Near Term TLANDO PDUFA with a Promising Pipeline

“Best In Class” TLANDO Franchise

Potential to be a TRT market leader in need of an oral option

- **TLANDO™**: ~\$2B+ opportunity in an established and growing market
 - Significant unmet need for an oral TRT
 - Differentiated product profile with potential for market expansion
 - Favorable market dynamics
- **TLANDO XR (QD)**: Unique long acting oral with potential to expand market/maintain leadership

Oral Testosterone Targeted for Pre-Cirrhotic/Cirrhotic NASH

Unmet need with no approved drug

- **LPCN 1144**: A differentiated oral modality with potential for mono/combo pre-cirrhotic NASH therapy
- **LPCN 1148**: Targeting cirrhotic NASH

Orphan Designated Candidate for the Prevention of Preterm Birth

- **LPCN 1107**: First oral alternative

Clinical Stage Biopharmaceutical Company

Innovative Product Candidates for Metabolic and Endocrine Disorders

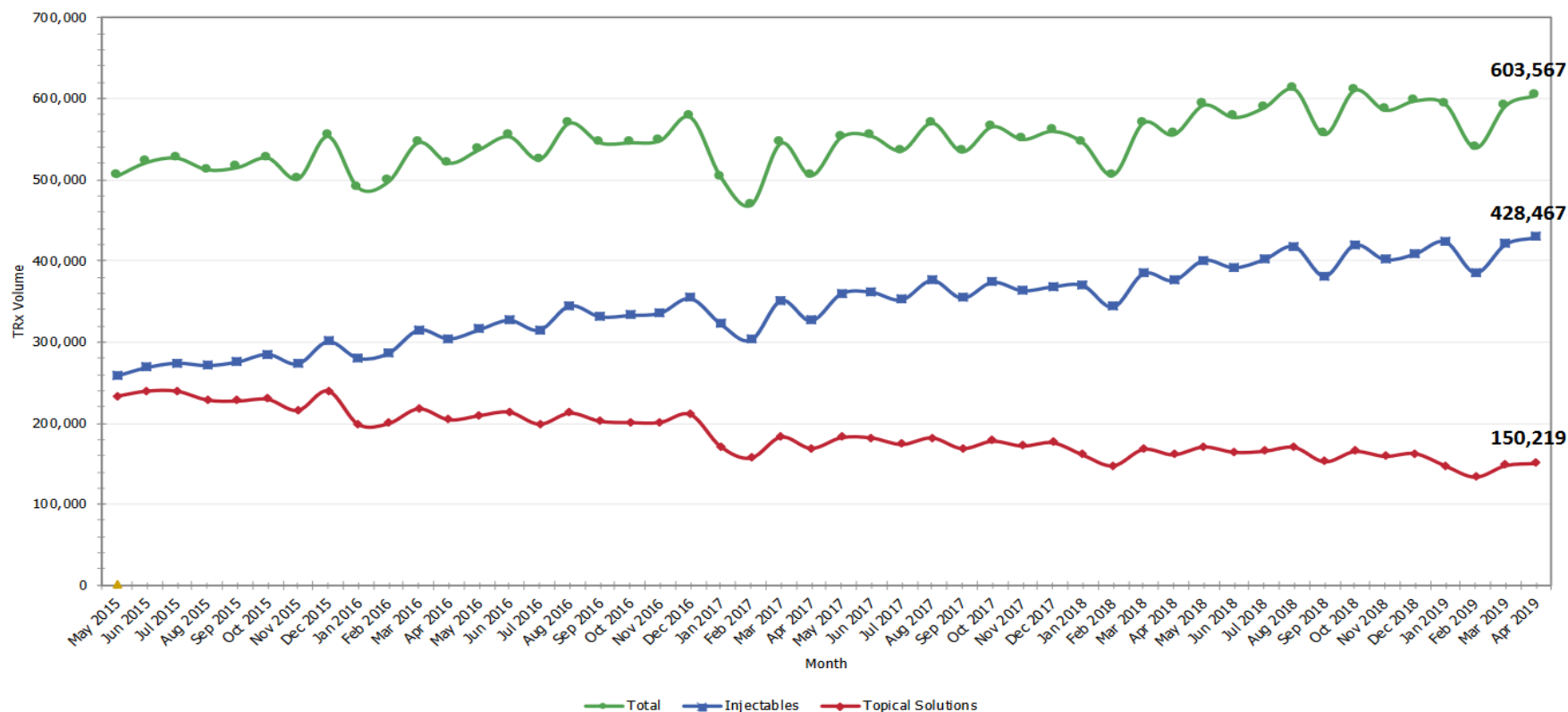
PRODUCT (Indication)		PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
Proprietary Drug Delivery Platform	TLANDO™ (Oral Testosterone for Testosterone Replacement Therapy "TRT")					PDUFA November 9, 2019
	TLANDO XR (Long Acting Oral Testosterone for TRT)				Phase 2 Complete	
	LPCN 1144 (Oral Testosterone for pre-cirrhotic NASH)			LiFT Phase 2 Paired Biopsy Clinical Study in NASH Initiated		
	LPCN 1148 (Oral Testosterone for NASH Cirrhosis)			POC Study Planned		
	LPCN 1107 (Oral HPC for Prevention of PTB)				EOP2 meeting Completed	

TLANDO[™]

~\$2B+ Opportunity in an Established and Growing Market

TRT Market is Growing Without an Oral Option

Current Promotional Spend at an All-Time Low



Source: Antares Pharma presentation at JEFFERIES 2019 HEALTHCARE CONFERENCE

TRx = Total prescriptions

Issues with Current Non-oral TRT Options

Significant Need for an Oral TRT Option



- **Black Box Warning**
 - Secondary exposure to testosterone
 - Pulmonary oil micro embolism (POME) and anaphylaxis shock
- **Inconvenient application or painful injection**
- **Poor persistence reflects need for oral**
 - Discontinuation rates as high as 50% among new patients after only 30 days with topicals
- **More than 50% of patients need dosage adjustment**
 - Burdensome for patients due to multiple doctor visits

TLANDO™ Attributes

Patient and Physician Preferred Option

Convenient Oral Route

- No risk of accidental T transference
- Non-invasive; easy to use
- Less cumbersome/burdensome
- Potential for higher persistence/adherence

Fixed Dosing Regimen

- Easy to use for patients and physicians to prescribe
- Unlike most TRT products, fixed “right” dose from the start of therapy with TLANDO™ for all patients
- No additional dose adjustment visits
- Not prone to titration decision errors; No risk of patients stuck on wrong dose
- Less prone to drop out after first Rx
- Fixed/predictable cost for payers with no titration

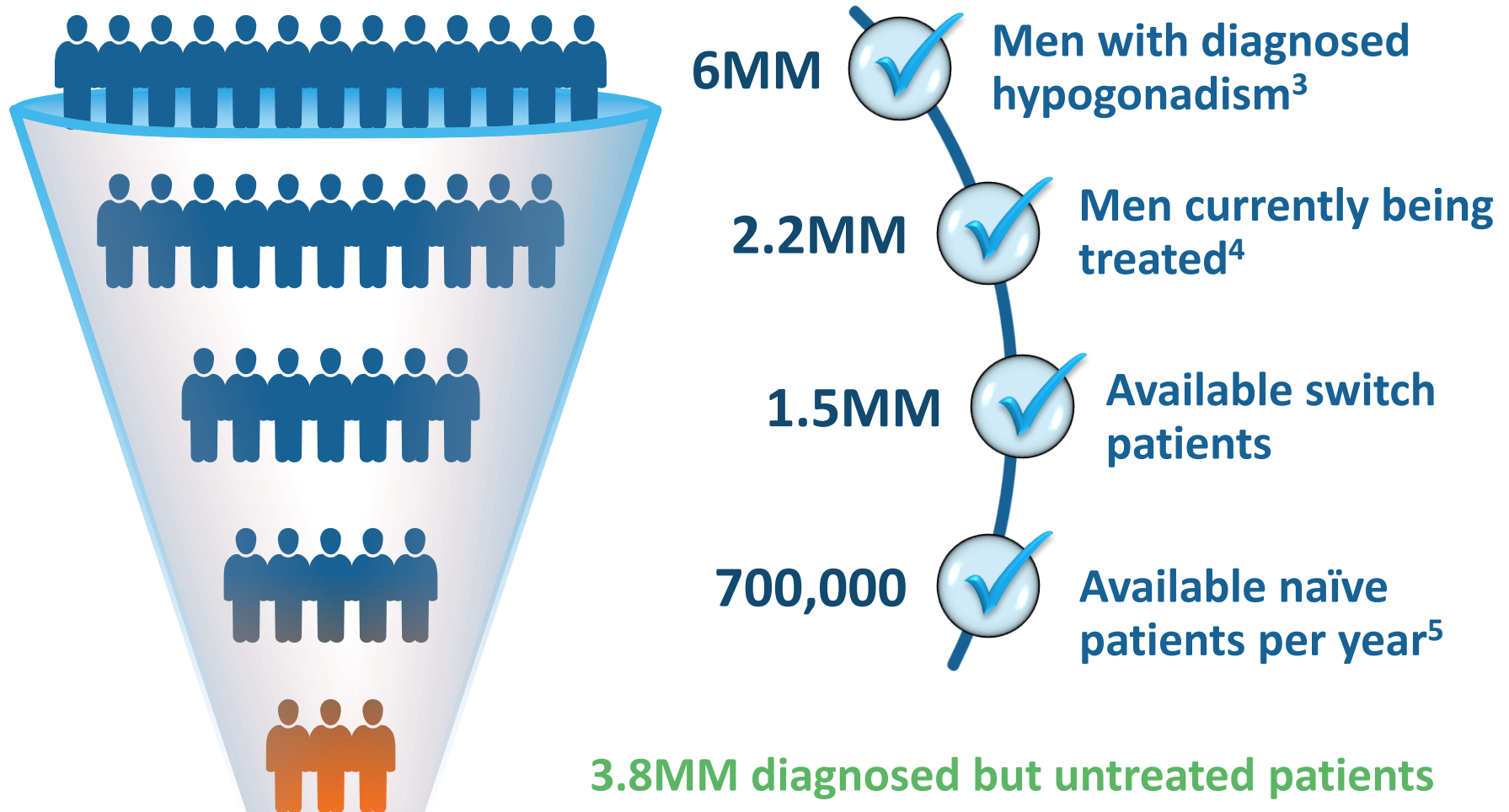
Differentiated Hypertension (“HTN”) Profile

- ~ 1% new anti-HTN starts or increase in anti-HTN dose

Consistent Restoration of T Levels

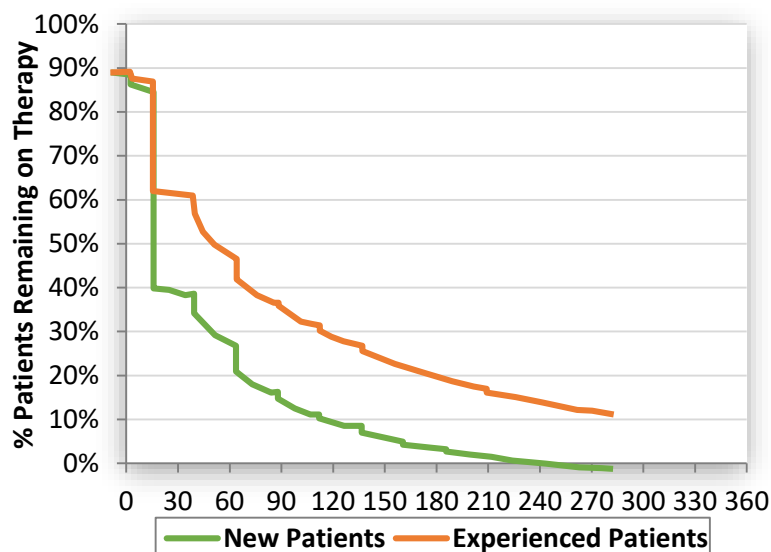
TLANDO™ Has The Potential to Drive Market Expansion

Hypogonadism Affects Up to 20 MM American Men^{1,2}



TLANDO™ Has Potential to Improve Persistence Issues with Some TRT Options

~50% Early New Patient Discontinuation



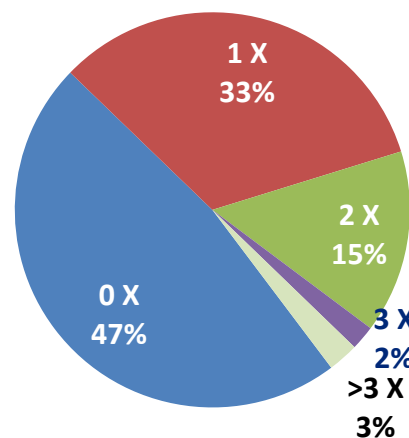
Patient Group	% Persistent Patients		
	Day 30	Day 180	Day 360
New	50.8%	18.0%	9.2%
Experienced	73.0%	36.7%	21.9%

Cohort Period: February 2016 – January 2017
Analysis Period: 12 Months
Look Back: 6 months for new patients

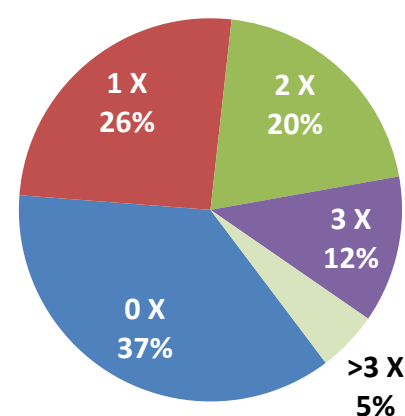
• Source: Adheris Health 2017

~50% Require Multiple Dose Adjustment

**Gel
(n=200)**



**Injectable
(n=137)**



Number of Current TRT Dose Adjustments by Form*

* 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?

Current Market Dynamics in TRT Space

Prime Opportunity for TLANDO™

Patient and physicians preferred¹

- 85% of physicians have strong interest in oral
- 95% of TRT patients likely to ask their doctor about TLANDO™

Current promotional spend all time low in this detail sensitive category²

- Able to have high share of voice with far less competitive promotion than in the past

Concentrated call points³

- Decile 7-10 prescribers (~ 10,000) write 40% of the scripts

Detail sensitive category

- Novel convenient oral option

Recent injectable TRT launch data⁴

- Significant early weekly script trends and growing
- ~45% of TRx from new patient starts

1. Lipocine Market Research; 2. iVH Research & Insights; 3. Prescriber Profiler 2019; 4. Antares Pharma presentation at JEFFERIES 2019 HEALTHCARE CONFERENCE

TLANDO™ - Opportunity in a Market Ready for Change

PDUFA Goal Date: November 9, 2019



~\$2B+ Opportunity in an Established and Growing Market



Significant Unmet Need for an Oral TRT



Differentiated Profile Appropriate for Market Expansion



Favorable Market Dynamics



Potential for Market Leadership

TLANDO XR

TLANDO XR Profile

First Long Acting Oral TRT Candidate

- Once daily oral testosterone
 - New molecule with associated IP
- TLANDO XR proof of concept established
 - Positive Phase 2b study results in hypogonadal men
 - ✓ Once daily oral dose provided T levels in the eugonadal range
- Next steps:
 - Obtain FDA feedback on Phase 3 clinical study design

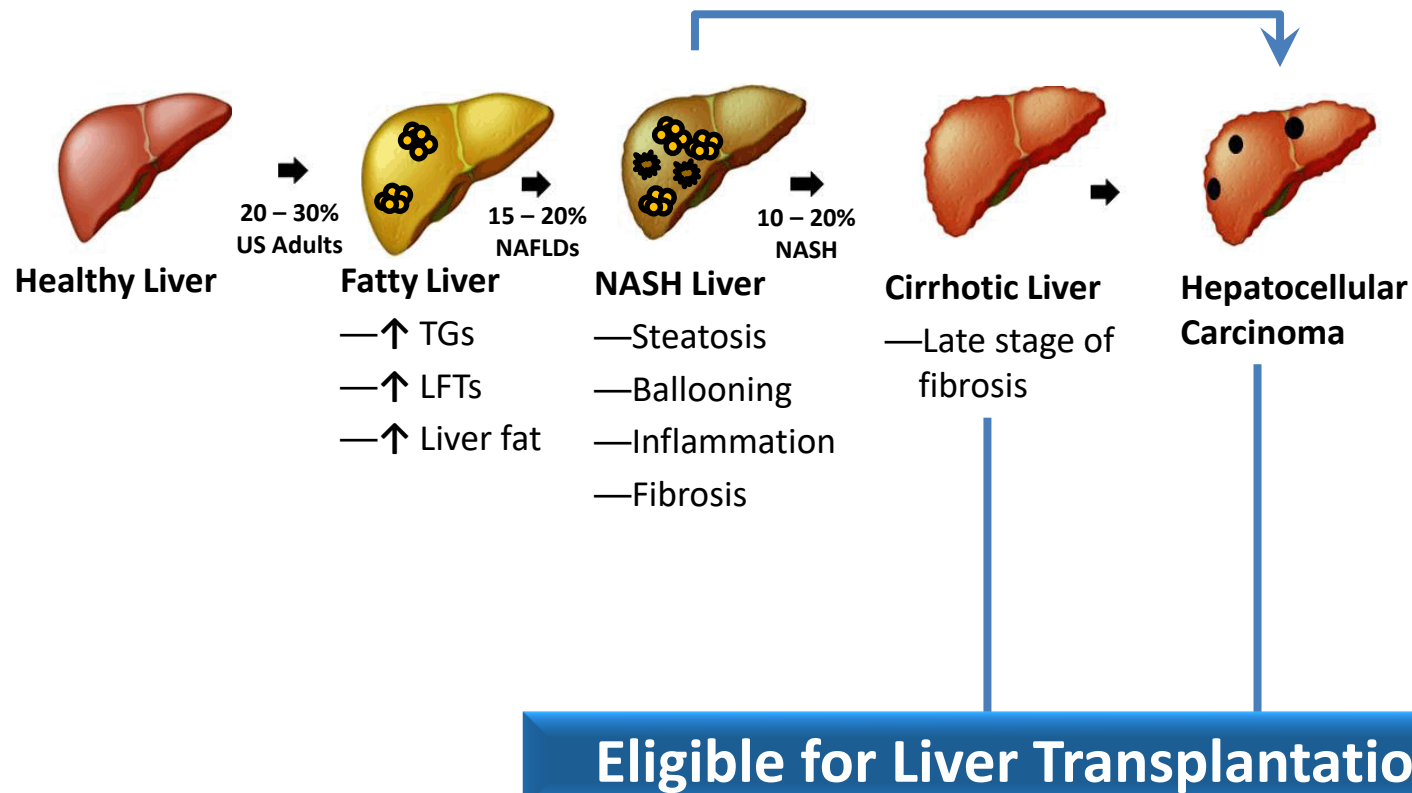
LPCN 1144

Targeted for Non-Alcoholic Steatohepatitis (“NASH”)

Non-Alcoholic Fatty Liver Disease (“NAFLD”)

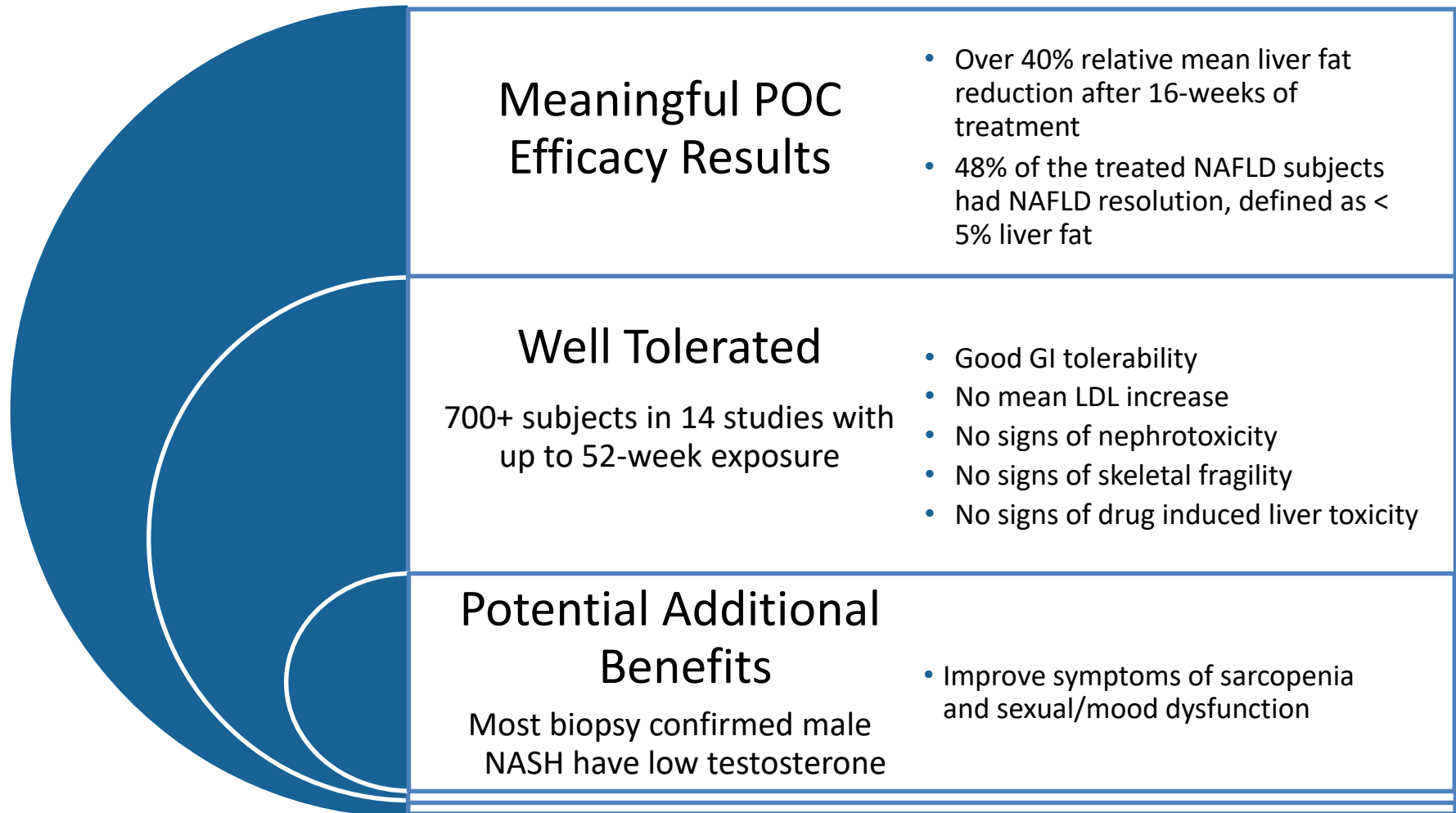
No Approved Product for the Treatment of NAFLD/NASH

Fatty liver is a reversible condition wherein large vacuoles of triglyceride (TG) fat accumulate in liver cells via the process of steatosis



LPCN 1144: Differentiated NASH Treatment Candidate

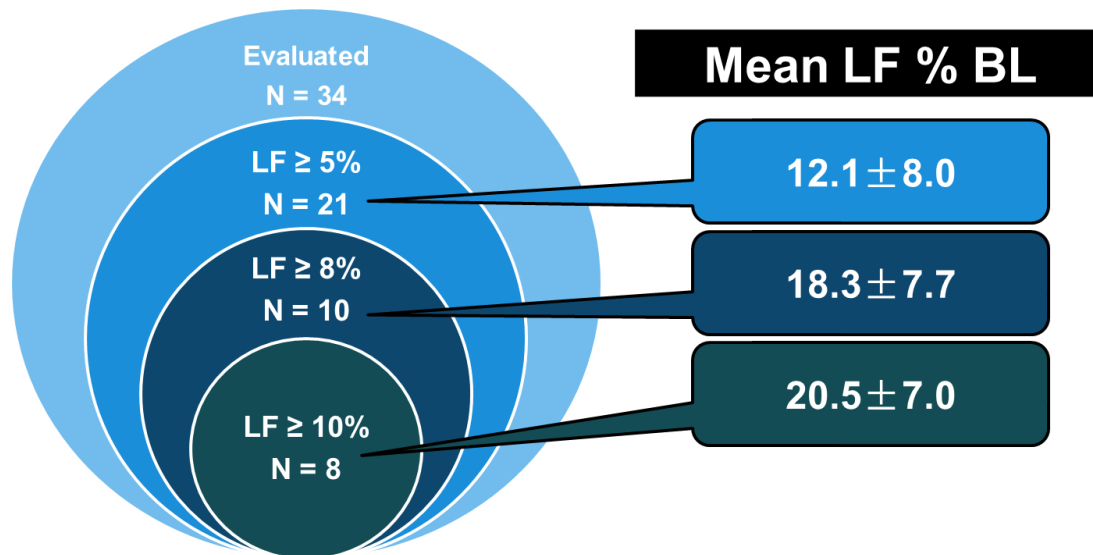
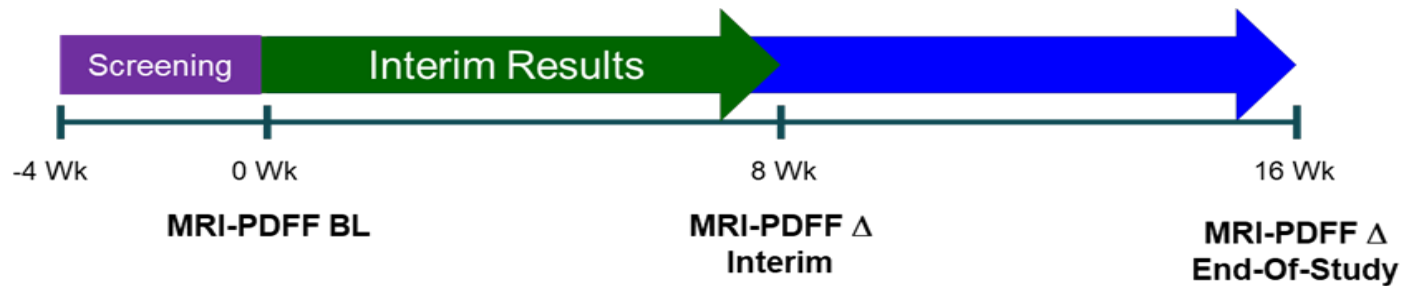
Potential for Mono/Combo Chronic Therapy



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

Sixty Percent of Hypogonadal Subjects had Fatty Liver (LF $\geq$ 5%)

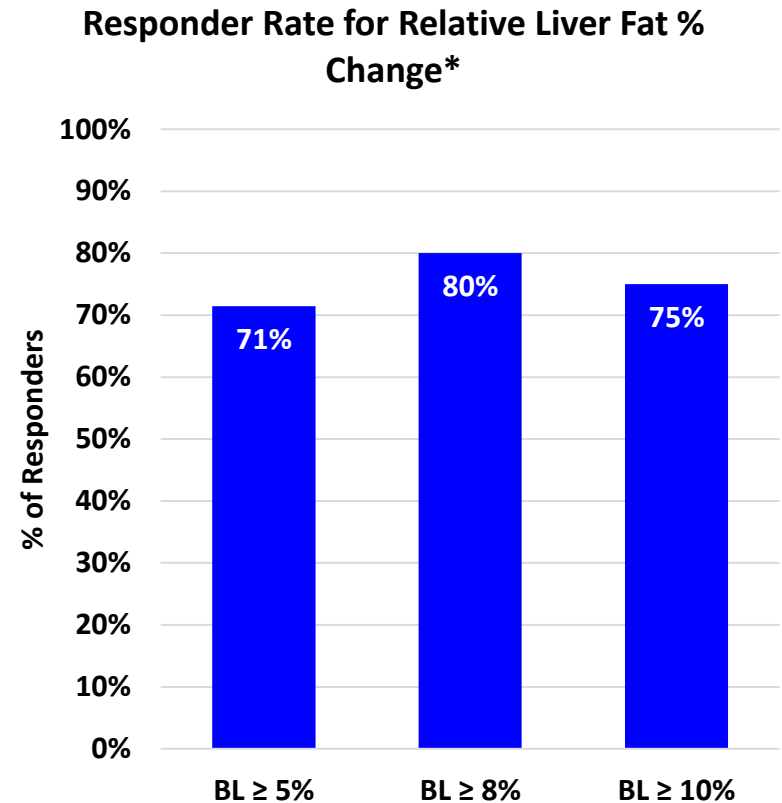
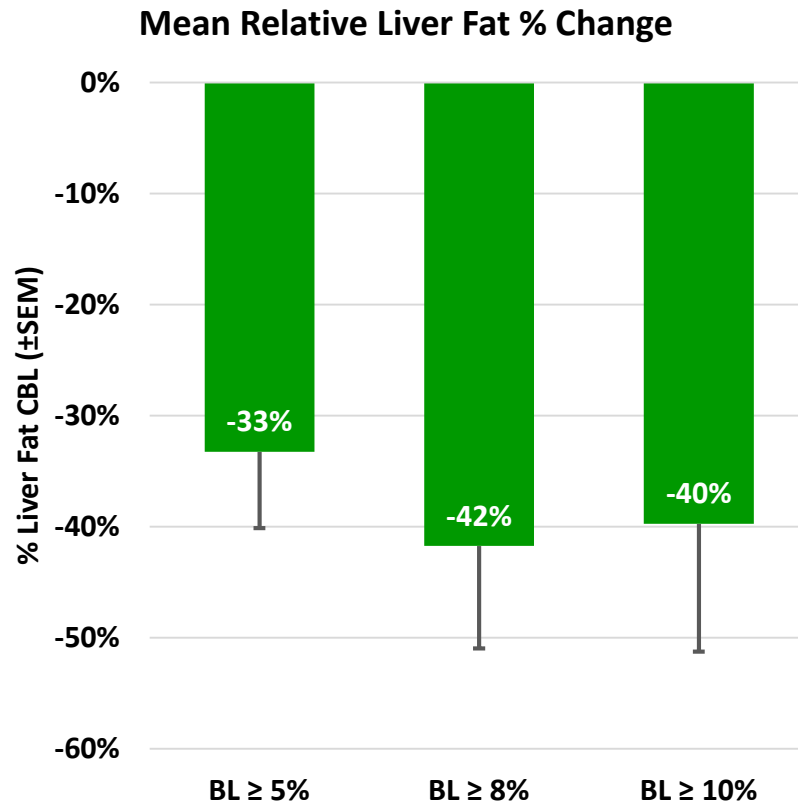
- LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males



LF = liver fat

LPCN 1144: Liver Fat Study Results

Meaningful Relative Liver Fat % Change and Responder Rate



* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.

LPCN 1144: Longitudinal Treatment Effect

Continued Improvement with NAFLD Resolution Over Time

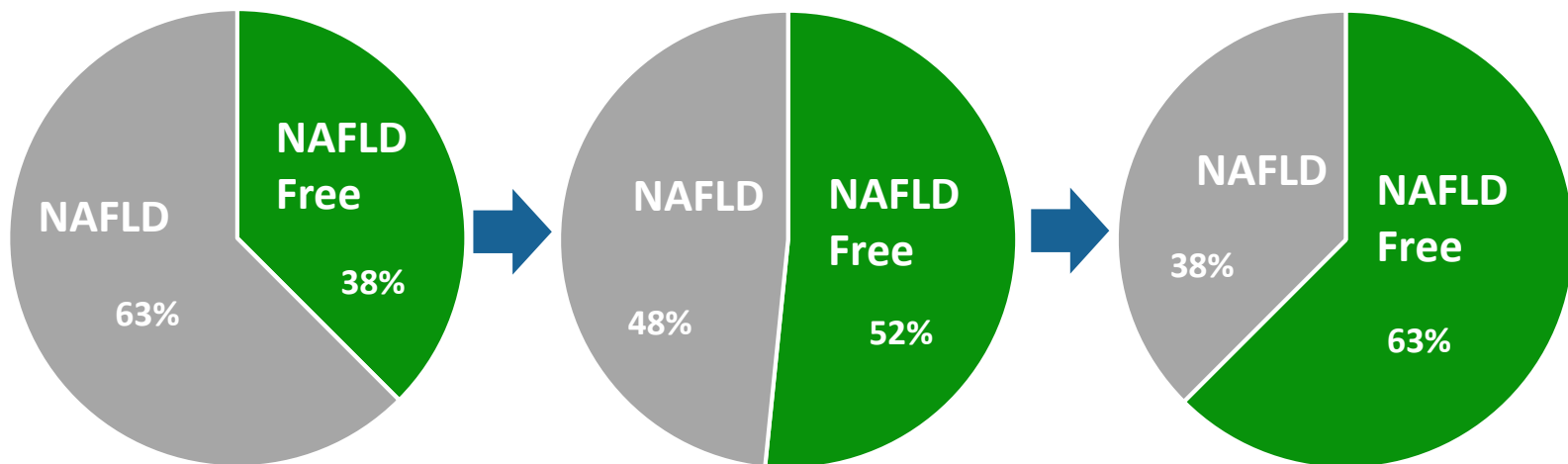
Liver Fat Based Subject Distribution at Each Visit

■ NAFLD Free (LF < 5%) ■ NAFLD (LF ≥ 5%)

Baseline (N=32)

Interim (Week 8, N=31)

End of Study (Week 16, N=32)



~40% more Subjects NAFLD Free

LPCN 1144: Next Step

Advancing Forward

- LiFT (Liver Fat intervention with oral Testosterone): Paired-biopsy Phase 2 clinical study in NASH subjects – Initiated
 - Study Design
 - Three-arm, double-blind placebo controlled
 - ~75 biopsy confirmed NASH male subjects with NAS ≥ 4
 - Paired biopsy at baseline and EOS (36-weeks)
 - Primary endpoint – 12-week MRI-PDFF liver fat reduction
 - First-patient dosing expected in 3Q 2019

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	PDUFA Date	November 9, 2019
LPCN 1144	<i>LiFT</i> Phase 2 Paired Biopsy Clinical Study in NASH Subjects - First Patient Dosed	3Q 2019

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	LPCN (Nasdaq Capital Market)
Closing Stock Price (8/5/19)	\$1.79/share
Market Capitalization (8/5/19)	\$44.5 million
Cash Balance (6/30/19)	\$19.5 million*
Bank Debt (6/30/19)	\$8.7 million

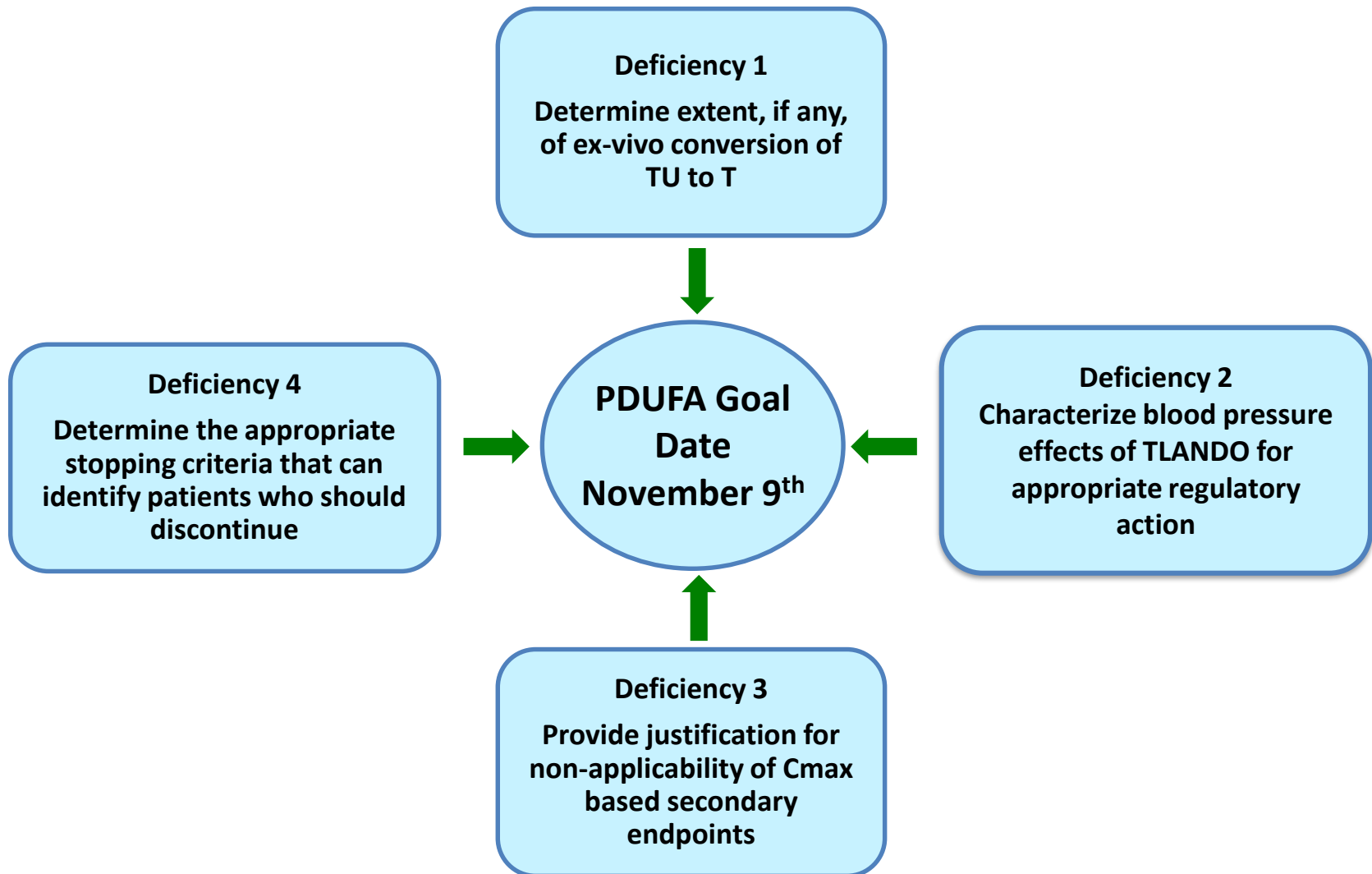
* \$5M restricted and becomes unrestricted upon TLANDO™ approval

Appendix

TLANDO™

TLANDO™: NDA Under Review

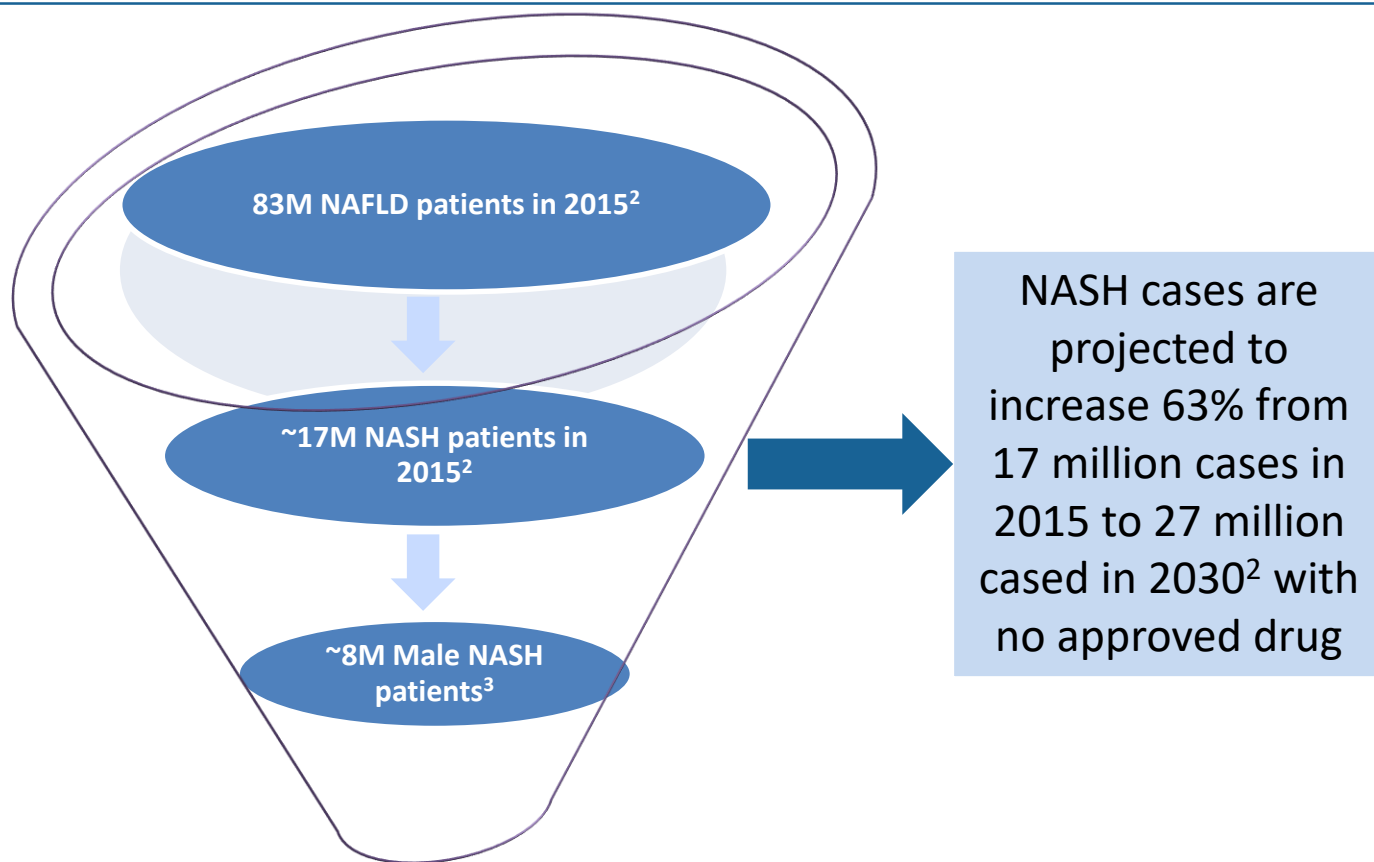
Near Term FDA Decision



LPCN 1144

Estimated LPCN 1144 Target Market

Reportedly 75% of NASH Male Patients Have Total T less than 372 ng/dL¹



FDA agreed with Lipocine rationale for enrolling eugonadal males in LPCN 1144 testing in NASH subjects

1. Sarkar et al. *Gastroenterology* 156(6):S-1258 & Poster Sa1623 Digestive Disease Week 2019

2. Estes et al, *Hepatology* 2018)

3. About 50% of males are accounted in the whole NASH population.

LPCN 1144: Multidimensional Mechanism of Action

Across the Full Spectrum of NASH Pathogenesis

Homeostasis Modifier ^{1, 2}	Anti-inflammatory ² / Antioxidant/Immuno- modulator ³	Regeneration Booster ^{5,6}	Anabolic Agent ⁹
• Alter lipid, cholesterol, and glucose metabolism • Reduce visceral abdominal fat • Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase	• Restore mitochondrial turnover and normalizes oxygen consumption⁴	• Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation⁷ • Increases circulating endothelial progenitor cells ("EPC")⁸	• Increase muscle mass, bone density in men with liver disease¹⁰

1. Shen and Shi, Int J Endocrinol, 2015

3. Sinclair et al., J Gastroenterol Hepatol, 2015

5. A. Francavilla et al., Digest Dis Sci, 1989

7. Sinha-Hikim et al., J Clin Endocrinol Metab, 2004

9. Gentile MA et al., J Mol Endocrine, 2010

2. Kelly and Jones, J Endocrinol, 2013

4. Linda Vignozzi et al., University of Florence, IT, unpublished, 2018

6. Vic et al., Hepatol 1982

8. Liao CH et al., Andrology, 2013

10. Sinclair et al., J Gastroenterol Hepatol 2016

Unmet Need in Pre-Cirrhotic NASH

Currently No Approved Product to Treat Pre-Cirrhotic NASH

Rationale for Using LPCN 1144 Alone or in Combination to Treat Pre-Cirrhotic NASH

Multi-dimensional mechanism of action/efficacy across the full NASH disease spectrum

Tolerable and suitable for chronic use

Majority of biopsy confirmed NASH adult males have low testosterone¹

Sarcopenia in patients with NAFLD is associated with a higher likelihood of having steatohepatitis or advanced liver fibrosis²

Sexual dysfunction is an underappreciated comorbidity in male NASH patients³

1. Sarkar et al. *Gastroenterology* 156(6):S-1258 & Poster Sa1623 Digestive Disease Week 2019

2. Dorota et al., *Sex Med Rev.* 2019, 1-2.

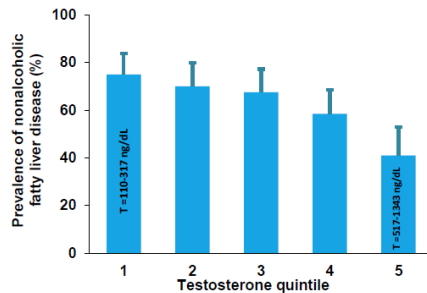
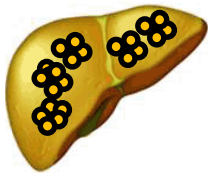
3. Yu et al. *BMC Gastroenterology* (2018) 18:51 <https://doi.org/10.1186/s12876-018-0776-0>

Clinical Relationship Between Testosterone and NAFLD

Across the Full Disease Spectrum

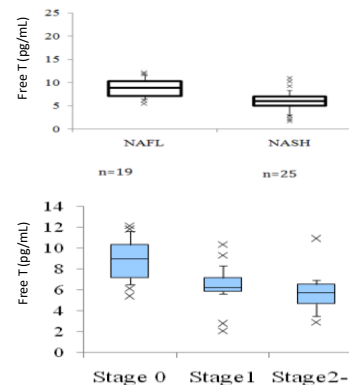
Hepatic Steatosis

“Men with low testosterone are at high risk for NAFLD.”¹



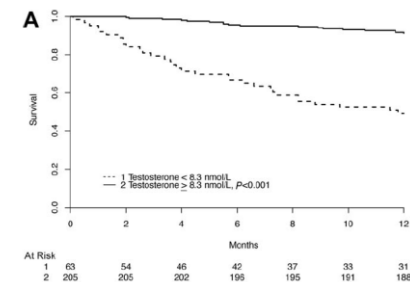
NASH

“Levels of free T decreased significantly with the increased incidence of lobular inflammation, hepatocyte ballooning, NAFLD activity score, and fibrosis.”²



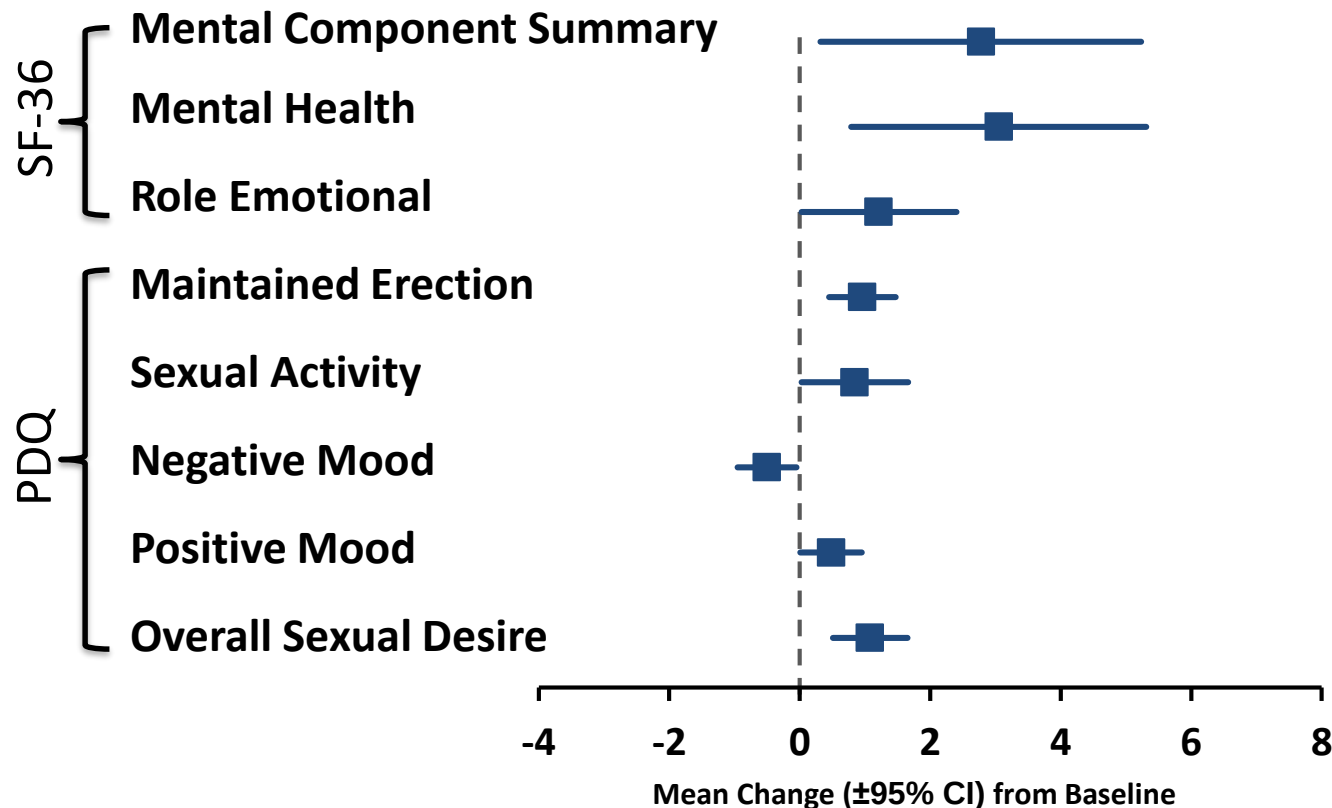
Cirrhosis

“Low T levels in cirrhotic men are associated with the combined outcome of death or transplantation.”³



LPCN 1144: Additional Health Benefits

Observed in Hypogonadal Subjects with Elevated ALT*



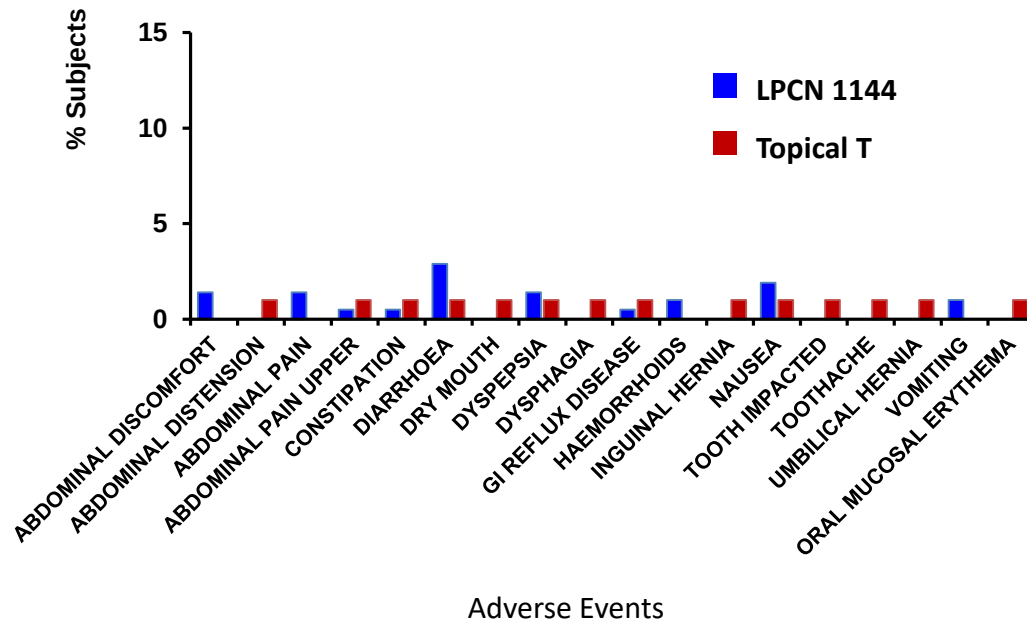
SF-36, Short Form-36 (0-100); PDQ, Psychosexual Daily Questionnaire (0-7); * ALT > 40 U/L at Baseline in 52 week SOAR Trial (N=33)

LPCN 1144: Extensive Clinical Safety Database

Demonstrated No Unexpected Risks

700+ subjects in 14 studies with up to 52 weeks exposure

- SOAR Trial (52 Week Study)
 - No drug related SAEs
 - No deaths or MACE events
 - Gastrointestinal Disorders $\geq 1\%$



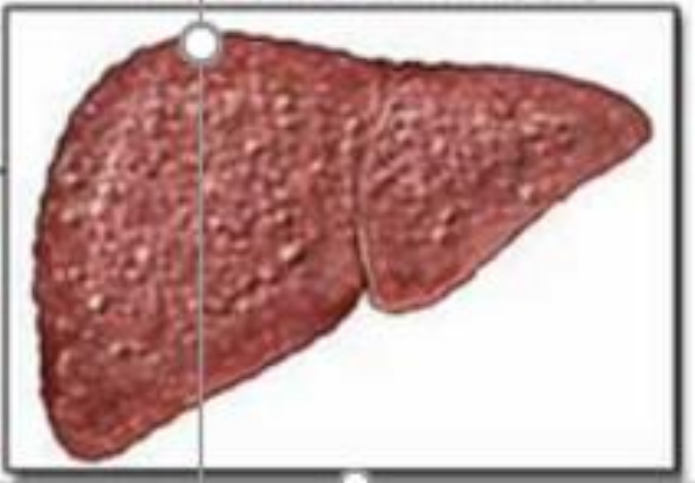
LPCN 1148

For Treatment of NASH Cirrhosis

LPCN 1148: Oral T for NASH Cirrhosis

No FDA Approved Product-Transplant Only Cure

Cirrhotic Liver



US Prevalence

Among NASH population (2015)*:

- Fibrosis grade 4 (cirrhosis) case: 1.3M
- Compensated cirrhosis 1.16M
- Decompensated cirrhosis: 134,400

In 2013, cirrhosis cause mortality was ~38,000** and consistently twice the rate in males as females **

Cirrhotic Patients Characteristics:

- Increased morbidity and mortality
- Symptoms of hypogonadism: altered hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia
- Late stage symptoms: jaundice, pruritis, hepatic encephalopathy, ascites, anasarca, GI bleeding

*Estes C. et al., Hepatology, 2018;**Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; surveillance report, 2016

Low Testosterone Increases Adverse Outcome in Male Cirrhotic Patients

T Levels Fall Progressively with Increasing Disease Severity¹

- Low T reported in up to 90% of NASH cirrhosis patients² and is a predictor of mortality³
- Low T associated with:
 - Increased risk of major infections, death and/ or transplantation rates¹
 - Increased risk of for hepatic decompensation⁴
 - Worsening of sarcopenia⁴
 - Higher Child Pugh score grade⁴
 - Severity of portal hypertension and ascites grade⁴
 - Higher MELD score⁵

1. Sinclair et al., Liver Transplantation, 2016

2. Kim et al., Male Hypogonadism, eds: Winters and Huhtaniemi, 2017

3. Sinclair M. et al., J. of Gastro and Hepatology, 2015

4. Paternostro et al, Hepatol Res 2019;

5. Sinclair et.al, Liver international, 2016

LPCN 1148: NASH Cirrhosis

Oral T Therapy

- **Potentially help patients survive longer while waiting for a liver transplant**
 - T levels positively correlate with muscle mass in men and modulates bone density, hemoglobin production, insulin resistance, and immunity , commonly impaired in cirrhosis¹
 - Testosterone therapy increased muscle mass in men with cirrhosis and low testosterone²
- **Next Steps:**
 - Proof of Concept study in male NASH cirrhosis subjects

1. Sinclair M et al., J. of Gastro and Hepatology, 2016

2. Sinclair M et al., J. of Hepatology, 2016