Enabling Oral Drug Delivery to Improve Patient Compliance

Corporate Presentation

September 23, 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)
Most male NASH patients have low testosterone with signs and symptoms of hypogonadism

• 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
<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>
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<tbody>
<tr>
<td><strong>TLANDO™</strong> (Oral Testosterone for Testosterone Replacement Therapy “TRT”)</td>
<td></td>
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<td>PDUFA November 9, 2019</td>
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<tr>
<td><strong>TLANDO XR</strong> (Long Acting Oral Testosterone for TRT)</td>
<td></td>
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<td>Phase 2 Complete</td>
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<tr>
<td><strong>LPCN 1144</strong> (Oral Testosterone for pre-cirrhotic NASH)</td>
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<td></td>
<td><em>LiFT Phase 2 Paired Biopsy Clinical Study in NASH Initiated</em></td>
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<tr>
<td><strong>LPCN 1148</strong> (Oral Testosterone for NASH Cirrhosis)</td>
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<td>POC Study Planned</td>
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<tr>
<td><strong>LPCN 1107</strong> (Oral HPC for Prevention of PTB)</td>
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<td></td>
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<td>EOP2 meeting Completed</td>
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</table>
~$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
- Fixed/predictable cost for payers with no titration

Differentiated Hypertension (“HTN”) Profile
- Marginal (~1%) new anti-HTN starts or increase in anti-HTN dose in a year long exposure
- Lower incidence of hematocrit increase as compared to injectables

Consistent Inter-Day Restoration of T Levels

Demonstrated Paradigm Shifting Liver Benefits
TLANDO™ Has The Potential to Drive Market Expansion

Hypogonadism Affects Up to 20 MM American Men\(^1,2\)

- Men with diagnosed hypogonadism\(^3\) 6MM
- Men currently being treated\(^4\) 2.2MM
- Available switch patients 1.5MM
- Available naïve patients per year\(^5\) 700,000
- 3.8MM diagnosed but untreated patients

TLANDO Has Potential to Expand the Market Through Improved Persistence

Some TRT Options Have ~50% Early Discontinuation and ~50% May Require Multiple Dose Adjustments

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?

Gel (n=200)

- 0 X 47%
- 1 X 33%
- 2 X 15%
- >3 X 3%

Injectable (n=137)

- 0 X 37%
- 1 X 26%
- 2 X 20%
- >3 X 5%

% Patients Remaining on Therapy

Days to Discontinuation

- New Patients
- Experienced Patients

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

Source: Adheris Health 2017
## Current Market Dynamics in TRT Space

### Prime Opportunity for TLANDO™

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Patient and physicians preferred¹</td>
<td>• 85% of physicians have strong interest in oral&lt;br&gt;• 95% of TRT patients likely to ask their doctor about TLANDO™</td>
</tr>
<tr>
<td>Current promotional spend all time low in this detail sensitive category²</td>
<td>• Able to have high share of voice with far less competitive promotion than in the past</td>
</tr>
<tr>
<td>Concentrated call points³</td>
<td>• Decile 7-10 prescribers (~10,000) write 40% of the Scripts</td>
</tr>
<tr>
<td>Detail sensitive category</td>
<td>• Novel convenient oral option</td>
</tr>
<tr>
<td>Recent injectable TRT launch data⁴</td>
<td>• Significant early weekly script trends and growing&lt;br&gt;• ~45% of TRx from new patient starts</td>
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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
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.

Healthy Liver

Fatty Liver
- ↑ TGs
- ↑ LFTs
- ↑ Liver fat

NASH Liver
- ↑ TGs
- ↑ LFTs
- ↑ Liver fat

Cirrhotic Liver
- → Late stage of fibrosis

Hepatocellular Carcinoma

LPCN 1144
- 10 – 20% NASH

LPCN 1148
- 20 – 30% US Adults

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

LFTs: Liver function test, especially Alaninine amino transferase (ALT) and Aspartame amino transferase (AST)
NASH: Non-alcoholic Steatohepatitis, TG: Triglyceride
LPCN 1144
Targeted for Non-Alcoholic Steatohepatitis (“NASH”)
## LPCN 1144: Differentiated NASH Treatment Candidate
### Potential for Mono/Combo Chronic Therapy

<table>
<thead>
<tr>
<th>Meaningful POC Efficacy Results</th>
<th>Well Tolerated</th>
<th>Potential Additional Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 40% relative mean liver fat reduction after 16-weeks of treatment</td>
<td>Good GI tolerability</td>
<td>Improve symptoms of sarcopenia and sexual/mood dysfunction</td>
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<td>48% of the treated NAFLD subjects had NAFLD resolution, defined as &lt; 5% liver fat</td>
<td>No mean LDL increase</td>
<td></td>
</tr>
<tr>
<td>700+ subjects in 14 studies with up to 52-week exposure</td>
<td>No signs of nephrotoxicity</td>
<td></td>
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<tr>
<td>Most biopsy confirmed male NASH have low testosterone</td>
<td>No signs of skeletal fragility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No signs of drug induced liver toxicity</td>
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</tbody>
</table>

- 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
- Good GI tolerability
- No mean LDL increase
- No signs of nephrotoxicity
- No signs of skeletal fragility
- No signs of drug induced liver toxicity
- Improve symptoms of sarcopenia and sexual/mood dysfunction
LPCN 1144: Liver Fat Imaging Study (“LFS”)
Over Sixty Percent of Hypogonadal Subjects had Fatty Liver (LF>5%)

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

† NAFLD identified by MRI-PDFF ≥ 5% in LPCN 1144 Liver Fat Study
‡ Prevalence of NAFLD diagnosed by imaging hepatosteatosis ≥ 5% liver fat in general population (Younossi et al, J Hepatol 2016)
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%)
- NALFD (LF ≥ 5%)

Baseline (N=32)*
- NAFLD Free: 38%
- NAFLD: 63%

Interim (Week 8, N=31)
- NAFLD Free: 52%
- NAFLD: 48%

End of Study (Week 16, N=32)
- NAFLD Free: 63%
- NAFLD: 38%

~66% more NAFLD free

* Full Analysis Set (FAS)
LPCN 1144: Next Step
Advancing Forward

• *LiFT* (Liver Fat intervention with oral Testosterone) Phase 2 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

<table>
<thead>
<tr>
<th>Event</th>
<th>Expected Timing</th>
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<tbody>
<tr>
<td><strong>TLANDO™</strong></td>
<td>PDUFA Date</td>
</tr>
<tr>
<td><strong>LPCN 1144</strong></td>
<td><em>LiFT</em> Phase 2 Paired Biopsy Clinical Study in NASH Subjects - First Patient Dosed</td>
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<tr>
<td></td>
<td>Primary Endpoint Results (Liver Fat Reduction via MRI-PDFF)</td>
</tr>
<tr>
<td><strong>LPCN 1148</strong></td>
<td>File Investigational New Drug Application</td>
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</table>
### Key Financial Metrics

#### Stock Price, Market Cap, Cash Balance

<table>
<thead>
<tr>
<th></th>
<th>LPCN (Nasdaq Capital Market)</th>
</tr>
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<tbody>
<tr>
<td>Closing Stock Price (9/19/19)</td>
<td>$2.90/share</td>
</tr>
<tr>
<td>Market Capitalization (9/19/19)</td>
<td>$75.5 million</td>
</tr>
<tr>
<td>Cash Balance (6/30/19)</td>
<td>$19.5 million*</td>
</tr>
<tr>
<td>Bank Debt (6/30/19)</td>
<td>$8.7 million</td>
</tr>
</tbody>
</table>

* $5M restricted and becomes unrestricted upon TLANDO approval
TLANDO™: NDA Under Review
Near Term FDA Decision

Deficiency 1
Determine extent, if any, of ex-vivo conversion of TU to T

Deficiency 2
Characterize blood pressure effects of TLANDO for appropriate regulatory action

Deficiency 3
Provide justification for non-applicability of Cmax based secondary endpoints

Deficiency 4
Determine the appropriate stopping criteria that can identify patients who should discontinue

PDUFA Goal Date
November 9th
Estimated LPCN 1144 Target Market
Reportedly 75% of NASH Male Patients Have Total T less than 372 ng/dL

83M NAFLD patients in 2015

~17M NASH patients in 2015

~8M Male NASH patients

NASH cases are projected to increase 63% from 17 million cases in 2015 to 27 million cases in 2030 with no approved drug

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

2. Estes et al, Hepatol 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**
- 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**
- Restore mitochondrial turnover and normalizes oxygen consumption

**Regeneration Booster**
- Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation
- Increases circulating endothelial progenitor cells ("EPC")

**Anabolic Agent**
- Increase muscle mass, bone density in men with liver disease

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
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 testosterone^1
- Sarcopenia in patients with NAFLD is associated with a higher likelihood of having steatohepatitis or advanced liver fibrosis^2
- Sexual dysfunction is an underappreciated comorbidity in male NASH patients^3

Clinical Relationship Between Testosterone and NAFLD Across the Full Disease Spectrum

**Hepatic Steatosis**
“Men with low testosterone are at high risk for NAFLD.”

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

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

1 Kim et al, Gastroenterol 2012; 2 Sumida et al, Gastroenterol Hepatol 2015; 3 Sinclair et al, Liver Trans 2016;
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
- No drug related SAEs
- No deaths or MACE events

Gastrointestinal Disorders ≥ 1% in SOAR Trial (52 Weeks)
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 Severity\(^1\)

- Low T reported in up to 90% of NASH cirrhosis patients\(^2\) and is a predictor of mortality\(^3\)
- Low T associated with:
  - Increased risk of major infections, death and/or transplantation rates\(^1\)
  - Increased risk of for hepatic decompensation\(^4\)
  - Worsening of sarcopenia\(^4\)
  - Higher Child Pugh score grade\(^4\)
  - Severity of portal hypertension and ascites grade\(^4\)
  - Higher MELD score\(^5\)

\(^1\) 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
\(^4\) Paterno et al, Hepatol Res 2019;
\(^5\) Sinclair et.al, Liver international, 2016
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 cirrhosis\(^1\)

• Testosterone therapy increased muscle mass in men with cirrhosis and low testosterone\(^2\)

• **Next Steps:**
  - Proof of Concept study in male NASH cirrhosis subjects