

LIPOCINE[®]

ENHANCING HEALTH

Enabling Oral Drug Delivery to Improve Patient Compliance

Corporate Presentation

May 1, 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, the expected timing of the resubmission of the NDA for TLANDO, FDA review process related to our resubmitted NDA for TLANDO™, the expected timing of 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

Metabolic and Endocrine Focus

Proprietary Drug Delivery Platform	PRODUCT (Indication)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
	LPCN 1144 (Oral Testosterone for pre-cirrhotic NASH)			Paired Biopsy Phase 2 Study in NASH		
	TLANDO (Oral Testosterone for TRT)					NDA Resubmission
	TLANDO XR (LPCN 1111) (Long Acting Oral Testosterone for TRT)				Phase 2 Complete	
	LPCN 1148 (Oral Testosterone for NASH Cirrhosis)			POC Study Planned		
	LPCN 1107 (Oral HPC for Prevention of PTB)				EOP2 Completed	

LPCN 1144

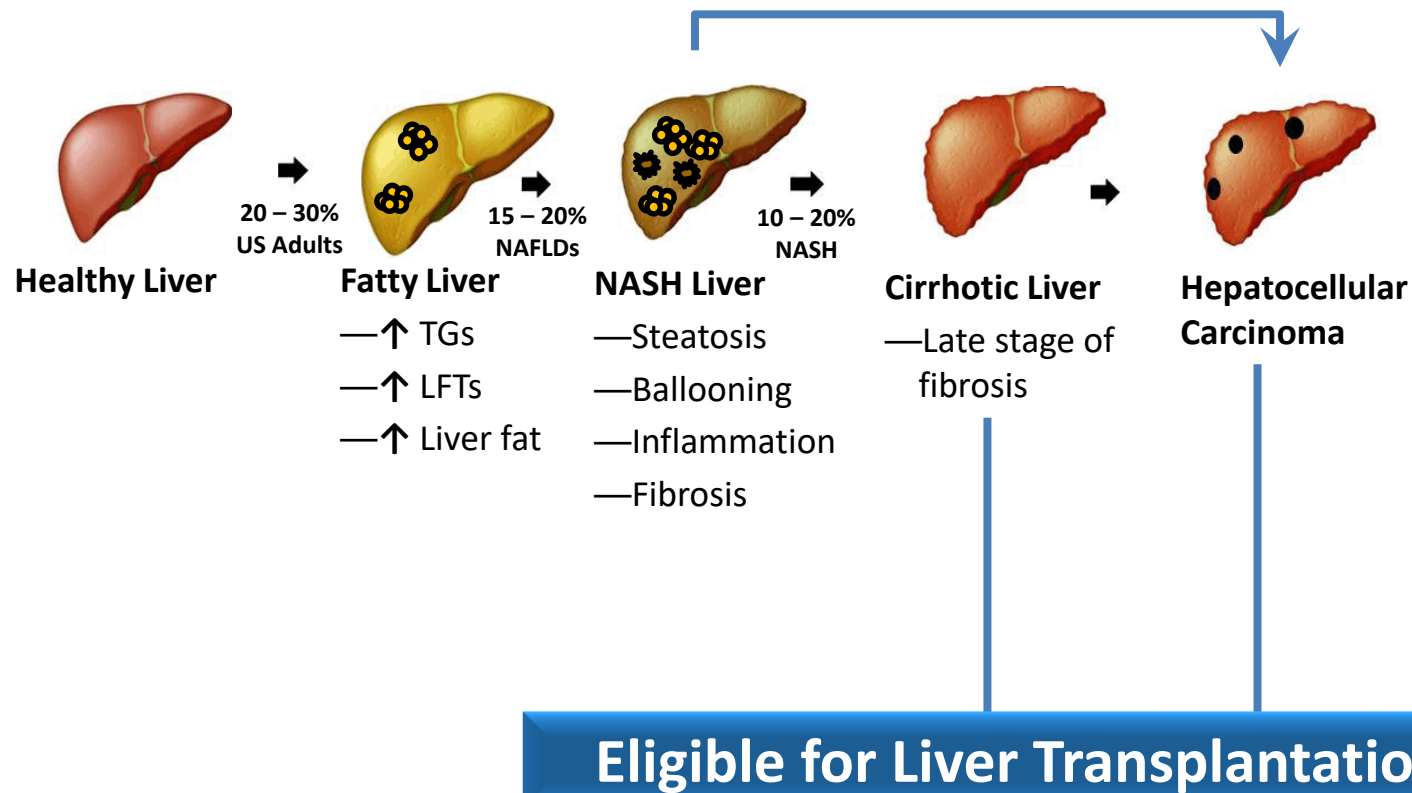
Targeted for Non-Alcoholic Steatohepatitis (“NASH”)

A silent killer that affects 30 million Americans¹

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

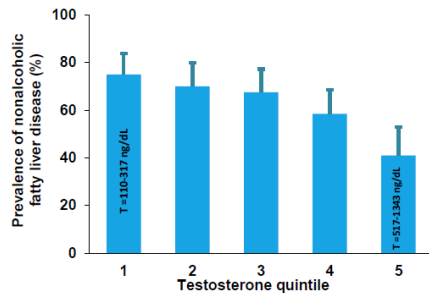
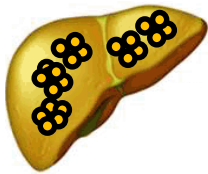


Clinical Relationship Between Testosterone and NAFLD

Across the Full Disease Spectrum

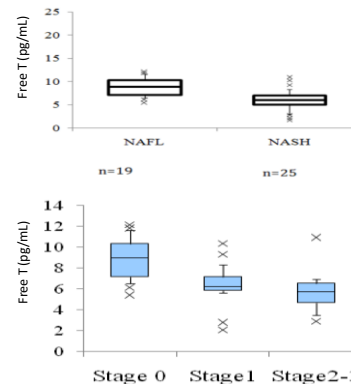
Hepatic Steatosis

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



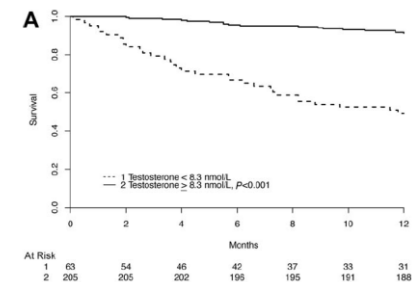
NASH

“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: A Differentiated Oral NASH Therapy Candidate

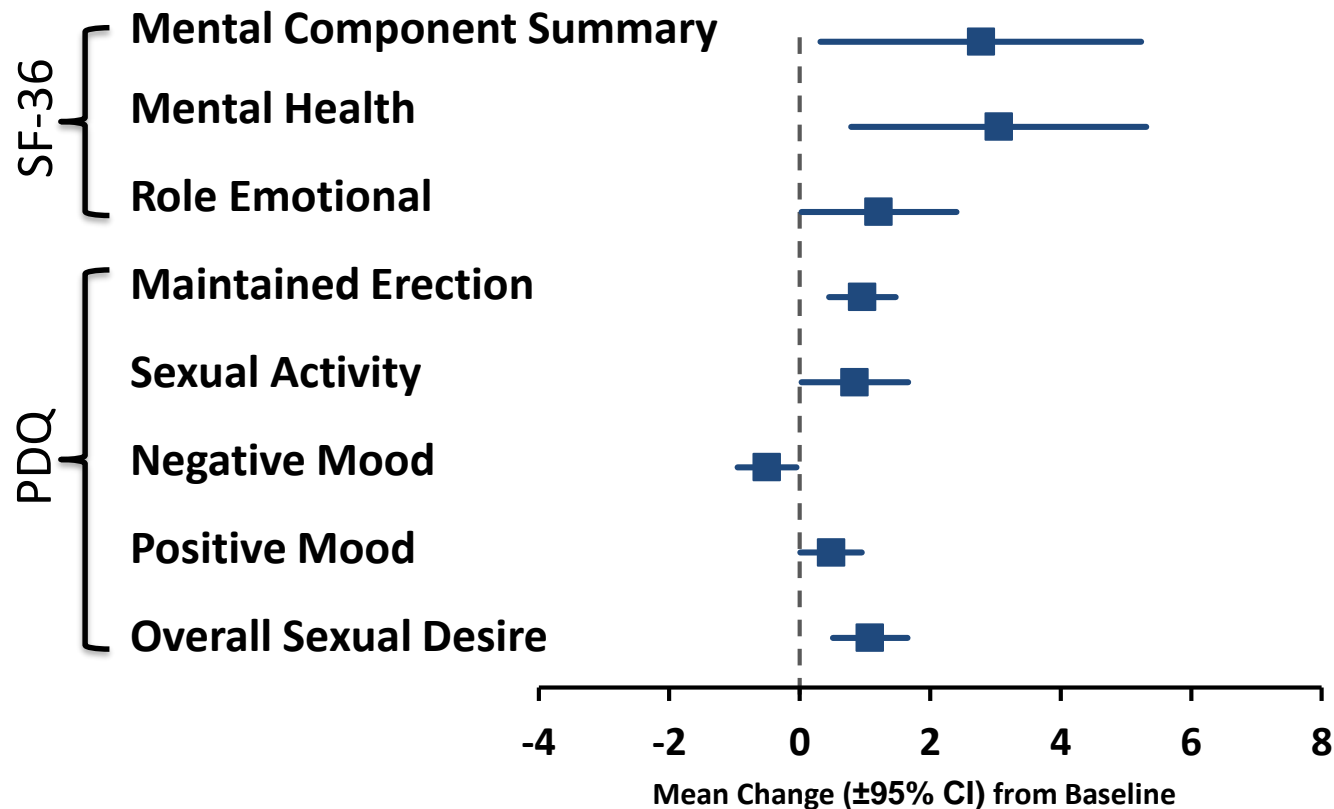
Prodrug of Endogenous Testosterone



Liver Fat Reduction and Key Serum Biomarkers	<ul style="list-style-type: none">• Over 40% relative mean liver fat reduction after 16-weeks of treatment• 48% of the treated NAFLD subjects had NAFLD resolution, defined as < 5% liver fat
Potential Favorable Benefits in Systems Outside the Liver	<ul style="list-style-type: none">• T therapy known to improve muscle mass, bone density, hemopoiesis, sexual/mood dysfunction
Suitable for Chronic Use	<ul style="list-style-type: none">• Good GI tolerability• No mean LDL increase• No signs of nephrotoxicity• No signs of skeletal fragility• No signs of drug induced liver toxicity

LPCN 1144: Additional Health Benefits

Observed in Hypogonadal Subjects with Elevated ALT*

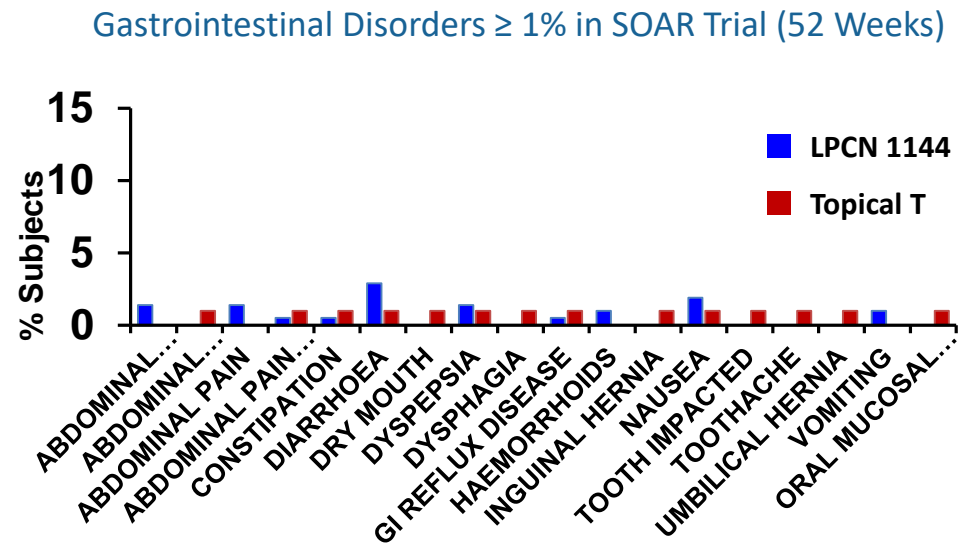


SF-36, Short Form-36 (0-100); PDQ, Psychosexual Daily Questionnaire (0-7); * ALT > 40 U/L at Baseline in 52 week SOAR Trial (N=33)

LPCN 1144: Extensive Clinical Safety Database

Demonstrated No Unexpected Risks

- 650+ subjects in 14 studies with up to 52 week exposure
- No drug related SAEs
- No deaths or MACE events



LPCN 1144: Multidimensional Mechanism of Action

Across the Full Spectrum of NASH Pathogenesis

Homeostasis Modifier^{1, 2}

- Alter lipid, cholesterol, and glucose metabolism
- Reduce visceral abdominal fat
- Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase

Anti-inflammatory²/ Antioxidant/Immuno- modulator³

- Restore mitochondrial turnover and normalizes oxygen consumption⁴

Regeneration Booster^{5,6}

- Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation⁷
- Increases circulating endothelial progenitor cells ("EPC")⁸

Anabolic Agent⁹

- 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

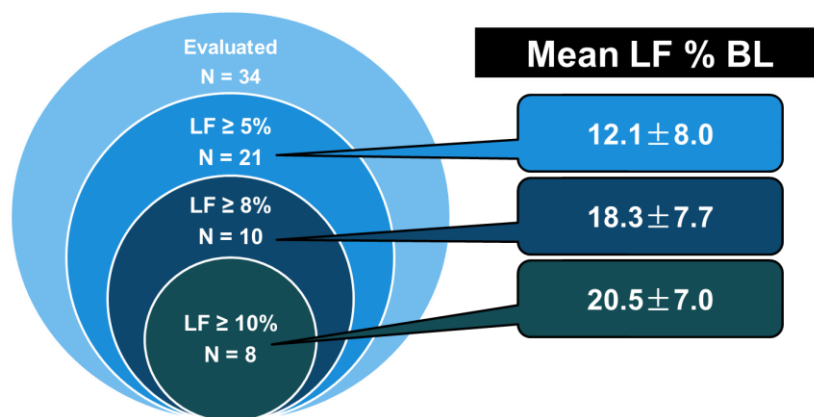
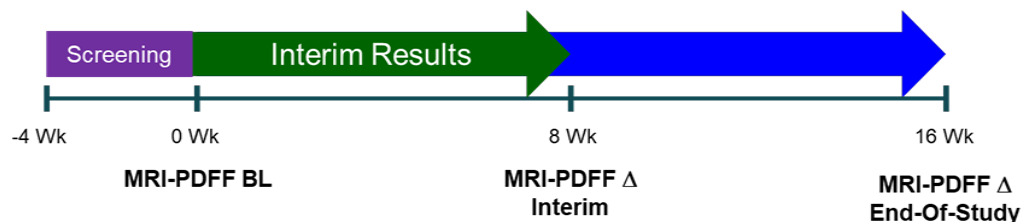
8. Liao CH et al., Andrology, 2013

10. Sinclair et al., J Gastroenterol Hepatol 2016

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

Study Design and Baseline Liver Fat Subject Distribution

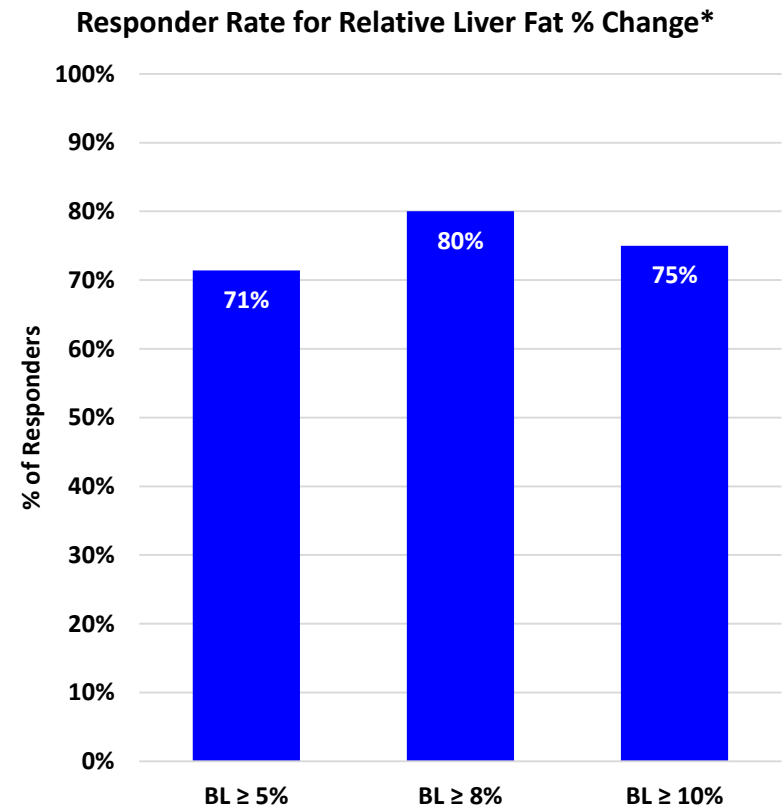
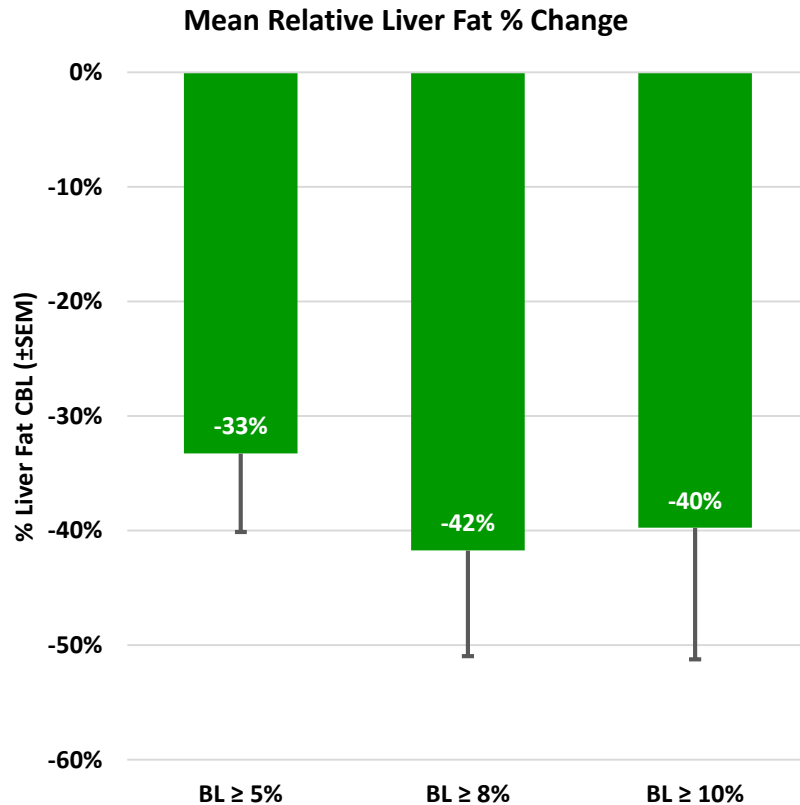
LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males



LF = liver fat

LPCN 1144: Liver Fat Study Results

Meaningful Relative Liver Fat % Change and Responder Rate



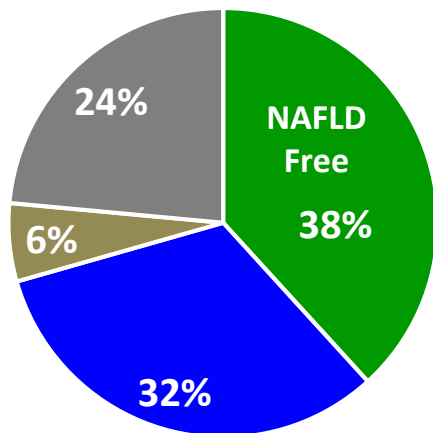
* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.

LPCN 1144: Liver Fat Study Results

Liver Fat Based Subject Distribution at Each Visit

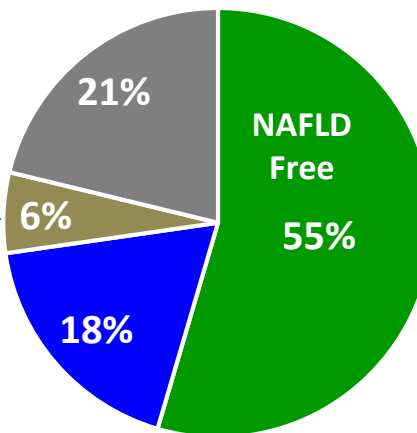
Longer Therapy Improved Proportion of Subjects with Disease Resolution

Baseline Pre treatment



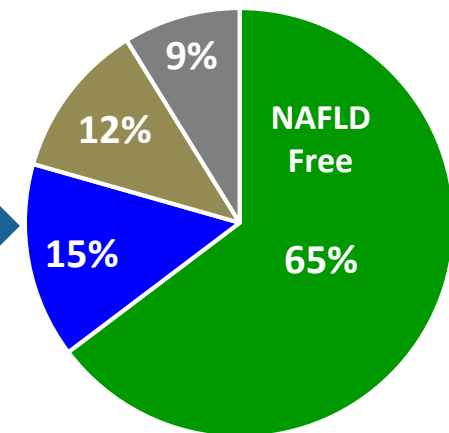
N=34

8 Week Treatment



N=33

16 Week Treatment



N=34

■ LF < 5% (NAFLD Free)

■ 5% ≤ LF < 8%

■ 8% ≤ LF < 10%

■ LF > 10%

LPCN 1144: Next Step

Advancing Forward

- Initiating paired-biopsy Phase 2 clinical study in NASH subjects
 - Study Design
 - Three-arm, double-blind placebo controlled
 - Biopsy confirmed NASH male hypogonadal subjects with NAS ≥ 4
 - Paired biopsy at baseline and EOS (36-weeks)
 - First-patient dosed targeted for 3Q 2019

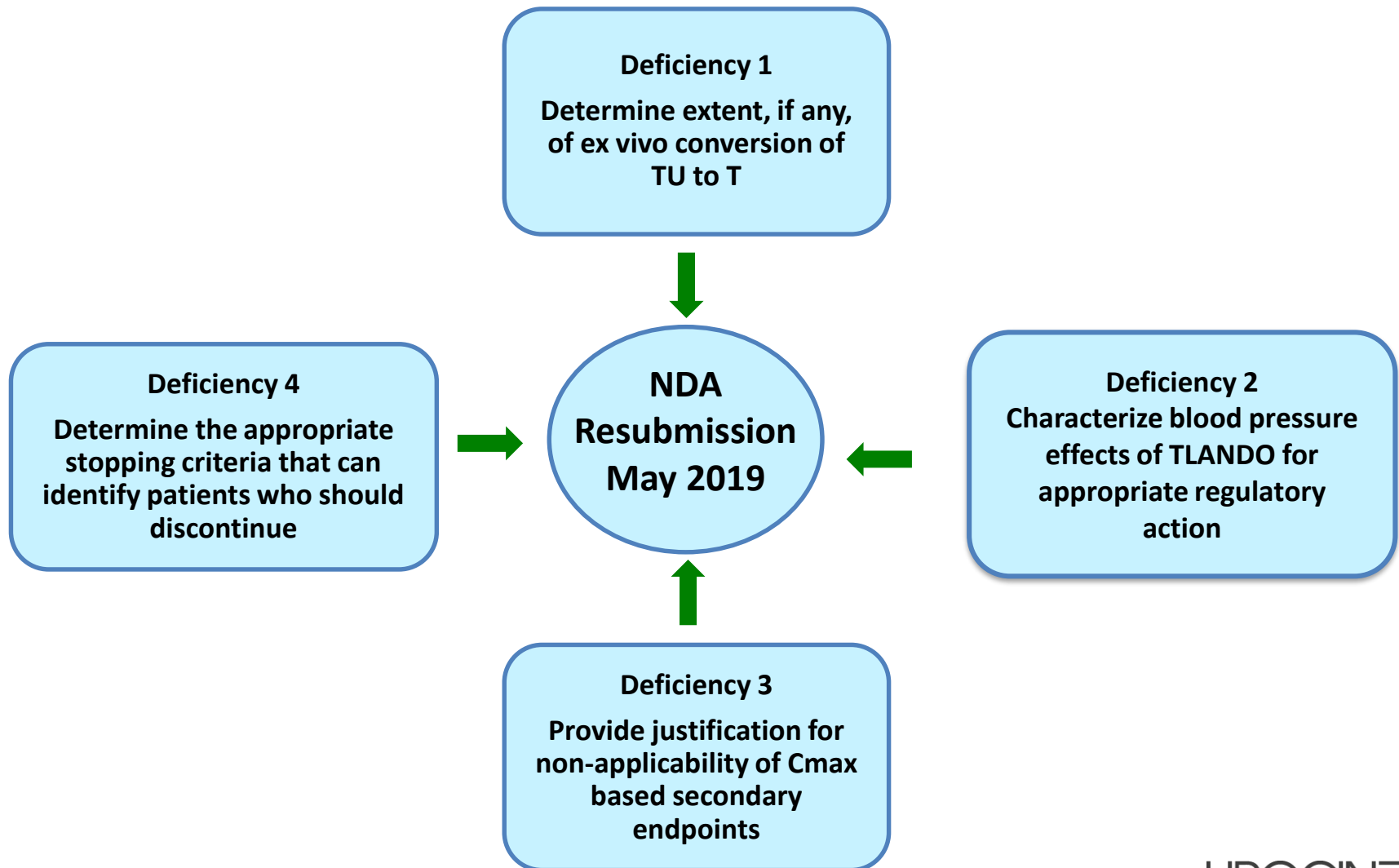
TLANDO™

Targeted for Testosterone Replacement Therapy

Annual TRx ~7M

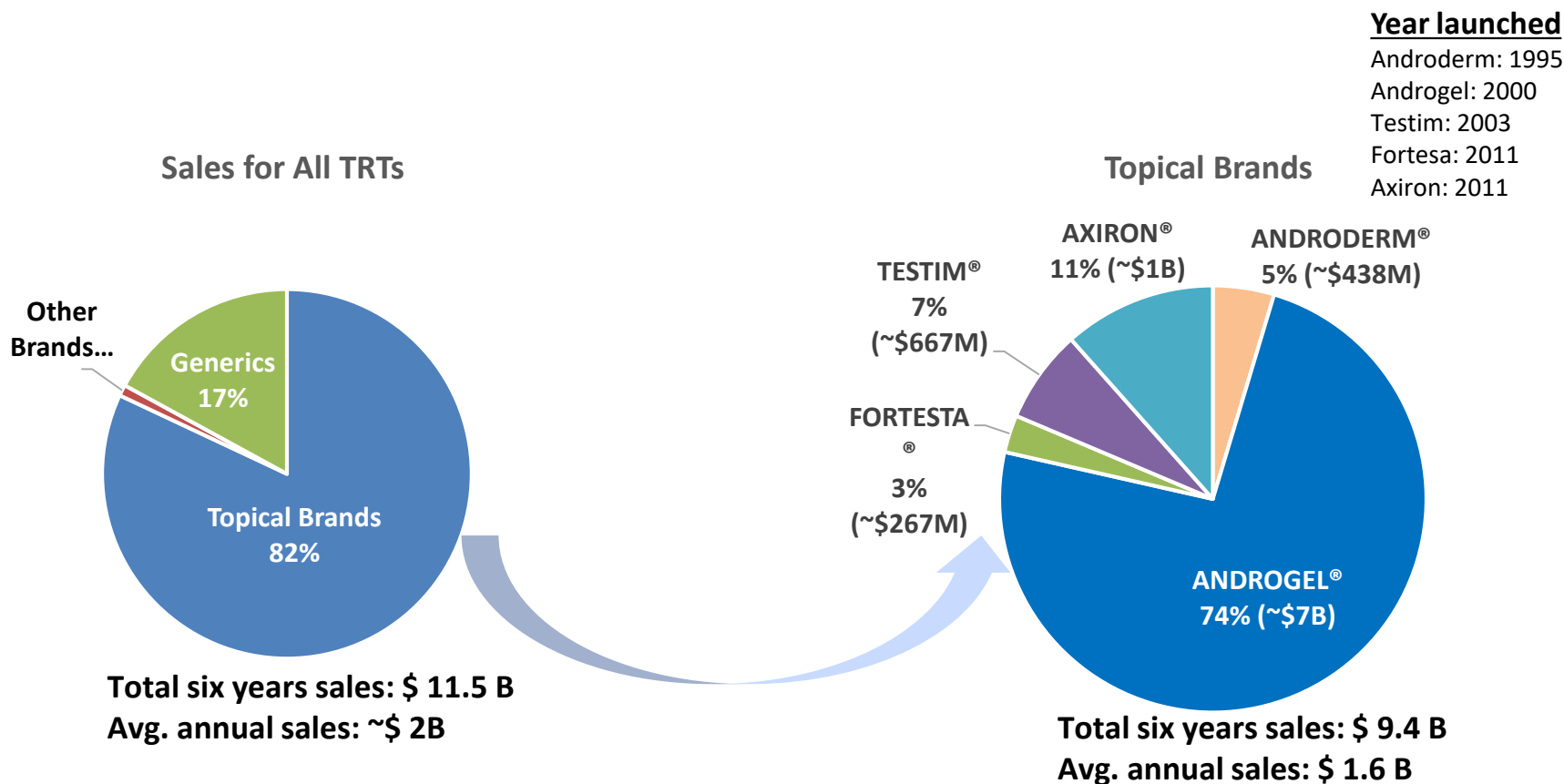
TLANDO™: Potential First Oral Option

Progressing to NDA Resubmission



Cumulative TRT Sales Last Six Years*

Branded Topicals Dominated TRT Sales



Source: IMS
*Feb 2013 to Jan 2019

Issues with Current Non-oral 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**
- **Poor persistence reflects need for oral**
 - Average days on therapy is 100 days
- **More than 50% of patients need dosage adjustment**
 - Burdensome for patients due to multiple doctor visits

TLANDO Attributes

Patient and Physician Preferred Oral Option

- Key Advantages of Oral Route:
 - No risk of accidental T transference
 - Non-invasive
 - Less cumbersome/burdensome
- Fixed dosing regimen
 - Easy to use for patients and physicians to prescribe
 - Fewer doctor visits (No dose adjustment visits for patients)
 - Fixed/predictable cost for payers
- Differentiated hypertension (“HTN”) profile
 - ~ 1% new anti-HTN starts or increase in anti-HTN dose
 - 32% of subjects with baseline sBP >140 mm Hg experienced a decrease to ≤140 mm Hg with mean change of -3 mm Hg

TLANDO XR

First Long Acting Oral

TLANDO XR (LPCN 1111): Profile

Once Daily Differentiated Oral TRT

- Once daily oral testosterone
 - New molecule with associated IP
 - Novel prodrug of testosterone for oral delivery through proprietary drug delivery technology
- TLANDO XR proof of concept established
 - Positive Phase 2b study results in hypogonadal men
 - Once daily oral dose provides T levels in the eugonadal range
- Phase 3 daily dose identified based on multiple dose Phase 2 studies in hypogonadal male
- Next steps:
 - Obtain FDA feedback on Phase 3 clinical study design

TLANDO XR (LPCN 1111): Phase 2b Results

Once-Daily Dosing Potential

- Steady state reached within 14 days
- Well tolerated and no SAE's
- Phase 3 starting dose identified
- Target QD dose met both primary and secondary endpoints
 - No subject exceed 1800 ng/dL
 - 90% of subjects restored to eugonadal range (300-1140 ng/dL)

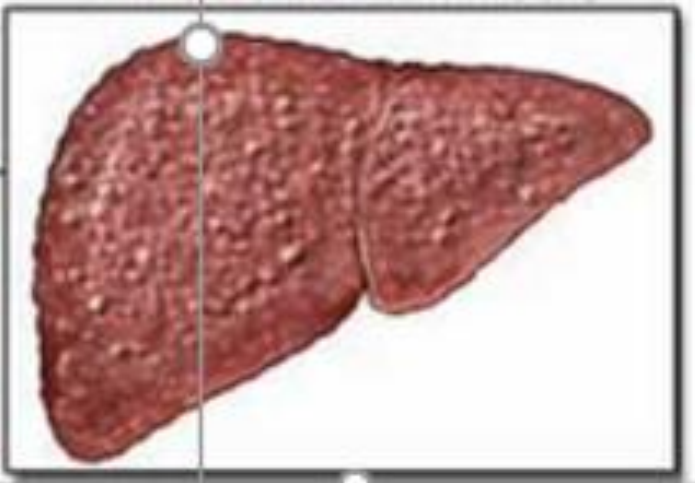
LPCN 1148

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

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	NDA Resubmission	May 2019
LPCN 1144	Paired Biopsy Phase 2 First Patient Dosed in NASH Patients	3Q 2019

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	LPCN (Nasdaq Capital Market)
Closing Stock Price (4/29/19)	\$1.89/share
Market Capitalization (4/29/19)	\$46.4 million
Cash Balance (12/31/18)	\$20.3 million*
Bank Debt (12/31/18)	\$10.0 million

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

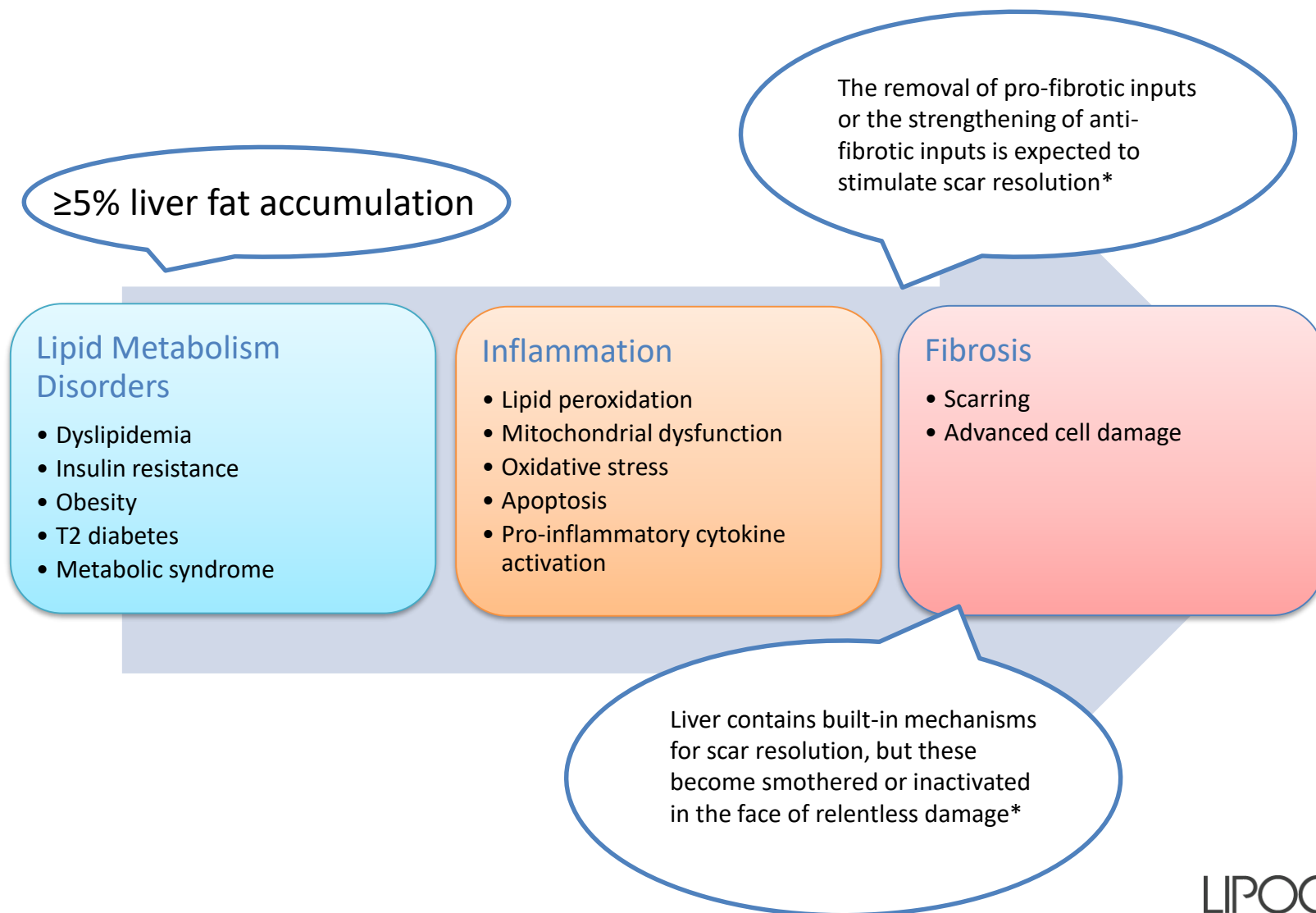
Appendix

LPCN 1144

Targeted for pre-cirrhotic NASH

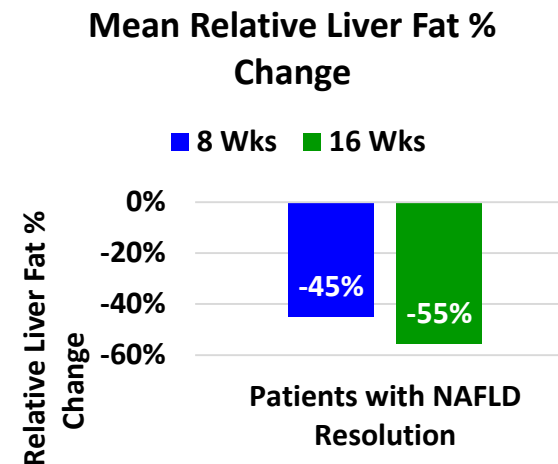
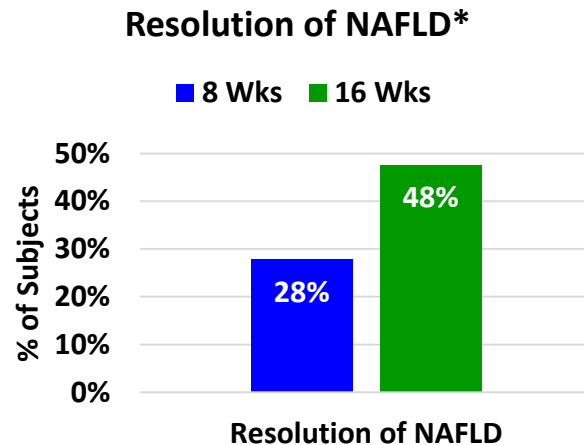
NASH Pathogenesis

Risk Factors and Clinical Progression



LPCN 1144: Liver Fat Study Results

Meaningful NAFLD Resolution and Corresponding Relative Liver Fat % Reduction



100% of patients experiencing NAFLD resolution had at least 35% of relative liver fat reduction from baseline

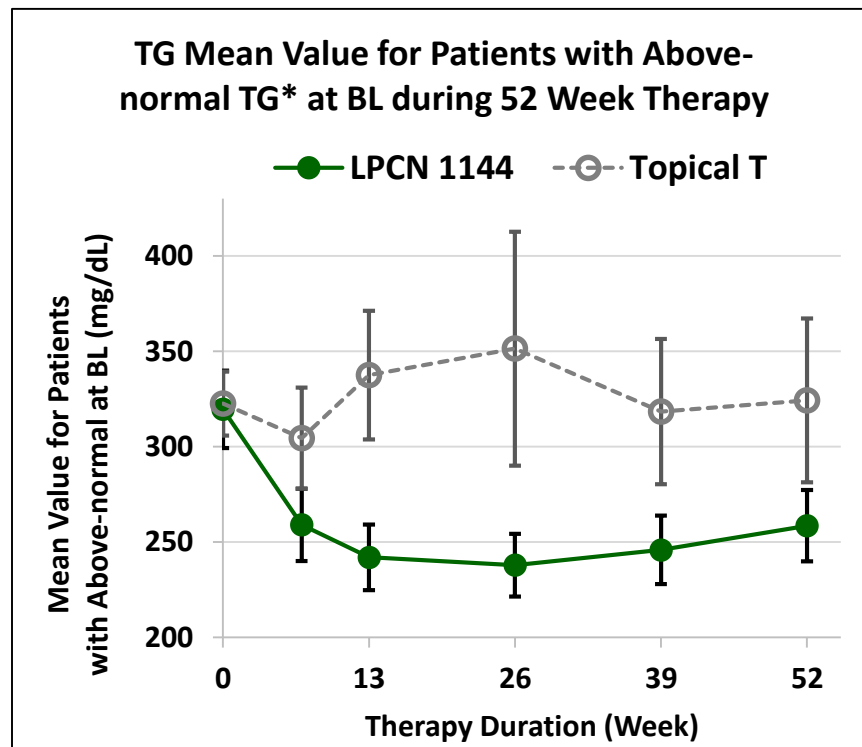
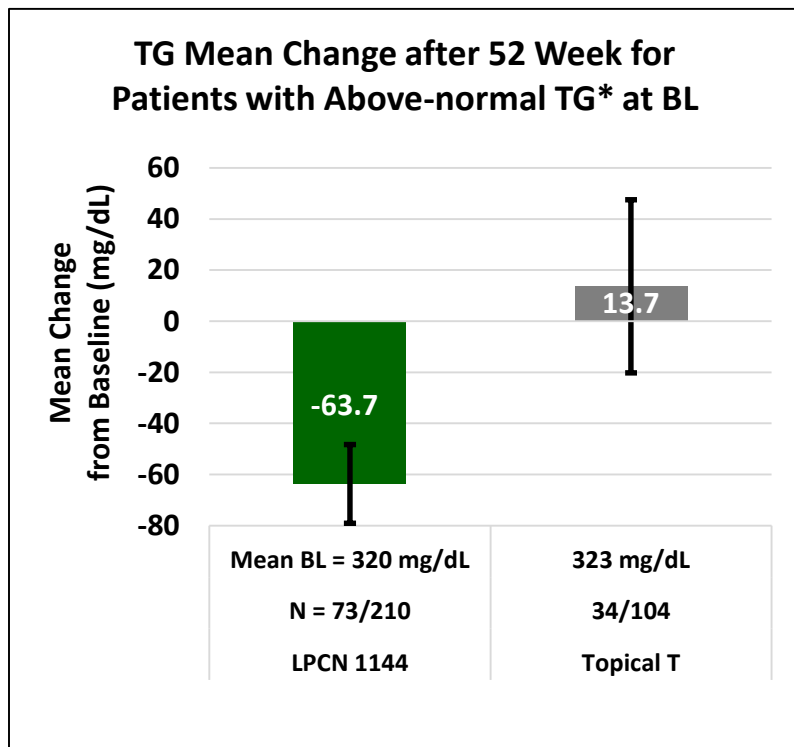
* Resolution of NAFLD is defined as when BL liver fat $\geq 5\%$ is reduced to $< 5\%$ at EOS.

LPCN 1144: Oral T

Unique TG Reduction Compared to Topical Gel

- **52 Week SOAR Trial**

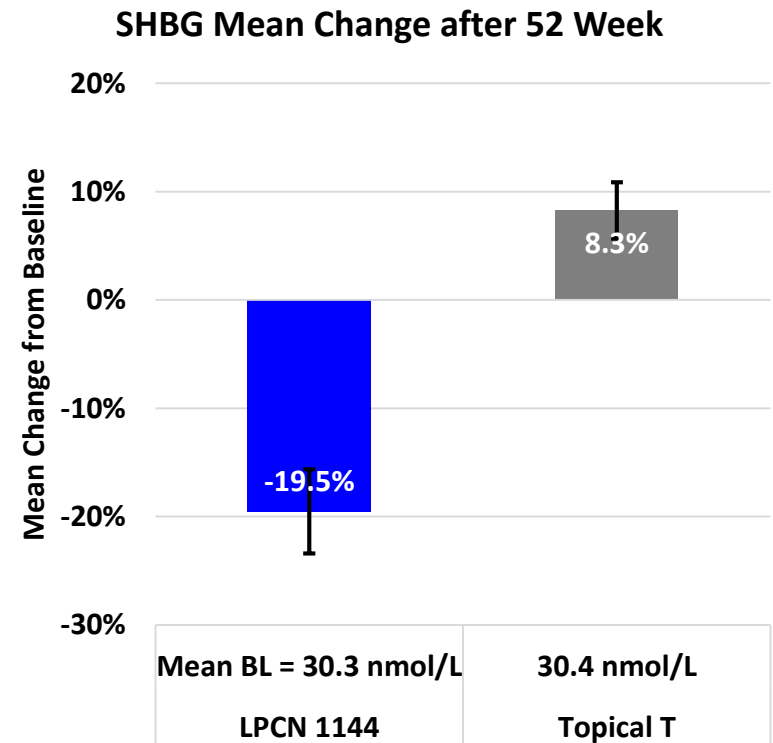
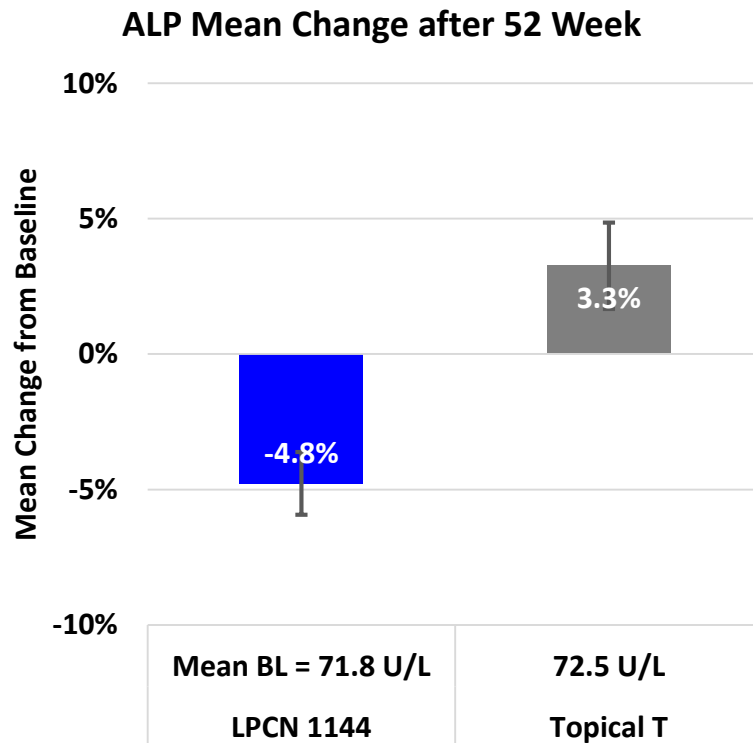
TG mean change post therapy in patients on oral T vs non-oral T therapy



LPCN 1144: Oral T

Unique Effects on Liver Compared to Topical Gel

- 52 Week SOAR Trial



TLANDO™

TLANDO™: Potential First Oral Option

Profile Demonstrated Clinically with Target Label Regimen



Efficacy

- Met primary endpoint
 - 80% response rate in “worst-case analysis” vs. FDA requirement of 75%
 - Justification for non-applicability of C_{max} based missed secondary endpoints



Safety

- 591 subject exposure
- Well tolerated in 52 week exposure
 - AE profile comparable to active control, including GI
 - No cardiac, hepatic or drug related SAEs
 - No increase in mean BP with cuff measurements
- No apparent correlation of the observed C_{max} excursions
 - ADRs, AEs, Meaningful changes in critical lab parameters

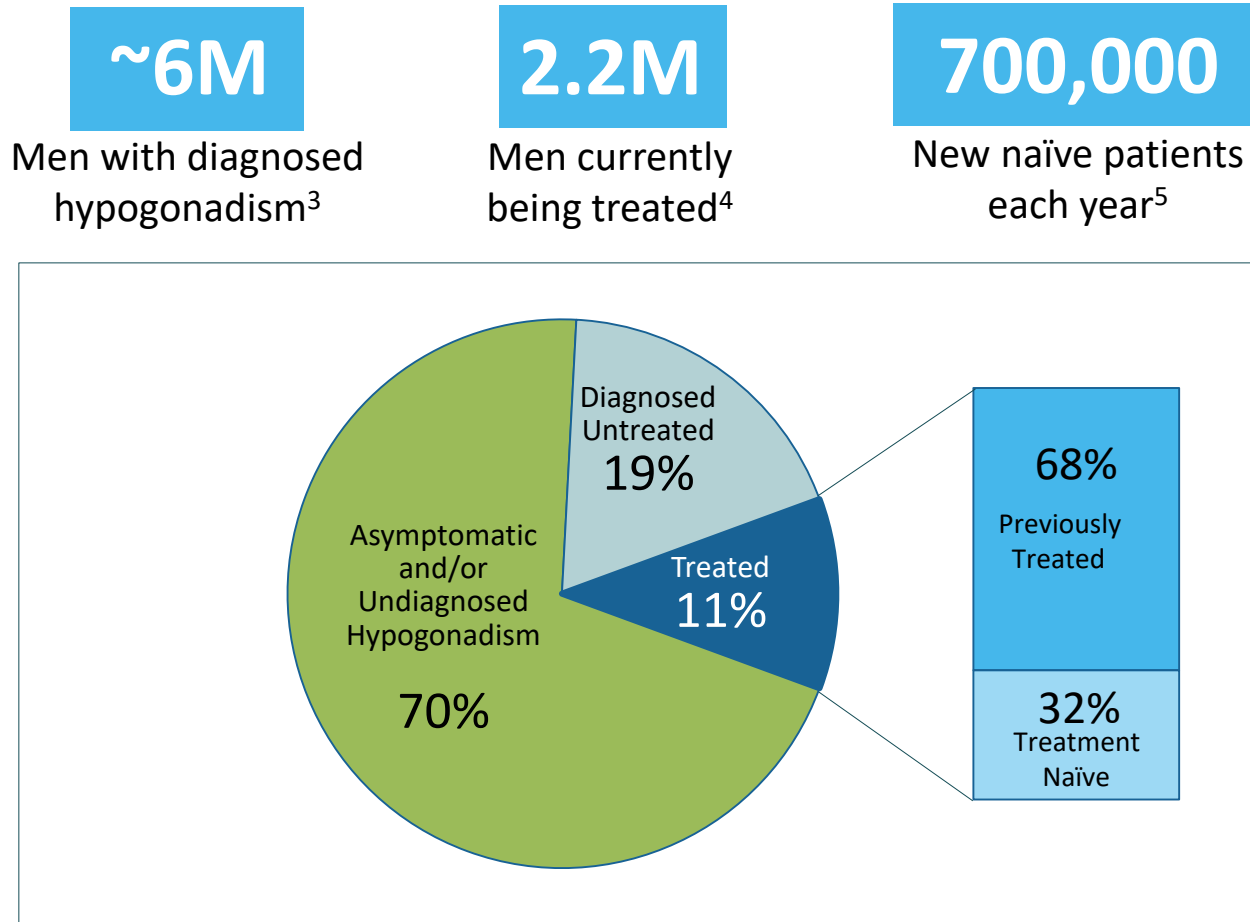


Clear Benefits

- Preferred oral option
 - No risk of accidental T transference
 - Non-invasive
 - Less cumbersome
 - Less burdensome
 - Simpler to prescribe
 - Fewer doctor visits
 - Easier for patients to properly use

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

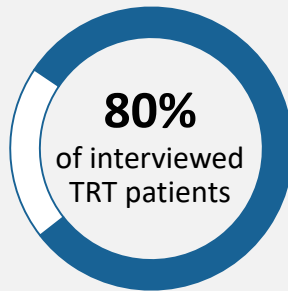
Significant Number of Untreated Hypogonadal Males



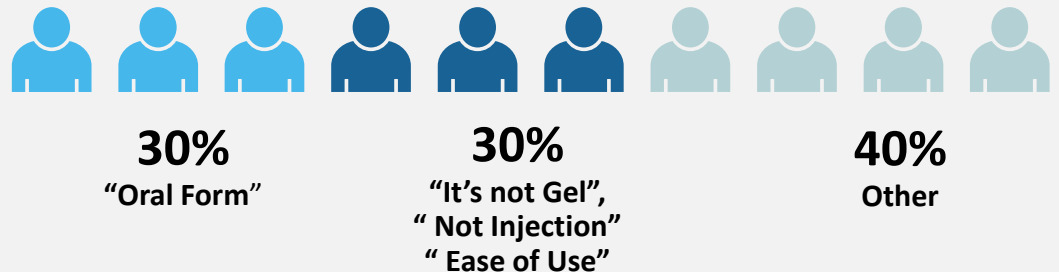
TLANDO: Patient Market Research

Patient Enthusiasm Evident About Oral TRT

Likely or Highly Likely to Ask Physician to Prescribe TLANDO



What Most Like About TLANDO?

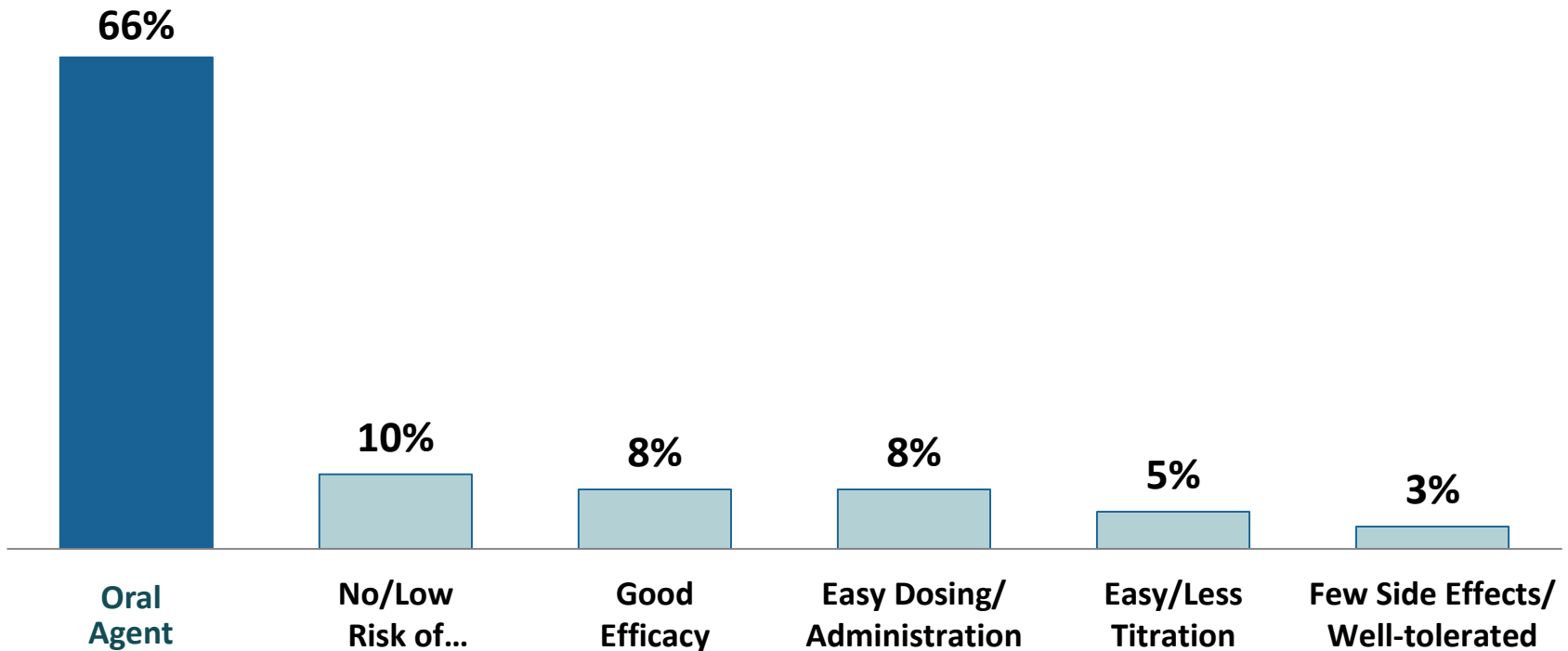


- TLANDO generates strong patient enthusiasm among current and prior TRT users
 - Oral administration and lack of transference viewed as key benefits
- For transdermal users, most common concern is transference risk
 - ***"Always worry with the kids."; "Right now we have to plan sex."***
 - Gels and roll-on are messy to apply and often cause skin irritation
- Injectable users complain about swings in testosterone levels resulting in "crash" before next dose
 - ***"I keep crashing two weeks after the injection"***
 - Needle phobia/needle fatigue are common
- Both transdermal and injection users also want better symptomatic efficacy

TLANDO: Physician Market Research

Oral Agent is Most Important Attribute for Prescribers

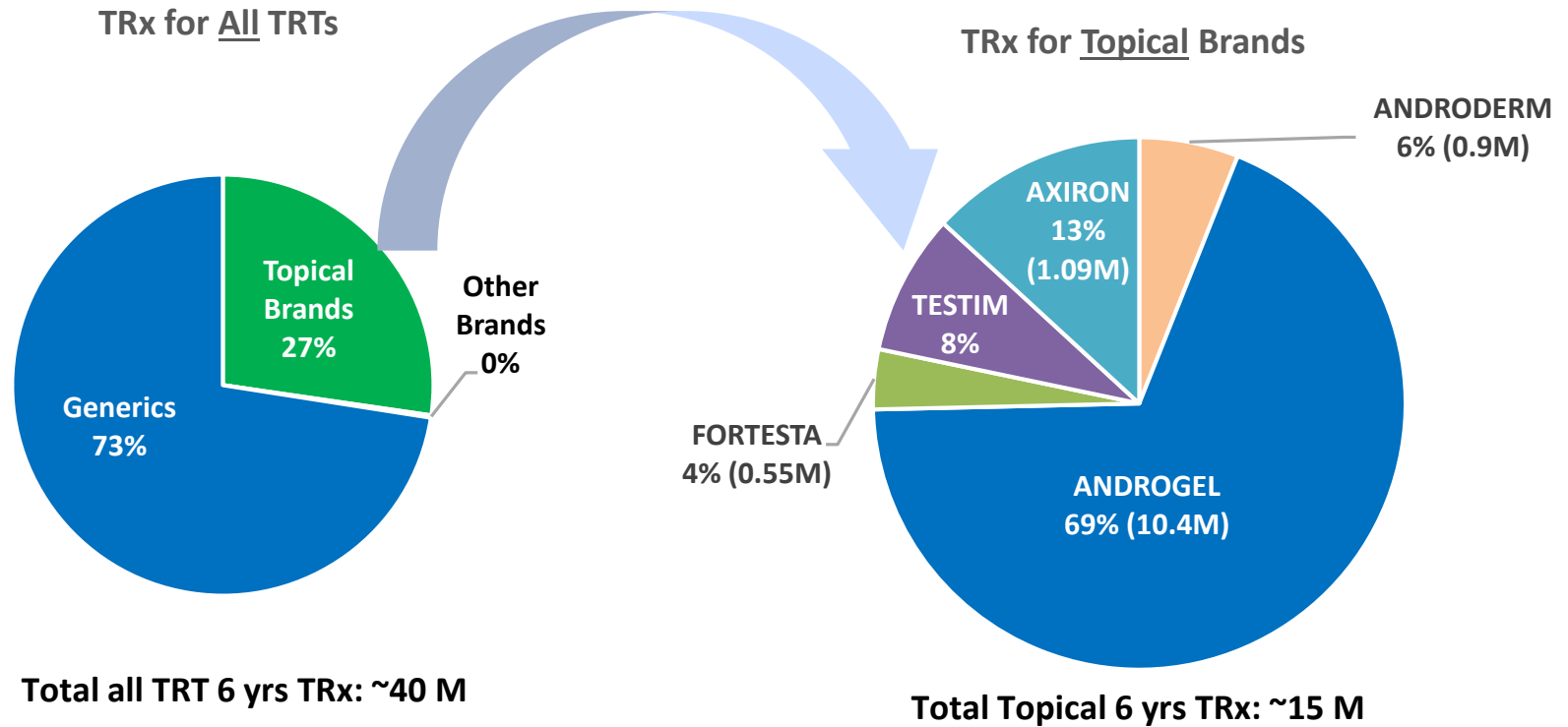
QUESTION:
What is the most important advantage of TLANDO?



N=212 (All Respondents; URO=54, ENDO=53, PCP=105), TVG conducted market research.
Q35a. In your opinion, what is the most important advantage of TLANDO?

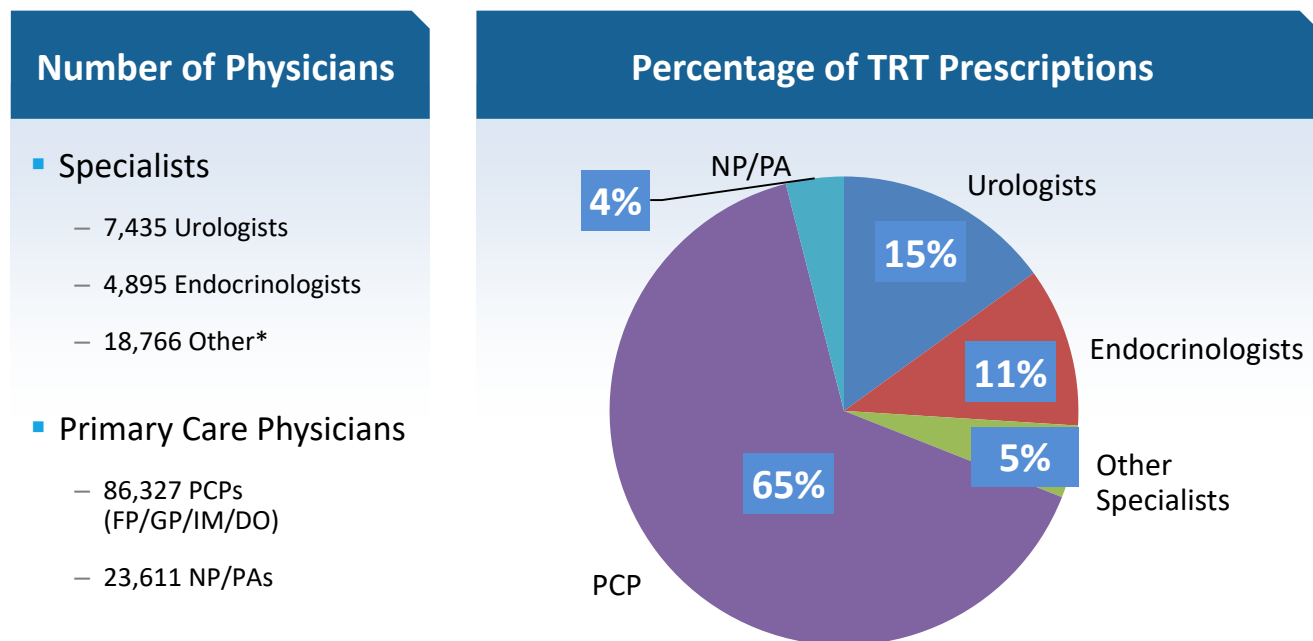
Cumulative TRx for TRT Products Last Six Years*

Multiple Branded Topicals with Significant Market Share



Source: IMS
*Feb 2013 to Jan 2019

Primary Care Physicians Prescribe 65% of TRT

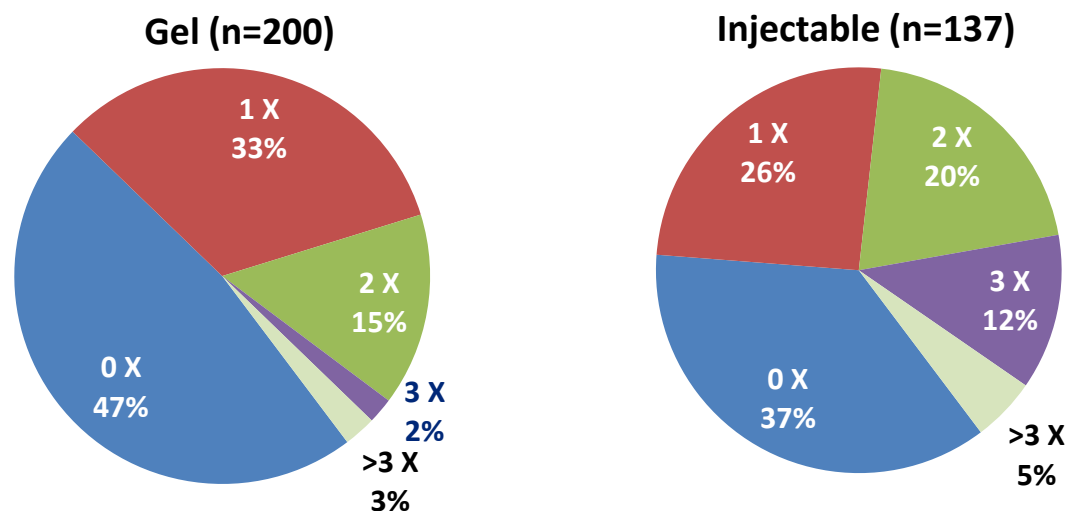


*Hem/Onc, Geriatrics, Pulmonology, Rheumatology, Surgery; excludes 1,661 OB/GYNs.

IMS Health August 2015.

CONFIDENTIAL

Over 50% of Patients Require Dose Adjustment with Current TRT Therapies



Number of Current TRT Dose Adjustments by Form*

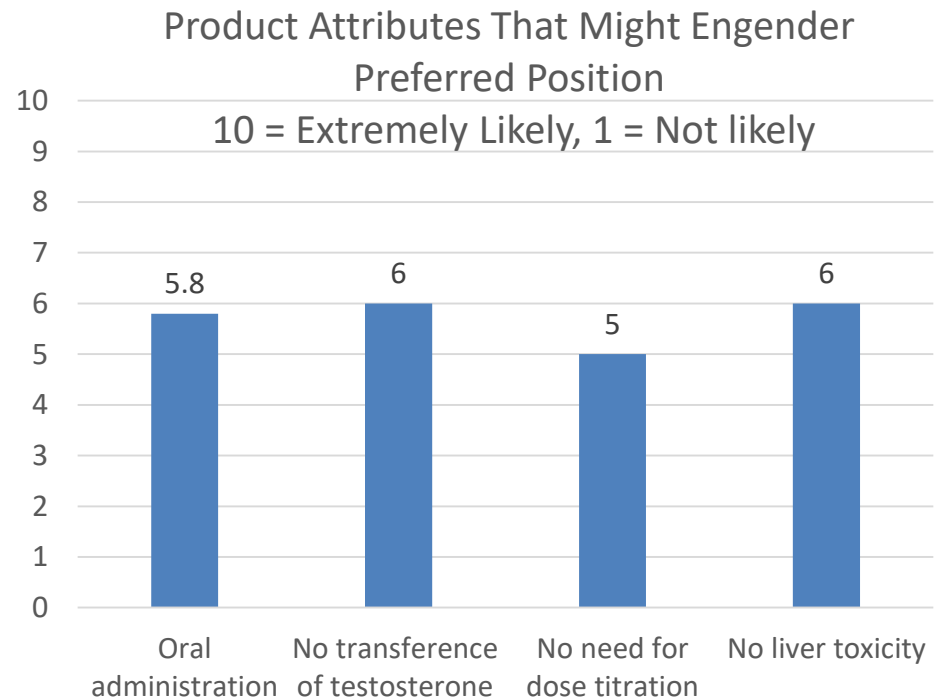
* Current TRT n=412

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?

TLANDO Market Research

Payers' Impression*

- Payers reported that the potential advantages of TLANDO were:
 - Oral administration
 - No unintentional transference of testosterone
 - No liver toxicity compared to methyltestosterone
 - No need for dosage titration
- However, none of these product attributes were considered likely to ensure that TLANDO could obtain a preferred position on their formularies



* Lipocine market research

TLANDO Market Research

Physician Respondents Viewed “No Titration” as a Positive Element*

- Respondents believe that a product that does not have to be titrated will be easier for them to prescribe, as well as easier for their patients to take
- The lack of titration will not require any additional office visits, as well as no additional phone calls inquiring about the next steps for dosing of the product
- One respondent specifically mentioned that the patients would not need to get any additional fasting labs

* Lipocine market research

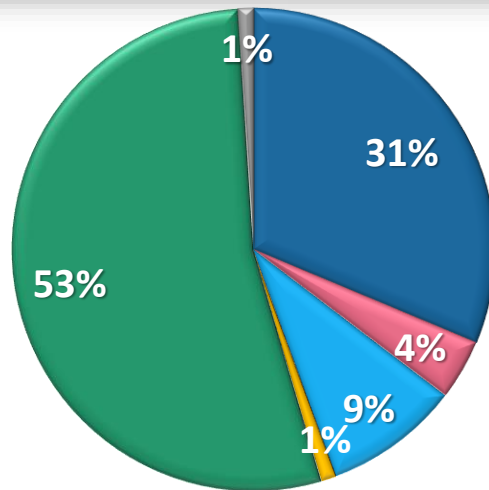
TLANDO™ XR

First Long Acting Oral

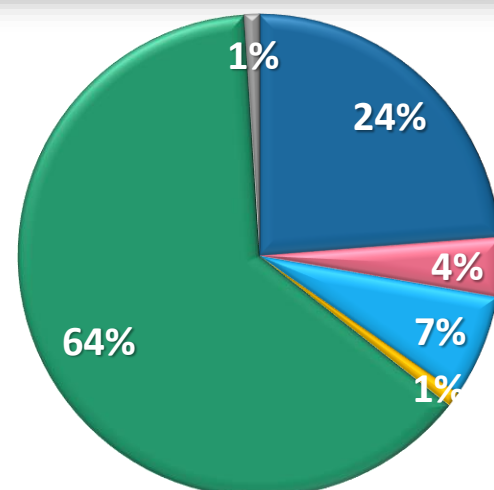
TLANDO XR (LPCN 1111): Market Research

Physician Intent-to-Prescribe Statistically Higher¹ with a QD

Future Prescribing Patterns with Entrenchment of Product X BID



Future Prescribing Patterns with Entrenchment of Product X QD



■ Androgel or Testim ■ Androderm ■ DepotTest ■ Android & Other Orals ■ Testopel ■ Product X ■ Other

CE11: Assume Product X is dosed QD vs, BID, adjust percentages to reflect intent-to-prescribe.

1. $P < 0.01$

LPCN 1107

High PTB Medical Costs

≥ \$26 Billion Economic Impact³



- 12% of all US pregnancies¹ (475 -500K) result in PTB (< 37 weeks)-a leading cause of neonatal mortality and morbidity
- First year medical costs for PTB infants are ~ 10x higher than for full term infants²
- 28% of preterm births are to women with histories of early delivery

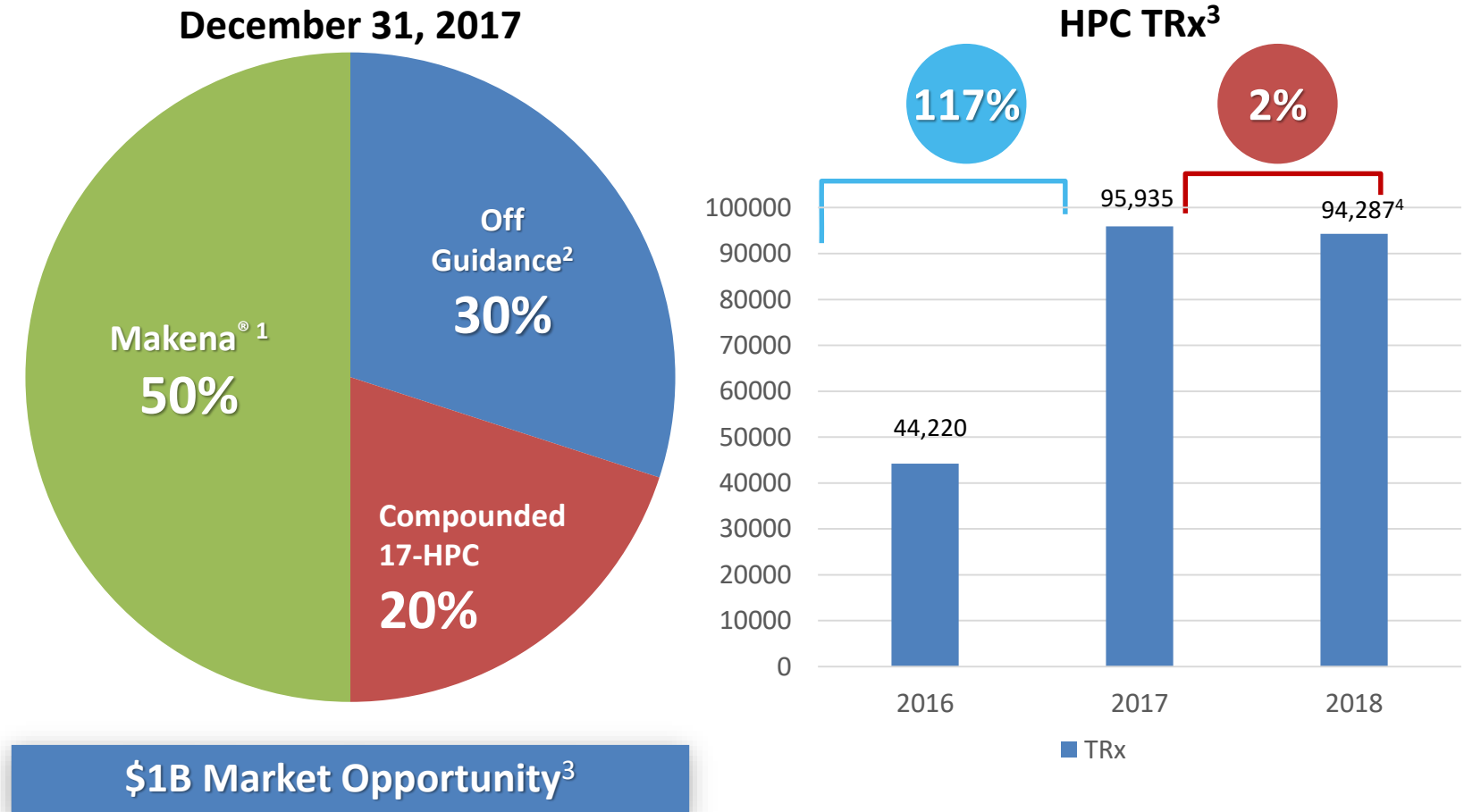
1. CDC (2010)

2. J. Maternal-Fetal and Neonatal Medicine, Dec. 2006, 19(12), 773–782

3. Institute of Medicine of the National Academies. July 2006

LPCN 1107: Prevention of Preterm Birth (PTB)

United States Market Landscape



1. AMAG estimates Makena market share based on distributor dispensing data and all other market share based on physician market research data conducted by AMAG.

2. Off guidance represents patients treated outside of guidance of Society for Maternal Fetal Medicine, including patients treated with unapproved therapies and untreated patients.

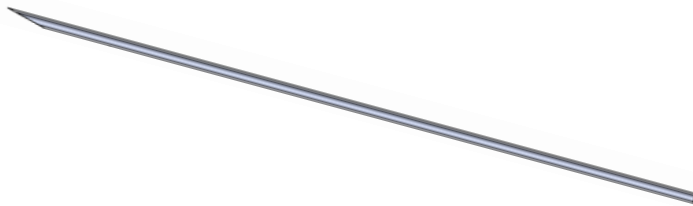
3. IMS data

4. Annualized September 30, 2018 data

LPCN 1107: First Oral PTB Candidate

Characteristics of the Only Approved Product Options for PTB

Makena 21 gauge needle



IM HPC, Makena®:

- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
 - Injection location: Upper-outer quadrant of the gluteus maximus
 - Weekly visit to/by health care provider
 - ~35% of patients experienced injection site pain during clinical trial
 - ~17% of patients reported site swelling-much greater than placebo during clinical trial

SubQ HPC, Makena®:

- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
 - Approved February 14, 2018
 - Auto injector-ready to use device
 - Injection location: Upper back of the arm
 - Weekly visit to/by health care provider
 - 37.3% of subjects identified injection site pain as a treatment emergent adverse event compared to only 8.2% of subjects in the IM arm

LPCN 1107: First Oral PTB Candidate

Addresses Unmet Need



LPCN 1107- Oral HPC

- Potential for superior efficacy with Phase 3 target dose
- No patient discomfort upon administration
- Steady state achieved in 7 days
- Orphan drug designation
 - Major contribution to patient care
- Next steps:
 - Explore partnering opportunities

LPCN 1107: Economic Impact

Potential Lower PTB Rate – US and Resulting Savings

Assuming 4.3% lower PTB rate relative to Makena[®]



~6000 fewer annual PTBs‡



Estimated annual cost saving in ~\$310M‡‡

‡: Assuming 100% of 140,000 eligible US population treated

‡‡: Assuming ~\$51,600 medical costs/PTB

LPCN 1107: First Oral PTB Candidate

Commercial Outlook/Drivers

First Oral HPC for Prevention of Recurrent PTB

- Preferred route-of-administration is oral

Strong Exclusivity Position

- Orphan Drug Designation
- Technology/IP protection

Potential for Superior Efficacy

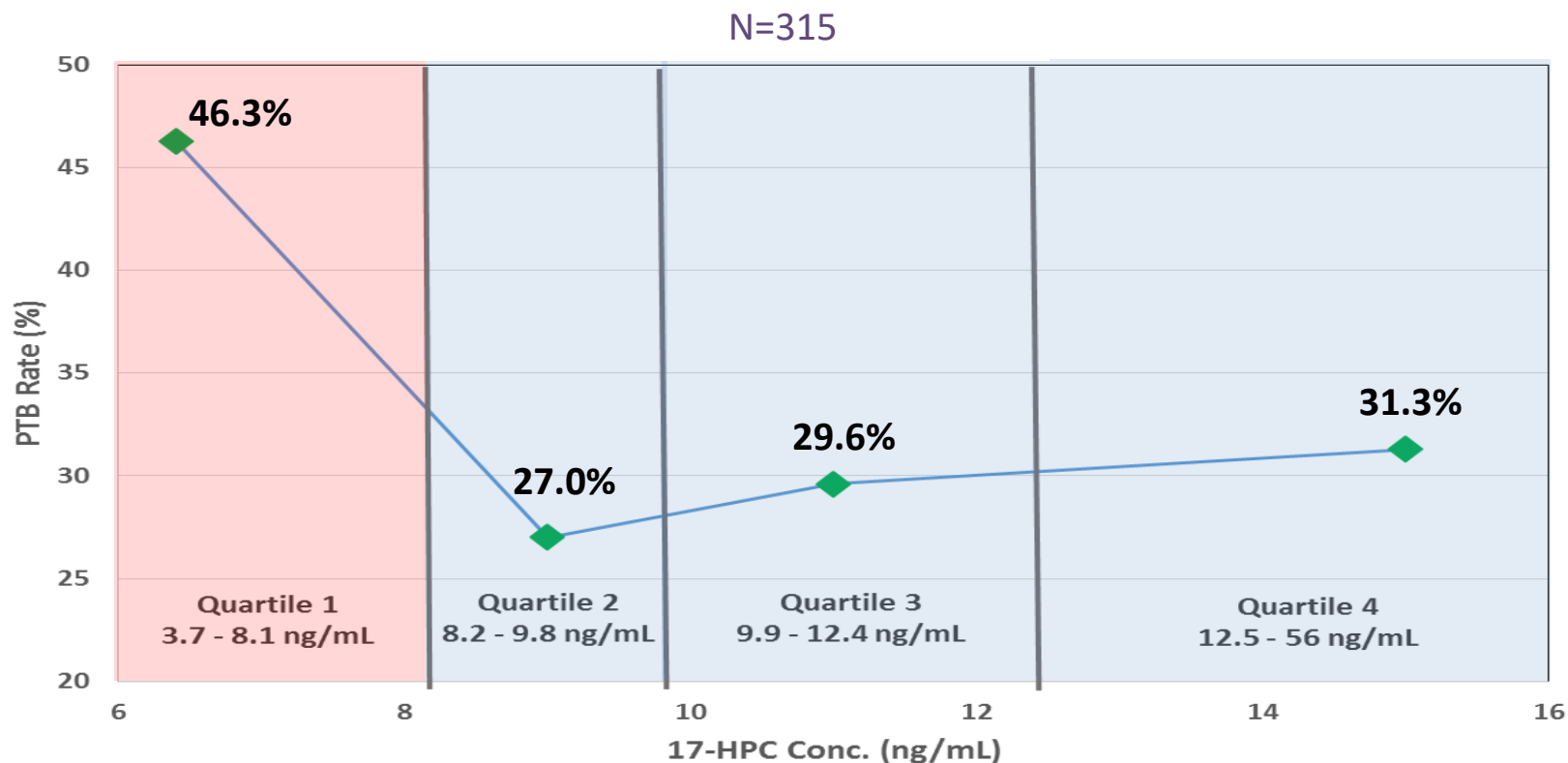
- Fewer PTB babies with significant healthcare cost savings

Strong Pharmaco-Economic Justification

- Minimize travel related cost/time and healthcare provider cost/time
- Premium pricing potential to generic IM injections

LPCN 1107: HPC PK-PD Correlation

HPC Concentration and PTB Rate with IM HPC, Makena¹



- Lower % PTB rate can be expected with daily C_{avg} ² HPC levels ≥ 8.2 ng/mL

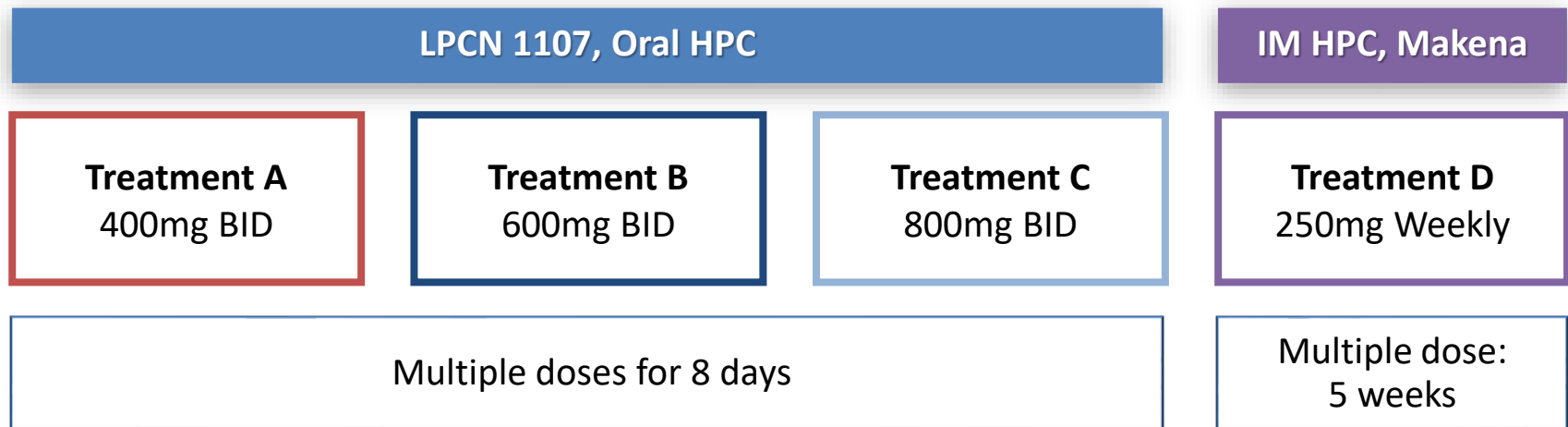
1. Caritis et al., Am J Obstet Gynecol. 2014 (N=315 subjects)

2. $C_{trough} \equiv C_{avg}$ for IM Makena®

LPCN 1107: Dose Finding Study Design

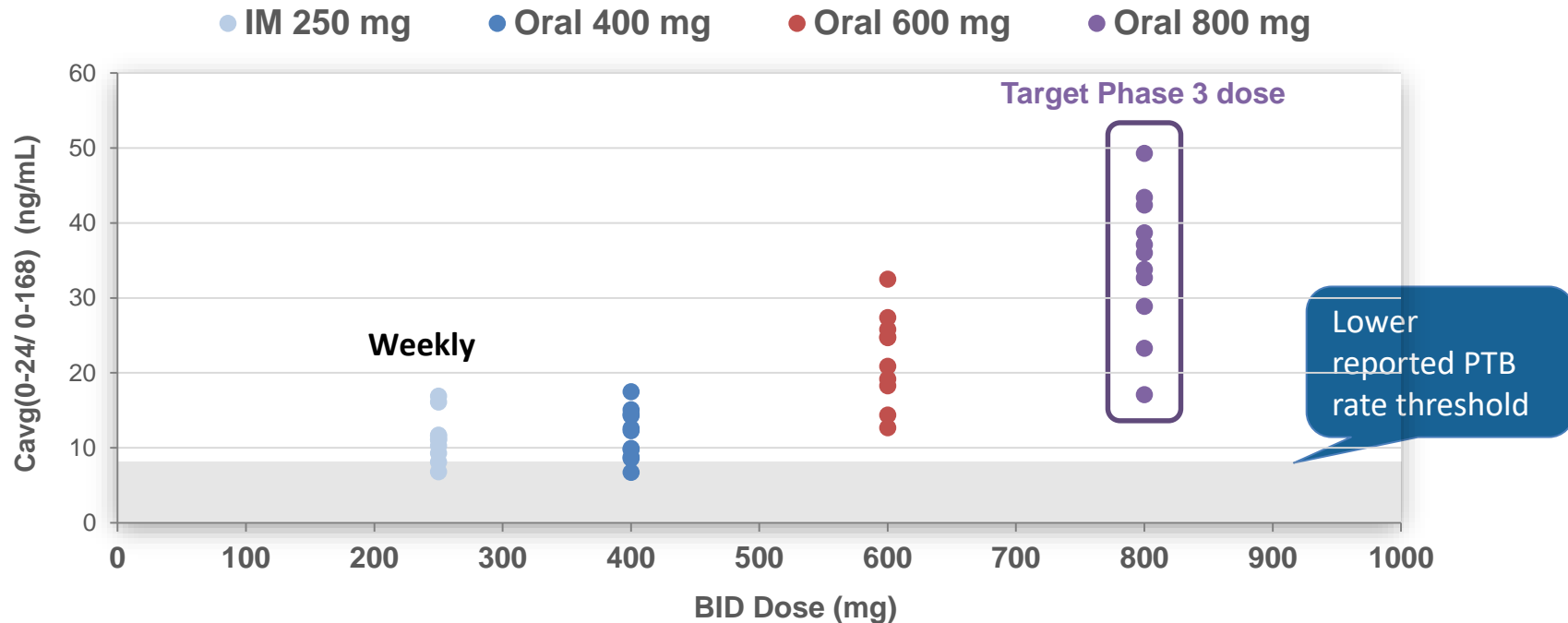
PK Study: Oral LPCN 1107 vs IM HPC, Makena

- Open-label, four-period, four-treatment study
- 12 healthy pregnant women- Ages 18-35 years; 16-18 weeks gestation
- All subjects received all four treatments



LPCN 1107: Dose-Finding PK Study Results¹

Oral LPCN 1107 vs IM HPC, Makena



- HPC levels below 8.2 ng/mL:
 - Target LPCN 1107 Phase 3 dose was 0% vs 20% subjects using IM HPC Makena per label
- Average HPC levels at target LPCN 1107 Phase 3 dose
 - ~ 3x greater than the comparator, IM HPC, Makena

LPCN 1107: Advancing to Phase 3 Readiness

Phase 3 Special Protocol Assessment – Progress

■ Concurrence with FDA to date:

— Study Design Elements

- Single Phase 3 study
- Open label, active comparator, two parallel arms (1:1 randomization)
- General inclusion and exclusion criteria and treatment duration
- LPCN 1107 dose of 800 mg BID

— Endpoints and Analysis

- Primary endpoint of proportion of PTB < 37 weeks
- Non-inferiority margin of 7%
- Secondary endpoint: Neonatal mortality and morbidity composite index
- Interim analysis with ability to resize the study
 - Study size: 500 to 1000 subjects per arm

■ Open Items

- Data from food effect study to inform dosing instructions
- Align on approach to fulfill infant follow up data requirement

■ Next Steps

- Continue interactions with FDA on Phase 3 protocol via Special Protocol Assessment
- Conduct Food/Fat Effect Study in preparation of Phase 3 study