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Disrupt Ophthalmology & change patients' lives.

20 / 03 / 2023

Agoranov · Medicen Paris Region · WILCO · bpifrance Servir l'avenir · ESSEC Ventures · Université de Lorraine · eit Health · Institut de la Vision

Lack of compliance: #1 unmet medical need in Ophthalmology (1)

IMPROVING THE EFFICACY OF EYE TREATMENTS

Prof. J.F. KOROBELNIK
M.D., Ph.D.

Most patients regularly ***forget about their eye drops,*** *favoring disease progression*

RETINA FRANCE

Frequent & unpleasont injections *cause patients to* ***cease treatment***

IRREVERSIBLE VISION LOSS

45% of patients do not adhere to their treatment (2)

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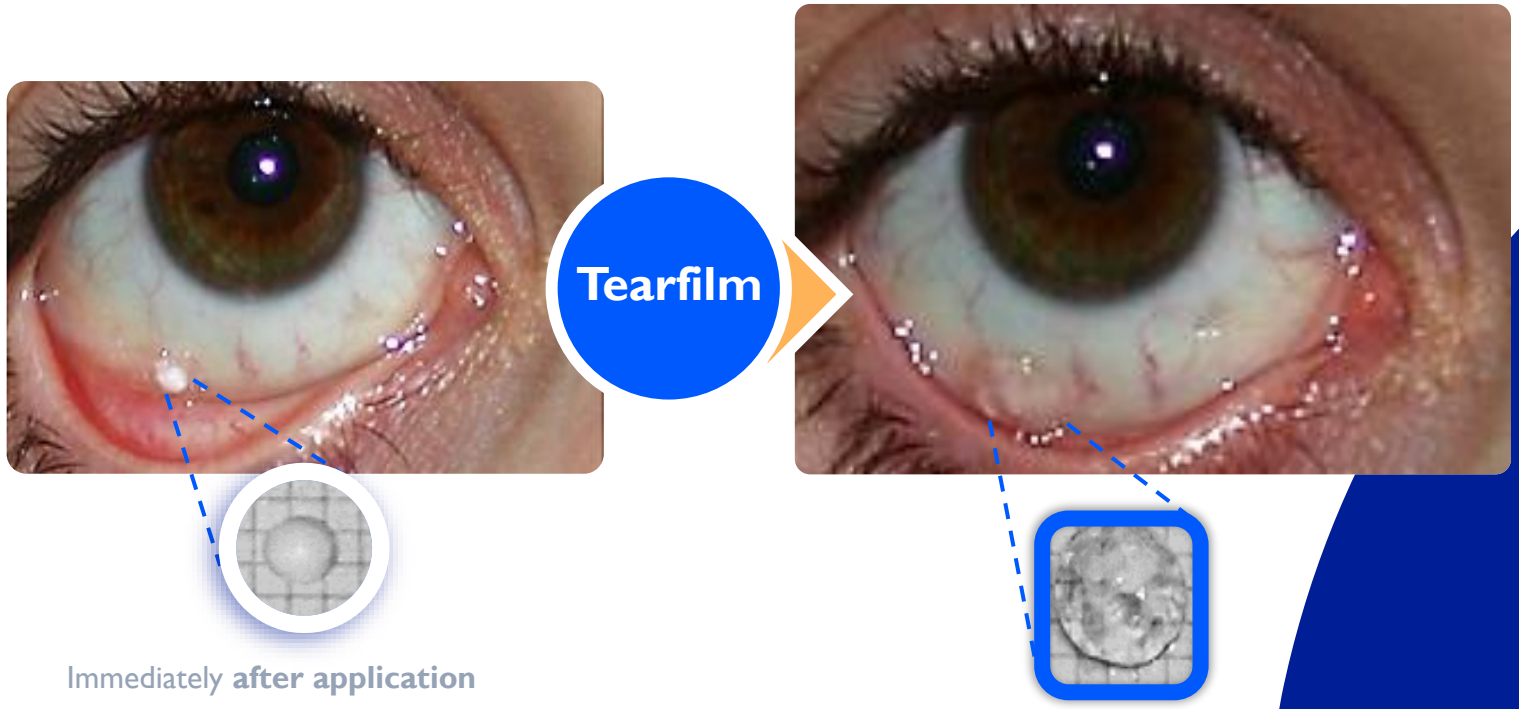
(1) Survey on 85 international ophthalmologists – Global Data 2017

(2) Okeke et al. – Ophthalmology Feb. 2009

Developing a new standard of care for ocular diseases

BREAKTHROUGH BIOPOLYMERS TECHNOLOGY THAT RELEASES DRUGS ON THE EYE



Immediately **after application**

After **several hours**

1. Easy to apply & Comfortable
2. *in-situ* Gelation & Strong adhesion
3. 7 days of continuous Drug Delivery

3 families of patents :

- **patent #1:** WO2011/039259
- **patent #2:** 2020/02 EP 20 305 118.0
- **patent #3:** 2021/08 EP 21 306 084.1

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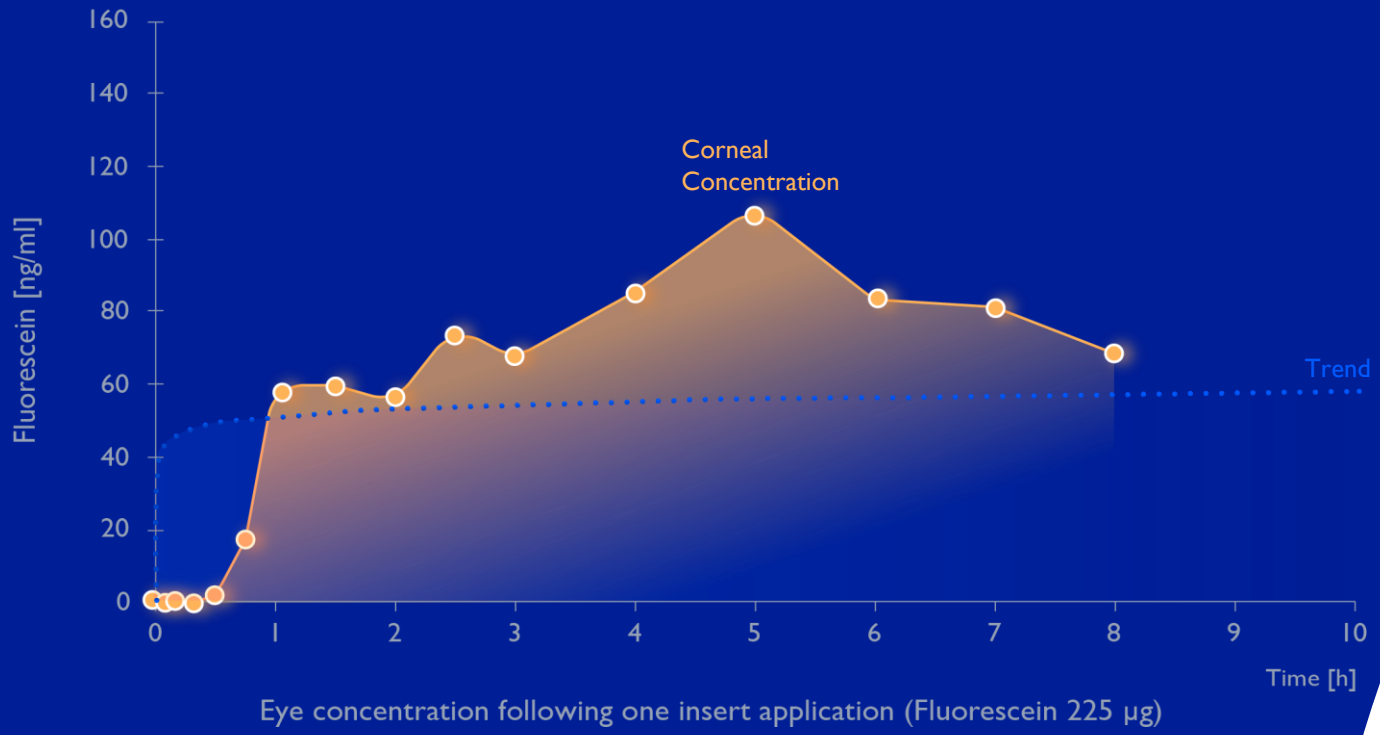
Our biopolymer inserts provides a sustained release of drug

proof of concept study
(14 participants)



Eye concentration following one insert application (Fluorescein 225 µg)

93%
LONG-TERM ACCEPTANCE

VERY GOOD TOLERANCE

CONTINUOUS DELIVERY

Source: research by Hornof et al.

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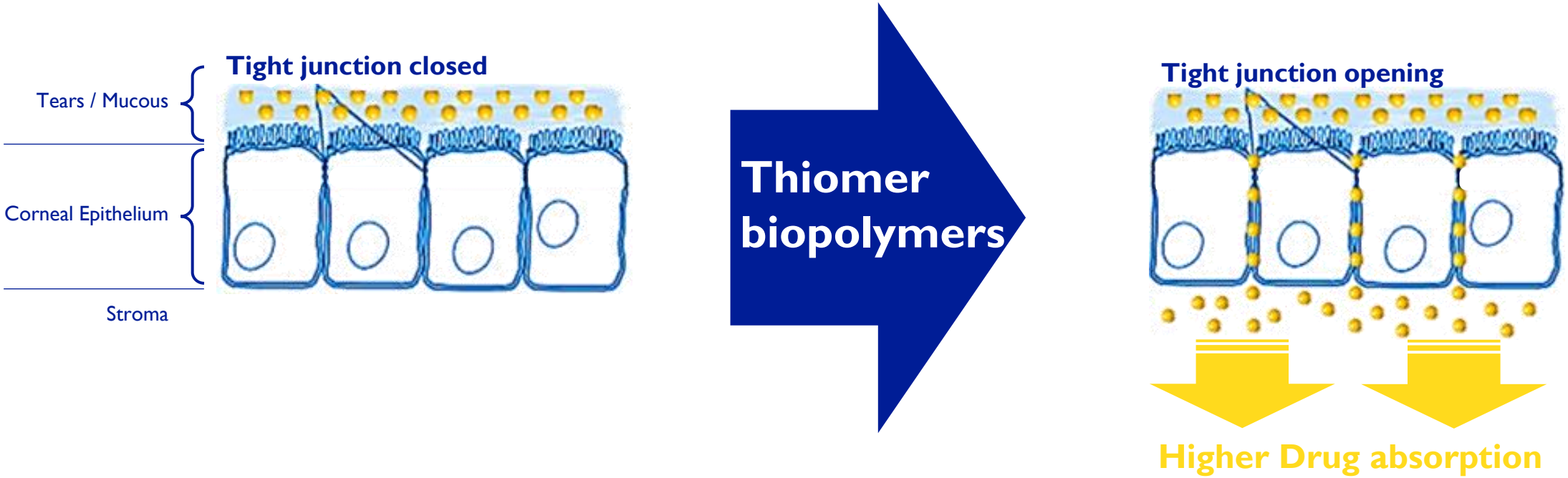
Topical treatment for treating retinal diseases

ENHANCED DRUG PERMEATION THROUGH THE EPITHELIUM



Increased Drug penetration boost the build-up of a Drug concentration gradient :

Greater Drug concentration for treating the back-of-the-eye

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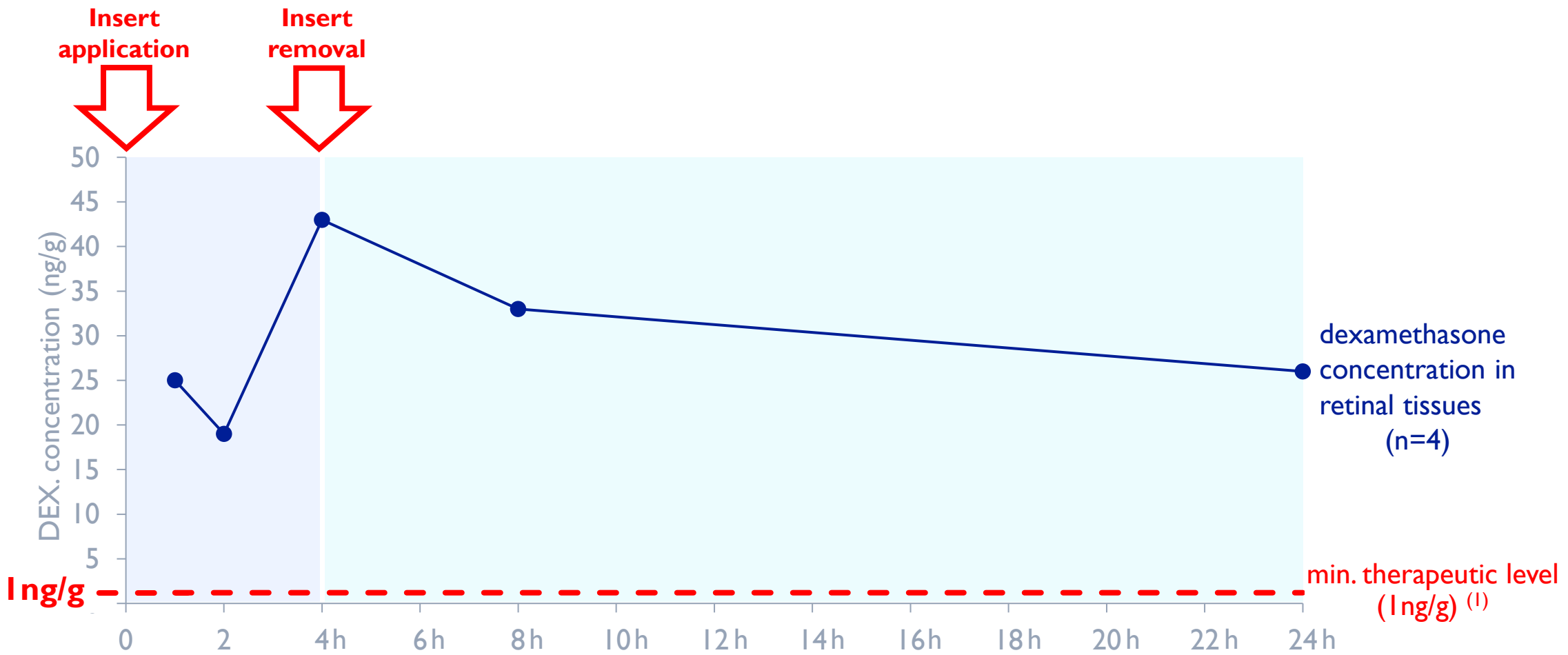
Insert quickly creates a therapeutic level at retina

DEXAMETHASONE PHARMACOKINETIC 24H EXPLORATORY STUDY



(1) Whitcup SM et al. Invest Ophthalmol 2018

The only topical treatment to generate a superior outcome

THE FIRST ONE-WEEK SUSTAINED RELEASE & NON-INVASIVE TREATMENT

TOPICAL

Ocular Insert

New eye drops

INJECTIONS

	Ocular Insert	New eye drops	Long-acting implants	Injection Devices	New biologic Drugs	Long-acting Gel Solutions
Companies	biophta	NOVALIQ Oculis	Allergan, ALIMERA SCIENCES	CLEARSIDE BIOMEDICAL	NOVARTIS, BAYER	graybug, RE·VANA
Better Eye tissues penetration	✓	✓	✓	✓	✗	✗
Prolonged Duration of Action	✓	✗	✓	✗	✓	✓

1. Topical, **non-invasive form**
2. **One-week** prolonged duration of action
3. **Increased drug penetration** in eye

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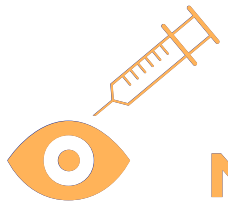
Retina : a disruptive non-invasive therapy for DME

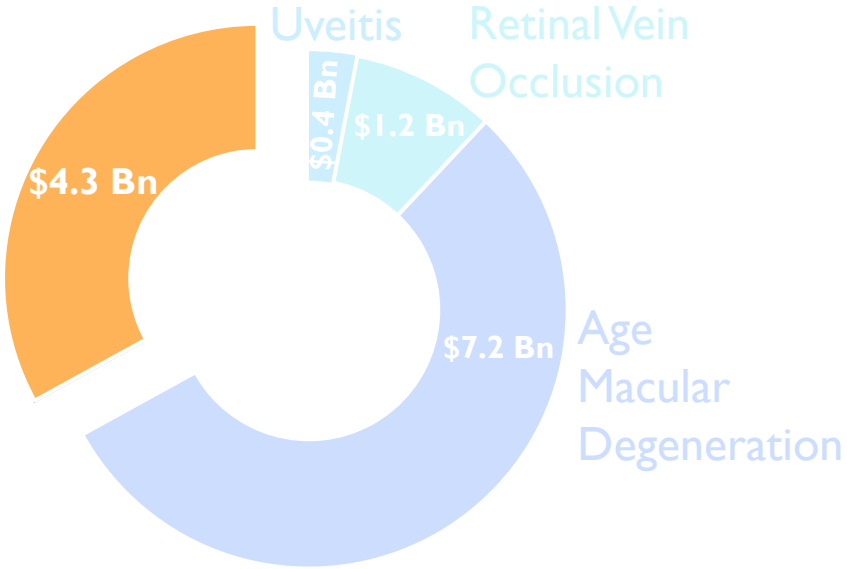
TOPICAL TREATMENT OF DIABETIC MACULAR EDEMA



Diabetic Macular Edema

1.5m diagnosed patients worldwide

→ regular injections of anti-VEGF / Steroids



Total Retina market :

- **$13 Bn globally**
- **11% CAGR**

Replacing frequent injections by one-week non-invasive ocular insert

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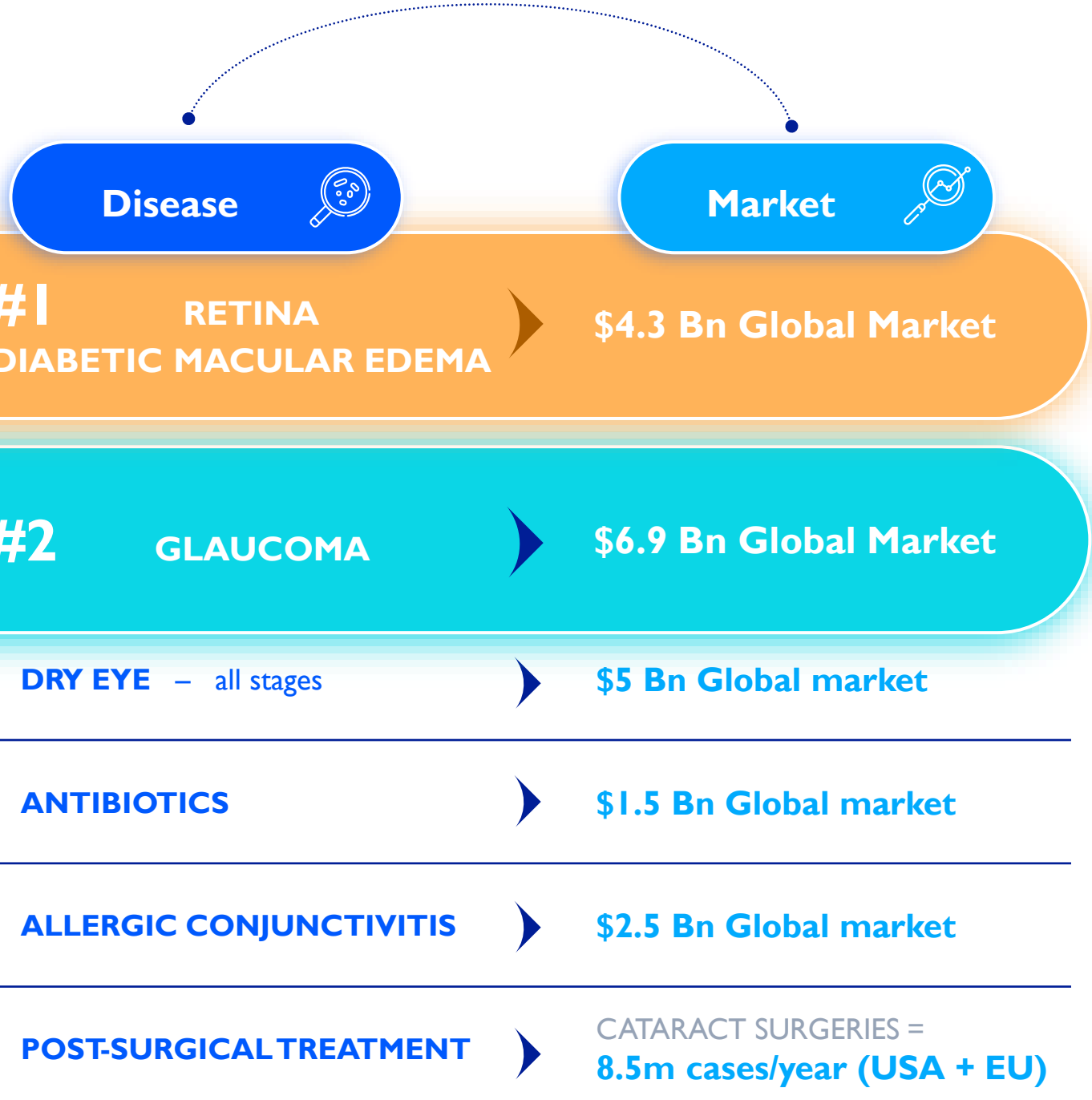
Source: Market Scope 2020

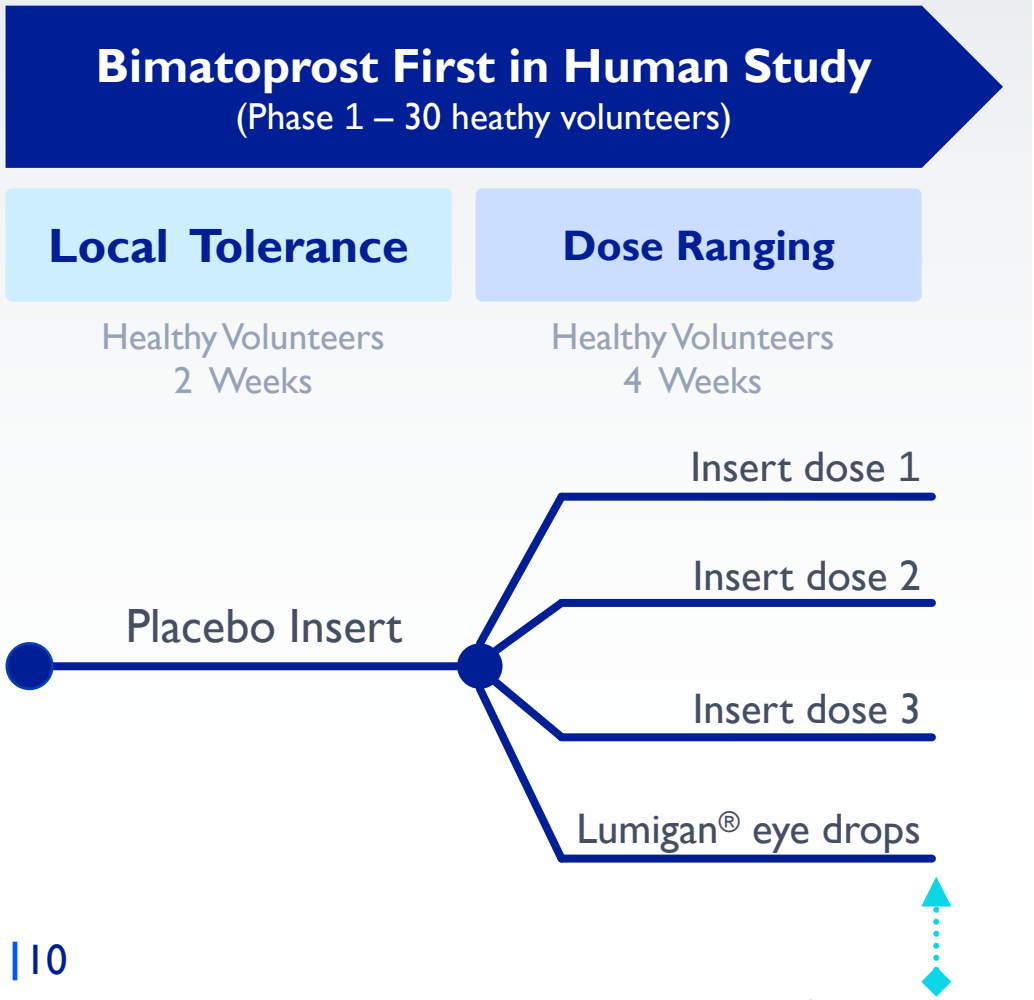
Our drug delivery platform has the ability to be used in multiple treatments.

ONGOING DISCUSSIONS WITH
5 OPHTHA. PHARMA COMPANIES.



Why start with Glaucoma ?

ABRIDGED DEVELOPMENT PATHWAY ALLOWS PHASE 1 STUDY ALREADY IN 2024



1. First-in-Human trial enables validation of delivery platform
2. Glaucoma indication allows direct comparison to an in-market product : fast track FDA pathway
3. 7-day drug delivery efficacy for reducing the IOP *

1st product outlicensing

(*) : IOP = Intra-Ocular Pressure

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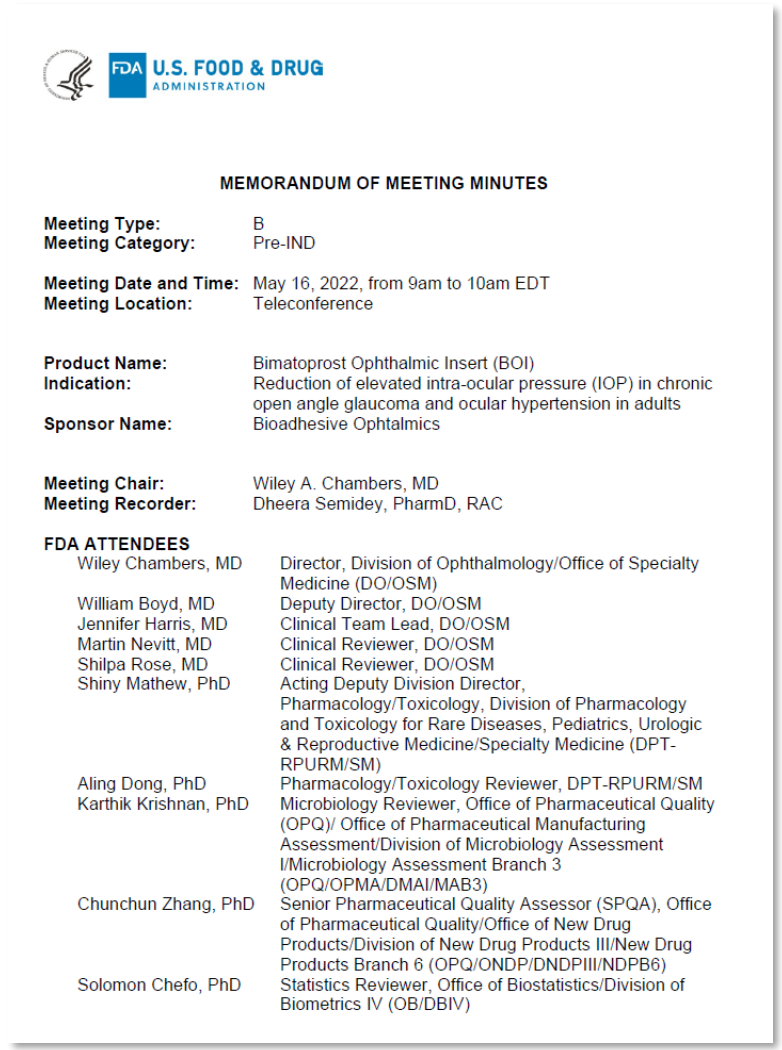
The FDA has validated our roadmap

POSITIVE FEEDBACK DURING pre-IND MEETING IN MAY 2022



U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM OF MEETING MINUTES

Meeting Type: B
Meeting Category: Pre-IND

Meeting Date and Time: May 16, 2022, from 9am to 10am EDT
Meeting Location: Teleconference

Product Name: Bimatoprost Ophthalmic Insert (BOI)
Indication: Reduction of elevated intra-ocular pressure (IOP) in chronic open angle glaucoma and ocular hypertension in adults
Sponsor Name: Bioadhesive Ophtalmics

Meeting Chair: Wiley A. Chambers, MD
Meeting Recorder: Dheera Semidey, PharmD, RAC

FDA ATTENDEES

Wiley Chambers, MD	Director, Division of Ophthalmology/Office of Specialty Medicine (DO/OSM)
William Boyd, MD	Deputy Director, DO/OSM
Jennifer Harris, MD	Clinical Team Lead, DO/OSM
Martin Nevitt, MD	Clinical Reviewer, DO/OSM
Shilpa Rose, MD	Clinical Reviewer, DO/OSM
Shiny Mathew, PhD	Acting Deputy Division Director, Pharmacology/Toxicology, Division of Pharmacology and Toxicology for Rare Diseases, Pediatrics, Urologic & Reproductive Medicine/Specialty Medicine (DPT-RPURM/SM)
Aling Dong, PhD	Pharmacology/Toxicology Reviewer, DPT-RPURM/SM
Karthik Krishnan, PhD	Microbiology Reviewer, Office of Pharmaceutical Quality (OPQ)/ Office of Pharmaceutical Manufacturing Assessment/Division of Microbiology Assessment I/Microbiology Assessment Branch 3 (OPQ/OPMA/DMAI/MAB3)
Chunchun Zhang, PhD	Senior Pharmaceutical Quality Assessor (SPQA), Office of Pharmaceutical Quality/Office of New Drug Products/Division of New Drug Products III/New Drug Products Branch 6 (OPQ/ONDP/DNDPIII/NDPB6)
Solomon Chefo, PhD	Statistics Reviewer, Office of Biostatistics/Division of Biometrics IV (OB/DBIV)

Dr. Wiley CHAMBERS – FDA, head of ophthalmology accepted BIOPHTA's plan for :

REGULATORY	Abridged registration pathway
CMC	Control strategy for the drug & Thiomer biopolymer
NON-CLINICAL	Preclinical trials & NC plan for Phase 1 study authorization
CLINICAL	Phase 1 First-in-Human study design & overall clinical plan

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BIOPHTA 3-step strategy

step 3

ASO – topical Gene therapy

- Vectorization of Antisens Oligonucleotides (ASO) for the treatment of retinal inherited diseases

step 2

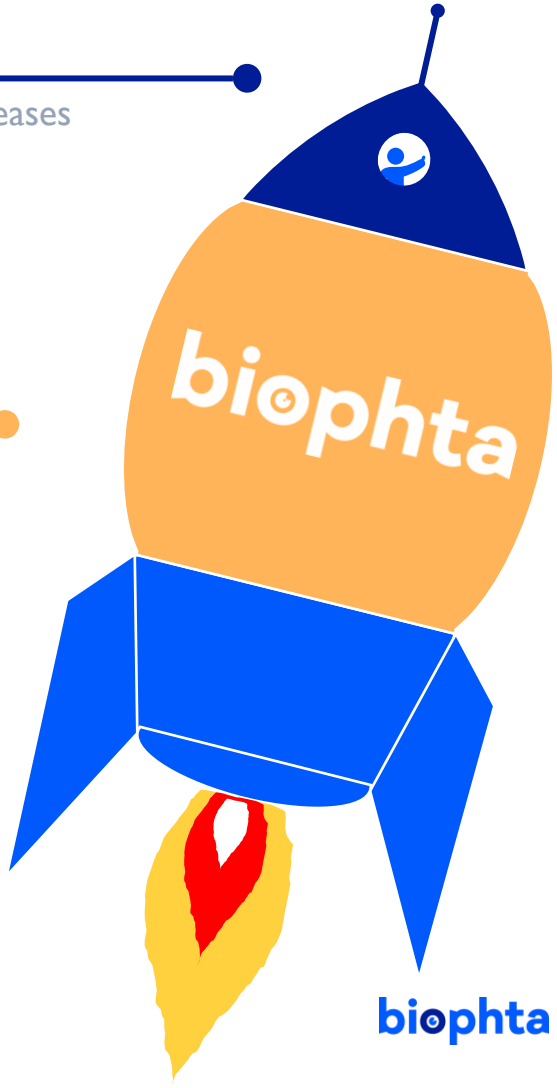
Retina – replacing intraocular injections

- First self-applied treatment allowing one-week of sustained Drug release

step 1

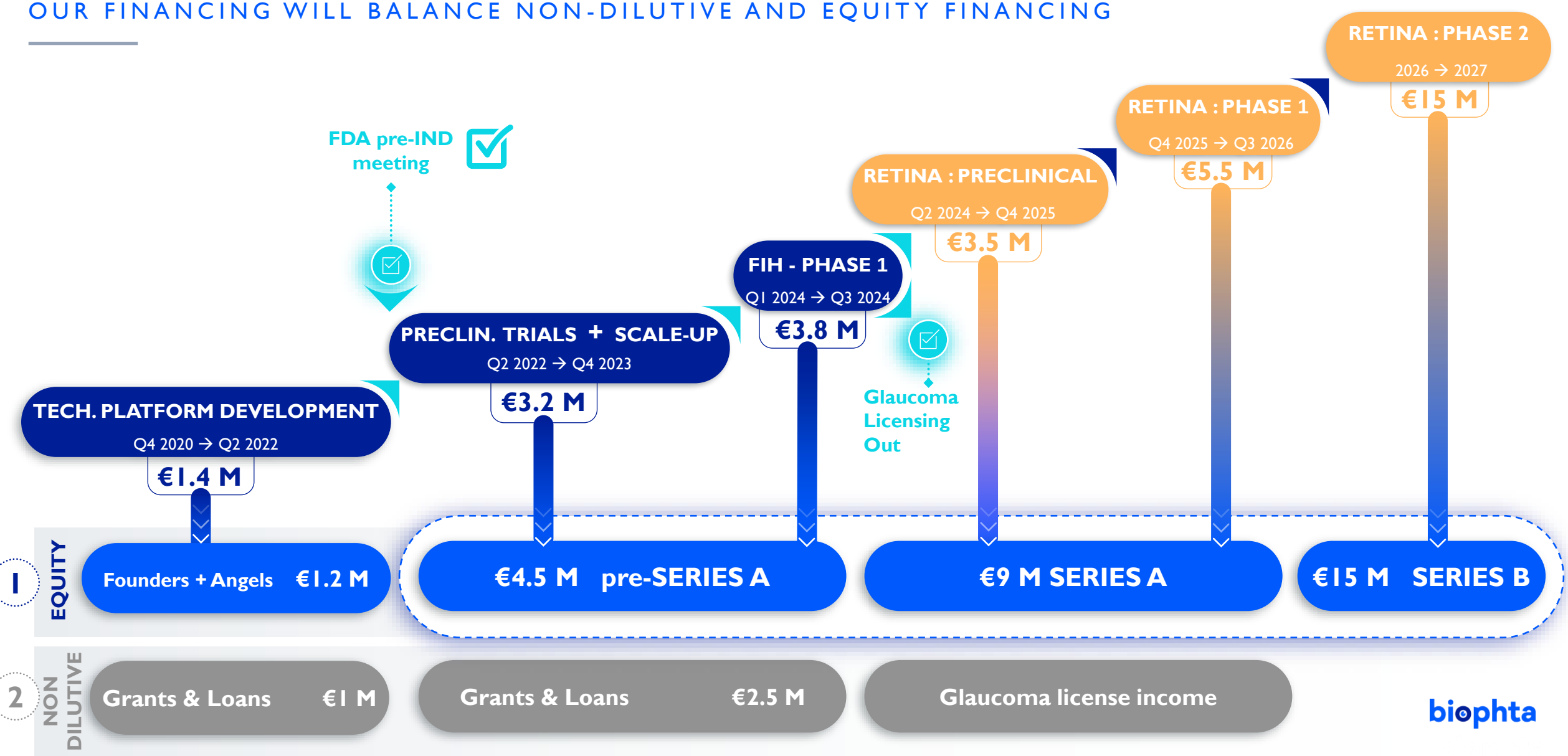
Glaucoma – platform validation

- 7-Days continuous treatment enables an accelerated pathway to First-in-Human



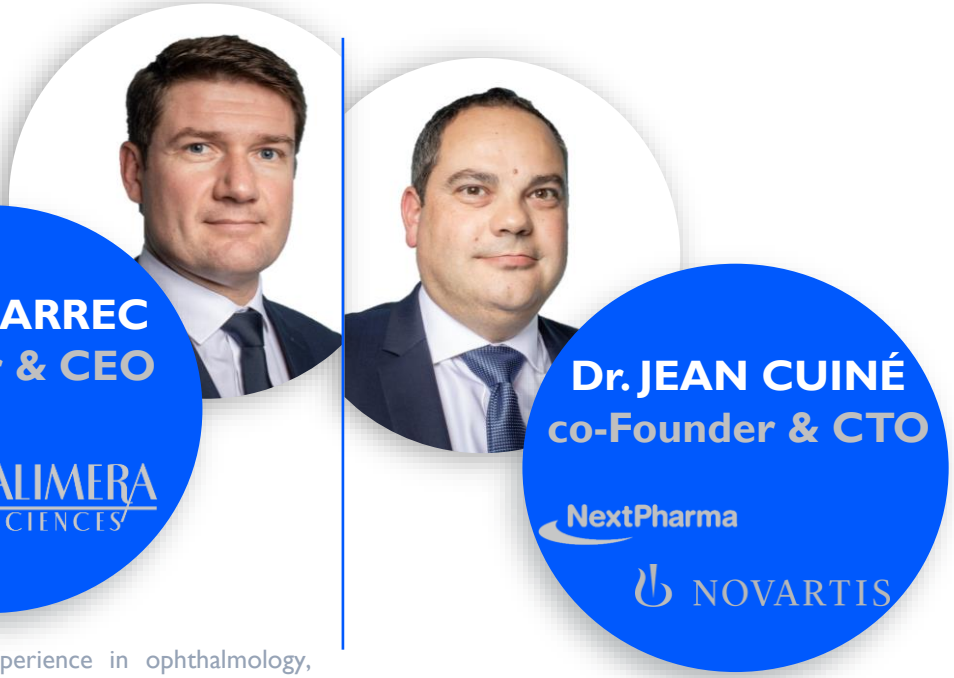
Financing phased on our R&D program needs

OUR FINANCING WILL BALANCE NON-DILUTIVE AND EQUITY FINANCING



Multi competent team developing game changing technology

HIGHLY COMPLEMENTARY CO-FOUNDERS



JEAN GARREC
Founder & CEO

Moria ALIMERA SCIENCES

Over 15 years experience in ophthalmology, excellent understanding of the market, challenges and players in eye pharmaceuticals. Several experiences of general management for building and steering compagnies provided him the required expertise for this venture.

Dr. JEAN CUINÉ
co-Founder & CTO

NextPharma NOVARTIS

Former biopharmacy researcher (University of Strasbourg & Monash University) followed by more than 15 years developing new drugs in the industry. His professional background gave him the experience of industrializing complex manufacturing processes to GMP grade.

ACADEMIC PARTNERS

INSTITUT DE LA VISION

Founded by Prof. José SAHEL, leading European research center on eye and retinal diseases.
INSERM – CNRS

UNIVERSITÉ DE LORRAINE

Research team specialized in biopolymers chemistry and galenic formulation.

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TRANSFORM OPHTHALMOLOGY

CHANGE PATIENTS LIVES

1

Unique non-invasive insert
7 days of continuous Drug Delivery

2

A platform addressing a $30 Bn market

3

€4.5 M
To achieve First in Human Study

info@biophta.com