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ENHANCING HEALTH

May 15, 2020

A photograph of a man in a suit and glasses speaking at a podium with a microphone. His hands are visible near the podium. The background is slightly blurred.

PD26-05

# EFFECTS OF A NEW ORAL TESTOSTERONE UNDECANOATE (TLANDO™) THERAPY ON LIVER

A close-up photograph of a hand holding a pen, writing on a document. The focus is on the pen and the paper.

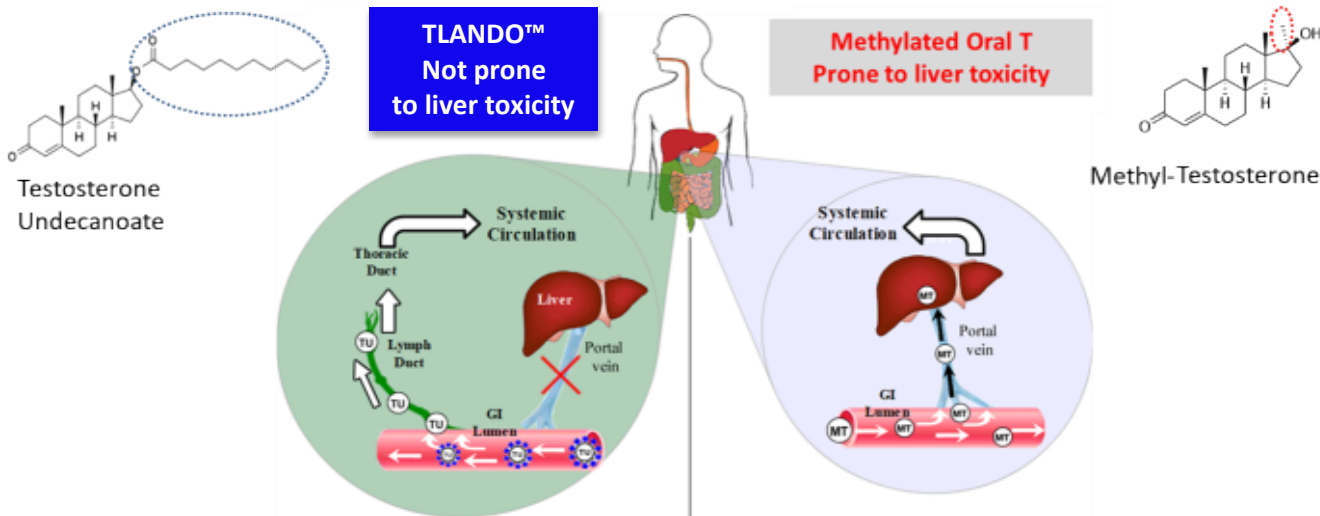
Presenter: Irwin Goldstein, MD

Director, Sexual Medicine, Alvarado Hospital, San Diego, CA  
Clinical Professor of Surgery, University of California at San Diego

On behalf of Lipocine Inc.



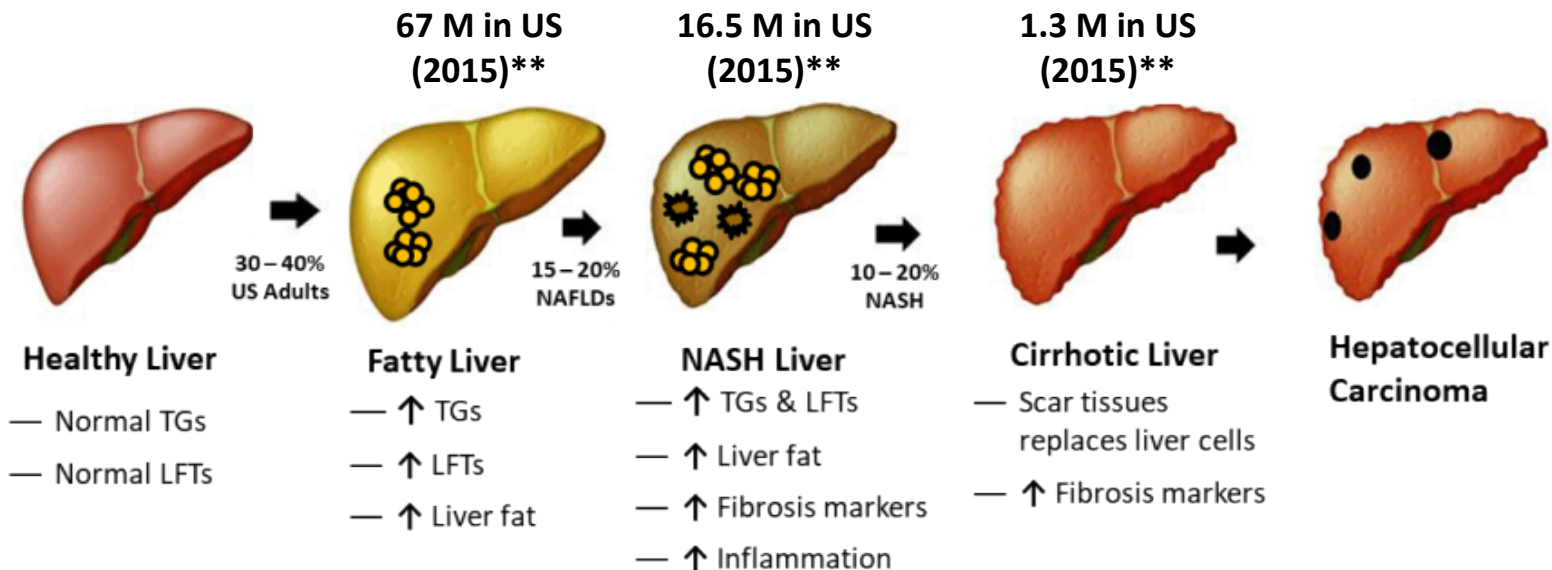
## TLANDO™ is A Non-Methylated, Orally Bioavailable Prodrug of Endogenous T



**TLANDO™ is Designed to Deliver T through Lymphatic Route Avoiding First Pass Metabolism**

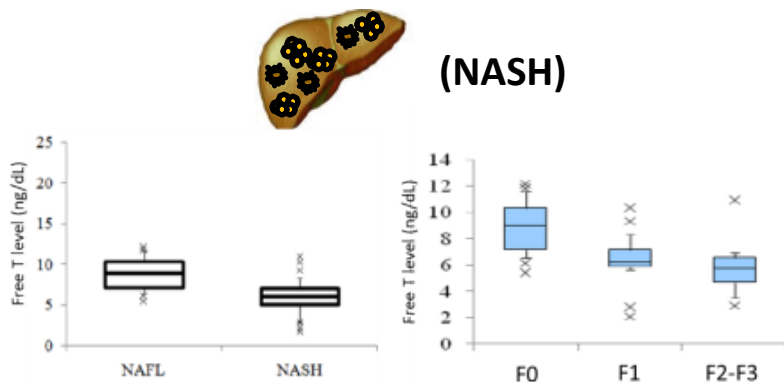


## Full Spectrum of Non-Alcoholic Fatty Liver Disease (NAFLD)\*

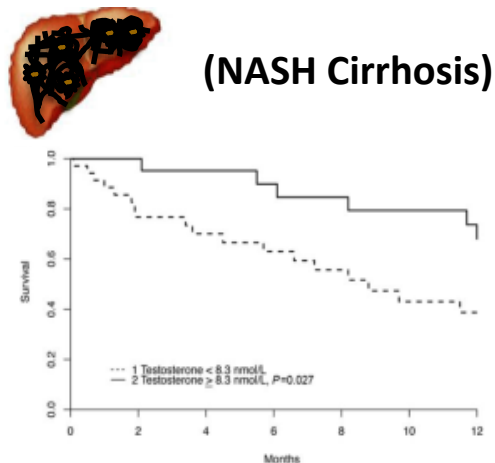




## Association Between Testosterone and Liver Disease



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



- Low T reported in up to 90% of NASH cirrhosis patients<sup>3</sup> and is a predictor of mortality.<sup>4</sup>



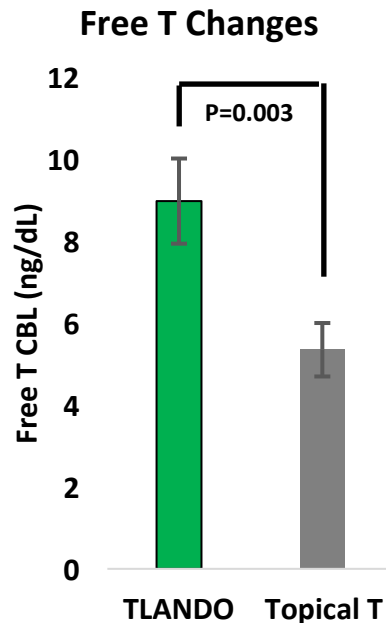
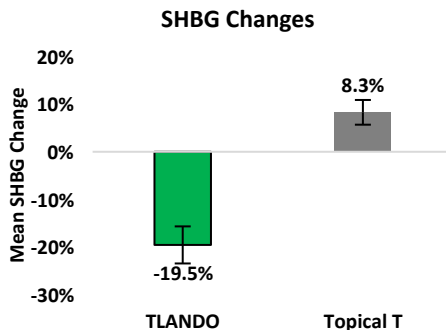
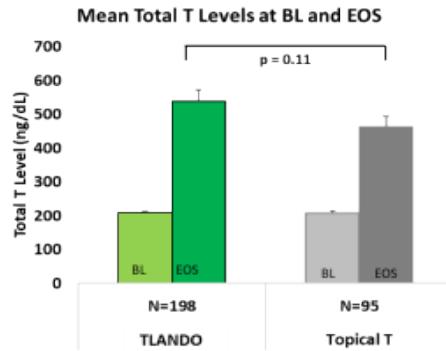
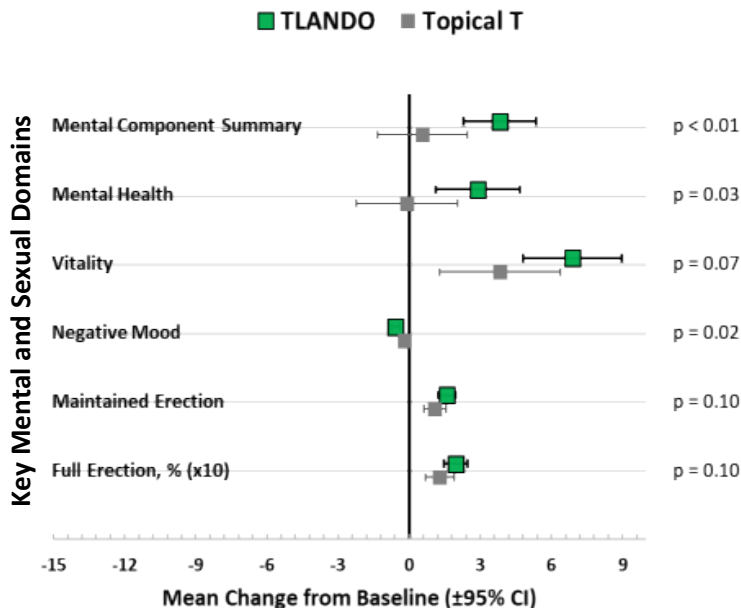
## TLANDO™ Clinical Experience

- Well tolerated in more than 700 subjects across 15 clinical trials with exposure of up to 52 weeks
  - Studies including assessment of liver health

Clinical Study	# of Subjects	Duration	Study Design	Endpoint
<b>Liver Fat Study (LFS)</b>	N = 36	4 months	Open labeled, multi-centered single arm study in hypogonadal males	Assessing liver fat %† Change in hypogonadal NAFLD males
<b>SOAR* Trial</b>	N = 315 210 – TLANDO™ 105 – Topical T**	1 year	Open labeled, multi-centered, active arm controlled study in hypogonadal males	Assessing change of liver injury markers

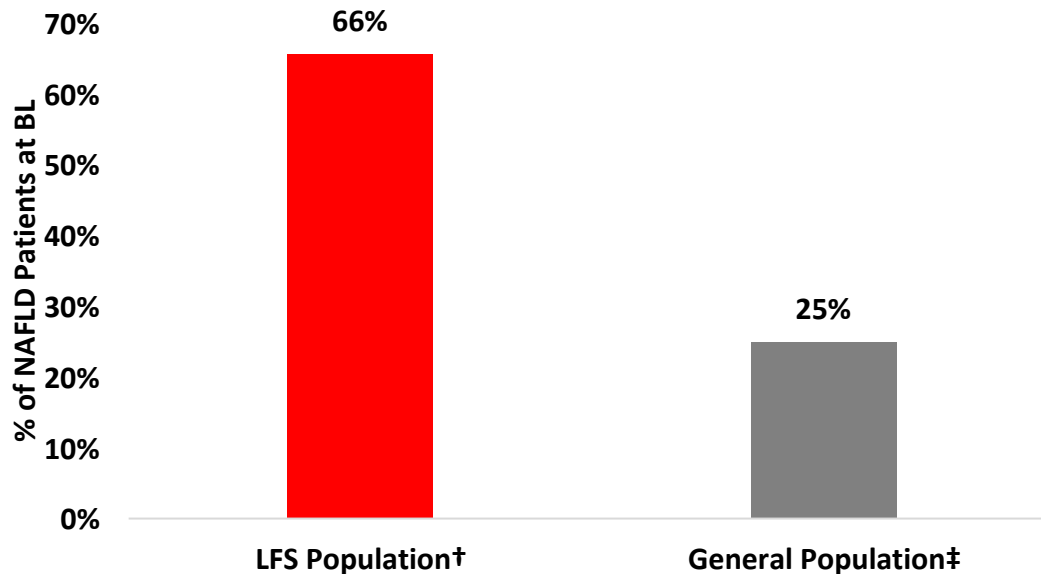


## Differentiated TLANDO™ Effects



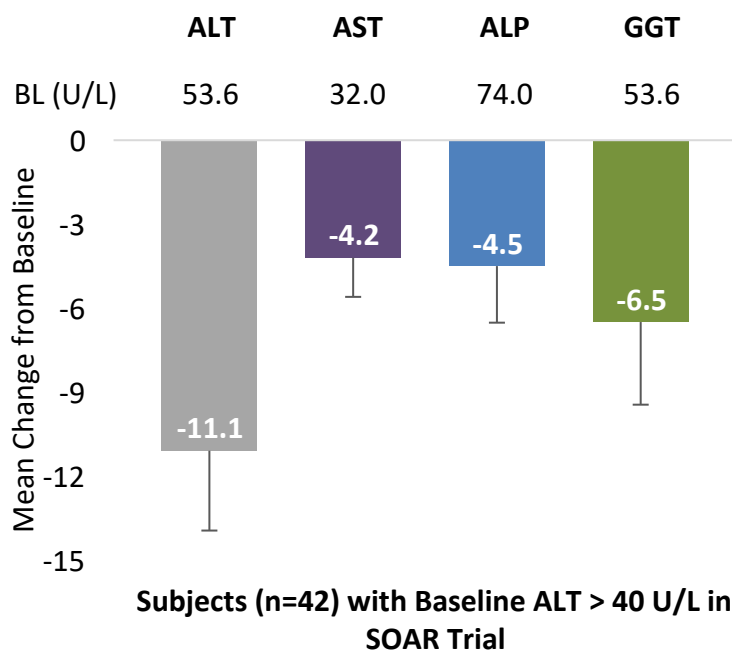


## NAFLD is Overly Prevalent in Hypogonadal Males

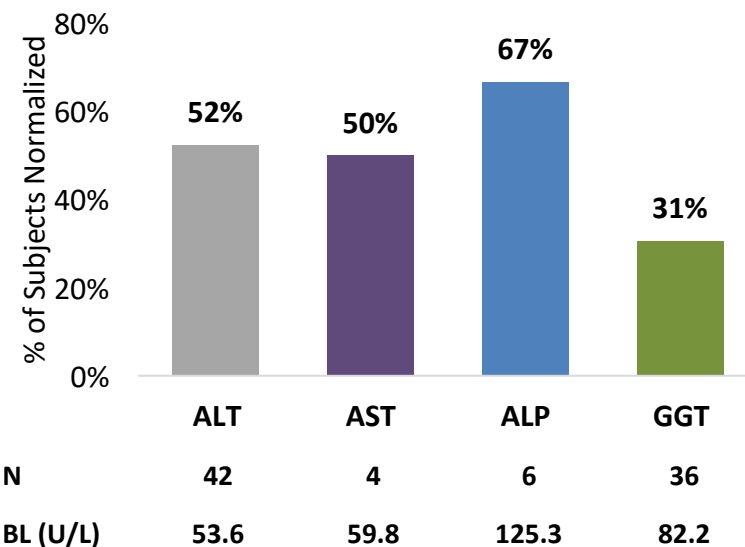




## Reduction of Elevated\* Liver Injury Markers



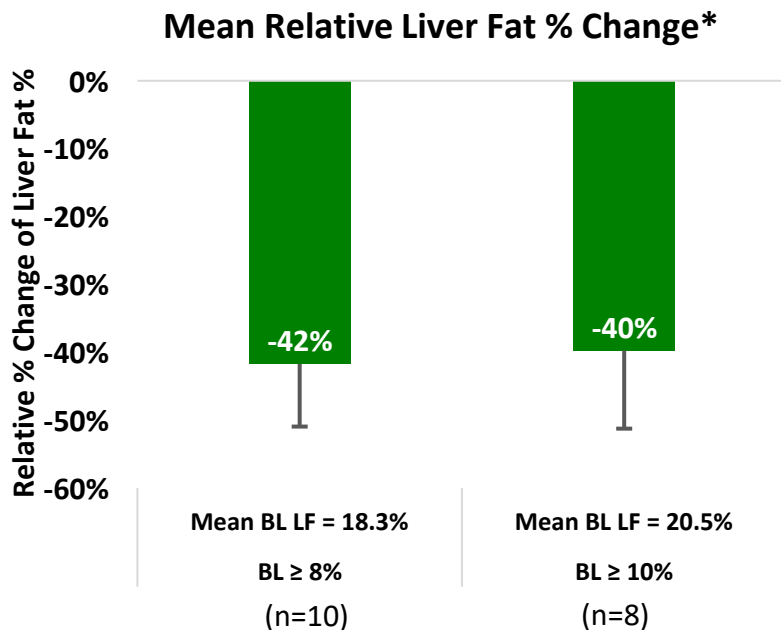
### Normalization of Elevated Liver Enzymes



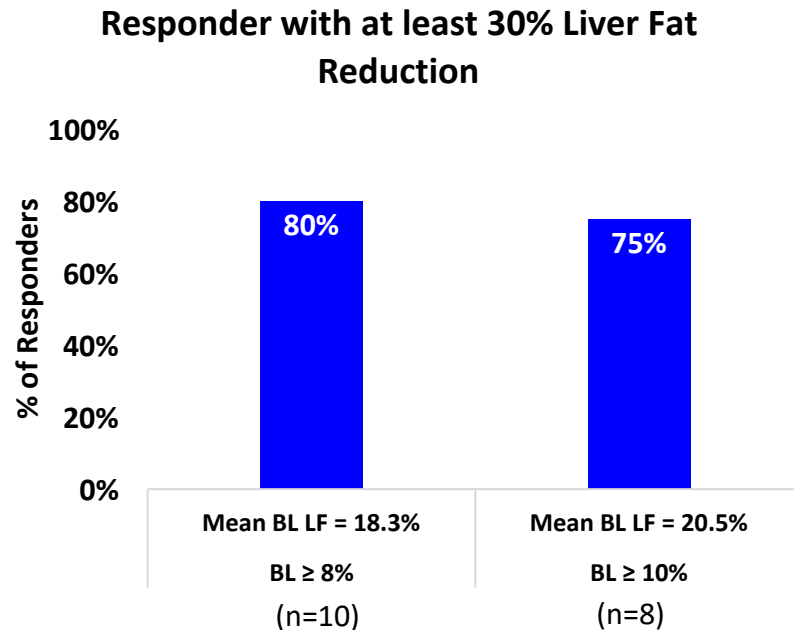




## Meaningful Liver Fat % Change and Responder Rate

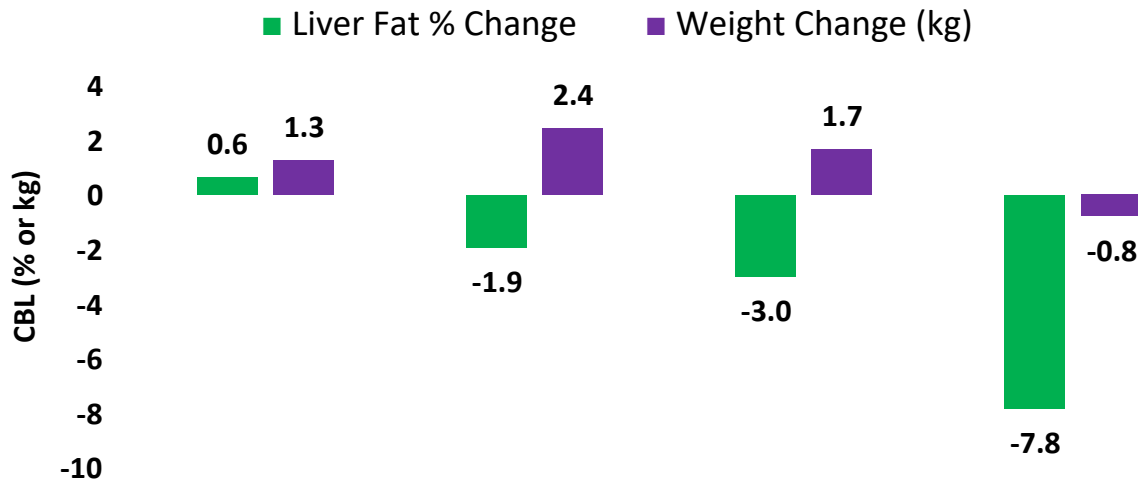


LF = liver fat; BL = baseline





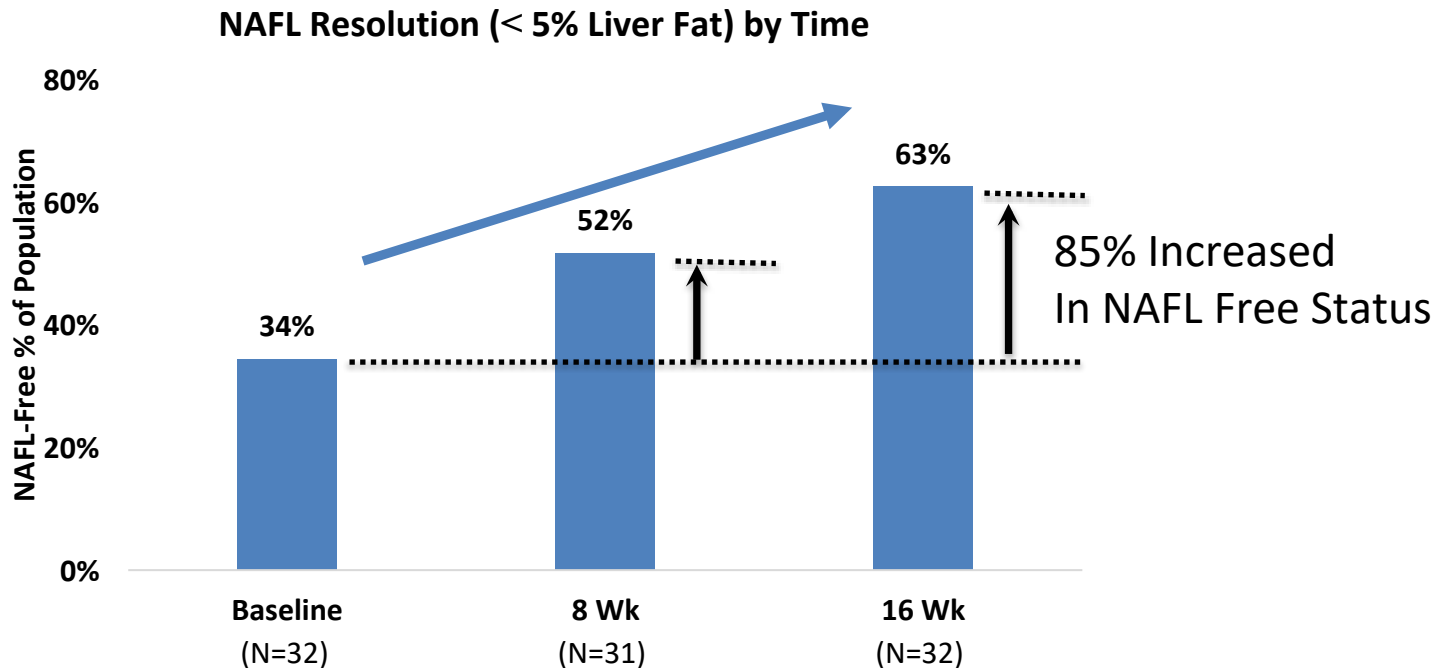
## Greater Liver Fat Reduction with Higher BMI\*



BL BMI (kg/m2)	< 30	30 - 35	35 - 40	> 40
N	7	13	6	6
BL Mean Weight (kg)	76.1	98.5	117.1	136.8
BL Mean Liver Fat (%)	3.3	7.6	9.7	17.2



## Improvement of NAFL\* Resolution Over Time





## Conclusion

- Contrary to hepatotoxic experience with methylated oral T, TLANDO™ (an innovative lymphatically delivered oral TU) is well tolerated upon chronic use.
- TLANDO™ restores normal T levels and improved mental and sexual domains in hypogonadal men.
- TLANDO™ is beneficial on liver health demonstrated by
  - About 50% of fatty liver subjects had Nonalcoholic fatty liver (NAFL) resolution
  - Meaningful reduction of elevated liver injury markers
  - Substantial normalization of elevated liver injury markers
- TLANDO™ safety was demonstrated in more than 700 subjects across 15 clinical trials with exposure up to 52 weeks.