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Strong candidate for accelerated FDA approval via breakthrough, fast track and orphan drug designations available for CIPN and other opportunities.

kannalife™
breakthrough therapeutics targeting inflammation

First-in-class small molecule therapeutic targeting GPCR & mitochondria to treat inflammation and peripheral neuropathy

Company Overview

Our lead therapeutic KLS-13019, is a first-in-class, novel synthetic cannabinoid that has been validated through IND-enabling studies to prevent and reverse chemotherapy-induced peripheral neuropathy (CIPN).

Market & Commercialization Strategy

CIPN market: ~$810M/yr, driven by refractory cancer patients in third-line chemo (e.g., paclitaxel, oxaliplatin, cisplatin). Once KLS-13019 clears safety trials, we can target US based opportunities such as $10.3B market for irritable bowel disease (IBD) and others including diabetic neuropathy ($4.3B).

Technical & Competitive Advantage

KLS-13019, features pioneering first-in-class chemistry and a small molecule drug (SMD) advantage and targets GPR55, a prime area for drug discovery. Its dual mechanism of action within synaptic mitochondria, engaging with both GPR55 and mNCX-1, underscores its comprehensive control over neuronal function and shows promise in neurological disorders. It is orally bioavailable, able to break the blood-brain barrier, and has a clean CNS safety profile. Strong preclinical data validated efficacy in both peripheral and central nervous systems, indicating broad therapeutic potential.

Regulatory Strategy

NDA pathway is advancing to IND in Q1 2025 and Ph 1a in Q3 2025. Strong candidate for accelerated FDA approval. Open to an out-license partnership for co-development. Completed Pre-IND briefing book, covers among other things, product profile, Q&A, regulatory interaction, issue management and endpoints.

Intellectual Property – Freedom to Operate to 2039

- **WIPO/PCT Patent WO2015/106108A2** – Composition & Method – Treat Oxidative Stress
- **WIPO/PCT Patent WO2021/097351A1** – Method – Radiation Dermatitis & Other Disorders
- **WIPO/PCT Patent WO2022/165332A1** – Method – Treat Inflammation and Pain

Capitalization History

		Total to Date	**$10.2M**
2013	**Equity**	**VC Initial Seed**	**$1.5M**
2017-2020	**Equity**	**VC Seed Follow**	**$3.4M**
2017-2020	**Debt**	**VC Follow-On**	**$2.0M**
2017-2023	**Federal Grant**	**NIH**	**$3.3M**
***Future Commitment**	**Equity**	**Prevail Partners**	**$1.5M**

Funding Needs

- **$30M to Fund Human Clinical Trials Ph 1a thru Ph 2a**

Near-Term Milestones

- **Completing IND Enabling Studies**
- **Pre-IND Briefing with FDA – Q3 2024**
- **First in Human Trials Begin – Q3 2025**

Seeking dynamic & strategic life sciences partner to join forces to seize multiple market opportunities.

Kannalife Sciences, Inc., a pioneering biotech company dedicated to developing small molecule therapeutics targeting inflammation

- Peripheral Nervous Systems (PNS) & Central Nervous System (CNS) disorders to prevent and reverse neuropathic pain
- Targets G protein-coupled receptor (GPCR), GPR55 and NLRP3 thru mNCX-1
- GPCRs are #1 targets for approved drugs

Highlights:

Awarded $3.3M in NIH Grants NINDS / NIDA - HEAL Initiative
Strong preclinical results solving Unmet Medical Needs With Treatment Platform:
Prevention and *Reversal* of neuropathic pain
Protection of sensory and hippocampal neurons
Reduction of oxidative stress and ROS
Advancing to IND in Q1 2025 and Ph 1a in Q3 2025
Full patent protection & freedom to operate
Experienced team of entrepreneurs, medicine experts, and clinical/business advisors

Key Professionals:

Dean Petkanas, CEO – Xechem, Neuropathix
William Kinney, PhD CSO – Wyeth, J&J, Magainin
Doug Brenneman, PhD Chief Bio – Pfizer, J&J, NIH (Section Chief)
Mark McDonnell, PhD Chief Chem – Fox Chase, J&J, PDDI
Tage Honoré, PhD, Dsc – Chm SAB Novartis, Novo Nordisk
Charles Loprinzi, MD – Senior SAB Mayo Clinic, FDA Clinic Expert