

**WE ARE DEVELOPING CUTTING-EDGE MEDICINE FOR
PRESERVING VISION AND HEARING FOR THE VETERINARY
MARKET AND THEN FOR HUMANS**



Kinostat® is our topical aldose reductase inhibitor for the treatment of diabetic eye complications

- Developed for companion animals under FDA INAD 11-785
- Need CMC for completion and final FDA approval, then transition to humans



OTC topical nutraceutical formulation containing patented ingredients that mirror the biological activity of our preclinical neuroprotective multifunctional redox modulators (MFRMs) in the eye

- Licensed to CLC Medica for the veterinary market as Optixcare Eye Health
- Treats tear flow in dry eye, delays cataracts, removes tear stain in dogs
- Shows dry eye treatment potential in human volunteers



Neuroprotective drugs for vision and hearing loss are in the pipeline

- Novel MFRM drugs represent an entirely new class of therapeutics

IP Protection

Kinostat®

US Patent 8,158,667: April 17, 2012
US Patent 9,308,165 : April 12, 2016
Patent obtained for Canada, Japan, China,
India, EU - UK, Germany, France, Italy, Spain,
Switzerland
Trademarked Kinostat

MFRM

US Patent 9,173,915:
November 3, 2015
Patent obtained for Canada,
Japan, China, India,
EU - UK, Germany, France,
Italy, Spain, Switzerland

Antioxidant Nutraceutical

US Patent 9,173,915: Nov. 3,
2015
Patent obtained for Canada,
Japan, China,
EU - UK, Germany, France,
Italy, Spain, Switzerland

NIH Validation and Commercial Success

Grants

NIH 1R21 EY016460-01; NIH 1R21 EY023679-01
NIH SBIR NIH 1R43 EY018013-01A ; 2R44 EY018013-02A ; 2R44 EY018013-2B; 1R21 EY023679-01
NIH Regulatory Assistance Consultation, NIH Sponsor to Bio2016 Conference; CAP Development Grant;
State of Nebraska SBIR Phase 1 and 2 Matching Grants

FDA Funding

Fee waivers, MUMS designation, Submission fee waivers

Research Contracts

Johnson and Johnson Pharmaceutical Company; Aventix Animal Health;
Vertex Pharmaceutical Company

Revenues

CLC Medica

The Problem

Within the first year of diabetes, 75% of dogs will develop blinding cataracts

- **Restoring vision requires costly cataract surgery because no drug can reverse or dissolve cataracts**

What if there was another cost-effective way?

The Problem

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Our Solution

Kinostat[®] brings a new paradigm to maintaining vision in diabetic dogs

Kinostat[®] Clinical Trial Results

Results from a 9-Month, Placebo Controlled, Multi-Center Clinical Trial Under FDA INAD 11-785 have shown that in the treatment according to protocol analysis of 44 placebo and 83 Kinostat[®] treated dogs

- **Kinostat[®] treated dogs are 85% less likely to develop cataracts compared to those treated with placebo**
- **Kinostat[®] treated dogs are 84% less likely to develop dry eye compared to those treated with placebo**

After the 9-month FDA trial, all remaining diabetic dogs with no cataracts were enrolled in a long-term compassionate use study where they received Kinostat[®] for the remainder of their life

- **Kinostat[®] maintained vision for up to 8 years in these diabetic dogs with no adverse side effects**

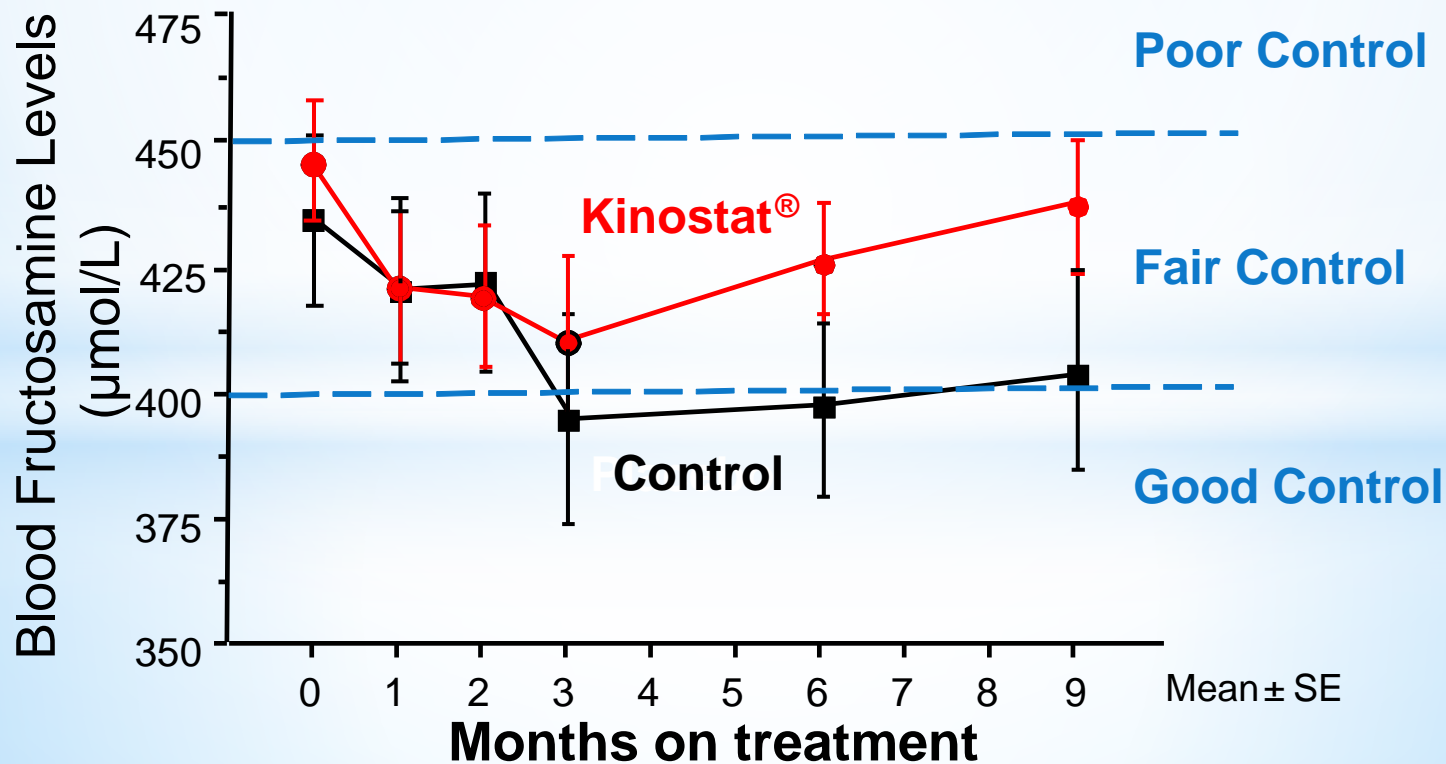
The Development of Ocular Diabetic Complications are Linked to Blood Sugar Levels (Hyperglycemia)

*The higher the blood sugar levels, the faster the onset
and progression of the diabetic complication*

That is why tight blood sugar control is so important

Kinostat[®] reduces the onset and progression of diabetic complications by blocking the metabolism of excess glucose to sorbitol

There was no significant difference in blood sugar levels between the Kinostat[®] and the placebo group

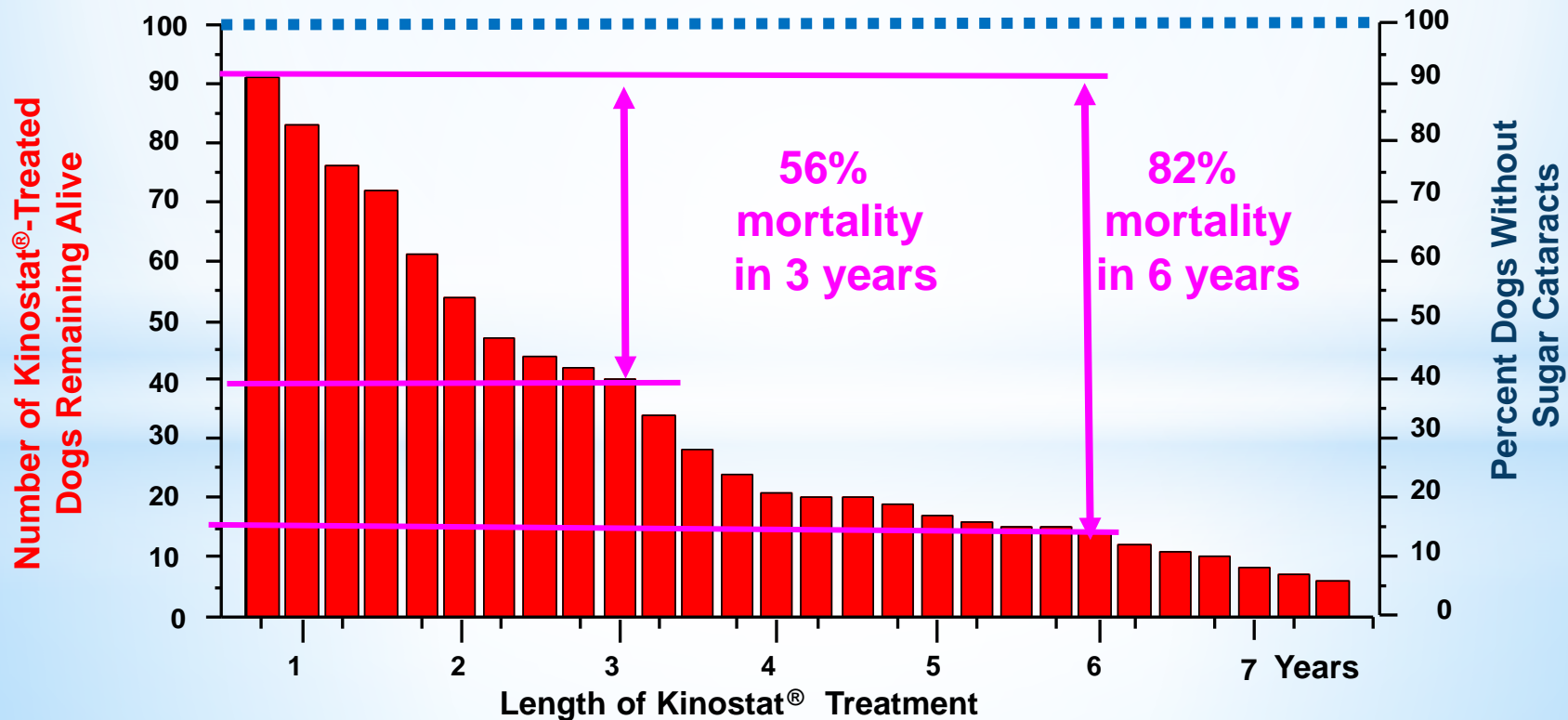


Dogs which develop diabetes:

- Are generally between 7-9 years of age
- Generally live an additional 3 years with diabetes

Kinostat[®] Treatment Maintained Vision in Diabetic Dogs for up to 8 Years, Independent of Blood Sugar Levels

Long-Term Compassionate Use Study Kinostat[®]-Treated Diabetic Dogs Without Blinding Cataracts



Kinostat[®] will be the first FDA Approved Topical Aldose Reductase Inhibitor

Kinostat[®] is the *first and only drug that has been clinically shown to prevent vision loss from cataracts and directly reduce dry eye formation* in diabetic dogs.

The FDA has given Therapeutic Vision provisional approval to market Kinostat[®] following completion of the Chemistry, Manufacturing and Controls submission (CMC) and a required bridging study.

- There is *no commercial competition* in either the animal or human market.
- Our FDA MUMS designation *gives us 7 years of exclusive marketing in the US.* We have 23 years of patent coverage remaining.

Initial Veterinary Sales & Marketing Models for Kinostat®

The veterinary market for Kinostat® in the US, EU, Canada, Australia, Japan and Brazil is estimated at over \$100 million.

Marketing in North America and Europe will be conducted by Aventix Animal Health, Burlington, Ontario, Canada

Note: The bottle sizes represent a one month's supply. The initial price manufacture / bottle should drop significantly as production for human product comes on stream.

Product Size	10 mL Bottle**	12 mL Bottle***
Manufacturing Cost to TVI	\$7.00	\$8.00
TVI Profit Dollars	\$14.00	\$16.00
Profit Margin	67%	67%
Cost to Aventix/CLC Medica (Master Distributer)	\$21.00	\$24.00
Aventix/CLC Medica Profit Dollars	\$13.00	\$15.00
Profit Margin	38%	38%
Cost to Subdistributer / Wholesaler	\$34.00	\$39.00
Subdistributer / Wholesaler Profit Dollars	\$5.00	\$6.00
Profit Margin	13%	13%
Cost to Veterinarian	\$39.00	\$45.00
Veterinarian Profit Dollars	\$39.00	\$45.00
Profit Margin	50%	50%
Monthly Cost to Customer	\$78.00	\$90.00
36-Month Cost* Compared to \$ 6,000 Surgery	\$2,808	\$3,240
* Est. life-span of dogs is 36 months after diagnosis of diabetes mellitus	** careful administration	*** found optimal in clinical trial

After veterinary commercialization, Kinostat[®] will transition to human KinoStat for the treatment of:

Diabetic Keratopathy and Diabetic Dry Eye Disease

- Loss of corneal sensation, delayed wound healing and loss of corneal clarity are reversed by aldose reductase inhibitors.
- The chance of developing dry eye disease increases to 50% in diabetics.

\$2 billion market with over 15% annual expected growth.

LASIK Surgery

- LASIK surgery is contraindicated in diabetics by the FDA because of the problems associated with diabetic keratopathy.

\$750 million market for prophylactic treatment before and after LASIK surgery, and DED treatments in diabetics.

- Potential orphan drug?

2021 ↔ 2022 ↔ 2023 ↔ 2024 ↔ 2025 ↔ 2026 ↔ 2027

Funding
obtained

Chemistry Manufacturing
and Controls (CMC)

Bridging Study

Plan Keratopathy and DED Trials
and Obtain IND Application

Kinostat[®]
on Market

Human Trials

Submission
for FDA
Approval

CMC Timeline for Veterinary Commercialization

2021 Funding obtained; RFP for manufacture

2022 Initial 1/10 size validation batch completed

2023 Validation for final formulation, bottled and packaged; sterility and shelf life validated
CMC report compiled and submitted to FDA; Bridging study initiated and completed

2024 Kinostat[®] approved; Full size commercial batch completed; product launched

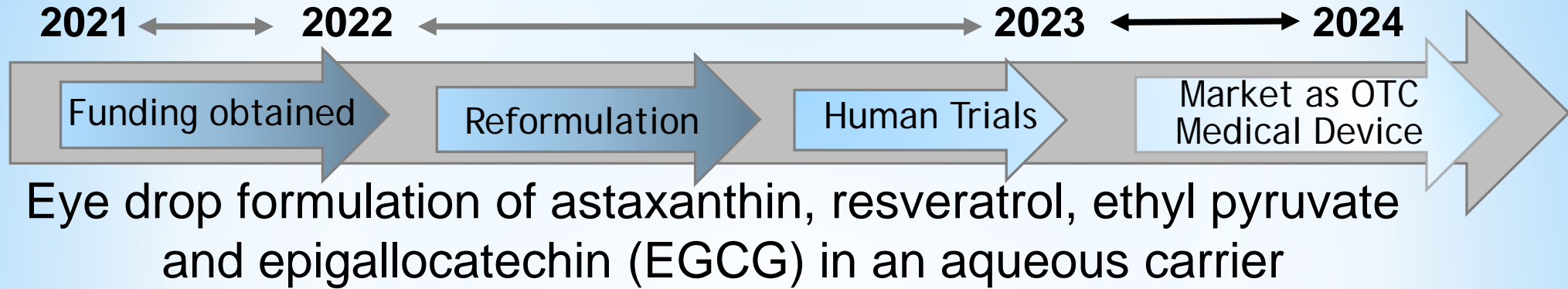
Transition to Humans (KinoStat)

2022 Plan clinical trials with ORA Clinical; explore possibility of Orphan Drug Status

2023 Obtain IND from FDA for Diabetic Keratopathy which includes DED using established endpoints; plan LASIK trial; begin Keratopathy trials

2024-2026 Finish trials, initiate LASIK trial based on Keratopathy results

2027 Submit results to FDA for approval



- For symptomatic relief of DED including eye inflammation, irritation and excess tearing
- Reduces oxidative stress and inflammation (free radical scavenging agents, anti-irritants and metal chelators)
- Nutraceutical (with potential reformulation into a stronger prescription medication) in a market size of \$2 billion in US, \$4 billion worldwide
- Competes with products from multiple manufacturers in the eye care section of drug store shelf space including nutraceutical brands, lubricants, artificial tears (all without claims) and several OTC pharmaceuticals (with claims)

Therapeutic Vision products are poised to enter the \$5+ billion market for dry eye disease, diabetic keratopathy, and cataract.

Therapeutic Vision, Inc seeks \$ 10.5 million in funding. These funds will be used to establish GMP production necessary to manufacture the Therapeutic Vision's products and launch marketing and selling efforts

Kinostat® (\$ 3.5 M)

- Complete CMC, conduct bridging study, finalize submission for FDA approval

TheraVision Eye Health Drops (\$ 1 M)

- Reformulate nutraceutical Optixcare Eye Health for human application
- Conduct proof of concept masked clinical trial of 50 patients for OTC market

KinoStat® Corneal Care Eye Drops and KinoStat® Surgical Care Eye Drops (\$ 4 M)

- Using Ora Ophthalmology CRO, conduct clinical trial evaluating diabetic keratopathy and subsequently LASIK study in diabetics

Multifunctional Redox Modulator (\$ 2 M)

- Conduct GMP preparation of our candidate drug, HK-2, for all subsequent studies including preclinical PK/PD, toxicology, safety and additional animal efficacy studies required for the IND application

Our Team Leaders



Peter F. Kador, Ph.D., F.A.R.VO., F.A.O.P.T., F.A.A.P.S.
Founder, President/CEO.
Former Chief of the Lab. of Ocular Therapeutics, NEI/NIH and Professor of Pharmaceutical Sciences and Ophthalmology at UNMC



Milton Wyman, M.S., D.V.M., D.A.C.V.O., is the Senior Veterinary Ophthalmologist. Professor Emeritus from the Ohio State University College of Veterinary Medicine; Founding member of MEDVET Animal Hospital .



Manley A. Paulos, Ph.D.
Served as Medical Director (Merrell-Dow); Director, Clinical and Regulatory Affairs (Bayer) President, Premier Research (CRO), and Komodo Pharma Services (drug delivery systems manufacturing).



Vince Bellavia, B.Sci., M.B.A.
President and CEO of AVENTIX Animal Health Corp.

Upon funding, Therapeutic Vision will immediately recruit an entrepreneurial CEO with relevant pharmaceutical company experience and conduct key hires that include a Vice President of Sales and Marketing, and Director of Medical, Clinical and Regulatory Affairs to guide the Company's clinical development.

Our Future

Within 10 years Therapeutic Vision, Inc. plans to be **the leading developer of new, veterinary ophthalmic drugs**. While we strive to become the leader in the discovery, development, manufacture, and marketing of therapeutics for the treatment of the anterior segment diseases of the eye using our novel aldose reductase and redox-based therapeutics, we also will seek a strategic partner for the development of our novel neuroprotectants for retinal disorders, glaucoma and hearing loss.

Thank you for your interest and support!

Visit us at **therapeuticvision.com** for more information