



Quick Facts

Industry:

Biotech: Biomaterials, Drug Delivery Systems

Management:

Executives:

- Brian Pan
- Dr. David Pan

Scientific Advisors

- Dr. Richard Register
- Dr. Jules Mitchel
- Dr. John Danias (pending advisor agreement)
- Dr. Robert Prud'homme (pending)

Number of Employees: 0
(3-4 contingent upon funding)

Financial information

- Self-funded \$30k
- Recent grants for submission: 2
- Seeking \$1.5M

Intellectual Property

- 1 patent pending – tPA as therapeutic agent for steroid induced glaucoma
- 2 provisional patents
 - DDS
 - Applicator
- Additional IP in development
 - IP in-licensing
 - In-house dev.
 - Search and Strategy

Purpose of Presentation:

Advice, Research Collaboration, Business Development, and Early Stage Financing

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Dr. David Pan, President and Chief Technology Officer
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Executive Summary

BioHealthWays prevents vision loss by sustaining delivery of biologics in the eye. Our implant reduces injections while improving compliance & convenience. Currently retinal vascular conditions affect 12M Americans (\$7B+).

Company History

BHW was founded in 2016, following Dr. David Pan's retirement from Xerox Corporation. Now located in Brooklyn's Downstate Biotech Incubator, BHW has internally developed a prototype drug delivery system. We are currently seeking research collaborations, team members, and early stage funding. Our model is to out-license rights.

Market Opportunity

In 2016, the global market for retinal vascular conditions, rose to over \$9B (\$15B by 2025). Two products are considered the gold standard, Eylea (Regeneron/Bayer) and Lucentis (Roche/Genentech/Novartis). These treatments require 7-9 intravitreal injections annually. Because conditions are often chronic, a patient often endures hardship, complications, inconvenience leading to non-compliance. Additionally, these products face a patent cliff in 2020-22.

Competition

Companies with leading approved biologics or biosimilars should invest in their next-generation sustained release delivery capabilities to extend the lifetime value of their product portfolio. Competitors engaged in delivering various drugs into the eye include: Ocular Therapeutix, Graybug, Ocugen, pSivida, Eyegate, and Dr. Reddy's Laboratory (OctoPlus NL). None of these competitors have successfully marketed a Drug Delivery System (DDS) lasting >6 months.

Products

BHW's biodegradable intraocular implant prototype may deliver biologics for >6 months (1-2 annual injections). Biologics are challenging to deliver in the eye; our design stabilizes and controls release, with minimal "burst" of too much therapeutic agent. BHW is also developing an accompanying prefilled injector syringe applicator.

Short-Medium Term Milestones

1. SBIR Phase 1/Phase 2 to conduct Toxicity, ADME/Pharmacokinetics, Efficacy to continue in vitro and animal models
2. Submit pre-IND
3. GMP manufacturing
4. Regulatory strategy and clinical protocol completion
5. Submit IND package
6. Begin FDA phase I

Financial Projections:

BioHealthWays Projects commercial launch 2023, peak share 25% in 2026, with annual sales \$2.6B.

Risk adjusted NPV >\$250-475M, royalty 8-14%.

Cost to develop: \$25-35M through 2023. Seeking \$1.5M Seed.

Precedent: 11/2016 Ocular Therapeutix-Regeneron Eylea ER deal \$10M Phase 1, \$305M in milestone payments, 8-14% royalties.