FSD PHARMA

**NASDAQ: HUGE**
**CSE: HUGE**
**FRA: 0K9A**

# DEVELOPING NOVEL SOLUTIONS

## FOR BRAIN AND INFLAMMATORY DISORDERS

lucid.
PSYCHECEUTICALS
(a wholly-owned subsidiary of FSD Pharma, Inc.)

September, 2022

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# NEW THERAPIES FOR NEURO AND INFLAMMATORY DISORDERS

## OPERATING PHILOSOPHY

MAINTAIN STRONG IP POSITION

THERAPEUTIC INDICATIONS BASED ON EVIDENCE, MARKET, REGULATORY/CLINICAL FEASIBILITY AND/OR OPPORTUNITY

INCORPORATE REGULATORY AND MARKET STRATEGIES INTO CLINICAL DEVELOPMENT

CONTINUOUSLY SCOUT FOR SYNERGISTIC PARTNERSHIPS

PURSUE ASSET-CENTRIC OPPORTUNITIES AND NEW FUNDS/REVENUE

# NEW THERAPIES FOR NEURO AND INFLAMMATORY DISORDERS

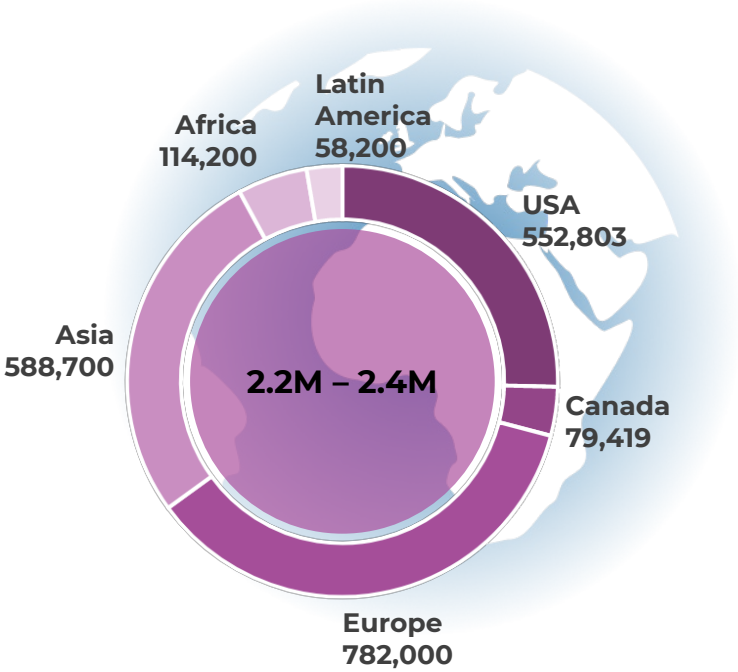
| | DISCOVERY | LEAD | IN VIVO POC | IND ENABLING STUDIES | PHASE-1 | PHASE-2 | PHASE-3 | MARKET LAUNCH |
|---|---|---|---|---|---|---|---|---|
| **LUCID-MS (Lucid-21-302)** | Multiple sclerosis (Neurodegenerative Disorders) | | | | **Q4 2022** | | | |
| **LUCID-PSYCH (Lucid-201)** | Major Depression Disorder (Mental Health) | | | | **Q4 2022** | | | |
| **FSD-PEA (FSD201)** | Pain and Inflammation | | | | | **Q2 2022** | | |

## NEURODEGENERATIVE DISORDERS
# MULTIPLE SCLEROSIS OVERVIEW

- A chronic inflammatory and neurodegenerative disorder
- Impaired and unpredictable symptoms including the decline of patient cognitive function
- Current treatments are immunomodulatory which do not address neurodegeneration mechanisms
- MS market is projected to grow at $24.1B globally by 2027*

Our solution:

- Lucid-21-302 is *first-in-class* neuroprotective/ non-immunomodulatory treatment for MS
  - robust preclinical efficacy and toxicity data
  - good understanding of the trials and KOL base
  - with well studies mechanism of action
  - which addresses white matter disorders (MS, PD, AD)

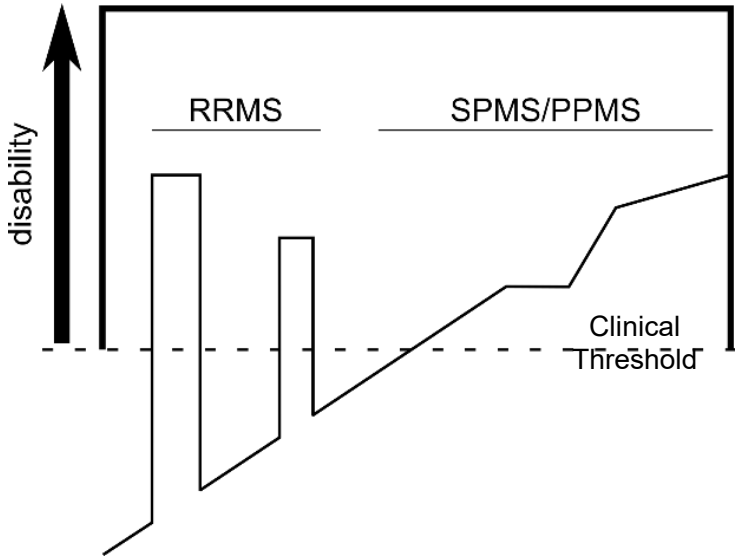



Prevalence of Multiple Sclerosis

*Source: 03/2022, Datamonitor Healthcare

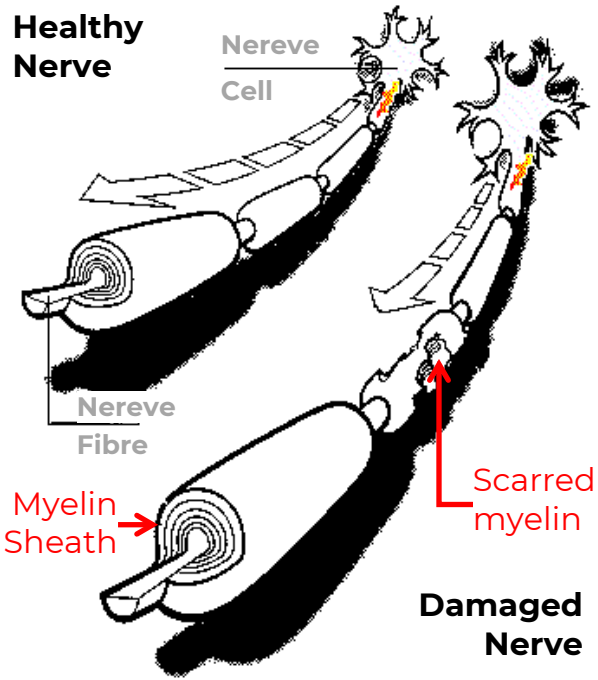
# MULTIPLE SCLEROSIS (MS)
## Stages of disease & pathophysiology

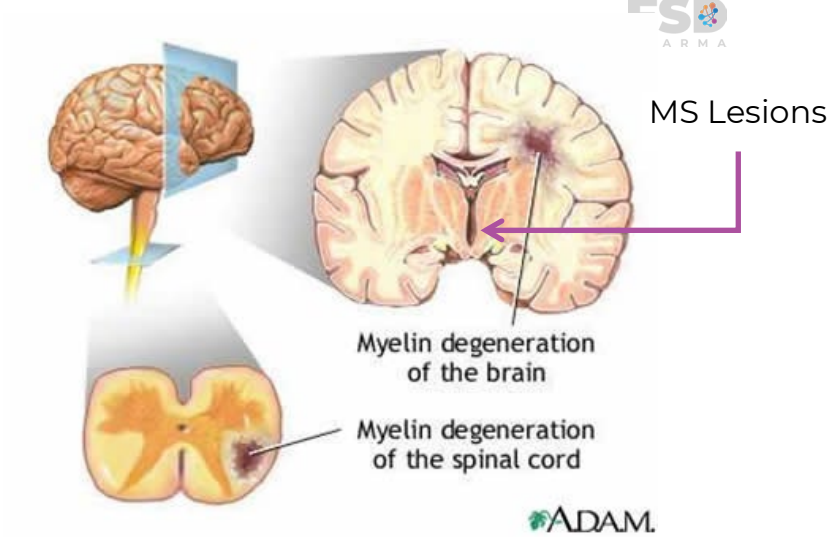
- MS is an autoimmune disease resulting in inflammatory demyelination and progressive neurodegeneration
- Mental health challenges are observed as prodromes




Stys et al., *Nat. Rev. Neurosci.* **2012**, *13 (7)*, 507-14.

# MULTIPLE SCLEROSIS
## Demyelinating Disease




**MS Pathology and Clinical Characterization**

Four Clinical Pathology Patterns:

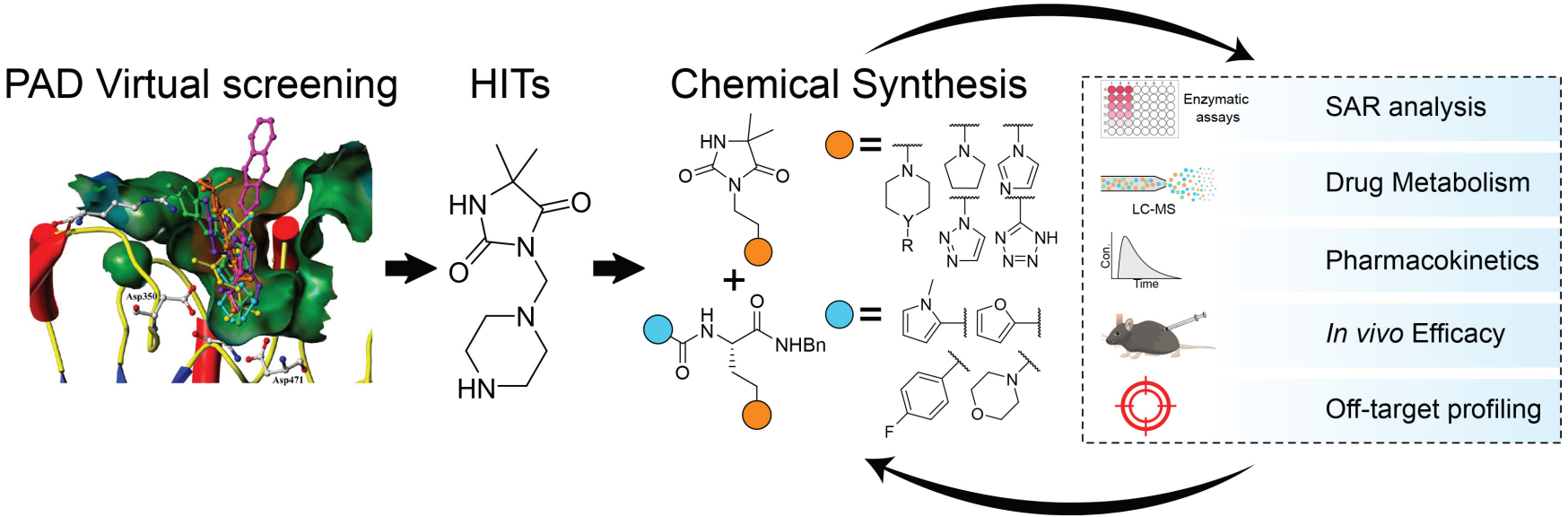
- I – Demyelination + macrophages
- II – Demyelination + T-cells (EAE Model)
- III – Oligodendrocytes + Apoptosis (ND4)
- IV – Apoptosis (very rare) (ND4)

Myelin Basic Proteins (MBP) are components of **Myelin Sheath**

# TARGET AND MECHANISM

## Hypercitrullination and Protein Arginine Deiminases

## Drug discovery & lead optimization

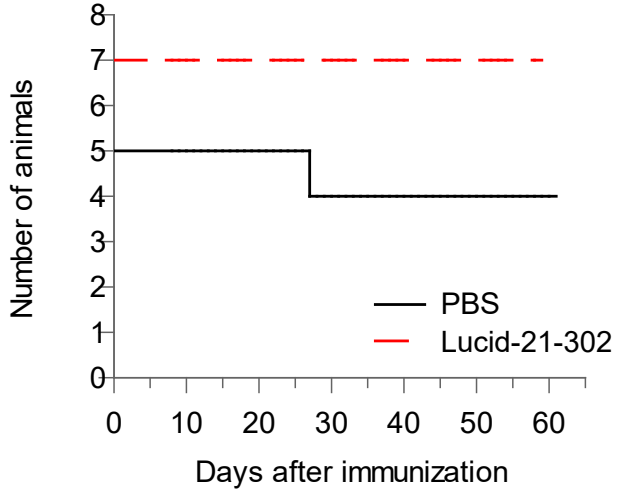


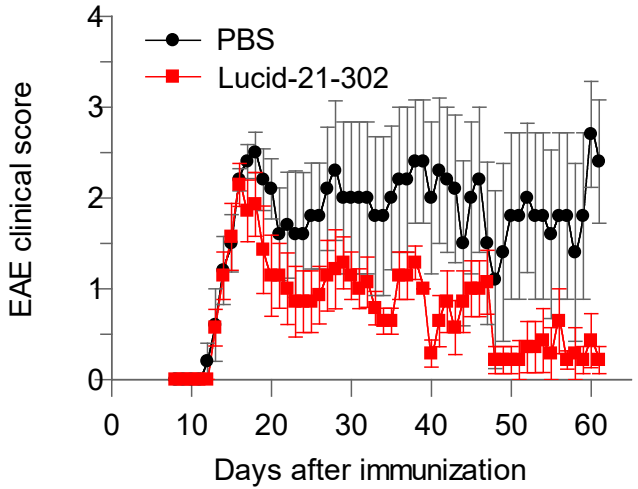

- Wei et al., J. Med. Chem. 2013, 56 (4), 1715-1722;
- Curiel Tejeda et al, J. Med. Chem. 2017, 60 (21), 8876–8887;
- University Health Network, US Patent# US 20180250307A1 (Exclusive worldwide license to Lucid Psycheceuticals)

# Lucid-21-302 – A NEW CLASS OF COMPOUND

## Lucid-21-302 reduced disease score – Mouse EAE Model

Study 6



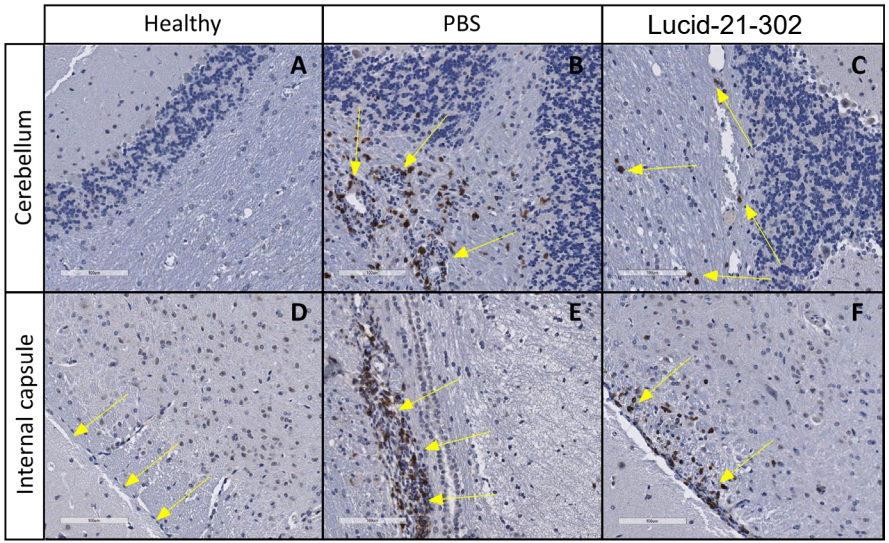




CLICK TO SEE VIDEO

Kotra et al., J. Med. Chem. 2017.

# Lucid-21-302: REDUCED INFLAMMATION IN BRAIN

## Lucid-21-302 reduced T-cell infiltration – Mouse EAE Model



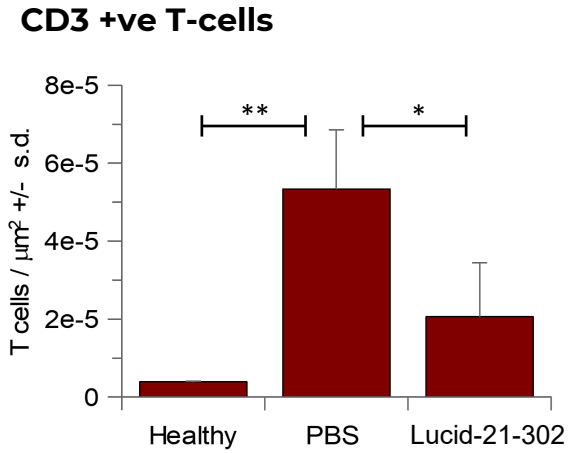
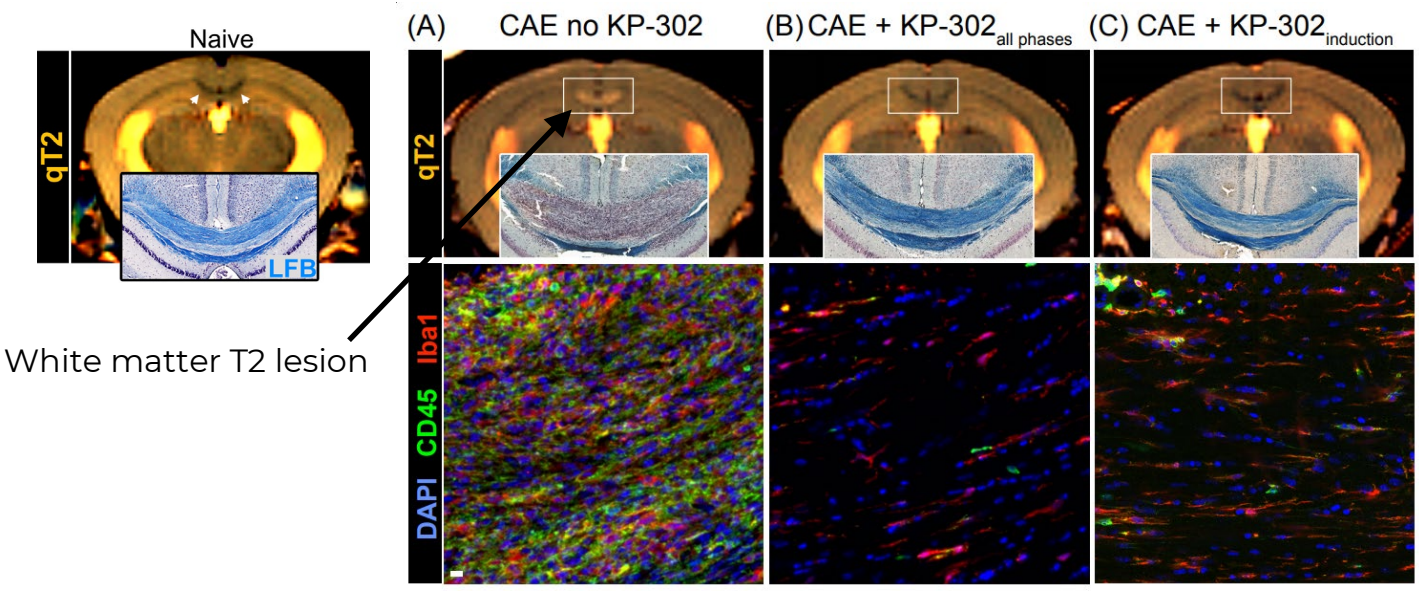




**Figure 4.** Immunohistochemistry of EAE affected mice brains. The tissue was probed with CD3+ve antibody to detect T lymphocytes in the CNS of healthy and sick mice. (** $p<0.01$, * $p<0.05$)

Kotra et al., J. Med. Chem. 2017.

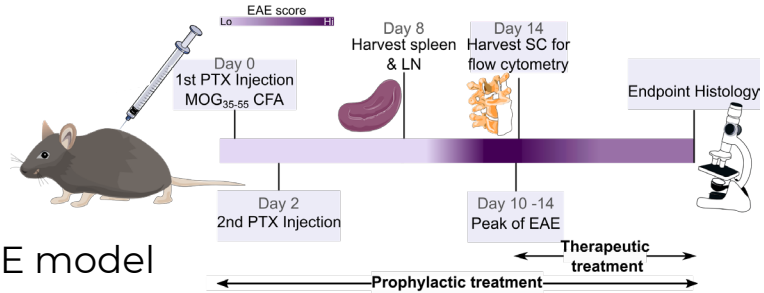
# Lucid-21-302: EFFECTIVE IN PROGRESSIVE MS MOUSE MODEL




Lucid-21-302 (formerly KP-302) dosed at 50 mg/kg, *q.d.* for 4 weeks

Stys/Kotra, *Proc. Natl. Acad. Sci.* (USA), **2018**.

# LUCID-21-302 DID NOT ELICIT IMMUNOMODULATORY EFFECTS




Mouse EAE model

- ✓ Did not elicit significant immunomodulatory effects
- ✓ Ameliorated symptoms when administered prophylactically or as a therapeutic agent following disease onset
- ✓ Monotherapy treatment reduced inflammatory demyelination and axonal loss in an immune-independent manner

# SUMMARY OF MS PROGRAM: Lucid-21-302 IS A DMT

- ✓ New mechanism of action to prevent and reduce neurodegeneration
- ✓ No suppression of immune system and no immunomodulation
- ✓ Excellent efficacy in various preclinical models of MS - over 11 years of R&D
- ✓ Accelerated functional recovery of diseased mice, preserved myelin and reduced axonal degeneration
- ✓ Exclusive worldwide license of patented technology
- ✓ IND filing anticipated in Q4, 2022

CLICK TO SEE VIDEO

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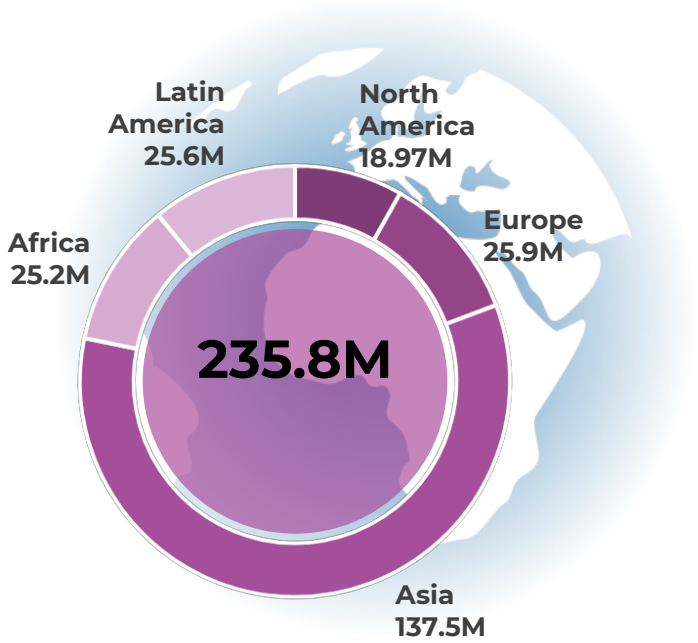
# MENTAL HEALTH (MAJOR DEPRESSION DISORDER and PTSD)

- Depressed mood or loss of interest in pleasure for at least 3 months
- Periods of remission and relapse over a lifetime
- Treatment resistant depression remains major market opportunity for the new drugs
- New mechanism of action is a key feature for novel therapies
- Economic burden in the USA is $210B annually
- First line of treatment is antidepressants with or without psychotherapy
- MDD in 7 MM is estimated to grow to $10.9 B by 2030*

**Alternative and Clinically Effective Solution to the Existing Treatment Options**




Diagnosed patients

*Source: 03/2022, Datamonitor Healthcare

# LEAD COMPOUND: LUCID-201

Psychoactive class of compound (Psilocybin-family)

Selected from 7 psychedelic compounds using machine learning algorithms for drug-like properties/ADME

Proprietary dosage form to reduce hallucinogenic effect but potentially maintain therapeutic efficacy

Lead compound with clinical evidence for efficacy

# SUMMARY OF MENTAL HEALTH PIPELINE

- Lucid-201 is a controlled substance (Schedule 1)
- Scale-up and GMP production in Narcotics-licensed facilities underway
- IND enabling studies and clinical protocols development are underway

**FSD Unique Advantage**

- Depression, anxiety and other mental health challenges are common in neurodegenerative disorders including MS – prodromes
- Strong epidemiological data available
- Lucid/FSD Pharma is addressing these challenges under the umbrella of Total Brain Health™

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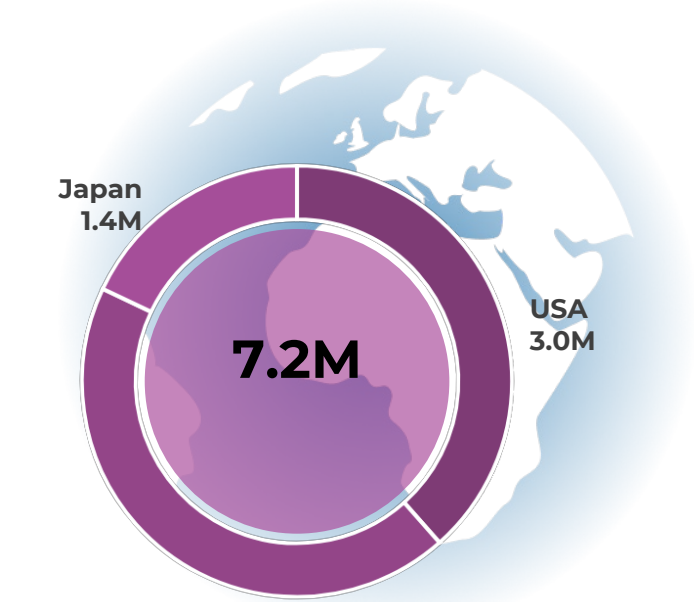
# INFLAMMATORY DISORDERS - OVERVIEW

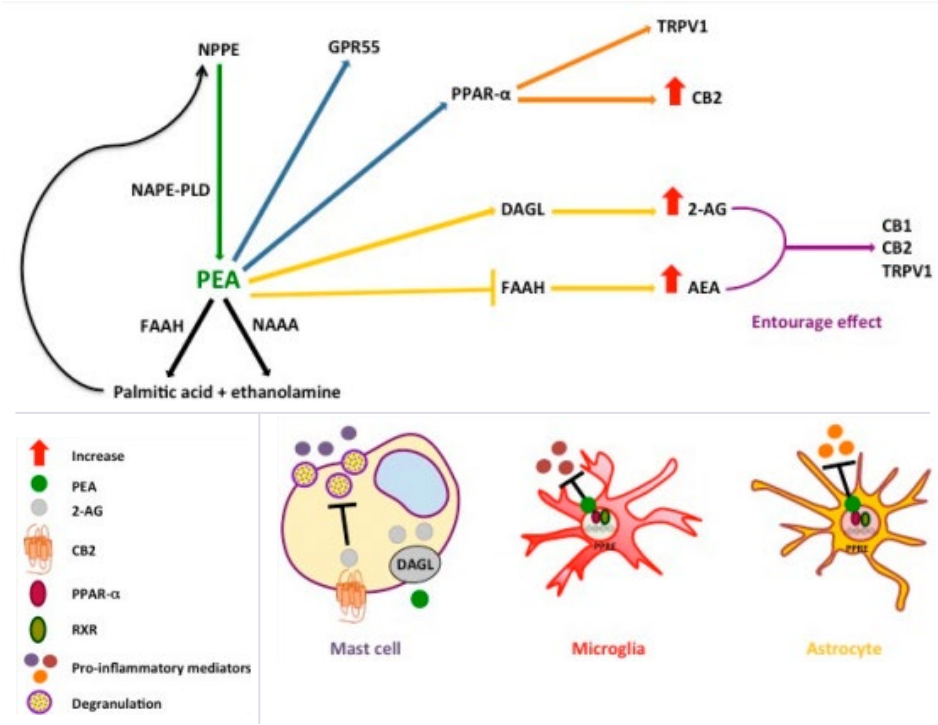
- FSD201 (FSD-PEA) is a proprietary ultramicronized palmitoylethanolamide (PEA) formulation
- PEA is an endogenous compound
- Inflammation conditions present in a variety of diseases including rheumatoid arthritis, osteoarthritis, inflammatory chronic pain
- Proven mechanism of action and clinical efficacy as an anti-inflammatory agent*




Prevalence of rheumatoid arthritis and psoriatic arthritis cases**

*Wirz S and Molderings GJ, Pain Physician 2017; 20:E849-E861
**Source: 03/2022, Datamonitor Healthcare

# MECHANISM OF ACTION – PEA:  Integral in the Endocannabinoid System




- Activates GPR55 and PPAR-α receptors
- Activates TRPV1 receptors enhancing CB2 receptors expression
- Increases the endogenous levels of 2-AG and AEA, respectively, which directly activate CB1, CB2, and TRPV1 receptors
- Inhibits the activation of mast cells through an indirect CB2- mediated mechanism
- Reduces the activation of microglia and astrocytes through a PPAR-α-mediated mechanism

*Int. J. Mol. Sci. **2020**, 21, 9526; J. Neuroinflammation 2019, 16, 274;  Br. J. Clin. Pharmacol. 2016, 82, 932.

# FSD201: Clinical Development

- FSD201 completed Phase-1 Safety and Tolerability Study “A Phase I, Randomized, Double-blind, Placebo-controlled Study To Evaluate The Safety, Tolerability, And Pharmacokinetics of Single And Multiple Ascending Doses Of Ultramicronized PEA In Normal Healthy Volunteers”
- FSD201 is safe and is well tolerated in normal healthy subjects
- No safety concerns were reported in this study when FSD201 was administered
- A phase-2 clinical study “A Randomized, Double-Blind Placebo Controlled Parallel Group Study of Safety and Efficacy of FSD201 in Patients with Chronic Widespread Musculoskeletal Nociplastic Pain Associated with Idiopathic Mast Cell Activation Syndrome” is underway

# FSD201: COMPETITIVE ADVANTAGE

- FSD201 has 505(b)1 (NME) status in the USA or equivalent designations in other countries
- Only PEA-based product in the world entering Phase 2 stage of clinical development
- Strong Phase-1 clinical safety data with FSD201
- Addresses unmet clinical need
- FSD201 Ready  for licensing and/or partnering opportunities
- Multiple commercialization routes through regulatory strategies
- Explore non-prescription Labels in regulated and unregulated markets, using FSD Proprietary technology

# COMPETITIVE ADVANTAGE

## Diversified product portfolio

- Neuro and inflammatory assets
- New mechanisms of action
- Focus on unmet clinical need

## Strong IP position

- Patent families are licensed on exclusive basis
- Composition of matter patents
- Exclusive IP rights

## Potential for growth

- Solid execution team
- Located in one of the largest biotech clusters in the world
- Acquire complementary assets
- Strong cash position
- Institutional investors and development partners

## Investor Relations

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**Zeeshan Saeed**
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**Lakshmi P. Kotra**
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