

SAMPLE **FOUNDER SCORE REPORT**

Company: BioSync Neuro
Technology: Implantable neurostimulator for chronic pain
Assessment Date: April 2026

68/100

Moderate - Addressable Gaps

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Executive Summary

BioSync Neuro presents a moderate-risk profile with addressable gaps across key evaluation domains. The technology demonstrates strong clinical foundations and solid technical engineering. However, regulatory pathway classification carries terminal risk that requires immediate strategic reassessment. Market opportunity is validated but competitive positioning requires strengthening. Manufacturing scale-up readiness presents a significant execution risk.

Domain Assessment Scores

Domain 1
74
Strong clinical evidence base and addressable gaps

Domain 2
58
Regulatory pathway presents critical risks

Domain 3
72
Market opportunity validated; positioning requires development

Domain 4
68
Technical sound; manufacturing readiness incomplete

Risk Summary: 2 terminal risks | 4 remediable risks identified

Methodology: This assessment evaluated BioSync Neuro across a proprietary framework. Domain identifiers are proprietary and fully disclosed in paid engagements. Benchmarked against 2,000+ life science outcomes with 98% predictive accuracy.

Domain 1 Analysis

Clinical Foundation & Evidence Base

Overall Domain Score: **74/100** **Strong**

Strong clinical foundation with growing evidence base. BioSync Neuro demonstrates robust pre-clinical data and early clinical validation. Technology has addressed key efficacy and safety questions.

Assessment Criteria (Redacted in Sample)

- [REDACTED IN SAMPLE] — Proprietary evaluation criterion 1
- [REDACTED IN SAMPLE] — Proprietary evaluation criterion 2
- [REDACTED IN SAMPLE] — Proprietary evaluation criterion 3
- [REDACTED IN SAMPLE] — Proprietary evaluation criterion 4
- [REDACTED IN SAMPLE] — Proprietary evaluation criterion 5

Key Finding: Clinical adoption feasibility is strong but requires additional physician feedback data to support clinical adoption.

Data Confidence: **HIGH**

Domain 2 Analysis

Regulatory Pathway & Classification Risk

Overall Domain Score:

58/100

Moderate Risk

Regulatory pathway presents the greatest risk to commercialization timeline. Current classification strategy carries significant uncertainty regarding pathway length and success probability.

Assessment Criteria (Redacted in Sample)

- [REDACTED IN SAMPLE] — Proprietary regulatory classification assessment
- [REDACTED IN SAMPLE] — Proprietary predicate device analysis
- [REDACTED IN SAMPLE] — Proprietary clinical evidence pathway scoring
- [REDACTED IN SAMPLE] — Proprietary timeline risk quantification
- [REDACTED IN SAMPLE] — Proprietary regulatory precedent mapping

Key Finding: Classification strategy needs revision. Early feedback indicates predicate device selection approach

Data Confidence: **MEDIUM**

TERMINAL RISK Classification strategy misalignment could extend pathway 3-5+ years. Current approach

Domain 3 Analysis

Market Opportunity & Competitive Positioning

Overall Domain Score: **72/100** **Strong**

Market opportunity is validated and growing. Chronic pain treatment market is expanding with increasing adoption of neuromodulation therapies. However, competitive positioning strategy remains underdeveloped relative to market potential.

Assessment Criteria (Redacted in Sample)

- [REDACTED IN SAMPLE] — Proprietary market size and growth analysis
- [REDACTED IN SAMPLE] — Proprietary competitive landscape assessment
- [REDACTED IN SAMPLE] — Proprietary differentiation analysis
- [REDACTED IN SAMPLE] — Proprietary customer demand validation
- [REDACTED IN SAMPLE] — Proprietary go-to-market feasibility scoring

Key Finding: Market demand is confirmed through physician and patient feedback. Differentiation strategy is u

Data Confidence: **HIGH**

Domain 4 Analysis

Technical Foundations & Manufacturing Readiness

Overall Domain Score:

68/100

Moderate

Technical foundations are sound and engineering team is capable. However, manufacturing scale-up readiness requires significant investment and planning. Transition from prototype to commercial production carries execution and timeline risk.

Assessment Criteria (Redacted in Sample)

- [REDACTED IN SAMPLE] — Proprietary IP protection and patent strength analysis
- [REDACTED IN SAMPLE] — Proprietary manufacturing feasibility assessment
- [REDACTED IN SAMPLE] — Proprietary supply chain risk evaluation
- [REDACTED IN SAMPLE] — Proprietary team capability assessment
- [REDACTED IN SAMPLE] — Proprietary capital requirements modeling

Key Finding: IP protection is adequate for current stage. Manufacturing readiness assessment indicates significant risk.

Data Confidence: **MEDIUM**

Risk Assessment Matrix

The following matrix categorizes identified risks by likelihood of occurrence and potential impact on commercialization success. Terminal risks require immediate mitigation. Remediable risks should be addressed during capital raise and operational planning.

	Low Likelihood	High Likelihood
Low Impact		
High Impact		

Terminal Risks (Red)

1. Regulatory pathway misclassification — Strategy reassessment needed with regulatory counsel
2. Insufficient clinical evidence for intended claims — Additional clinical data or claims refinement required

Remediable Risks (Yellow)

1. Manufacturing scale-up timeline — Requires detailed planning and supplier engagement
2. IP coverage gaps — Additional filings may strengthen competitive moat
3. Reimbursement strategy incomplete — CPT coding and payer discussions needed
4. Competitive differentiation — Marketing and clinical evidence positioning required

Note: Risk identification and categorization methodology is proprietary and used consistently across all portfolio assessments.

Recommended Next Steps

The following prioritized actions address the highest-impact risks and position BioSync Neuro for successful capital raise and commercialization.

1. Engage regulatory counsel

Reassess classification strategy and develop remediation roadmap with FDA precedent analysis

2. Strengthen clinical evidence

Execute targeted physician feedback study to support clinical utility claims

3. Develop manufacturing plan

Establish timeline and capital requirements for scale-up with qualified suppliers

4. File IP claims

Complete additional patent filings to strengthen competitive protection

5. Refine reimbursement strategy

Engage with payers and health economics experts before investor meetings

Available Engagement Options

Consulting Engagement: Full regulatory pathway analysis, competitive intelligence, clinical strategy, manufacturing roadmap, reimbursement planning, and investor meeting preparation. Includes strategy calls and report updates.

Surveillance Service: Ongoing quarterly monitoring of competitive landscape, regulatory developments, clinical publications, and reimbursement changes. Includes alerts and quarterly briefing calls.

This is a redacted sample report. Paid engagements include proprietary scoring methodology, full domain labels and anal

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