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The leader in remote monitoring of movement disorders

Point of Contact

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Management Team

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The Market: The Parkinson’s disease (PD) treatment market is expected to reach \$5.69B by 2022.

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 KinesiaU™ motor assessment system allows for personalized, efficient, and accurate therapy titration and reduces excessive office visits for therapy adjustment, saving patients time and money. Minimizing office visits is particularly important in rural areas and during pandemics.

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™ products can help remotely 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. The availability of Kinesia remote monitoring will encourage doctors to recommend and patients to opt for specific therapies, thereby accelerating growth for those specific therapies. Additionally, adding Kinesia as a companion device provides a delivery method that can extend a therapy company’s proprietary position.

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* 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. 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 40 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.

We’re looking for \$30M-50M to build up our sales, marketing, and reimbursement teams, integrate data reports into common electronic health records systems, achieve translations and other international regulatory requirements to launch KinesiaU worldwide, and execute a clinical trial involving hundreds of patients to provide further real-world evidence on the improved outcomes and reduced costs resulting from KinesiaU. The table below provides an estimated cost breakdown.

	Costs	Schedule (years)
Sales and marketing Sales and marketing staff and advertising, including patient engagement efforts	\$15M-20M	0-5
Reimbursement CMS and other reimbursement experts and large clinical study to further demonstrate cost savings	\$5-10M	0-3
Software enhancements Integration with Epic and other EHR systems as well as updates to the KinesiaU patient app for improved functionality	\$0.5M for Epic \$2.5M for others \$2M for app updates	0-1 for Epic 2-5 for others 0-2
International regulatory Consultants and local experts in an estimated 20 countries	\$5M-10M (0.5M per country)	0-5

We plan to enter the market in two ways:

1. We will build up our sales staff to sell directly into the patient care market for remote patient monitoring. Based on the number of people with Parkinson’s and current remote patient monitoring CPT codes, we estimate revenues totaling over \$130 million in the US alone in the first five years.
2. We will license and optimize our technology for therapy manufacturers for use with their specific therapies. Clinicians will show a preference toward using a therapy that can be aided by Kinesia technology compared to current techniques. This can increase revenues by billions of dollars due to product differentiation and increased referrals.

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.