# G R E A T L A K E S NEUROTECHNOLOGIES

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## The leader in remote monitoring of movement disorders

#### Point of Contact

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#### **Management Team**

Exec. VP & Gen. Counsel, Brian M. Kolkowski, PhD

### Looking for VC or Parkinson's Therapy Strategic Partner

The Market: The Parkinson's disease (PD) treatment market is expected to reach \$12.1B by 2030.

Problem: PD is extremely complex and optimizing therapy can take years of repeated office visits to get dosing just right; then the patient's reaction to the therapy changes, requiring the process to start all over again. Parkinson's symptoms often fluctuate throughout the day and across days, but a once or twice a year clinic visit only provides a subjective snapshot of the disease.

Solution: Our FDA-cleared and CE-marked KinesiaU™ motor assessment system allows for personalized, efficient, and accurate therapy titration and reduces excessive office visits for therapy adjustment. Partnering with KinesiaU will differentiate the partner's therapy product from the competition and improve clinician preference for its product.

Competitive Advantage and Value Proposition: Real world evidence in published clinical trials demonstrates the Kinesia technology's value for remote patient monitoring for both therapeutic efficacy as well as for digital therapeutic adjustment. Clinical trials performed with the key opinion leaders in movement disorders demonstrate that Kinesia<sup>™</sup> products can help remotely

- Digital Therapeutic to distinguish your therapy
- Protected with over 50 US and **International Patents and 30 Pending Applications**
- Extend patent protection for expiring therapeutic patents
- Remote Patient Monitoring CPT codes make doctors more money
- Proven Technology and over 80 publications
- Data for Artificial Intelligence
- FDA Cleared and CE Marked
- Recommended in the UK
- Can Be Used to Drive More Patients to Advanced Therapy

titrate medication, assist in clinical decision making, improve therapy compliance, identify candidates for advanced therapies such as deep brain stimulation and drug pumps, and increase the efficacy and efficiency of deep brain stimulation (DBS). Alternatively, KinesiaU can show continued improvement in base therapies (pills and patches) and show that the additional cost of advanced therapies may not be required.

Tight integration of the KinesiaU technology with therapy systems improves the clinician experience and workflow as well as creates differentiation for a therapy partner by providing a system that identifies when a patient could benefit from a therapy adjustment and optimizes therapy. The availability of KinesiaU remote monitoring will encourage doctors to recommend and patients to opt for specific therapies, thereby accelerating growth for those specific therapies. Clinician time spent reviewing the KinesiaU data will be reimbursable using RPM CPT codes, further increasing clinician preference for our therapy partners' products. The addition of KinesiaU as a companion device to an existing therapy may also allow therapy manufacturers with products off patent (or generics) to extend their proprietary position with a novel delivery/dosing method. The cost of adding KinesiaU to a partner's therapy will likely pale in comparison to the cost of the therapy. Even small increases in market share due the increased clinician preference provided by KinesiaU will more than pay for the addition of KinesiaU.



**Company Milestones:** Four Kinesia products have been designed, completed, and released to market, derisking the technology. Regulatory risk is minimal as Kinesia technology is FDA-cleared and CE marked and has been validated in over 80 peer reviewed journal articles and presentations. These include clinical validation of the proprietary motor quantification algorithms and real-world evidence studies demonstrating the technology improves patient care as described above. Results from a recently published research study in *Digital Biomarkers*<sup>1</sup> demonstrate KinesiaU provides clinically relevant information, aids in the clinical management of patients with PD, and may reduce the need for traditional office visits for therapy adjustment. In 2023, KinesiaU was recommended by NICE (National Institute for Health and Care Excellence) in the UK for remote monitoring of PD in its evidence based recommendations for devices for remote monitoring of PD. Larger planned clinical studies of KinesiaU in the real-world will further demonstrate improved patient outcomes, patient satisfaction, and cost savings compared to standard care. We are also developing technology to automatically identify candidates for advanced Parkinson's therapies such as deep brain stimulation and drug pumps and technology to provide actionable suggestions on ways to optimize treatment. The KinesiaU product is ready for market.

**Intellectual Property:** Kinesia technology is well protected by over 50 issued US and international patents and over 30 pending applications covering proprietary real-time monitoring, data transfer, high-sensitivity sensors and algorithms, artificial intelligence for quantifying symptom severities, adjusting medication or neuromodulation therapy based on motor assessment, and open and closed-loop therapy titration. Our proprietary motor quantification algorithms have been developed and validated in clinical studies over the past 15+ years and, even if unprotected, would take tens of millions of dollars to replicate.

**Product Development and Regulatory Strategy:** The Kinesia technology is ready to market and FDA-cleared under a 510(k) and CE marked.

**Financial Overview:** Our Kinesia technology has been developed over the past two decades using a combination of over \$40M in internal funding and non-dilutive grant funding from the NIH and State of Ohio.

**Management Team:** Our management team has taken two companies onto the Inc. 500 and is the only team to have been awarded Michael Porter's Harvard Business School's Inc. Inner City 100 seven times in the first seven years of the program. The team has created technology that has received a STEVIE Award (America's Business Oscar), Edison Award, Frost & Sullivan North American Product Innovation of the Year Award, NeuroTech Leaders Forum 2007 Gold Electrode Award for Best New Product, and Healthcare Tech Outlook Magazine 10 Most Promising Telemedicine Solution Providers 2017.



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<sup>&</sup>lt;sup>1</sup> <u>https://www.karger.com/Article/FullText/518571</u>