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Ophthalmic Drug Delivery

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Current ophthalmic drug delivery:

Drops (95%+ of \$8-12 billion mkt), gels and ointments

Advantages of drops:

Established, inexpensive manufacturing, accepted standard of care

Disadvantages:

Variable, messy and difficult dosing, compliance issues, short residence time, dilution and washout, require high drug concentration, systemic side-effects

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Exploit opportunity to substantially improve ophthalmic drug delivery with non-invasive, topical devices

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**Nanosphere-antibiotic
corneal contact lens**



**Topical
Ophthalmic
Drug
Delivery
Device™**

Nanosphere-antibiotic corneal contact lens

- Deliver dose continuously for 7-14 days
- Protects cornea as a bandage lens
- Improved convenience, compliance, efficacy
- Customized encapsulation to control release
- Unique, compatible with lens material
- Biodegradable, non-toxic, stable
- Shell and core functionalized independently

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Nanosphere-antibiotic corneal contact lens

PA-06-009 Bioengineering Nanotechnology Initiative

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Year 1

- Synthesis of nanospheres and encapsulation of antibiotic
- Polymerize nanospheres into hydrogel material
- Testing release characteristics of drug from the lens

Year 2

- Casting and manufacturing specifics determined
- Pre-clinical safety, efficacy per FDA guidelines

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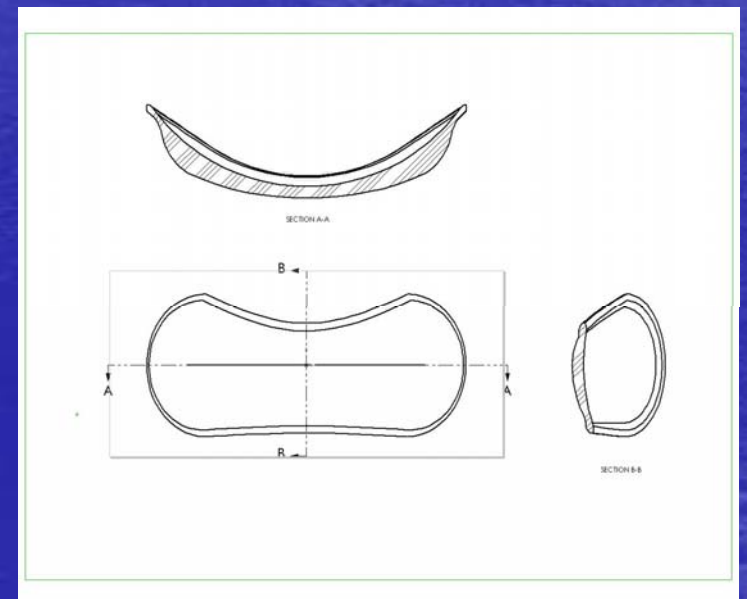
TODDD™

- Small elastomeric device inserted under and concealed by the eyelid
- Worn continuously for up to 13 weeks and then replaced
- Drug releases slowly over months

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TODDD™ Design Development: Ocular device with contact lens design features to fit under the lid onto the inferior or superior sclera (not the cornea). The design features include:

- Central curvature
- Peripheral curves
- Edge apex contours
- Edge lift
- Substantial volume



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QuickTime™ and a
DV/DVCPRO - NTSC decompressor
are needed to see this picture.

Initial Application of TODDD™

- Glaucoma is a progressive disease that leads to blindness (120,000 blind in U.S.)
- Still have 24-59% non-compliance
- 2 million diagnosed
- 2nd leading cause of blindness, after cataracts
 - Physicians seek to lower intraocular pressure (IOP) to slow progression of the disease
 - Because TODDD delivers drug 24/7 and its inherent compliance, it has great potential to improve treatment and outcomes dramatically by better control of the IOP

Progress to Date

- National Institute Health SBIR Phase I grant (\$100K)
- NIH SBIR Phase II grant (\$800K)
- Internal funding and development, MEP grant - M2D2
- 3 polymer systems developed and tested
- Tailored systems to incorporate 5 different drugs
- Demonstrated release of drugs over 180 days
- Produced prototype device (worn continuously 24/7 for 200+ days)
- Filed separate patents on design and polymer systems
- Developed a pilot manufacturing process to cast mold device (will develop scale-up with M2D2)
- Completed animal safety studies
- Demonstrated efficacy in 90 day timolol animal study

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TODDD™ Next Stage

- Conduct human feasibility clinical trial
- Continue design validation, manufacturing scale-up
- Pursue FDA approval
- Execute development plans for additional drug-specific TODDD products

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Development Team

Robert Thompson

Charles Leahy, O.D., M.S.

Edward Ellis, Ph.D.

Kathryn Crawford, Ph.D.

Ophthalmic Product Development

Executive management

Clinical Expertise

Ophthalmic material expertise

Over 30 patents

\$2 billion in sales

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Scientific and Regulatory Advisors

- Prof. Aldo Crognola - College of Engineering, U. Mass. – Lowell
- Prof. Edwin Jahngen - Chm.of Chem. Dept., U. Mass. – Lowell
- Prof. Francis Lai - Plastics Engineering Dept., U. Mass. - Lowell
- Mark Abelson, M.D. - Ophthalmic Research Assoc.
- William Gleason, O.D. - Foresight Regulatory Strategies

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Conclusion

- Worldwide ophthalmic drug market of \$8-12 billion and growing
- Innovative, proprietary technologies to:
 - Significantly improve therapeutic efficacy
 - Provide greater inherent compliance
 - Reduce or eliminate systemic side effects
- Demonstrated proof of principle
- Solid patent protection pending
- Experienced, talented, successful management team