Platform Technology Transforming Ocular Drug Delivery

Bob Thompson, CEO
rthompson@gmail.com
(781) 891-9351
Rob Kirk, Corporate Finance Advisor
dr.kirk.amorphex@gmail.com
818-807-8868

Overview

Amorphex Therapeutics, a MA based medical device company is developing a novel, patented Topical Ophthalmic Drug Delivery Device -TODDD™, a soft, flexible device that floats on the tear film completely concealed under the eyelid.
The TODDD™ platform technology provides much more reliable drug delivery with a single dose capable of supplying multiple drugs for months resulting in:

- Easier and more effective therapy for patients
- Easy to adopt, improved disease management for physicians
- Reduced total patient care costs for providers and insurers
- Distinct competitive advantages for pharma companies

The first application of TODDD will be for the treatment of glaucoma, a chronic disease affecting over 2 million Americans requiring pharmaceutical treatment for the rest of their lives.
Animal testing and preliminary human trials have confirmed TODDD's safety and efficacy for this treatment.

Team

Bob Thompson - President & CEO

- Experienced in medical device start-ups
- Former president of two Bausch & Lomb divisions
- In depth ophthalmic product development and marketing background

Edward Ellis, Ph.D. - VP Science & Technology

- 30+ patents with more than $2 billion in sales
- Co-founder of Polymer Technology (acquired by B&L)

Charles Leahy, O.D. , M.S. - VP Clinical Affairs

- Practicing clinician* - Massachusetts Eye & Ear Infirmary - Harvard Medical School
- Extensive ocular pharmaceutical clinical testing experience
- Contact lens design and fitting expert – inventor of TODDD™

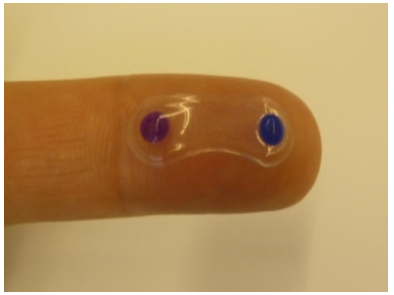
*2 days per week

Disadvantages of Eye Drop Drug Delivery

Major execution and compliance issues

- Difficult to instill
- Variable dosing
- Rapid dilution and washout
- Require high drug concentrations
- Increase ocular and systemic side effects
- Only about 50% of US glaucoma patients are compliant
- Medical costs escalate dramatically as they progress through stages of blindness

TODDD™ Platform



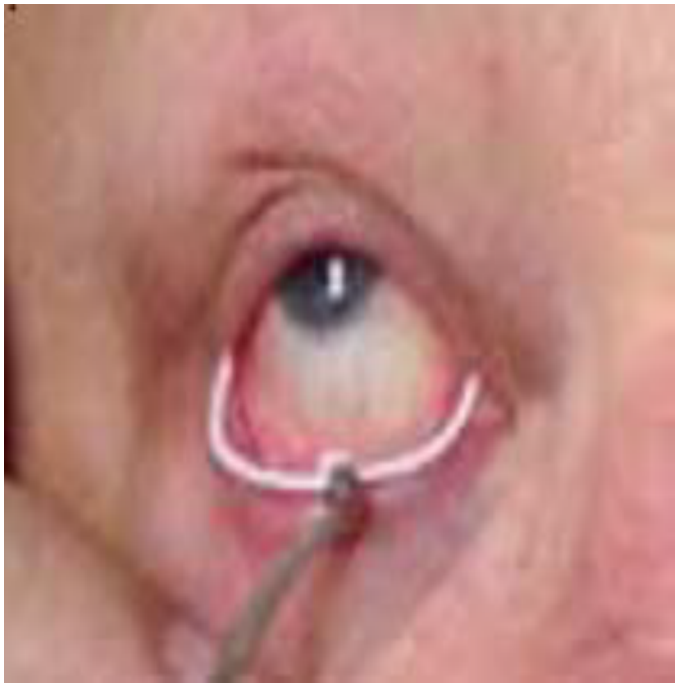
- Resolves each eye drop problem
- Drug containing soft elastomeric material
- Any topical drugs - timolol, prostaglandins, pilocarpine, acetazolamide, brimonidine, dexamethasone, prednisolone, ciprofloxacin, ibuprofen, lidocaine (partial list)
- Not a contact lens - no water content, no surface deposits, no optical or oxygen requirements
- Eliminates daily execution and compliance issues
- Continuous micro-dosing - drug is readily absorbed
- Unlike drops, no detectable drug in plasma – reducing/ eliminating systemic side effects

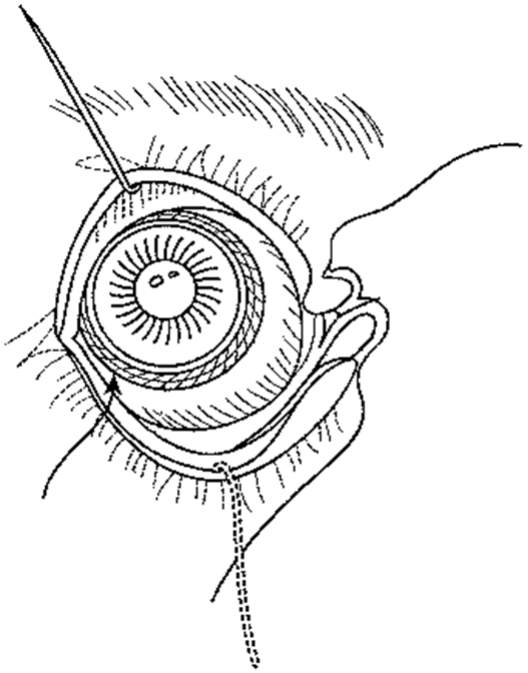
Competition in Development

A punctal plug highlighted in one of TODDD's drug depot cavities

Competition in Development

A conjunctival ring





Competitive Comparison

	TODDD™	Punctal Plug	Pellet Injection	Conjunctival Ring	Prolonged Drops
Solves drops instillation issues	Yes	Yes	Yes	Yes	No
Inherent Compliance	Yes	Yes	Yes	Yes	No
One dose multi-month delivery	Yes	Maybe	Yes	Yes	No
Anesthetization for placement	No	Yes	Yes	Yes	No
Replaceable by support staff	Yes	No	No	No	Yes
Fast and easy replacement	Yes	No	No	No	Yes/No*
Facility required for replacement	No	Yes	Yes	Yes	No
More than one size to fit	2 to 3	Maybe	No	Yes	NA
Momentary awareness	Mild	Mild	Yes	Extended	Mild
Non-invasive	Yes	Yes	No	Yes	Yes
Unaware ejection	No	Yes	No	No	NA
Drug Payload Capacity	XL	XS	S	L	NA

* Fast but not easy to instill correctly for most patients

TODDD™ Development Progress

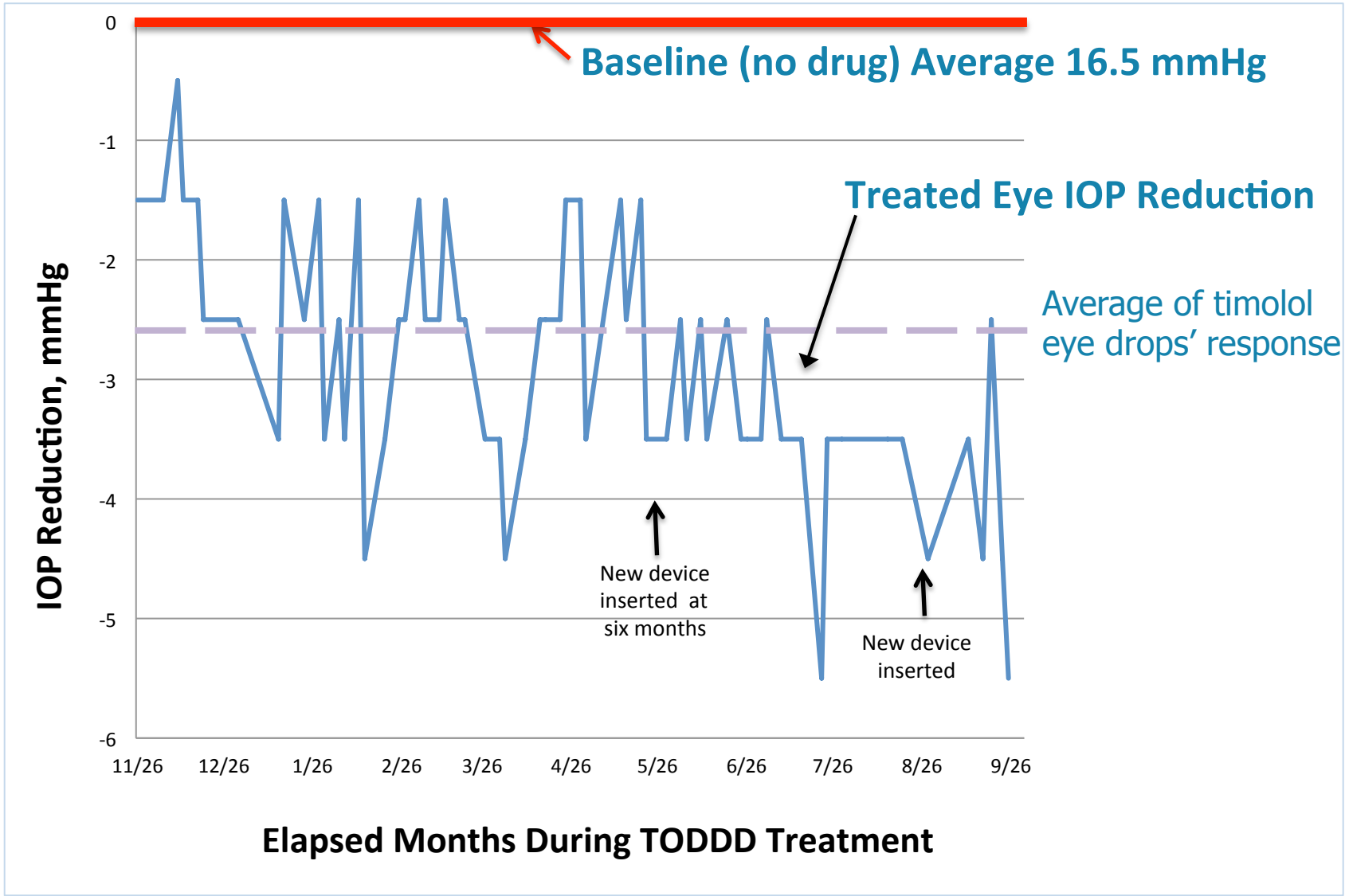
- Completed 3rd NIH SBIR grant ($2.5 million in total)
- Patents issued (US, Europe, Japan, Canada)
- Developed pilot cast molding manufacturing process
- Confirmed abbreviated regulatory path with FDA
- Animal safety and efficacy studies completed
  - Timolol rabbit study
  - Prostaglandin beagle dog study

TODDD™ Without Drug - Comfort and Acceptance

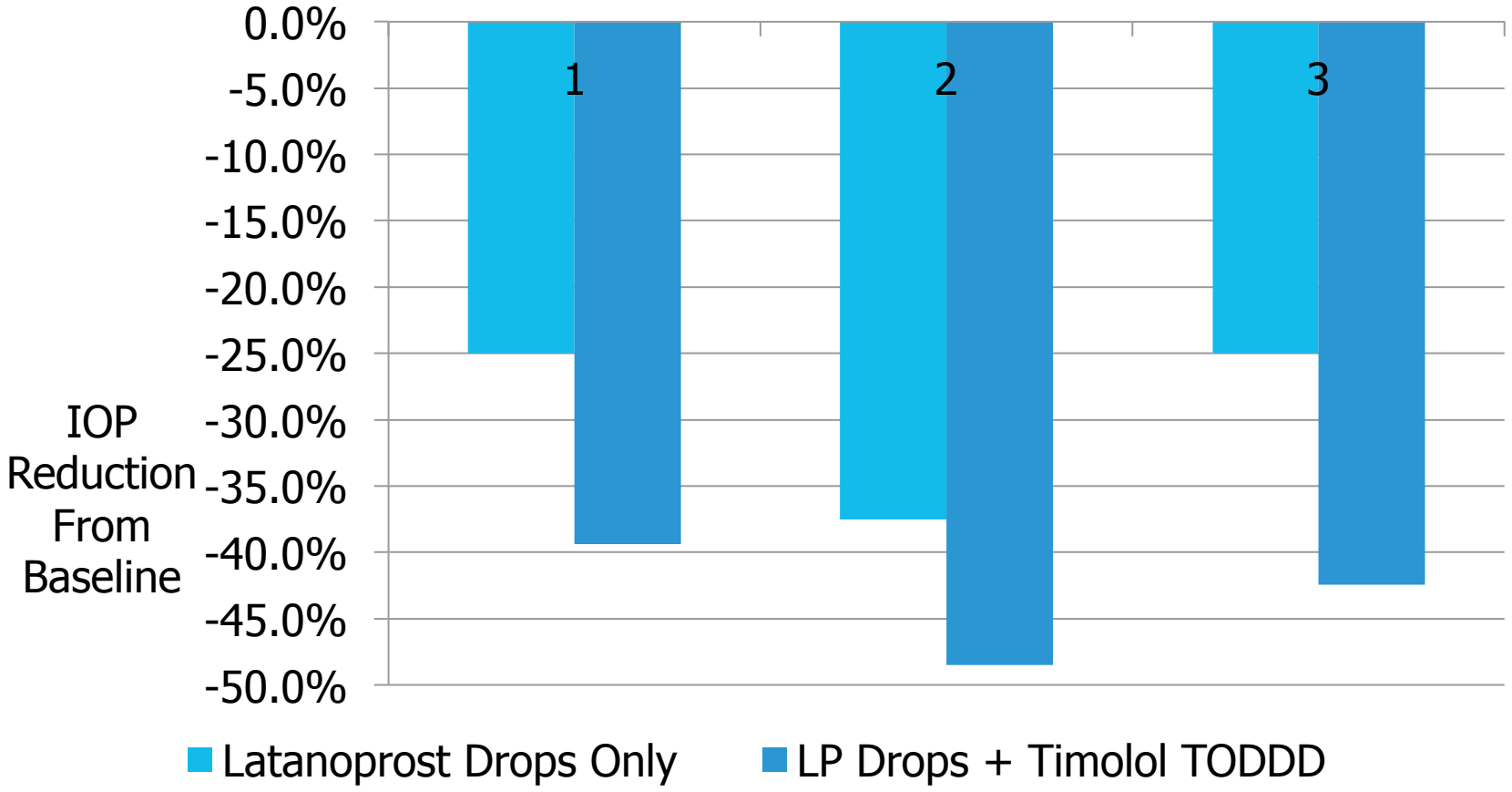
New England College of Optometry Study

- Only one size tested, 2-3 sizes anticipated
- 24 subjects enrolled, 10 elderly
- 2 sites, urban and suburban
- 75% completed full 4 weeks of 24/7 wear
- Rated comfort 0 to 1 (0-4 scale, 0 best)
- Rated tolerability 0 to 1 (0-4 scale, 0 best)
- Excellent retention
- 2nd size completing prototype development

One Timolol TODDD™ Provides 6 months of IOP Reduction Equivalent to Compliant Daily Eye Drop Treatment



Greater Efficacy with Combination



Combination Averaged 49% Greater IOP Reduction

TODDD™ delivering both prostaglandin and timolol should provide optimal therapy

TODDD™ PLATFORM - Near Term Product Pipeline

TODDD Product	Disease Addressed	Year 1	Year 2	Year 3	Market Size
timolol	Glaucoma (mild to moderate)	90-day Human Safety, Feasibility Clinical			$2+b Annual sales
prostaglandin	Glaucoma (mild to moderate)	Pre-Clinical, 90-day Human Safety, Feasibiity Clinical			
prostaglandin + timolol	Glaucoma (moderate)	Pre-Clinical, 90-day Human Safety, Feasibiity Clinical			
*olopatadine**	Ocular Allergies	Formulation, Drug Release	Pre-Clinical Safety and Analysis		$1+b Annual sales
*dexamethasone**	Inflammation	Formulation, Drug Release	Pre-Clinical Safety and Analysis		$1+b Annual sales
dexamethasone + NSAID*	Inflammation		Formulation, Drug Release	Pre-Clinical Safety and Analysis	

* non-confidential options

Use of Funds

- Funding to Date: $4.0 million
  - (including $2.5m NIH grants)

- Funds sought - $7.0 million (36 months)
  - $3.4 million through initial human safety/efficacy clinical
  - $3.6 million follow-on
  - Expenditures approx. $2.2 million each year
  - Nearly 90% of committed capital applied to R&D

- Results
  - 3 TODDD™ products through initial human safety/efficacy clinical protocols
  - 3 additional products through pre-clinical development

Multiple Next Stage Options

- Multiple licenses of TODDD™ for specific drugs
- Continue development of most promising prostaglandin TODDD™ through Phase 2 for higher deal valuation
- Also take pre-clinical products into Phase 1
- Prepare for IPO or acquisition

TODDD™ Summary

- TODDD™ technology ready to be used in human trials
- Tenured, experienced team committed to TODDD™
- Great need for significantly better topical ocular drug delivery is widely recognized
- TODDD™ has distinct comparative advantages over eye drop therapy and other alternatives in development
- Patents issued with no freedom to operate issues identified
- Clear path to multiple liquidity options and substantial increases in valuation

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