Gaze Engine Inc.
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Industry:
Medical Device

Management:
Glen Prusky PhD, (Vision Science)
Founder, Chairman
Scott Mooney PhD, (Vision Science)
Founder, CTO
Shauna Pringle, BA
COO

Seeking to fill roles:
- Chief Executive Officer
- VP of Finance
- VP of Sales

Board:
Seeking members

SAB:
Seeking members

Support/Advisors:
David Gould, MD MBA (Biotechnology Development & Medical Affairs)

Finance:
Current Investors / Financing to Date:
Founders: $10K
Financing Sought: $7M
For:
- Clinical Validation Studies
- FDA Device Approval
- CME Approval
- Operations Costs
- Overhead

IP: Seeking

Legal: Seeking

Business Description / Company Background:
Gaze Engine is C-Corp academic startup spun out of the Burke Neurological Institute in 2023. As part of an NIH-funded research program, the founders invented a device that improves the assessment of human visual health and disease. The idea for the device came after challenging ourselves to develop a measure of visual contrast sensitivity -the most useful metric of perceiving visual form- that could be used with non-communicative children wit brain injury. We formed a company around IP that was generated on the project in order to bring this practical measure of contrast sensitivity to general medical practice.

Market Opportunity / Unmet Need:
The loss of contrast perception is a highly debilitating symptom of visual disease that is more impairing and earlier to manifest than acuity loss. Despite its importance as a visual metric and superior sensitivity to acuity tests in detecting and grading visual disease in a laboratory setting, contrast sensitivity tests are among the least used measures of visual health. This is because objective, quantitative and easily administered clinical tests have not been available. The current US market for assessing vision using eye chart tests is ~$1B annually, and the deployment of an efficient clinical test of contrast sensitivity would address the most significant unmet need for diagnosing visual impairment and treatment outcomes while growing the vision testing market.

Product – Launched & Pipeline:
Gradiate™: A (2024) device that uses proprietary computer algorithms to automatically detect evidence of seeing from eye tracking of moving stimuli, and determines the limit of ability by rapidly changing stimulus visibility until the threshold for seeing is obtained. Without the need for specific user training, Gradiate™ generates a visual contrast sensitivity function in a few minutes, and includes a measure of visual acuity. To provide more value for our customers interested in fast screening, testing time can be further reduced with a novel measure we call Concuity™ (2024): A combined visual contrast and acuity metric that efficiently grades impairment with a single statistic. The device is an advanced prototype at TRL-6 that is ready for pre-FDA clearance market sales. Clinical trials are planned to secure FDA device clearance and CME reimbursement codes to serve optometry, ophthalmology, and clinical trial applications.

Commercial / Technical Milestones:
Completed: Developed and patented algorithms that collect evidence of seeing from gaze interactions (captured by an eye tracker) with visual stimuli that decrease spatial visibility with continued engagement. (U.S. prov. Pat. app. serial #63/167,220 (2021); U.S. pat. #11,583,178, February 21, 2023; U.S. pat. #11,122,999, September 21, 2021). Adapted system to a tablet format, and improved automation and data interpretation over the laboratory model.
In process: Clinical trials are set to begin this year and FDA clearance is expected in 2027; CME clearance by 2028. Trial design will evaluate the safety and efficacy of Gradiate™ and Concuity™ for use in standard visual exams.

Competition / Competitive Advantages / Customer Benefits:
Subjective chart contrast sensitivity testing providers (Precision Vision; Keeler, Bernell, Good-Lite, Lighthouse Guild, Vector Vision); and computerized contrast sensitivity testing (Adaptive Sensory Technology) which makes geometric assumptions about the contrast sensitivity function, and which is not feasible for use in non-communicative subjects. Gradiate™ captures the precision of laboratory tests and the efficiency of chart tests, and is the only contrast test that has been successfully used with the large, underserved population of children with brain injury who have visual dysfunction (40%) and may not be able to effectively communicate. Patients will benefit from better disease diagnosis, prognosis and treatment. Providers will benefit from improved metrics, improved patient outcomes, and longer patient lifetime value.

Financial Projections (Unaudited): Gaze Engine will scale business in 2 steps; first with pre-approval research and wellness device sales, and after regulatory approval, with medical vision health sales. The medical revenue model will be based on hardware purchases ($5K), and per-test license fees ($35) for regulated vision health applications.

	Year 1	Year 2	Year 3)FDA	Year 4)CME	Year 5
Revenue	$0.05M	$0.1M	$0.58M	$4.25M	$9.88M
Growth Rate		100%	475%	633%	133%
Gross Profit	$0.005	$0.01M	$0.12M	$2M	$7.5M
Gross Margin	10%	10%	21%	47%	76%