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

<table>
<thead>
<tr>
<th>PRODUCT (Indication)</th>
<th>PRE-CLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>NDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TLANDO™</strong>&lt;br&gt; (Oral Testosterone for Testosterone Replacement Therapy “TRT”)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PDUFA Date August 28, 2020</td>
</tr>
<tr>
<td><strong>TLANDO XR</strong>&lt;br&gt; (Long Acting Oral Testosterone for Testosterone Replacement Therapy “TRT”)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phase 3 Dose Identified</td>
</tr>
<tr>
<td><strong>LPCN 1144</strong>&lt;br&gt; (Oral Testosterone for Pre-Cirrhotic NASH)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LiFT Phase 2 Paired Biopsy Clinical Study Ongoing</td>
</tr>
<tr>
<td><strong>LPCN 1148</strong>&lt;br&gt; (Oral Testosterone for Cirrhosis)</td>
<td></td>
<td></td>
<td></td>
<td>IND Submission March 2020</td>
<td></td>
</tr>
<tr>
<td><strong>LPCN 1107</strong>&lt;br&gt; (Oral HPC for Prevention of PTB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phase 3 Dose Identified</td>
</tr>
</tbody>
</table>
TLANDO™

Fixed Dose Oral TRT
Hypogonadism Affects Up to 20M Men\textsuperscript{1, 2}

TLANDO Franchise has the Potential to Drive Market Expansion

Hypogonadism Under Treatment in US

- Close to 6M men with diagnosed hypogonadism\textsuperscript{3}
- 2M men being treated\textsuperscript{4}

5. IMS Health Sept 2015.
Monthly TRT TRx Trend
TRT Market is Growing Without Oral Option

2019 Annual TRx of 7.3 million

Source: IMS database
TRx = Total prescriptions
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 Has Potential to Improve Persistence
Titration Requirements of Current TRTs

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

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?

Source: Adheris Health 2017
TLANDO™ Attributes

Fixed Dose Oral TRT Option

Convenient Oral Route

• Patient and Physician preferred

Easy to Prescribe Fixed Dosing Regimen

• No additional dose adjustment visits
• Less prone to drop out after first Rx
• The “right” dose from the start of therapy with TLANDO™ for all patients
• 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
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
Enabling Oral Drug Delivery to Improve Patient Compliance

LPCN 1144 for Pre-Cirrhotic NASH
LPCN 1144: Rationale to Target Pre-Cirrhotic NASH
Currently No Approved Treatment

Estimated Market*

17 M NASH Patients\(^1\)

11 M Male NASH Patients\(^1,2\)

3.5 M Male NASH with F2-F3\(^1,2\)

~6.9 M Male NASH F2-F3 in 2030\(^1,2\)

Multi-billion $ Opportunity

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

*2015 data
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

### Mechanistic Evidence
- Anti-steatosis
- Anti-inflammatory
- Anti-oxidative
- Cell regenerative

### 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
Association Between Testosterone and Liver Disease
Clinical Evidence

- ~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\(^2\)

“Low T reported in up to 90% of NASH 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;
LPCN 1144 Proposed Mechanism
Across the Full Spectrum of NASH Pathogenesis

Healthy Liver

<table>
<thead>
<tr>
<th>Comorbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Obesity</td>
</tr>
<tr>
<td>• Insulin Resistance</td>
</tr>
<tr>
<td>• Dyslipidemia</td>
</tr>
<tr>
<td>• Metabolic Syndrome</td>
</tr>
<tr>
<td>• Hypogonadism (Low T)</td>
</tr>
</tbody>
</table>

LPCN 1144

- Anti-steatosis
- Anti-inflammatory
- Anti-oxidant

Regeneration Booster

The removal of pro-fibrotic inputs or the strengthening of anti-fibrotic inputs is expected to stimulate scar resolution

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

-4 Wk  0 Wk  8 Wk  16 Wk
MRI-PDFF BL  MRI-PDFF Δ Interim  MRI-PDFF Δ End-Of-Study

Evaluated
N = 34

- LF ≥ 5%
  N = 21
  Mean LF % BL: 12.1±8.0
- LF ≥ 8%
  N = 10
  Mean LF % BL: 18.3±7.7
- LF ≥ 10%
  N = 8
  Mean LF % BL: 20.5±7.0

LF = liver fat
LPCN 1144: Liver Fat Reduction
Meaningful Relative Liver Fat % Change and Responder Rate

Mean BL LF = 18.3%
Mean BL LF = 20.5%

BL ≥ 8%
(n=10)

BL ≥ 10%
(n=8)

Responders with 30% change for Liver Fat

Mean BL LF = 18.3%
Mean BL LF = 20.5%

BL ≥ 8%
(n=10)

BL ≥ 10%
(n=8)

LF = liver fat
BL = baseline
NCT03868059
LPCN 1144: Longitudinal Treatment Effect
Improved NAFL Resolution Over Time

NAFL Resolution to < 5% Liver Fat

<table>
<thead>
<tr>
<th>Time</th>
<th>NAFL-Free % of Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>34% (N=32)</td>
</tr>
<tr>
<td>8 Wk</td>
<td>52% (N=31)</td>
</tr>
<tr>
<td>16 Wk</td>
<td>63% (N=32)</td>
</tr>
</tbody>
</table>

NAFL is non-alcoholic fatty liver with ≥ 5% liver fat
NCT03868059
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

<table>
<thead>
<tr>
<th>Subject (n=42), Baseline ALT &gt; 40 U/L*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT</td>
</tr>
<tr>
<td>Baseline (U/L)</td>
</tr>
<tr>
<td>Mean Change from Baseline</td>
</tr>
</tbody>
</table>

* Sanyal et al, Hepatol, 2015

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

*Website: www.lift-study.com*
## Upcoming Milestones
### Near Term Value Drivers

<table>
<thead>
<tr>
<th>Event</th>
<th>Expected Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TLANDO™</strong></td>
<td>PDUFA Date</td>
</tr>
<tr>
<td></td>
<td>August 28, 2020</td>
</tr>
<tr>
<td><strong>LPCN 1144</strong></td>
<td><em>LiFT</em> Primary Endpoint Results</td>
</tr>
<tr>
<td></td>
<td>2H 2020</td>
</tr>
</tbody>
</table>
# Key Financial Metrics

**Stock Price, Market Cap, Cash Balance**

<table>
<thead>
<tr>
<th>Ticker Symbol</th>
<th>LPCN (Nasdaq Capital Market)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closing Stock Price (3/12/20)</td>
<td>$0.415/share</td>
</tr>
<tr>
<td>Market Capitalization (3/12/20)</td>
<td>$19.9 million</td>
</tr>
<tr>
<td>Cash Balance (12/31/19)</td>
<td>$19.1 million*†</td>
</tr>
<tr>
<td>Bank Debt (12/31/19)</td>
<td>$7.1 million</td>
</tr>
</tbody>
</table>

* $5M restricted and becomes unrestricted upon TLANDO approval
† Does not include $6.0 M in gross proceeds raised in February 2020 in Registered Direct Offering
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 Pre-Cirrhotic NASH/Cirrhosis

- **LPCN 1144**: A differentiated modality with potential for mono/combo pre-cirrhotic NASH therapy
- **LPCN 1148**: Targeting cirrhosis
  - Unmet need with no approved drug
  - Meaningfully reduced liver fat in POC study
  - Well tolerated in 700+ subjects with up to 52-week exposure

Orphan Designated Oral Candidate for the Prevention of Preterm Birth

- **LPCN 1107**: Superior Cavg to standard of care (Makena®)
TRT Market Dynamics
# Current Market Dynamics in TRT Space

## Prime Opportunity for TLANDO™

<table>
<thead>
<tr>
<th>Segment</th>
<th>Key Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient and physicians preferred</strong></td>
<td>• 85% of physicians have strong interest in oral</td>
</tr>
<tr>
<td></td>
<td>• 95% of TRT patients likely to ask their doctor about TLANDO™</td>
</tr>
<tr>
<td><strong>Current promotional spend all time low in this detail sensitive category</strong></td>
<td>• Able to have high share of voice with far less competitive promotion than in the past</td>
</tr>
<tr>
<td><strong>Concentrated call points</strong></td>
<td>• Decile 7-10 prescribers (~10,000) write 40% of the Scripts</td>
</tr>
<tr>
<td><strong>Detail sensitive category</strong></td>
<td>• Novel convenient oral option</td>
</tr>
<tr>
<td><strong>Recent injectable TRT launch data</strong></td>
<td>• Encouraging TRx trend in 2019</td>
</tr>
<tr>
<td></td>
<td>• ~47% of TRx from new patient starts</td>
</tr>
</tbody>
</table>

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LPCN 1111: Market Research
Physician Intent-to-Prescribe Statistically Higher\(^1\) with a QD

Future Prescribing Patterns with Entrenchment of Product X BID

Future Prescribing Patterns with Entrenchment of Product X QD

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

1. \(P<0.01\)
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
Enabling Oral Drug Delivery to Improve Patient Compliance

LPCN 1144 for Pre-Cirrhotic NASH
Unmet Needs in Pre-Cirrhotic NASH
Currently No Approved Treatment

- NASH Resolution and/or Fibrosis Improvement
- Safety & Tolerability for Chronic Use
- Improvement of Sarcopenia\(^1\)
  (35%-67% sarcopenia in NASH\(^2,3\))
- Improvement of Sexual Dysfunction\(^4\)
  (68% experienced erectile dysfunction\(^5\))
- Improvement of Mental Health/QOL\(^5,6\)
  (27% of NAFLD has depression\(^6\))

Comorbidities

1. Bhanji et al, Hepatol 2017
2. Koo et al, J Hepatol 2017
3. Petta et al, Aliment Pharmacol Ther 2017
7. Assimakopoulos et al., J Psychosom Res 2018
LPCN 1144: Multi-Dimensional Mechanism of Action Across the Full Spectrum of NASH Pathogenesis

**Homeostasis Modifier**<sup>1, 2</sup>
- Alter lipid, cholesterol, and glucose metabolism
- Reduce visceral abdominal fat
- Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase

**Anti-inflammatory*/Antioxidant/Immuno-modulator**<sup>3</sup>
- Restore mitochondrial turnover and normalizes oxygen consumption<sup>4</sup>

**Regeneration Booster**<sup>5, 6</sup>
- Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation<sup>7</sup>
- Increases circulating endothelial progenitor cells (“EPC”)<sup>8</sup>

**Anabolic/Androgenic Agent**<sup>9</sup>
- T induces muscle fiber hypertrophy by promoting myogenesis by inhibiting adipogenesis<sup>10</sup>
- Inhibit myostatin<sup>11</sup>
- Increase free T (lowering SHBG)
- Improve sexual dysfunction<sup>12</sup>

---

2. Kelly and Jones, J Endocrinol, 2013
3. Sinclair et al., J Gastroenterol Hepatol, 2015
4. Linda Vignozzi et al., University of Florence, IT, unpublished, 2018
5. A. Francavilla et al., Digest Dis Sci, 1989
6. Vic et al., Hepatol 1982
7. Sinha-Hikim et al., J Clin Endocrinol Metab, 2004
8. Liao CH et al., Andrology, 2013
9. Gentile MA et al., J Mol Endocrine, 2010

---

32
### Potential of Testosterone Therapy in NAFLD

#### Preclinical Model Results

<table>
<thead>
<tr>
<th>Model</th>
<th>Mouse Model¹</th>
<th>Rat Model²</th>
<th>Pig Model³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>▪ Testicular-feminized + High cholesterol diet</td>
<td>▪ Castrated + High fat diet</td>
<td>▪ Castrated + High fat and cholesterol diet</td>
</tr>
<tr>
<td>Disease</td>
<td>▪ Hepatic Steatosis</td>
<td>▪ NAFLD</td>
<td>▪ Hepatic steatosis, inflammation, elevated ALT</td>
</tr>
<tr>
<td>T Therapy Effect</td>
<td>▪ Hepatic lipid deposition ↓ ▪ Lipogenesis ↓</td>
<td>▪ Hepatic steatosis ↓ ▪ Hepatic apoptosis ↓ ▪ Vesicular inflammation ↓</td>
<td>▪ Hepatic lipids ↓ ▪ Liver injury ↓ ▪ Hepatic steatosis ↓</td>
</tr>
</tbody>
</table>

Potential of Testosterone Therapy
Results from high fat diet (HFD) induced rabbit model*

Effects on TNF-α (Inflammatory/Fibrosis Marker)

- **Serum TNF-α**
  - RD
  - HFD
  - HFD+T
  - HFD+OCA
  - **P < 0.001**
  - **P < 0.02**

- **Liver TNF-α mRNA**
  - RD
  - HFD
  - HFD+T
  - HFD+OCA
  - **P < 0.001**
  - **P < 0.04**

Effects on Liver Histology

- **Masson’s Trichrome Staining**
- **Red Oil Staining**
- **Giemsa–PAS Staining**

- **RD**
- **HFD**
- **HFD + T**

- **TRT ↓ fibrosis**
- **TRT ↓ steatosis**
- **TRT ↓ inflammation**

* Vignozzi et al., Mol Cell Endocrinol 2014
  T: Testosterone; OCA: Obeticholic Acid
T Therapy Effects in Liver Regeneration

Results from Hepatectomized Rat Model*

No Treatment Group 1 (n=50) → 100% died within 40 hours

T Treatment Group 2 (n=50) → 80% survived beyond 40 hours

Liver Mass Recovery (50% had a normal life span)

- Testosterone Pretreatment
- 40% recovery
- 60% recovery
- Total liver mass recovery completed

Day-30 → Day 0 → Day 3 → Day 4 → Day 15

Hepatectomy

Testosterone

*90% hepatectomized, Vic et al., Hepatol 1982
LPCN 1144: Clinical Tolerability Experience
Oral Prodrug of Endogenous Testosterone

- 654 subjects in multiple studies with up to 52-week exposure
  - No death, no drug-related SAEs, no major cardiovascular events, no hepato-toxic events were reported.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>N=654 subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1.50%</td>
</tr>
<tr>
<td>Acne</td>
<td>0.90%</td>
</tr>
<tr>
<td>Hematocrit Increased</td>
<td>1.20%</td>
</tr>
<tr>
<td>Blood Pressure Increased</td>
<td>0.30%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.20%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.60%</td>
</tr>
</tbody>
</table>
Sarcopenia is Associated with NAFLD/NASH\(^1\)

LPCN 1144 has Potential to Improve Sarcopenia\(^2,3\)

Comorbidity

Therapeutic Evidence

✓ Sarcopenia endpoint(s) under evaluation in the ongoing LiFT trial

1. Bhanji et al., Hepatol 2017
2. Bhasin S., J Gerontol 2003
3. Sinclair et al., J Gastroenterol Hepatol 2016
Sexual Dysfunction is Associated with NAFLD/NASH\textsuperscript{1}

T Therapy has Potential to Improve Sexual Dysfunction\textsuperscript{2}

✓ Sexual dysfunction endpoint(s) under evaluation in the ongoing \textit{LiFT} trial

\textsuperscript{1} Hawksworth et al., Sex Med Rev 2019  
\textsuperscript{2} Rizk et al., Curr Opin Urol 2017  
\textsuperscript{3} SOAR Trial: SOAR Trial: subjects with baseline ALT > 40 U/L (N=33)
Depression is Prevalent in NAFLD Patients\(^1\)

T Therapy has Potential to Improve Mental Health\(^2\)

Comorbidity

Original Research Reports

Depression in Patients with Nonalcoholic Fatty Liver Disease and Chronic Viral Hepatitis B and C

Ali A. Weinstein, Ph.D., Jillian Kallman Price, M.S., Maria Stepanova, Ph.D., Laura W. Pons, M.S., M.P.H., Yun Fang, M.S., Juhi Moon, M.D., Fatema Nader, M.S.B.M., Zobair M. Younossi, M.D., M.P.H.

Background: Patients with chronic liver disease (CLD) and depression may be at a higher risk for various complications, including impaired quality of life and more advanced liver disease. The purpose of this study was to determine the prevalence of depression in CLD patients (non-alcoholic fatty liver disease (NAFLD), Hepatitis B (HBV), and Hepatitis C (HCV)) and to identify potential clinical and laboratory correlates of depression in these patients. Methods: We used a database of CLD patients that contains extensive clinical (including self-reported depression) and laboratory data for each patient. We compared the prevalence of depression in patients with HBV, HCV, and NAFLD. We also used regression models to find independent predictors of depression in these patients. Results: Of 878 CLD patients, 207 (23.6%) had a diagnosis of depression (NAFLD 27.2%, HCV 29.8%, and HBV 3.7%). Examination of predictors of depression differed by the type of chronic liver disease. For NAFLD, independent predictors of depression were the presence of hypertension, smoking, history of lung disease, being female, and non-African-American. For HBV patients, the only independent predictor of depression was excessive alcohol consumption (defined as >10 g/d), while for HCV patients, independent predictors were being female and non-Asian, presence of fatigue, and excessive alcohol intake. Conclusions: This study demonstrates that individuals with NAFLD and HCV have a higher prevalence of depression than HBV patients and the rates of depression reported for the general population. The most consistent correlates of depression status in CLD patients are being female and excessive alcohol consumption.

(Psychosomatics 2011; 52:127–132)

Therapeutic Evidence

- Mental Composition Summary
- Mental Health
- Role Emotional
- Maintained Erection
- Sexual Activity
- Negative Mood
- Positive Mood
- Overall Sexual Desire

Mean Change from Baseline with 95% Confidence Interval

✓ Mental health endpoint(s) under evaluation in the ongoing LiFT trial

2. Celec et al., Front Neurosci 2015
3. SOAR Trial: subjects with ALT BL > 40 U/L (N=33)
LPCN 1148
(Oral Testosterone)
for Liver Cirrhosis
LPCN 1148: Oral T for Cirrhosis

No FDA Approved Drug

Common Causes

- **Alcoholic liver disease**
- **Nonalcoholic Fatty Liver Disease (NAFLD)**
- **Chronic hepatitis B**
- **Chronic hepatitis C**
- **Cryptogenic**

Liver Cirrhosis in US

- Estimated 1.3 M patients with liver cirrhosis
- 44,478 deaths in 2017

1. Estes C. et al., Hepatology, 2018; 2. Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; Surveillance Report #114, 2019
# High Economic Burden of a Liver Transplant

Transplant Only Cure for Liver Cirrhosis

## Estimated Total of $812,500/ Transplant in U.S.

<table>
<thead>
<tr>
<th>Event</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Days Pre-Transplant</td>
<td>$41,400</td>
</tr>
<tr>
<td>Procurement</td>
<td>$94,000</td>
</tr>
<tr>
<td>Hospital Transplant Admission</td>
<td>$463,200</td>
</tr>
<tr>
<td>Physician during Transplant Admission</td>
<td>$56,000</td>
</tr>
<tr>
<td>180 Days Post-Transplant Discharge</td>
<td>$126,900</td>
</tr>
<tr>
<td>Op Immunosuppressants &amp; Other Rx</td>
<td>$30,800</td>
</tr>
</tbody>
</table>

Bentley & Phillips, Milliman Research Report 2017
Impact of Low Testosterone* on Cirrhosis
Progressive Drop in T level With Increasing Disease Severity¹

MELD Score: Model For End-Stage Liver Disease Score; Child-Pugh Score for Cirrhosis Mortality

*Most cirrhotic male patients have low T²
Enabling Oral Drug Delivery to Improve Patient Compliance

LPCN 1107
Prevention of Preterm Birth
Unmet Medical Need
One Preterm Birth (PTB) Every Minute\textsuperscript{1}

- A leading cause of neonatal mortality
- \(\geq\) $26 billion economic impact\textsuperscript{2}
- 10\% of all US pregnancies\textsuperscript{3}
  - PTB in singleton pregnancies: 8.1\%
- Medical costs for PTB infants are \(\sim\)10x higher than for full term infants\textsuperscript{4}

1. Pediatric Research (2006) 60, 775–776
2. Institute of Medicine of the National Academies. Jul 200
LPCN 1107 Opportunity
Market Potential: ~$1 Billion

Potential to be the First Oral HPC for Prevention of Recurrent PTB

- Preferred route-of-administration is oral
- ~140,000 annually pregnancy with history of at least one singleton spontaneous PTB*

Potential for Clinical Success

- Superior Cavg to Makena®
- Targeting high-risk population (similar to MEIS trial)

Strong Pharmaco-Economic Justification

- Fewer PTB babies with significant healthcare cost savings
- Minimize travel related cost/time and healthcare provider cost/time
- Premium pricing potential to generic IM injections

Strong Exclusivity Position

- Orphan Drug Designation
- Technology/IP protection

*Deutsche Bank Markets Research, 11 June 2015
**LPCN 1107 – First Oral HPC for Prevention of PTB**

**17-α Hydroxy Progesterone Caproate (17-HPC)**

- **LPCN 1107 Oral 17-HPC**
  - Twice daily dose
    - No injection site reactions
    - Steady state achieved in 7 days
  - Higher HPC levels (potentially better efficacy than Makena®)
  - Orphan drug designated
    - Major contribution to patient care
  - Therapy duration
    - Up to 23 weeks

- **Injectable IM 17-HPC, Makena® (Standard of Care)**
  - Total of 18-22 injections
    - Weekly Injections
    - Viscous oily injection takes up to a minute
    - Patients experienced injection site pain
    - Weekly visit to/by health care provider
  - Therapy duration
    - Up to 21 weeks
PK-PD Correlation
HPC Concentration and PTB Rate

- Lower % PTB rate can be expected with daily Cavg$^2$ HPC levels ≥ 8.2 ng/mL

2. Ctrough for IM HPC ≡ Cavg, Makena
LPCN 1107: Dose Finding Clinical Study
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

<table>
<thead>
<tr>
<th>Oral HPC, LPCN 1107</th>
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<tbody>
<tr>
<td>Treatment A</td>
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<tr>
<td>400 mg BID</td>
</tr>
<tr>
<td>Treatment B</td>
</tr>
<tr>
<td>600 mg BID</td>
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<tr>
<td>Treatment C</td>
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<tr>
<td>800 mg BID</td>
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<tr>
<td>Treatment D</td>
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<tr>
<td>250 mg</td>
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<tr>
<td>Weekly</td>
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Multiple doses for 8 days
Multiple dose: 5 weeks
PK Results*
LPCN 1107 vs. Injectable Makena®

- Average HPC levels at target LPCN 1107 greater than the comparator, Makena®
- HPC levels below 8.2 ng/ml: 0% subjects on LPCN 1107 vs. 20% subjects on IM Injection

* PK results obtained from post 5 weeks for weekly IM Injection & post 8 days of BID dosing for LPCN 1107 from the dose finding study