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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



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Company Profile

Industry Sector: Medical Devices

Company Overview:

LKC is a privately-owned medical device manufacturer specializing in the production of visual electrophysiology testing systems. LKC is post-revenue, profitable, and self-sustaining with strong brand name recognition. LKC has in place all required regulatory approvals and industry certifications, including FDA establishment registration and predicate device 510(k) approvals, as well as ISO 13485:2003 and Class IIa CE Certificate. LKC has significant export experience and success with its current product line to over 40 countries.

Target Market(s):

Target the worldwide market to screen diabetics for diabetic retinopathy at the point of care. There are 285 million diabetics in the world served by over 2 million physicians including Ophthalmologists, Optometrists, General Practitioners, Internists, endocrinologists, clinics, and visiting healthcare professionals who comprise the market for this device

Key Value Drivers

Technology*: A capital efficient opportunity to launch a device to fundamentally change the way diabetics are tested for Diabetic Retinopathy. This patented, easy to use, hand-held, portable, non-mydratic device will provide immediate results in less than five minutes per patient. This device assesses the level of ischemia present in the retina and correlates to the level of Diabetic Retinopathy present. This is a functional test, not an imaging test.

Competitive Advantage: This device is fast, accurate, and inexpensive. It requires minimal training and can be administered anywhere the patient encounters their care. It requires no dilation and provides instant, accurate results based upon well understood and peer reviewed published science. It is patent protected by one U.S. issued patent and there are other U.S. and international patents pending. LKC has over 30 years of experience and expertise manufacturing and delivering devices based upon visual electrophysiology

Plan & Strategy: seeking a strategic partner or investment capital

Management

Leadership:

- James J. Datovech, President and CEO
- Quentin Davis, Ph.D., VP of Operations and Development
- George Barstis, Chief Financial Officer

Scientific Advisory Board:

- **Karen Holopigian, Ph.D.** Professor, Department of Ophthalmology NYU
- **Stephen R Fransen, MD** Associate Professor of Ophthalmology, Dean McGee Eye Institute, University of Oklahoma
- **Mary Johnson, Ph.D.** Associate Professor of Ophthalmology and Visual Sciences, Director, Electrodiagnostics Service, University of Maryland Medical Center
- **J. Vernon Odom, Ph.D.** Professor of Ophthalmology and Physiology, West Virginia University

Product Pipeline

	2Q12	3Q12	4Q12	1Q13	2Q13	3Q13	4Q13
Device development							
Regulatory strategy							
Clinical testing							
CE clearance							
EU channel development							
EU launch							
FDA clearance							
US channel development							
US launch							

Additional future product offerings under consideration include glaucoma and macular edema diagnosis and monitoring.