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.
<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>LPCN 1144 (Oral Testosterone for NASH)</td>
<td></td>
<td></td>
<td>Phase 2 Study in Biopsy Confirmed NASH</td>
<td></td>
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<tr>
<td>LPCN 1148 (Oral Testosterone for NASH Cirrhosis)</td>
<td></td>
<td></td>
<td>POC Study Planned</td>
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<tr>
<td>TLANDO (Oral Testosterone for TRT)</td>
<td></td>
<td></td>
<td></td>
<td>NDA Resubmission</td>
<td></td>
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<tr>
<td>LPCN 1111 (Next Gen Oral Testosterone for TRT)</td>
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<td></td>
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<td>Phase 2 Completed</td>
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<tr>
<td>LPCN 1107 (Oral HPC for Prevention of PTB)</td>
<td></td>
<td></td>
<td></td>
<td>EOP2 Completed</td>
<td></td>
</tr>
</tbody>
</table>
Targeted for Non-Alcoholic Steatohepatitis ("NASH")

A silent killer that affects 30 million Americans

1. CNBC; published December 30, 2018
Non-Alcoholic Fatty Liver Disease ("NAFLD")
No Approved Product for the Treatment of NASH

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

<table>
<thead>
<tr>
<th>Healthy Liver</th>
<th>Fatty Liver</th>
<th>NASH Liver</th>
<th>Cirrhotic Liver</th>
<th>Hepatocellular Carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 – 30% US Adults</td>
<td>↑ TGs</td>
<td>↑ LFTs</td>
<td>↑ Liver fat</td>
<td>↑ Steatosis</td>
</tr>
</tbody>
</table>

LFTs: Liver function test, especially Alanine amino transferase (ALT) and Aspartame amino transferase (AST)
NASH: Non-alcoholic Steatohepatitis, TG: Triglyceride
NASH Pathogenesis
Risk Factors and Clinical Progression

Lipid Metabolism Disorders
- Dyslipidemia
- Insulin resistance
- Obesity
- T2 diabetes
- Metabolic syndrome

Inflammation
- Lipid peroxidation
- Mitochondrial dysfunction
- Oxidative stress
- Apoptosis
- Pro-inflammatory cytokine activation

Fibrosis
- Scarring
- Advanced cell damage

≥5% liver fat accumulation

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

Liver contains built-in mechanisms for scar resolution, but these become smothered or inactivated in the face of relentless damage*

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

---

1 Kim et al, Gastroenterol 2012; 2 Sumida et al, Gastroenterol Hepatol 2015; 3 Sinclair et al, Liver Trans 2016;
LPCN 1144: Oral Testosterone
Targeting The Full Spectrum of NASH Pathogenesis

A Differentiated Oral NASH Therapy Candidate

• Well tolerated - suitable for chronic use
• Favorable benefits outside the liver

Clinical Data to Advance in Phase 2 Testing

• Meaningful liver fat reductions as early as eight weeks and we believe the potential to improve upon longer treatment duration
• Substantial reductions in key elevated serum markers
• We believe there is potential for histological improvement in NASH patients
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/Immunomodulator**

- 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

---

LPCN 1144: A Differentiated Oral NASH Therapy Candidate
Prodrug of Endogenous Testosterone

Liver Fat Reduction and Key Serum Biomarkers

- 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

- T therapy known to improve muscle mass, bone density, hemopoiesis, sexual/mood dysfunction

Suitable for Chronic Use

- Good GI tolerability
- No mean LDL increase
- No signs of nephrotoxicity
- No signs of skeletal fragility
- No signs of drug induced liver toxicity
LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males.
LPCN 1144: Liver Fat Study Results
Meaningful Relative Liver Fat % Change and Responder Rate

Mean Relative Liver Fat % Change

<table>
<thead>
<tr>
<th>% Liver Fat CBL (±SEM)</th>
<th>BL ≥ 5%</th>
<th>BL ≥ 8%</th>
<th>BL ≥ 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>-33%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-42%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-40%</td>
<td></td>
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</tbody>
</table>

Responder Rate for Relative Liver Fat % Change*

<table>
<thead>
<tr>
<th>% of Responders</th>
<th>BL ≥ 5%</th>
<th>BL ≥ 8%</th>
<th>BL ≥ 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>71%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>80%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>75%</td>
<td></td>
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</tr>
</tbody>
</table>

* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.
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 ≥ 5% is reduced to < 5% at EOS.
LPCN 1144: Liver Fat Study Results
Liver Fat Based Subject Distribution at Each Visit

Longer Therapy Improved Liver Fat Reductions and Proportion of Subjects with Disease Resolution

Baseline Pre treatment
- NAFLD Free: 38%
- LF < 5% (NAFLD Free): 24%
- 5% ≤ LF < 8%: 6%
- 8% ≤ LF < 10%: 32%

N=34

8 Week Treatment
- NAFLD Free: 55%
- LF < 5% (NAFLD Free): 21%
- 5% ≤ LF < 8%: 18%

N=33

16 Week Treatment
- NAFLD Free: 65%
- LF < 5% (NAFLD Free): 12%
- 5% ≤ LF < 8%: 15%

N=34
LPCN 1144: Next Step
Advancing Forward

• Initiate Phase 2 clinical study in biopsy confirmed NASH subjects
  – Study Design
    • Three-arm, placebo controlled
    • Biopsy confirmed F2/F3 NASH male hypogonadal subjects with NAS ≥ 4
    • Paired biopsy at baseline and EOS
    • 36-weeks duration
  – IND cleared by FDA
LPCN 1148

For Treatment of NASH Cirrhosis
LPCN 1148: Oral T for NASH Cirrhosis
No FDA Approved Drugs-Transplant Only Cure

Cirrhotic Liver

US Prevalence

Among 2015 NASH population*:
- 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: 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 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, edrs: 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 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

Targeted for Testosterone Replacement Therapy

Annual TRx ~7M
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™: Potential First Oral Option
Progressing to NDA Resubmission

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

NDA Resubmission 2Q 2019
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 Cmax 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 Cmax 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
## Upcoming Milestones
### Near Term Value Drivers

<table>
<thead>
<tr>
<th>Event</th>
<th>Expected Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLANDO™</td>
<td>NDA Resubmission</td>
</tr>
<tr>
<td>LPCN 1144</td>
<td>Phase 2 Study Start in Biopsy Confirmed NASH Patients</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 (3/26/19)</td>
<td>$2.19/share</td>
</tr>
<tr>
<td>Market Capitalization (3/26/19)</td>
<td>$52.3 million</td>
</tr>
<tr>
<td>Cash Balance (12/31/18)</td>
<td>$20.3 million*</td>
</tr>
<tr>
<td>Bank Debt (12/31/18)</td>
<td>$10.0 million</td>
</tr>
</tbody>
</table>

* $5 M restricted
LPCN 1144
Targeted for pre-cirrhosis NASH
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: General Safety
Well Tolerated

- Extensive clinical safety database with LPCN 1144
  - 700+ subjects in 14 studies with up to 52 week exposure
  - No drug related SAEs
  - Safety profile well-characterized and demonstrated no unexpected risks
  - Good gastrointestinal tolerability with no signs of skeletal fragility or nephrotoxicity
  - No signs of drug induced liver enzyme toxicity, no deaths or MACE events
LPCN 1144: Gastrointestinal Safety
Gastrointestinal Disorders ≥ 1% in SOAR Trial (52 Weeks)
LPCN 1144: Consistent Liver Function Improvement Across Studies*
Effect Observed as Early as 3 Weeks

Mean Change from BL (±SEM)

-17.4%  -18.8%
-10.3%  -13.2%
-5.1%   -10.1%
-9.6%   -18.5%

Mean BL (U/L)
ALT  53.6
AST  55.6
ALP  32.0
GGT  32.6

-15%  -20%  -25%  -30%

SOAR (52 Week)  16-002 (3 Week)

• LPCN 1144 Patients for ALT > 40 U/L at BL; SOAR (NCT02081300), N=42, 16-002 (NCT03242590), N=13;
LPCN 1144: Oral T
Appreciable % of Patients Experienced Normalization of ALT, GGT, TG, LDL-C, and Lp-PLA2

• 52 Week SOAR Trial

![Normalization of Biomarkers with LPCN 1144](image)

<table>
<thead>
<tr>
<th>Biomarker</th>
<th>% Normalized at Baseline</th>
<th>N</th>
<th>BL (Normal Limit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT*</td>
<td>52%</td>
<td>42</td>
<td>40 U/L</td>
</tr>
<tr>
<td>GGT*</td>
<td>31%</td>
<td>36</td>
<td>49 U/L</td>
</tr>
<tr>
<td>TG*</td>
<td>34%</td>
<td>73</td>
<td>200 mg/dL</td>
</tr>
<tr>
<td>LDL-C*</td>
<td>56%</td>
<td>16</td>
<td>160 mg/dL</td>
</tr>
<tr>
<td>Lp-PLA2*</td>
<td>52%</td>
<td>25</td>
<td>235 ng/mL</td>
</tr>
</tbody>
</table>

* ALT, GGT, TG, LDL-C, and Lp-PLA2 normal range upper limit is 40 U/L, 49 U/L, 200 mg/dL, 160 mg/dL, and 235 ng/mL, respectively
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

---

**TG Mean Change after 52 Week for Patients with Above-normal TG* at BL**

<table>
<thead>
<tr>
<th>Therapy Duration (Week)</th>
<th>Mean Value for Patients with Above-normal at BL (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>LPCN 1144: 320 mg/dL 323 mg/dL Topical T 34/104</td>
</tr>
<tr>
<td>13</td>
<td>39/104</td>
</tr>
<tr>
<td>26</td>
<td>39/104</td>
</tr>
<tr>
<td>39</td>
<td>39/104</td>
</tr>
<tr>
<td>52</td>
<td>39/104</td>
</tr>
</tbody>
</table>

Mean BL = 320 mg/dL
N = 73/210
LPCN 1144

---

* TG normal range in SOAR Trial: 45 – 200 mg/dL
LPCN 1144: Oral T
Unique Effects on Liver Compared to Topical Gel

• 52 Week SOAR Trial

ALP Mean Change after 52 Week

Mean Change from Baseline

-10% 0% 5% 10%

Mean BL = 71.8 U/L 72.5 U/L
LPCN 1144 Topical T

SHBG Mean Change after 52 Week

Mean Change from Baseline

-30% -20% -10% 0% 10% 20%

Mean BL = 30.3 nmol/L 30.4 nmol/L
LPCN 1144 Topical T
Hypogonadism Affects Up to 20 M American Men\textsuperscript{1,2}

Significant Number of Untreated Hypogonadal Males

- \textbf{\~6M} Men with diagnosed hypogonadism\textsuperscript{3}
- \textbf{2.2M} Men currently being treated\textsuperscript{4}
- \textbf{700,000} New naïve patients each year\textsuperscript{5}

Asymptomatic and/or Undiagnosed Hypogonadism

- 70%
- Diagnosed Untreated 19%
- Treated 11%

68% Previously Treated
32% Treatment Naïve

TLANDO™: Patient Market Research
Patient Enthusiasm Evident About Oral TRT

- 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
QUESTION: What is the most important advantage of TLANDO?

- **Oral Agent**: 66%
- **No/Low Risk of...**: 10%
- **Good Efficacy**: 8%
- **Easy Dosing/Administration**: 8%
- **Easy/Less Titration**: 5%
- **Few Side Effects/Well-tolerated**: 3%

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?
TLANDO™: Definitive Phlebotomy Study

Ex Vivo Conversion Assessment

- **Study objective:**
  - To evaluate the extent, if any, of clinically meaningful *ex vivo* conversion of TU to T in serum blood collection tubes to confirm the reliability of TLANDO data results

- **Study design:**
  - Open-label, single dose study (N=12)
  - Blood sampling post 225 mg TU dose: at 3 hr. and 5 hr. post dosing (N=24)
    - Control: Time zero (immediately processed) plasma tubes with EDTA (“PT”)
    - Test: Serum separation tubes (“SST”) per manufacturer’s recommendation-30 min.

- **Top-line results:**
  - Mean percentage difference and the associated percentage standard deviation post dose of T concentrations measured between SST samples and PT samples are -1.0% and 9.2%, respectively
  - The difference was not statistically significant (p = 0.91)
TLANDO™: Ambulatory Blood Pressure Monitoring Study
Results Consistent with a Recently Approved Testosterone Replacement Therapy

Study objective:
- To characterize blood pressure effects of TLANDO for appropriate FDA regulatory action, including Risk Evaluation and Mitigation Strategy (“REMS”) beyond labeling.

Study design (NCT03868059):
- Open-label, single-arm study in male hypogonadal subjects
  - 144 subjects enrolled, 138 subjects received at least one dose of study drug, 126 subjects completed the study with 118 subjects having evaluable ABPM data at both baseline and end of study.
  - Four months of treatment with TLANDO, 225 mg BID
  - 24-hour blood pressure measurements taken at baseline and at the end of the study.

Top-line results:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean Change, mm Hg (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour SBP</td>
<td>3.82 (1.69, 5.96)</td>
</tr>
<tr>
<td>24-hour DBP</td>
<td>1.20 (0.31, 2.08)</td>
</tr>
</tbody>
</table>
High PTB Medical Costs

≥ $26 Billion Economic Impact

- 12% of all US pregnancies (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 infants
- 28% of preterm births are to women with histories of early delivery

1. CDC (2010)
3. Institute of Medicine of the National Academies. Jul 200
LPCN 1107: Prevention of Preterm Birth (PTB)
United States Market Landscape

December 31, 2017

Makena® 1
50%

Off Guidance2
30%

Compounded 17-HPC
20%

$1B Market Opportunity3

HPC TRx4

117%
2%

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. Based on 140,000 patients, >16 injections/patient and net revenue of ~$425-$450/injection.
4. IMS data
5. Annualized September 30, 2018 data
LPCN 1107: First Oral PTB Candidate

Characteristics of the Only Approved Product Options for PTB

**IM HPC, Makena®:**
- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
  - Injection location: Upper-outter 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

- 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, Makena\(^1\)

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

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

<table>
<thead>
<tr>
<th>LPCN 1107, Oral HPC</th>
<th>IM HPC, Makena</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment A</strong></td>
<td>Treatment D</td>
</tr>
<tr>
<td>400mg BID</td>
<td>250mg Weekly</td>
</tr>
<tr>
<td><strong>Treatment B</strong></td>
<td>Multiple dose:</td>
</tr>
<tr>
<td>600mg BID</td>
<td>5 weeks</td>
</tr>
<tr>
<td><strong>Treatment C</strong></td>
<td></td>
</tr>
<tr>
<td>800mg BID</td>
<td></td>
</tr>
</tbody>
</table>

Multiple doses for 8 days
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

1. PK results obtained post 8 days of BID dosing for LPCN 1107 and post 5 weeks for weekly 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