GATE NEUROSCIENCES

Company Overview

Gate Neurosciences is a biotech company developing precision medicines to treat brain health disorders. The company was founded in 2019 in Indianapolis by a world-class neuroscience team, including former leaders at Eli Lilly and IU Medicine. Our focus is restoring and enhancing the function of synapses, or connections between neurons, to address underlying biology of diseases like depression, schizophrenia, and Alzheimer's. We are developing drug candidates that modulate the activity of NMDA receptors, a highly validated target critical to synapse strength and function. Our lead program, zelquistinel, is initiating a Phase 2 clinical study in 2024 to confirm efficacy in patients with depression. In previous human studies, zelquistinel was safe and showed rapid antidepressant effects in just 1 week after a single dose. Gate's development approach applies cutting-edge precision medicine tools, such as EEG biomarkers and patient enrichment, to maximize development success and patient impact.

Problem or Market Opportunity

Over 21 million Americans live with depression. Standard of care therapies (i.e. SSRIs) can be effective for some patients, but generally have low response rates (<50%), slow onset of effect (~4 weeks), and poor side effects (weight gain, sexual dysfunction). There is a high need for better depression therapies with safer and more potent rapid-acting mechanisms of action. Gate's lead drug candidate, zelquistinel, works through a highly different mechanism from standard of care. Zelquistinel is a once-weekly oral pill that is rapid-acting (efficacy within 1 week), highly potent, and well-tolerated, representing a potential best-in-class depression treatment. Gate's commercialization strategy is to confirm zelquistinel efficacy in a Phase 2 depression study initiating in 2024, followed by pivotal Phase 3 studies for FDA approval. In parallel, we will also evaluate zelquistinel for schizophrenia and Alzheimer's. Capturing just 5% of the diagnosed, treated, and addressable depression market yields peak US sales >$2.5B annually.

Technical & Competitive Advantage

Gate's lead program, zelquistinel, is a positive modulator of NMDA receptors (NMDAR PAM). Only in the past ~15 years has the psychiatry field made significant advances in understanding the role of NMDARs for the rapid treatment of mood cognitive disorders. This lead to recent FDA approvals of new drugs targeting NMDAR: J&J's Spravato in 2019 and Axsome's Auvelity in 2022 (both on track for $1B+ in sales). Spravato and Auvelity are NMDAR antagonists and have severe side effects (i.e. dissociation) and safety issues due to blocking the receptor. Zelquistinel, however, is an NMDAR PAM with significant competitive advantages to NMDAR antagonists. Zelquistinel's NMDAR PAM mechanism is a more direct approach to enhancing synaptic strength and function, and bypasses safety issues with antagonists while maintaining comparable rapid and potent antidepressant effects.

Regulatory Strategy & Intellectual Property

Gate's lead program, zelquistinel, has IP protection out to the late 2030s with opportunities for novel IP from our clinical studies to extend protection into the mid-2040s. We acquired our IP portfolio from AbbVie/Allergan, who established a robust global patent strategy to protect the molecules.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q3 2024	Study Initiation	Apimostinel: Initiation of Phase 2 clinical study in acute psychiatry.
Q4 2024	Study Initiation	Zelquistinel: Initiation of Phase 2 clinical study in secondary indication
Q2 2025	Data Readout	Zelquistinel: Interim readout of Phase 2 clinical study (high dose) in depression.
Q4 2025	Data Readout	Zelquistinel: Interim readout of Phase 2 clinical study (low dose) in depression

Capitalization History

Year	Grant or Equity Type	Description	Amount
2019	Seed Funding	Acquired IP and launched company.	$3.5M
2020-23	Convertible Notes *(Series A)*	De-risked portfolio with Phase 1 studies, EEG biomarker readout, preclinical data.	$26M
2024	Series B	Mutiple Phase 2 efficacy studies.	$60+M

Current Round, Terms, and Use of Proceeds

Currently raising a $60m+ Series B financing to fund multiple Phase 2 efficacy studies.

Key Team Members and Advisors

Derek Small | Co-Founder and Chairman

Founding Managing Director of Luson Bioventures Co-Founder and CEO of Assembly Biosciences ($ASMB) Founding CEO of Naurex (acq. by Allergan in 2015 for $560m).

Anantha Shekhar | Co-Founder and CSO

Dean of UPitt School of Medicine Executive Dean of Research and Founder of CTSI at IU School of Medicine Psychiatry Key Opinion Leader, PI on >10 NMEs including Karuna (acq. BMS for $14b).

Mike McCully | Co-Founder and CEO

20+ year biotech executive and entrepreneur. Recombinant Capital/Deloitte. Head of BD at Elan Pharma. Head of Strategy at Coherus. CBO of Charleston Labs.

Gate Neurosciences | 1210 Waterway Blvd., Indianapolis, IN 46202
Robert Houghtaling | (302) 379-5385 | rob.houghtaling@gateneuro.com