Accelerating Innovation: Our Regulatory Roadmap

October 2024

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The information contained in this presentation represents approximate timelines for clinical studies and regulatory submissions. These timelines are subject to change due to various factors, including, but not limited to, unforeseen events, regulatory requirements, and the specific progress of the development process. Actual timelines may vary, and there is no guarantee that any of these milestones will be achieved within the stated timeframe.

The timeline for conducting clinical studies is heavily influenced by the availability and acquisition of necessary funding. Delays in securing funding can lead to significant setbacks in research progress, potentially affecting the overall duration of the clinical study. It is crucial to establish a robust funding strategy and actively seek support from various sources to ensure that the clinical studies can proceed according to the planned timeline

MOOD DISORDER INDICATIONS - INSOMNIA		
Item	**Milestone**	**Date**
1	Submit Breakthrough Device Designation requests to FDA for HALO for Insomnia. Anticipate designation for Insomnia indication by Q2 2025.	Q4 2024 – Q2 2025
2	Start pilot clinical study for Insomnia	Q4 2024
3	Completion of Insomnia pilot clinical study and data analysis	Q2 2025
4	Start pivotal clinical studies for Insomnia	Q3 2025
5	CE Mark HALO device for Insomnia in EU using pilot study data	Q3 2025
6	Register HALO device for Insomnia in OUS markets using CE Mark	Q4 2025
7	Completion of Insomnia pivotal clinical studies and data analysis	Q4 2025 to Q1 2026
8	Submit US FDA De Novo Request submission for Insomnia indications	Q4 2025
9	Anticipated approval of US FDA De Novo Request for Insomnia	Q2 2026

MOOD DISORDER INDICATIONS - DEPRESSION		
Item	**Milestone**	**Date**
1	Submit Breakthrough Device Designation requests to FDA for HALO for Depression indications. Anticipate designation for Depression indication by Q2 2025.	Q4 2024 – Q2 2025
2	Start pilot clinical study for Depression	Q2 2025
3	Completion of Depression pilot clinical study and data analysis	Q4 2025
4	Start pivotal clinical study for Depression	Q4 2025
5	CE Mark HALO device for Depression Indication using pilot study data	Q4 2025
6	Register HALO device for Depression in OUS markets using CE Mark	Q1 2026
7	Complete pivotal clinical study for Depression and data analysis	Q3 2026
8	Submit US FDA De Novo Request submission for Depression indications	Q3 2026
9	Anticipated approval of US FDA De Novo Request for Depression indications	Q4 2026

MOOD DISORDER INDICATIONS - ANXIETY		
Item	**Milestone**	**Date**
1	Submit Breakthrough Device Designation requests to FDA for HALO for Anxiety indications. Anticipate designation for Anxiety indication by Q2 2025.	Q4 2024 – Q2 2025
2	Start pilot clinical study for Anxiety	Q3 2025
3	Completion of Anxiety pilot clinical study and data analysis	Q2 2026
4	Start pivotal clinical study for Anxiety indications	Q3 2026
5	CE Mark HALO device in EU for Anxiety using pilot study data	Q3 2026
6	Register HALO device for Anxiety in OUS markets using CE Mark	Q4 2026
7	Completion of Anxiety pivotal clinical study and data analysis	Q4 2025 to Q1 2026
8	Submit US FDA De Novo Request submission for Anxiety indications	Q1 2026
9	Anticipated US FDA De Novo Request approved	Q2 2026

MILITARY INDICATIONS		
Item	**Milestone**	**Date**
1	Start UCSD study for mild TBI (mTBI)	Q1 2025
2	Submit FDA Breakthrough Device Designation Request for mTBI indication using data from UCSD study	Q3 2025
3	US FDA De Novo Request submission for mTBI indications	Q4 2025
4	US FDA De Novo Request approved	Q2 2026
5	Kick-off DoD/VA multisite assessment and treatment of PTSD project	Q4 2025

LONG TERM INDICATIONS – ALZHEIMER'S / DEMENTIA		
Item	**Milestone**	**Date**
1	FDA Pre-submission for Alzheimer's/Dementia clinical study and Regulatory Strategy. Request for device classification.	Q1 2025
2	Submit Breakthrough Device Designation request for Alzheimer's indication using data from OUS published clinical studies	Q2 2025
3	FDA approval of IDE and clinical study protocols for Alzheimer's	Q3 2025
4	Start Alzheimer's pilot study	Q3 2025
5	Start Alzheimer's pivotal study	Q1 2026
6	End pilot study and complete initial data analysis	Q3 2026
7	CE Mark in EU using pilot data and OUS data for Alzheimer's/dementia indication	Q4 2026
8	Register in OUS markets using CE Mark	Q1-Q2 2026
9	Completion of pivotal study and data analysis	Q1 2027
10	FDA Submission (DeNovo or PMA for Alzheimer's / Dementia Indication	Q2 2027
11	FDA approval for Alzheimer's / Dementia Indication (dependent upon FDA classification)	Q4 2027 – Q2 2028

LONG TERM INDICATIONS – SUBSTANCE ABUSE		
Item	**Milestone**	**Date**
1	FDA Pre-submission for Opioid addiction. Includes clinical study protocols, regulatory strategy and pathway and discussion of and request for Breakthrough designation.	Q1 2025
2	FDA Feedback on Pre-sub, approval of study design and protocols	Q2 2025
3	Start pilot clinical study for Opioid addiction	Q3 2025
4	Complete pilot study and data analysis	Q4 2025
5	Start pivotal clinical study for Opioid addiction (may start sooner if interim data analysis is promising)	Q1 2026
6	Complete pivotal study and data analysis	Q3 2026
7	FDA submission (based on device classification but assume DeNovo)	Q4 2026
8	CE Mark in EU using pilot data	Q2 2026
9	Register OUS using CE Mark	Q2-Q3 2026
10	FDA approval for Opioid addiction	Q2 2027

Forward-Looking Statements

This press release contains statements that constitute “forward-looking statements,” These statements relate to future events or Nexalin’s future financial performance. Any statements that refer to expectations, projections or other characterizations of future events or circumstances or that are not statements of historical fact (including without limitation statements to the effect that Nexalin or its management “believes”, “expects”, “anticipates”, “plans”, “intends” and similar expressions) should be considered forward looking statements that involve risks and uncertainties which could cause actual events or Nexalin’s actual results to differ materially from those indicated by the forward-looking statements. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Report on Form 10-K for the year ended December 31, 2023 and other filings as filed with the Securities and Exchange Commission. Copies of such filings are available on the SEC’s website, www.sec.gov. Such forward-looking statements are made as of the date hereof and may become outdated over time. Such forward-looking statements are made as of the date hereof and may become outdated over time. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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