



## Corporate Presentation

September 2022

Enabling Effective Oral Drug Delivery



# Forward-Looking Statements

This release contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding our product development efforts, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, the application of our Lip'ral platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at [www.sec.gov](http://www.sec.gov). Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

# Investment Highlights

## Validated Proprietary Lip'ral Technology Platform

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Enabling Effective Oral Delivery

## Curated Clinical Development Focus

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LPCN 1154: Fast Acting Oral Antidepressant

LPCN 1148: Unique MOA for Management of Cirrhosis

LPCN 2101: Novel MOA for Treating Women with Active Epilepsy

Exploratory Preclinical CNS Candidates

## Value Through Partnering of Non-CNS Assets

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Testosterone Replacement Therapy: TLANDO® and LPCN 1111

Prevention of Preterm Birth: LPCN 1107

Chronic Liver Disease: LPCN 1144, LPCN 1148

## Near-Term Value-Enhancing Events

### 4Q 2022

LPCN 1148 Phase 2 POC study  
enrollment completion



### 1Q 2023

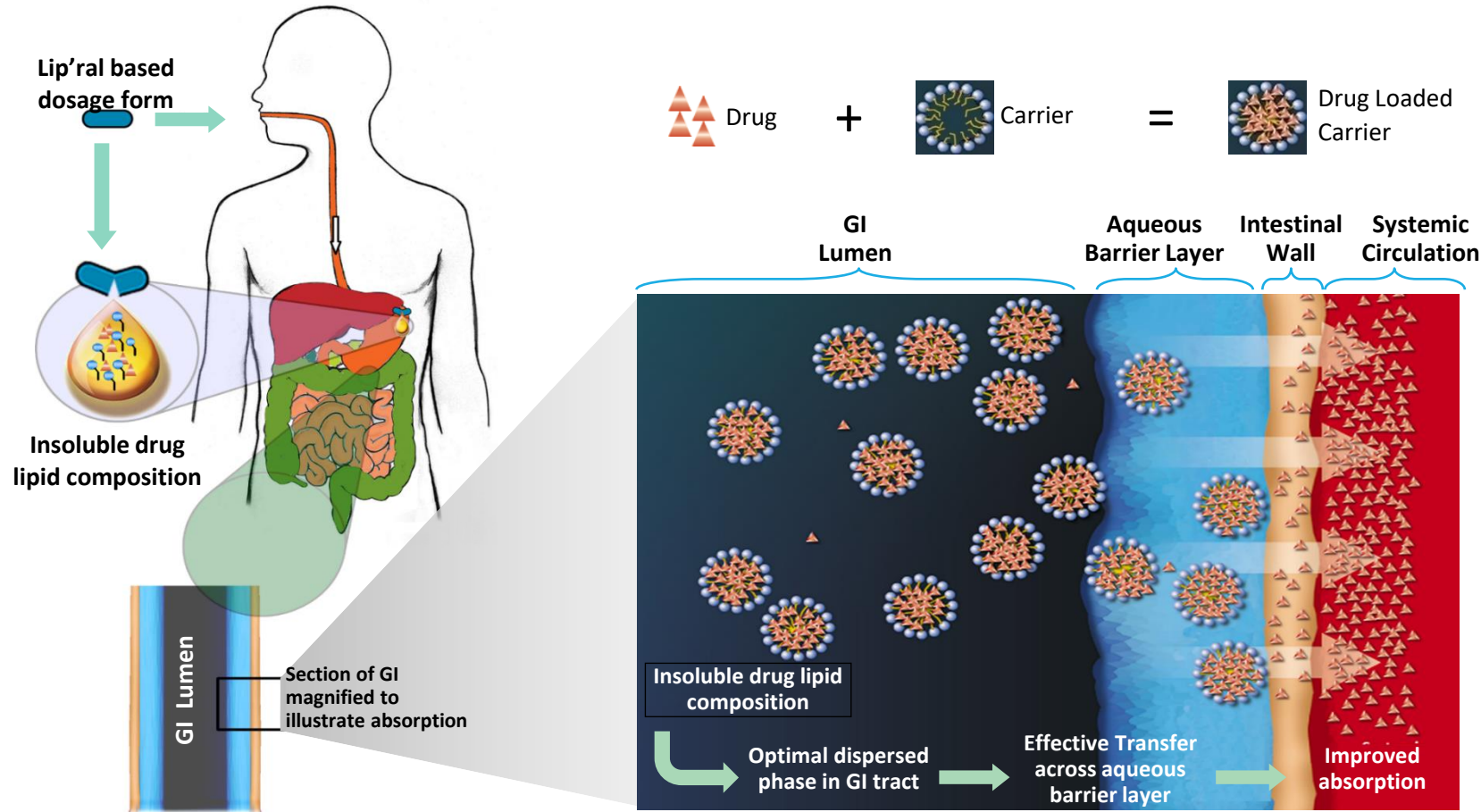
LPCN 1154 Pilot PK bridge study  
topline results



### 1H 2023

LPCN 1148 Phase 2 POC cirrhosis study  
topline results

# Validated Proprietary Lip'ral Technology Platform



Superior Oral Bioavailability  
e.g., TLANDO®

Enable effective oral delivery  
e.g., endogenous neuroactive steroids, 17-hydroxyprogesterone caproate

# Curated Clinical Development Focus

## Oral Endogenous Neuroactive Steroids (NASs)

### Significant unmet needs in CNS

#### Psychiatry

**Depression Disorders:** Rapid onset antidepressant

#### Neurology

**Epilepsy:** Novel MOA targeting women with active epilepsy (WWE)

**Movement Disorders:** No medications developed specifically for essential tremors (ET), only one approved >50 yrs. ago

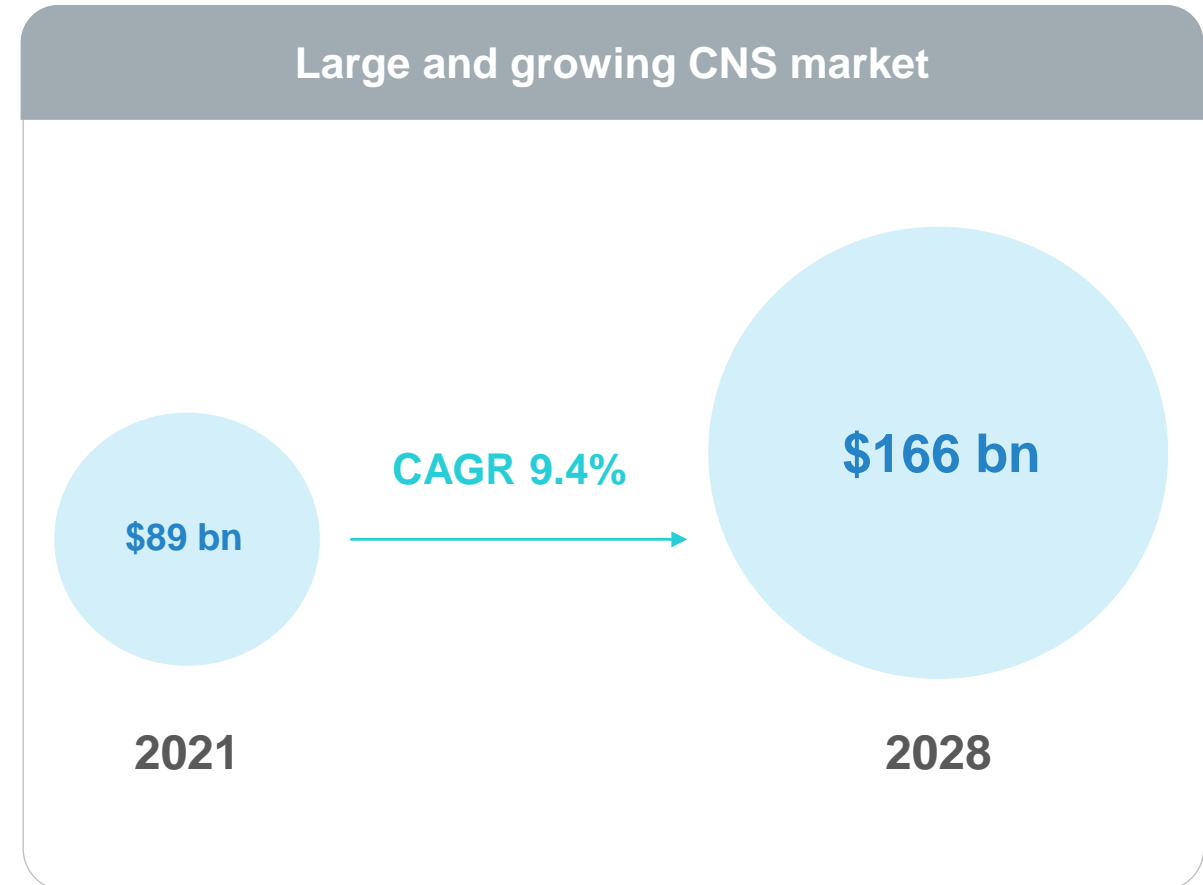
### Targeting Differentiating Value Propositions

#### LPCN 1154

Oral fast acting antidepressant for PPD

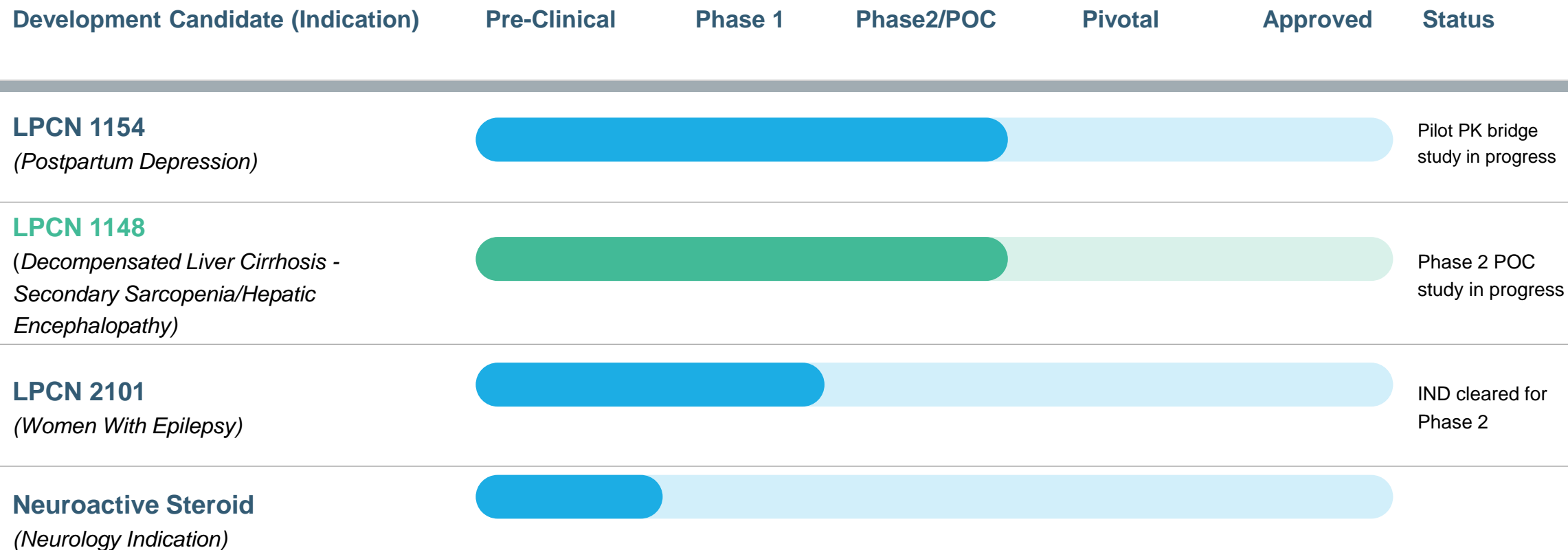
#### LPCN 2101

New MOA for treating women with active epilepsy



<https://www.verifiedmarketresearch.com/product/central-nervous-system-therapeutics-market/>

# Lipocine Clinical Development Pipeline





# LPCN 1154

Oral Brexanolone for  
Postpartum Depression (PPD)



# Postpartum Depression (PPD) – A Substantial Opportunity

## Market in Need of a Convenient Fast-Acting Oral Antidepressant

### Prevalence

~ 1 in 8 women in US suffer from PPD after giving birth<sup>1</sup>

U.S Women with Moderate-Severe PPD estimated: ~175K annually<sup>2</sup>



### Standard of Care Limitations

Burdensome invasive infusion  
Inpatient administration  
Frequent monitoring  
Access



### Unmet Need

Convenient non-invasive  
Fast-acting  
Outpatient administration  
No excessive sedation



1. CDC, "Depression Among Women"

2. CDC, "Symptoms of Depression Among Adults: United States, 2019" NCHS Data Brief, No.379, September 2020



# LPCN 1154

## First Oral Brexanolone

### Product Candidate Attribute

Positive Allosteric Modulator (PAM) of the GABA<sub>A</sub> receptor  
Oral dosage form comprising brexanolone

### Product Candidate Differentiation

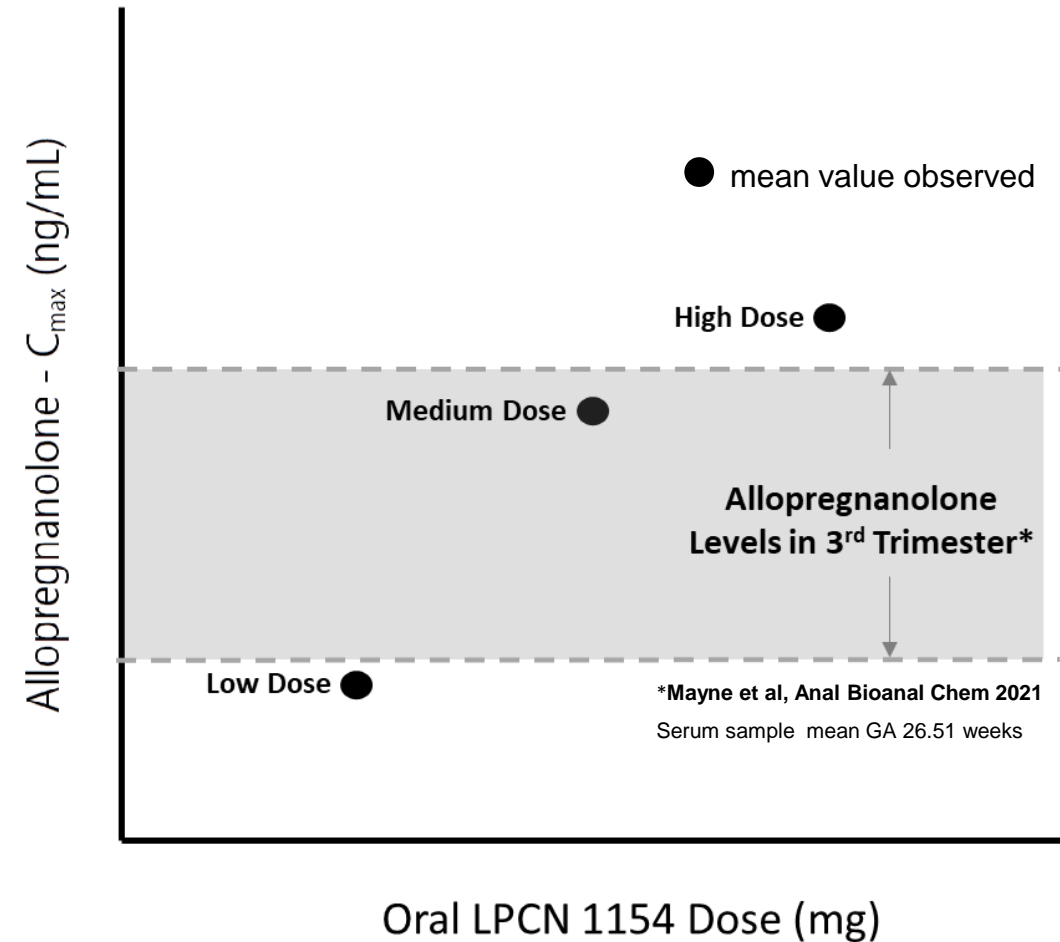
Non-invasive oral option with rapid onset  
No IV infusion challenges  
Potential for outpatient administration

# LPCN 1154 - Achieved Levels Comparable to 3<sup>rd</sup> Trimester Pregnancy

## Enablement of Oral Brexanolone (a.k.a. allopregnanolone )

### Phase 1 Study of Results

- Sequential single dose escalation study in post menopausal women (n=8) with Lip'ral based oral capsules.
- LC-MS/MS assays of blood samples



# LPCN 1154 - Development Status

## Favorable Regulatory Outlook

Efficacy can be achieved thru PK bridge to IV infusion brexanolone

505 (b) (2) NDA

## Validated regulatory pathway

I.V. Brexanolone approved for PPD

### Phase 1

**Successful single dose study completed** – established feasibility of oral administration

### Pilot PK Bridge Study

**Pilot PK Bridge Study in Progress**  
Topline results expected Q1 2023

### Planned Pivotal Study

**Pivotal study required for filing**

# LPCN 1148

for the Management of Liver Cirrhosis



# Liver Cirrhosis Management – Opportunity

## Prevalence

Over 2 million cases<sup>1</sup>;  
500k+ with  
decompensation<sup>2</sup>

62% on liver transplant  
waitlist are male<sup>3</sup>

40-70% of cirrhotic  
men have sarcopenia<sup>4,5</sup>

~30-40% of cirrhotics  
experience overt HE<sup>6</sup>



## Standard of Care Limitations

No approved drug for  
Secondary Sarcopenia  
(**SS**)

Rifaximin for Hepatic  
Encephalopathy (**HE**)

- Limited efficacy
- Tolerability issues



## Unmet Need

**SS:** Improve survival/  
quality of life for patients  
on transplant list

Improvement of post-  
transplant outcomes  
/lowered cost of care

**HE:** Novel MOA



1. Moon, Clin Gas and Hep, 2019

2. GBD 2017 Cirrhosis Collaboration, Lancet, 2021

3. Sarkar et al. J Hepatol. 2015

4. Sinclair, Ailment Pharmacol Ther, 2016

5. Lai, Am J Transplant, 2014

6. Grønkjær et al., Gastroenterol Nurs. 2018 Nov/Dec;41(6):468-476.

# LPCN 1148

## Management of Liver Cirrhosis: Secondary Sarcopenia; Hepatic Encephalopathy

### Product Candidate Attribute

Androgen receptor agonist

Oral dosage form comprising testosterone laurate, a unique prodrug of endogenous testosterone

Potential for Orphan Drug Designation

### Product Candidate Differentiation

Only candidate in development for secondary sarcopenia in cirrhosis: no approved SOC

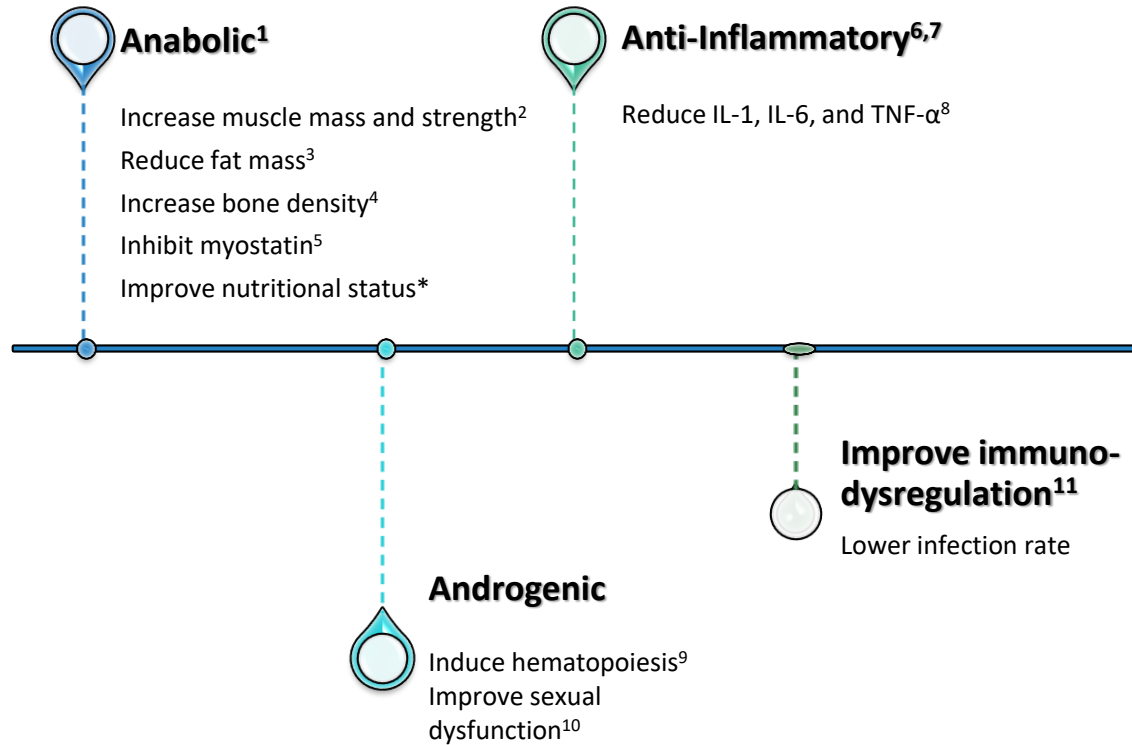
Novel Multi-Modal MOA

- Reduction of ammonia accumulation for treatment of HE

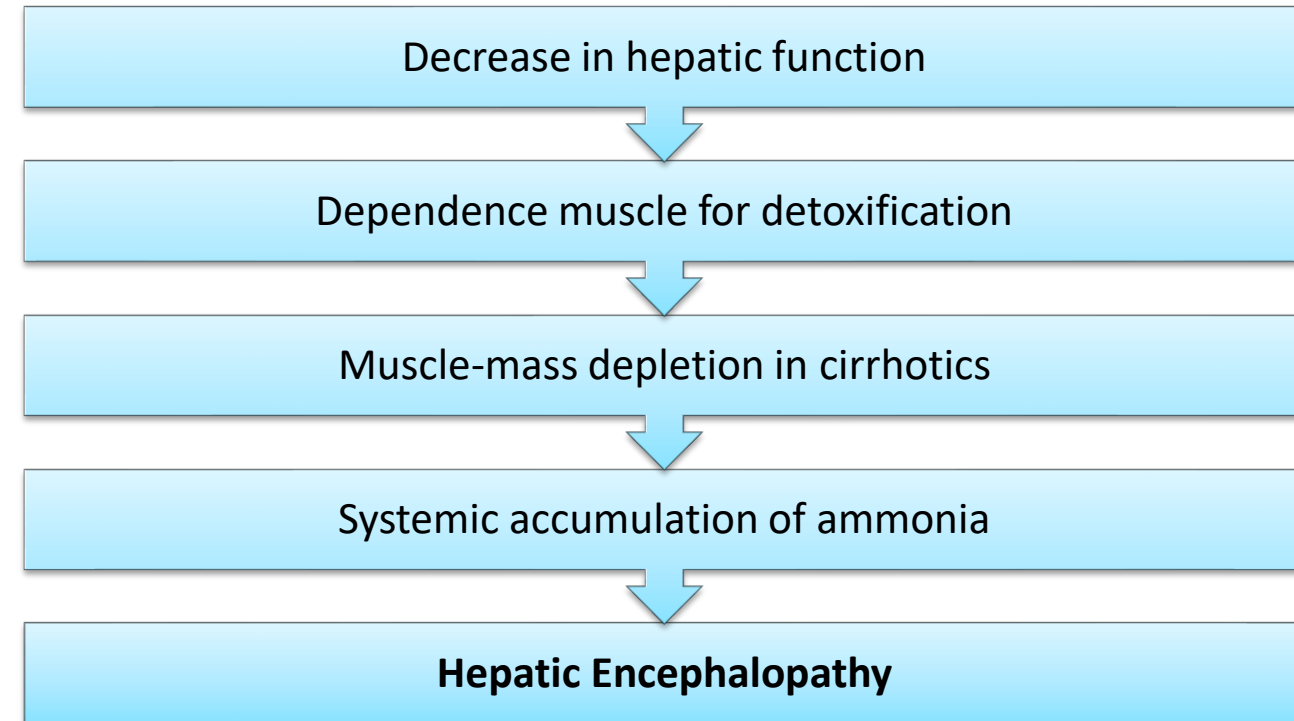


# LPCN 1148 - Novel Multi-Modal MOA for Liver Cirrhosis

## Hepatic Encephalopathy is Associated with Sarcopenia



### Precipitation of HE



1. Gentile MA et al., J Mol Endocrine, 2010  
2. Sinclair et al., J Gastroenterol Hepatol 2016  
3. Shalender Bhasin, Clin Infect Dis. 2003;37 Suppl 2:S142-9  
4. Snyder et al. JAMA Intern Med. 2017 Apr 1;177(4):471-479  
5. Dasarthy and Merli, J Hepatol. 2016  
6. Kelly and Jones, J Endocrinol, 2013

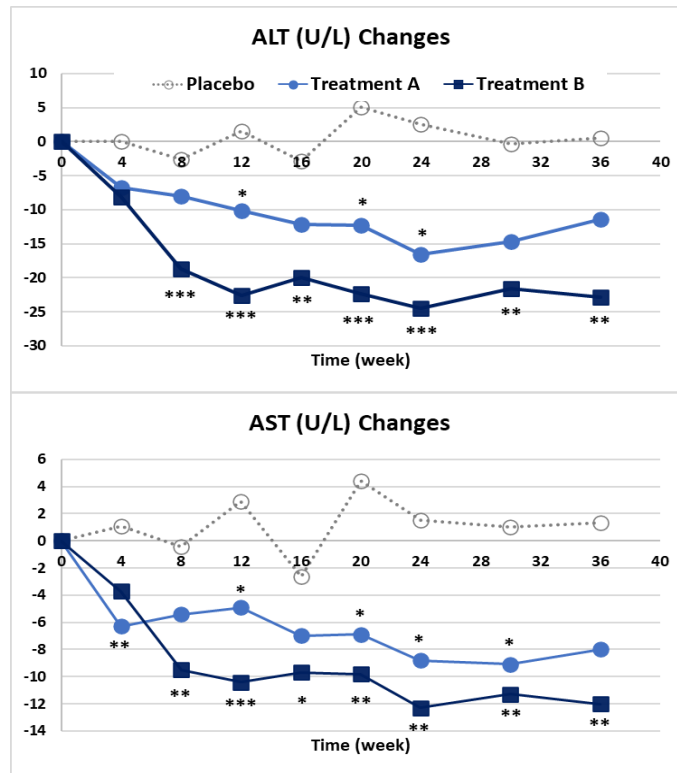
7. Zhang et al., J Cardiovasc Pharmacol Ther. 2021 Nov;26(6):638-647  
8. Mohamad et al. Aging Male. 2019 Jun;22(2):129-140.  
9. Basaria, S., Dobs, A.S. (2003). Androgens and the Hematopoietic System. In: Bagatell, C.J., Bremner, W.J. (eds) Androgens in Health and Disease.  
10. Rizk et al., Curr Opin Urol 2017  
11. Nakashima et al., Kidney Int Rep. 2017 Nov; 2(6): 1160–1168

\*Individual's health condition as it is influenced by the intake and utilization of nutrients

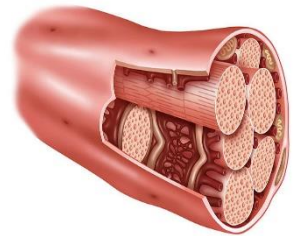
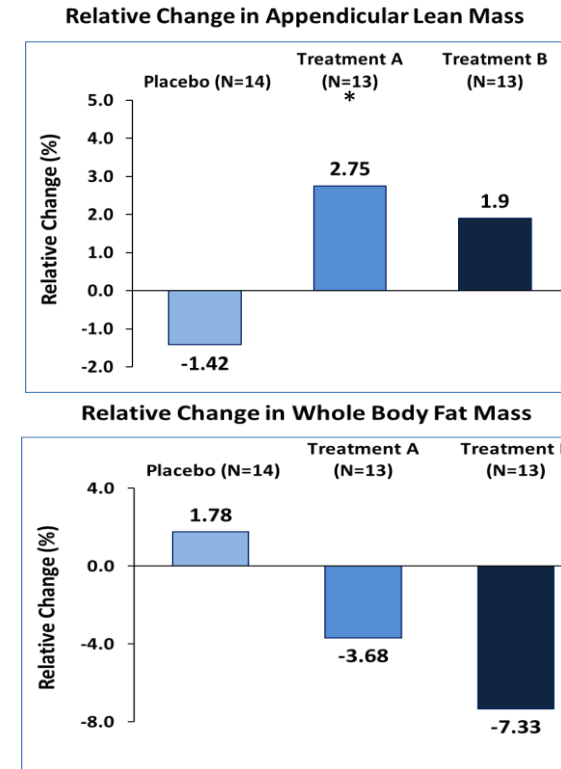
# LPCN 1148 – Potential Beneficial Effects

## Effects Observed in Subjects with Chronic Liver Disease<sup>#</sup>

### Liver (primary organ) Injury Marker Reduction



### Muscle (secondary organ) Positive Effects on Body Composition<sup>†</sup>



<sup>#</sup>LiFT Study in Biopsy Confirmed NASH Subjects (NCT04134091)

<sup>†</sup> All available data at Week 36 (Last Observation Carry Forward ("LOCF"))  
\* p < 0.05 vs placebo

# LPCN 1148 - Development Status

POC Topline Results Expected in 1H 2023

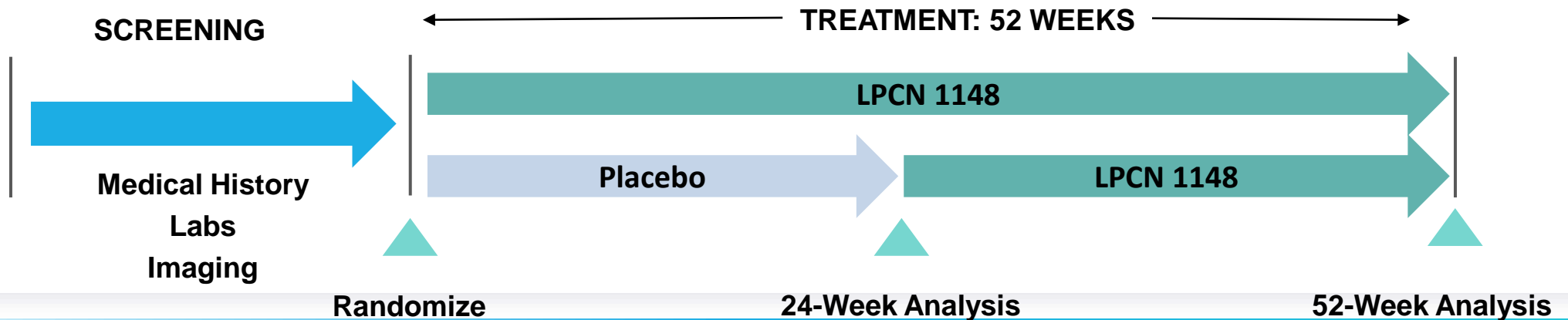
Phase 2 POC study (NCT04874350) in male cirrhotic subjects – in progress Multi-center, randomized, placebo-controlled study in male sarcopenic cirrhotic patients

## Endpoints:

**Primary:** Change in Skeletal Muscle Index at Week 24

### Key Secondary:

Overall survival, hospitalization rates  
Change in number of waitlist events  
Rates of breakthrough hepatic encephalopathy/ascites  
Change from baseline in Liver Frailty Index, Myosteatosis  
Patient Reported Outcomes (PRO's)



# LPCN 2101

for Women With Active Epilepsy  
(WWE)



# Women with Epilepsy (WWE) of Childbearing Age - Opportunity

## Prevalence

~ 900,000 of women of childbearing (CB) suffer from active epilepsy in US<sup>1,2</sup>

~ 80% of WWE reported at least one unintended pregnancy<sup>3</sup>

Depression is the most frequent psychiatric comorbidity in epilepsy<sup>4</sup>



## Standard of Care Limitations

No drug approved specifically for WWE

Most approved ASMs have fetal toxicity risk

~ One third of adult patients are non-responsive<sup>5</sup>

Limited options to address mood disorder comorbidities

Drug-drug interaction risk



## Unmet Need

Seizure control with low/no teratogenic risk

Address special considerations for WWE

Novel MOA

Address associated mood disorders



1. <https://www.statista.com/statistics/241488/population-of-the-us-by-sex-and-age/>

2. <https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a1.htm>

3. Herzog et al. Neurology. 2017 Feb 21;88(8):728-733

4. Kanner AD, Epilepsy Curr. 2006 Sep; 6(5): 141-146

5. <https://www.epilepsy.com/treatment/medicines/drug-resistant-epilepsy>

# LPCN 2101

## Novel Potential Alternative for WWE

### Product Candidate Attribute

Positive Allosteric Modulator (PAM) of the GABA<sub>A</sub> receptor

Oral dosage form comprising a neuroactive steroid

### Product Candidate Differentiation

Novel MOA specifically addressing WWE unmet needs

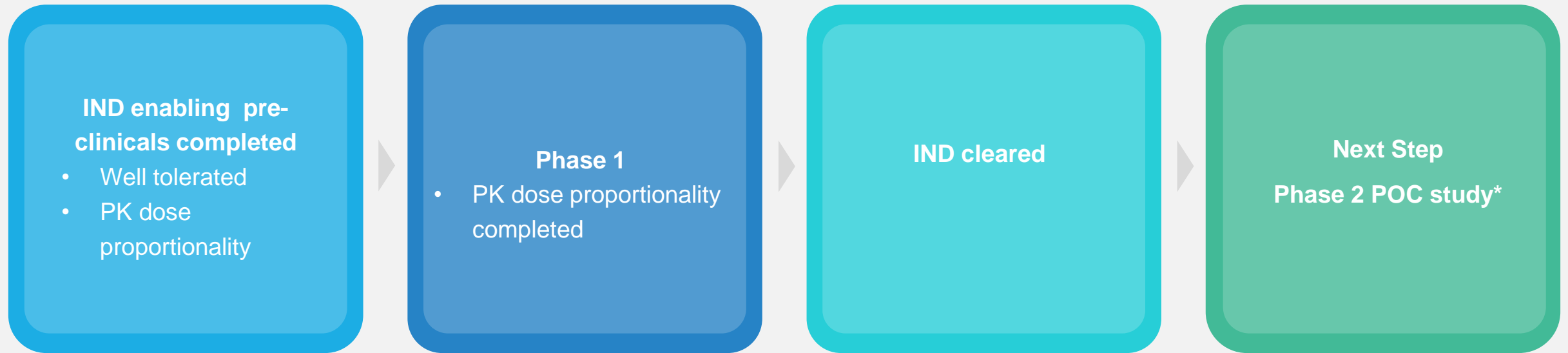
Active is endogenous to women

Potential to address psychiatric comorbidities (depression, anxiety, sleep disorders)

Potential for favorable drug-drug interactions



# LPCN 2101 Development Status



# Value Through Partnering of Non-CNS Assets

# Unlocking Value Through Partnering

## Why Partnering?

- Enables focus on CNS opportunities
- Candidate advancement
- Risk diversification
- Potential for non-dilutive financing
- Improved resource management

## Assets Available for Partnering

Development Candidate (Indication)	Pre-Clinical	Phase 1	Phase2/POC	Pivotal	Approved
<b>TLANDO®</b> (Testosterone Replacement Therapy)	<div></div>				
<b>LPCN 1111</b> (Once Daily Testosterone Replacement Therapy)	<div></div>				
<b>LPCN 1107</b> (Prevention of Preterm Birth)	<div></div>				
<b>LPCN 1144</b> (Non-Cirrhotic NASH)	<div></div>				
<b>LPCN 1148</b> (Decompensated Liver Cirrhosis)	<div></div>				

# TLANDO® Attributes

## Convenient Oral Route

- No inadvertent transference or pulmonary oil micro embolism risks
- Single strength and dose

## TRT without titration requirement

- Enables selection of an effective dose at the start of therapy without delay
- No “efficacy gap” upon switching from other TRTs
- No additional pharmacy and clinic copays to reach efficacious dose
- No dose adjustment clinic and pharmacy visits
- No dose adjustment invasive samplings
- No titration decision errors

## Bioequivalent exposure in low/med/high fat food

**Not known to produce hepatic adverse events associated with 17-methylated testosterone**

## Physician Research: Physicians View No Titration Product as Positive

Cited “easy/less titration” as an important advantage of TLANDO™

Finding the adequate TRT dose through titration is burdensome for physicians and patients

**TLANDO®: Launched 2Q22 in U.S.**  
Commercialization Partner - Antares Pharma

**LPCN 1021 (TLANDO®): Available for Licensing for ex-US Markets**

# LPCN 1111

## Once-A-Day Oral Testosterone Replacement Therapy

### Product Candidate Highlights

Oral dosage form comprising testosterone tridecanoate

Convenient option for large and growing market

Patients and physicians preferred once a day oral testosterone

Positive phase 2 study results

“Phase 3 ready”

# LPCN 1107

## Potential to be SOC in Prevention of Preterm Birth

### Product Candidate Highlights

Oral dosage form comprising 17-hydroxyprogesterone caproate

>\$2B Market potential

Strong pharmaco-economic justification

Oral, a Major Contribution to Patient Care (MC to PC), including no injection site reaction

Compelling efficacy rationale

Accelerated approval pathway; Orphan Drug Designation



# LPCN 1144

## Novel MOA in Non-Cirrhotic NASH

### Product Candidate Highlights

Oral dosage form comprising testosterone ester

No approved drug

Fast Track Designation

Compelling P2 Biopsy Results in the FDA approvable endpoint

✓ Safety support with 72 weeks exposure

Mono- or adjunct therapy

Differentiated profile

✓ Oral with unique benefit to risk profile

✓ Potential for additional benefits including sexual/mental and musculoskeletal domain

✓ Weight neutral approach

Accelerated approval pathway

# Financial Summary

**Market Capitalization**     \$43.8M<sup>1</sup>

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**Debt**     No outstanding debt

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**Cash**     \$37.4M<sup>2</sup>

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**Additional funding**     Potential for non-dilutive funding through partnerships

## Research Coverage includes:

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Cantor Fitzgerald

Jennifer Kim

Ladenburg Thalmann

Matt Kaplan

Zacks

John Vandermosten

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