Plumeria Therapeutics Inc.
Precision Medicine Approach for Painful Diabetic Neuropathy:
Novel Non-Opioid Pain Drug and Companion Diagnostic

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COMPANY OVERVIEW

Plumeria Therapeutics is a New Jersey-based, clinical stage startup developing a novel, non-opioid pain drug and a companion diagnostic to guide its use. Plumeria negotiated an option to the program from a big pharma who evaluated it in nine clinical trials including a phase IIa in painful diabetic neuropathy (PDN) and found a clinical efficacy signal. With funding from the NIH and the State of New Jersey, Plumeria identified a biomarker in the blood samples from the patients in the trial and is now developing a companion diagnostic (CDx) to continue clinical evaluation of the drug in patients most likely to respond. Plumeria will use the CDx to establish inclusion/exclusion criteria for the next clinical trial.

MARKET & COMMERCIALIZATION STRATEGY

We are initially addressing the painful diabetic neuropathy market, estimated at 5 million patients and $4B in annual drug sales. Our drug's mechanism of action suggests we can pursue other large market indications including osteoarthritis, rheumatoid arthritis, multiple sclerosis, and others.

We have identified a biomarker predictive of patient response to our drug, and our business model is focused on raising venture or corporate funding to advance development to proof-of-concept phase II. At that point, we aim to exit via acquisition or licensing of the program. In the interim, we are pursuing non-dilutive funding from the NIH HEAL initiative and related funding programs for clinical development, as well as NJ funding programs incentivizing in-state R&D.

TECHNICAL & COMPETITIVE ADVANTAGE

There are currently no biomarker-based diagnostics for PDN, or pain in general. Our discovery is unique and offers a powerful approach to establish patient inclusion criteria for clinical trials and ultimately for physicians to treat chronic pain associated with PDN.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

We aim to develop a Laboratory Developed Test (LDT) and then to pursue a CDx and the drug concurrently. We anticipate meeting with the FDA in mid- to late-2025. Following venture funding and initial regulatory strategy, we will hire a CRO with expertise in pain clinical trials.

Plumeria has filed IP on its precision medicine approach which covers methods, kits, Dx and uses. Additional IP will be filed through our counsel, WilsonSonsini. The IP covers the entirety of our business, and we intend to have the biomarker listed in the Orange Book to prevent Paragraph IV certification of generic drugs. Further, we will pursue a regulatory exclusivity utilizing the new drug pathway granting five years of market exclusivity following approval of an innovator drug and precludes the evaluation of a generic. The diagnostic IP extends to 2041. Further, we have a statutory advantage for exclusivity via FDA guidelines for new drug.

KEY MILESTONES (next 18-24 months)

- ☐ Create Laboratory Developed Test (LDT); establish operations; Q2 2025; requires $3M
- ☐ Co-Development of Companion Diagnostic and compound; Q3 2027; requires $28M
- ☐ Identify partners and negotiate acquisition or license; Q4 2027; requires $2M

CAPITALIZATION HISTORY

Plumeria has received $1.18M in nondilutive government grants from both federal and state sources.

MANAGEMENT TEAM

Founder, President and CEO, Thomas P. Richardson, PhD, MBA
Co-founder and CSO, Lei Yu, PhD