Photobiomodulation for Dry Age Related Macular Degeneration

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Company Highlights

- Ophthalmic medical device company focused on treating Dry - Age Related Macular Degeneration (Dry AMD)
- Novel use of Photobiomodulation (PBM) already successfully used in multiple therapeutic areas of the body
- Compelling clinical and pathological results from 3 clinical studies
- EU CE Mark Approved
- Intellectual Property – 9 patents issued and multiple PCT National phase applications
The Valeda™ Light Delivery System –
The First Approved Treatment for Dry AMD using Photobiomodulation
The AREDS Category Distribution in the LIGHTSITE I Study at Baseline

- 30 patients distributed 1:1 into PBM or Sham treatment
- 46 eyes (ITT)
- ~8.0 years since AMD diagnosis
- Similar distribution between Sham and PBM groups
The Effect of PBM on VA Letter Score in the LIGHTSITE I Study

- Treatment 3 x per week treatments for 3 weeks
- Retreatment after 6 months
- 50% of PBM patients get 5+ letter benefit
- Retreatment needed at ~6 month interval
The Effect of PBM on Vision in Early Stage Dry AMD Patients and Correlation to Geographic Atrophy with Central Foveola Involvement

- Subset of high PBM responders with 5+ letter improvement
- 11 of 12 (91.6%) did not have foveola with GA involvement
- Subset of Low PBM responders with <5 letters improvement
- 10 of 12 (83.3%) had foveola with GA involvement
The Effect of PBM on Contrast Sensitivity in the LIGHTSITE I Study

- 46 eyes
- 3 x per week treatments for 3 weeks
- CS shows statistically significant (p<0.05) benefits out to 12 months following treatment
The Effect of PBM on Central Drusen Volume in the LIGHTSITE I study

- 46 eyes
- 3 x per week treatments for 3 weeks
- Statistically significant reductions in Drusen Volume seen at 1 year ($p = 0.05$)
The Effect of PBM on Central Drusen Volume in a LIGHTSITE I Subject

Baseline

Month 12 after 2 PBM sessions
LIGHTSITE I: The Effect of PBM on VFQ Activities of Daily Living Endpoints at 3 M

Statistically significant VFQ-25 composite score, p = 0.003

Q5: reading ordinary print in newspapers

Q8: reading street signs or the names of stores

Q10: noticing objects off to the side while you are walking along

Q11: seeing how people react to things you say

Q14: going out to see movies, plays, or sports events
Ongoing Activities

- Soft launch at EURetina 2018
  - Photobiomodulation Symposium: An Innovative, Mitochondrial-Targeted Therapy for Dry AMD and Other Ocular Diseases
- EU multi-center and registry studies
- Established distribution channel partner with Optos, LLC for 12 EU and Scandinavian countries
- Ongoing dialog with additional country channel partners
- USA companion study under development
Management Team

• **Clark E. Tedford, PhD** - President and CEO, 30 years of Pharmaceutical and Medical Device Management Experience (Schering Plough, Gliatech, Solentix, Omeros, PhotoThera)

• **Cindy Croissant** - Vice President of Clinical Operations, 25 years of clinical research and industry experience including phase I-IV drug, device and biologics trials (Vital Therapies, Aeolus Pharmaceuticals, PhotoThera, and PAREXEL).

• **Duane R. Morrison** - Vice President, Sales, (TLC Vision Corporation, TearLab Corporation)

• **Robert Bard, JD** - Acting Vice President Regulatory and Quality Affairs, 40 years of compliance, ethics, legal and regulatory affairs, quality control, quality assurance, clinical affairs and development, and manufacturing and operations experience in pharmaceuticals, devices, biotech and biologics industries. (Sciele Pharma, Aastrom Biosciences, Gliatech).

• **Scott Bradley** - Director, Product Development, 25 years of experience including engineering design and program management for research, clinical trial, and commercial device development. (Vital Therapies, PhotoThera, Peak International, Biolase Technology, Inc.)

• **Tracy Puckett** – Acting Vice President of Marketing, 25 years experience firmly grounded in building sustainable brand propositions to meet P&L objectives. National and global experience in packaged goods, pharmaceuticals and medical devices. (TearLab, Alimera Sciences, Novartis Ophthalmics, Inc, Adair-Greene Healthcare Communications)

• **Andrew Amiel** – Acting Vice President of Business Development, 15 years experience in institutional financing and strategic alliances.. (B&P, Go4Venture, Landmark Ventures, Inc., Lamiel Partners, Medisens Wireless, InjectSense, Inc.)

• **Paul Kruglik** – Acting Chief Financial Officer, 25 years experience in operations and financial management. (Traverse, Tatum, College Success Foundation, CFO Brands, BuzzBee, ABCn)

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USA and UK Office Locations

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