

Section 1: Executive Summary

MLB-001 is expected to deliver morphine-level pain relief with reduced euphoria, lowered respiratory risk, and longer duration — at the same price as morphine — positioning it as possibly the first realistic replacement for morphine in the \$22B global market.

MLB-001: A Next-Generation Morphine Replacement

MLB-001 is a first-in-class, morphine-based combination therapy designed to deliver powerful pain relief with significantly reduced euphoria, lower abuse liability, and a dramatically improved safety profile. GNQ Insilico, an independent AI-driven drug development group, completed a comprehensive mechanistic and predictive modeling assessment of MLB-001. Their findings validate MLB-001 as potentially a true next-generation alternative to morphine, capable of reshaping the acute pain market.

Key Findings from the GNQ Assessment

Note: All clinical outcomes below are projections from GNQ's pathway-driven causal inference modeling. These require validation through human clinical trials.

1. MLB-001 Demonstrates Superior Clinical Potential vs. Morphine

GNQ's modeling shows MLB-001 can deliver:

- Superior efficacy at lower morphine doses (8.1-11.5 mg) compared to standard opioid regimens (20-100 mg)
- 8 – 11% Higher pain relief scores (SPID-48)
- 2-4 times longer duration of action (6-8 hours vs 1-4 hours)
- 63-71% reduction in rescue medication requirements (0.8-1.5 doses vs 2.8-4.0 doses)

This would represent ~4× improvement in opioid efficiency—better pain control with significantly reduced dose, fewer breakthrough pain episodes, and lower dependence risk.

Projected Outcome	MLB-001	Morphine	Advantage
Morphine Dose Required	8.1-11.5 mg	20-100 mg	↓ 50-60% Opioid Sparing
Pain Relief (SPID-48)	130-195 units	130-170 units	↑ 4-15% Superior
Duration of Action	6-8 hours	1-4 hours	↑ 2-4× Longer
Onset of analgesia (<1 hour)	62-82%	75-82%	Comparable onset profile
Rescue-medication use	0.8-1.5 doses	2.8-4.0 doses	↓ 63-71% Lower
≥50% Pain Responders	48-75%	50-70%	Comparable to superior

2. MLB-001 has the potential to reduce Euphoria and Abuse Liability

MLB-001 is predicted to reduce the abuse liability by reducing the "reward" function. This is driven by:

- Dextromethorphan's active attenuation of dopamine reward signaling
- 11-38% reduction in drug-liking scores (Drug Liking VAS: 42-78 vs 68-88)
- 11-38% reduced desire to re-use (Take Drug Again: 28-82% vs 45-92%)
- 20-23% improvement in euphoria and abuse liability
- 40-45% reduction in tolerance development

Key pathways influencing Euphoria and Abuse Liability include Opioid Signaling, Dopaminergic synapse, Class A/1 (Rhodopsin-like receptors), G alpha (i) signaling events, Neuroactive ligand-receptor interaction, and Amine ligand-binding receptors.

Projected Abuse Metric	MLB-001	Morphine	Improvement
Drug Liking VAS (0-100)	42-78	68-88	↓ 11-38% Lower
Take Drug Again (% positive)	28-82%	45-92%	↓ 11-38% Lower
Good Effects VAS (0-100)	35-82	52-92	↓ 11-33% Lower
Euphoria and Abuse Liability	22-32%	28.6-40%	↓ 20-23% Lower
Tolerance Development	12.9-18%	23.5-30%	↓ 40-45% Lower

3. Major Safety Improvements projected: Respiratory Depression Reduced by ~43-48%

GNQ projects that MLB-001's combination therapy approach translates to:

- 43-48% lower respiratory depression risk (7.3-11.5% vs 12.9-22.0%)—the primary cause of opioid overdose deaths
- Adverse event profile 8-82% higher than morphine but manageable (1.08-1.82 vs 1.00)
- Elevated QT prolongation risk (2.8-12.5% vs 0.9-2.1%) but manageable through dose optimization and ECG monitoring
- 40-45% improvement in tolerance and physical dependence risk

MLB-001's multi-mechanism design creates a wider therapeutic window, positioning it as the analgesic with morphine-level relief and a fundamentally safer profile.

Projected Safety Endpoint	MLB-001	Morphine	Improvement
Respiratory Depression Risk (%)	7.3-11.5%	12.9-22.0%	↓ 43-48% Lower
OINV Incidence (%)	25.2-49.5%	12.8-44.8%	Comparable to slightly higher
Adverse Event Profile vs Morphine	1.08-1.82	1.00	↑ 8-82% Higher (manageable)
QT Prolongation Risk (% increase)	2.8-12.5%	0.9-2.1%	↑ Higher; Dose-titratable
Tolerance Risk	12.9-18%	23.5-30%	↓ 40-45% Lower

4. Large Commercial Opportunity

MLB-001 will address a multi-billion dollar market gap in pain management, positioning MindLab for significant commercial success through a differentiated mechanism that directly tackles the opioid crisis.

- The Total Addressable Market is \$22.6B annually (2029 projection)
- Peak sales projection: \$1.13B-\$2.94B based on 5-13% market share
- Key differentiators: Superior efficacy at lower doses, reduced abuse liability, respiratory safety, tolerance prevention

Revenue projections across bear/base/bull scenarios show rapid market penetration with peak sales achieved by 2029 (Year 1 post-launch).

Year	Bear (5%)	Base (10%)	Bull (13%)
2028 (Launch)	\$340M	\$678M	\$882M
2029 (Peak)	\$1,130M	\$2,260M	\$2,940M
2030	\$1,130M	\$2,260M	\$2,940M
2031	\$1,074M	\$2,147M	\$2,793M
2032	\$1,017M	\$2,034M	\$2,646M

5. Valuation Framework

MindLab prices MLB-001 at morphine parity (\$15-20/script), eliminating adoption barriers.

- Why Investors Should Care: MLB-001 is not a "slightly improved opioid." It is a fundamentally safer, more effective, and more predictable alternative to morphine — the world's most widely used analgesic.
- MLB-001 is positioned at critical juncture with GNQ's pathway analysis validating the therapeutic hypothesis; preclinical safety data demonstrating manageable risk profile; clear clinical development timeline
- Real Options Valuation: Current Pre-IND valuation \$151M-\$393M with potential to reach \$2.83B-\$7.35B at product launch

See Valuation Summary table below

Development Phase	Bear Case	Base Case	Bull Case	Avg (Prob-Wt.)
Current (Pre-IND)	\$151M	\$302M	\$393M	\$282M
Post-Phase I/II (2027)	\$533M	\$1.07B	\$1.39B	\$997M
Post-Phase III (2028)	\$1.06B	\$2.12B	\$2.76B	\$1.98B
Post Launch (2029)	\$2.83B	\$5.65B	\$7.35B	\$5.28B

Valuation Summary

Key inflection points for value de-risking:

- Phase I/II Completion (Jan 2027): Validates safety/PK + efficacy signals; demonstrates lack of unexpected QT signal; confirms abuse liability reduction vs morphine. Valuation inflection to \$533M-\$1.39B.
- Phase III Completion (Jan 2028): Efficacy readout provides go/no-go on commercial pathway. Valuation inflection to \$1.06B-\$2.76B.
- Post Product Launch: Commercial launch validation. Valuation inflection to \$2.83B-\$7.35B.

MLB-001 appears to represent a differentiated pain management platform with significant commercial and financial upside potential positioned at a critical juncture in clinical development. Combined Phase I/II trial strategy compresses development timeline by 6-9 months vs sequential phases, reducing capital requirements and accelerating path to commercialization. GNQ's pathway analysis validates the therapeutic hypothesis through comprehensive mechanism mapping across 115 pain-related pathways; preclinical safety data demonstrate manageable risk profile with potentially low respiratory depression at clinical doses; clear clinical development timeline provides probability-weighted value realization across multiple inflection points.

Overall Confidence Score: Moderate-High

Evidence base: Solid preclinical data; clinical analogues available; established mechanistic pathways.