



Cloudbreak<sup>TM</sup>  
Pharma

An Innovative Biotech  
with a Robust R&D Engine  
for the Development of  
First-in-Class and Best-In-Class  
Ophthalmic Drugs

[Partners@CloudbreakPharma.com](mailto:Partners@CloudbreakPharma.com)

# Forward-looking statements



This presentation contains forward-looking statements regarding the future performance, plans and prospects of **Cloudbreak Pharma, Inc.** (with effect from 3 July 2025, shares listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**HKEX**”)).

These statements may include research and development (R&D) activities, clinical trial progress and outcomes, regulatory submissions, timelines and approvals, manufacturing and supply operations, product launches and partnerships and/or financial outlook and business strategy.

Statements are based on management’s current expectations and assumptions. Actual results may differ due to various factors, including clinical or regulatory outcomes (e.g., US or other markets), competitive developments and market dynamics, and/or economic or operational uncertainties.

Cloudbreak Pharma, Inc. undertakes no obligation to update or revise any forward-looking statements, except as required by law. The information contained in this presentation may not be complete and may not contain all particulars required to be disclosed by us under the Rules Governing the Listing of Securities on the KHEX and the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

Investors or interested parties should review our public filings with the HKEX and our company’s website ([cloudbreakpharma.com](https://cloudbreakpharma.com)) for additional information.

# Cloudbreak Pharma (HKEX: 2592)

We are the Biotech R&D Engine for best-in-class ophthalmic drugs



**Our lead technology, Multi-Kinase Inhibitors (MKI)**, is de-risked with human clinical results and uniquely suitable for both front-of-eye and back-of-eye diseases.

Under the MKI platform, **our lead asset, the eye drop CBT-001**, is in mid-Phase 3 in multiple regions for the treatment of pterygium, a disease impacting 15 million people in the US alone. **CBT-004**, also an eye drop and our second asset, is entering Phase 3 for pinguecula, a disease impacting about half of all people over age 70.

*CBT-001 and CBT-004 will potentially be the first and only FDA-approved drug therapies for these high-value conditions*

**We have additional high-value technologies** with pre-clinical through Phase 2 product candidates.

**Our team of experienced ophthalmologic scientists and business professionals** is uniquely qualified to bring product candidates from pre-clinical to NDA approval.

We are seeking **investors to support our high-value development program** while actively **engaging with strategics to commercialize** and maximize the value of our clinical assets.

# Leadership team with extensive industry and scientific expertise



## Founder and CEO



**Jinsong Ni, PhD**

**Founder and Chief Executive Officer**

- 30+ years of experience
- Expertise in discovery, development, clinical trials and product registration



## Business Team



**Michael Rowe, MSc**  
**Chief Business Officer**

- 35+ years of experience
- Expertise in global asset partnering in eye care with Leadership Roles at:



**Gregory Brooks, BSc**  
**Commercial Advisor**

- 35+ years of experience
- Expertise in marketing, sales health outcomes and business development



**Elizabeth Capan, JD**  
**Chief Compliance and Chief Patent Officer**

- 16+ years of experience
- Expertise in global IP strategy



## Scientific Team and Advisors



**Van Son Dinh, MBA**  
**Co-Founder and Chief Operating Officer**

- 26+ years of experience
- Expertise in CMC, formulation development and manufacturing



**Rohan Gandhi, PhD**  
**Medical Affairs Advisor**

- 20+ years of experience
- Expertise in translating pre-clinical biology into first-in-human studies in ophthalmology



**Rong Yang, PhD**  
**Chief Scientific Officer**

- 24+ years of experience
- Expertise in drug discovery, development and clinical trials



**Wen Kui Fang, PhD**  
**Chief Innovation Officer**

- 20+ years of experience
- Expertise in medical research of new and innovative drugs



**Abu Abraham, MD**  
**Chief Medical Officer**

- 14+ years of experience
- Expertise in clinical development and product registration



**Scott Whitcup, MD**  
**Scientific Advisor**

- Extensive experience in clinical development and product registration
- Former Allergan R&D Head



# Cloudbreak Pharma is focused on key technologies:

MKI (multi-kinase inhibitors) and SFA+ (semi-fluorinated alkane) delivery



Technology	Drug Candidate	Indication	Commercial Availability	Patent Status	Pre-clinical	Phase 1	Phase 2	Phase 3	Clinical Trial Authority	Regulatory Pathway	Status
MKI (PDGFRs, VEGFRs, FGFRs, PIGFRs, and/or TGF-β)	CBT-001	Pterygium (hyperemia, symptoms, size)	Global (Ex. China and Japan)	Granted US, EU, China, JPN, AUS, Brazil, CDN, S. Korea, Mexico, HK, Taiwan. Pending AUS, EU, JPH, S. Korea, HK	Phase 2 successfully completed (NCT03049852)				FDA NMPA	FDA 505(b)(2) NMPA chemical drug application	Results of first MRCT expected Q3 2026
	CBT-004	Pinguecula (hyperemia, symptoms)	Global	Granted US, AUS, S. Korea, CDN, JPN, Mexico. Pending ROW	Phase 2 successfully completed (NCT04884256)				FDA NMPA	FDA 505(b)(2) NMPA chemical drug application	Agreement reached with FDA for Phase 3 design
	CBT-007	Glaucoma surgery	Global	Granted US, China, JPN, AUS and S. Korea. Pending ROW							Deprioritized pending proof of concept evaluation
SFA+ Delivery	CBT-009 (muscarinic receptor agonist)	Pediatric Progressive Myopia	Global	Granted US, Japan. Pending ROW	Phase 1 in US not needed under 505(b)(2) pathway				FDA	FDA 505(b)(2)	IND in US accepted
	CBT-199 (Parasympathomimetic miotic agent)	Presbyopia	Global	Pending	Phase 1 in US not needed under 505(b)(2) pathway				FDA NMPA	FDA 505(b)(2) NMPA chemical drug application	IND submitted to US FDA for Phase 2 trial
	CBT-358 (TRPM8 agonist)	Aqueous-deficient PLUS evaporative dry eye	Global	Pending							Toxicity evaluation of potential clinical formulations in progress
	CBT-145	Presbyopia pro-drug	Global	Pending							Pending CBT-199 results
ADS (antibody – drug synergism)	CBT-011 (antibody drug synergism)	DME / age-related macular degeneration	Global	Pending							Evaluating formulation partners
Cholesterol dissolving agent	CBT-006	MGD associated dry eye disease	Global	Granted US, JPN. Pending ROW							Phase 2b study paused due to priority change

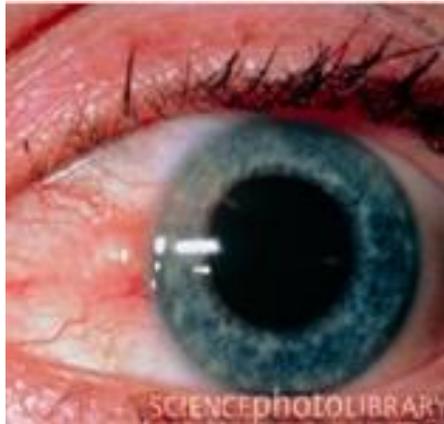
# Pterygium overview

A Disease impacting 15M people in the U.S. and with no FDA approved drug therapy



Pterygium is a **triangular fibrovascular growth on the cornea**, connected to the conjunctiva. It is **commonly caused by UV exposure** and can lead to redness, irritation, and **vision problems**.

Symptoms range from mild and painless, to sight-threatening



**MILD**

Painless area of raised white tissue  
Burning irritation/foreign body sensation/redness



**MODERATE**

More moderate burning irritation/ foreign body sensation/redness



**SEVERE**

Continued pterygium growth, affected/ impaired vision due to growth in cornea

**15M** People impacted by pterygium in the U.S.

**7.5M** Patients are seen by an eye doctor annually

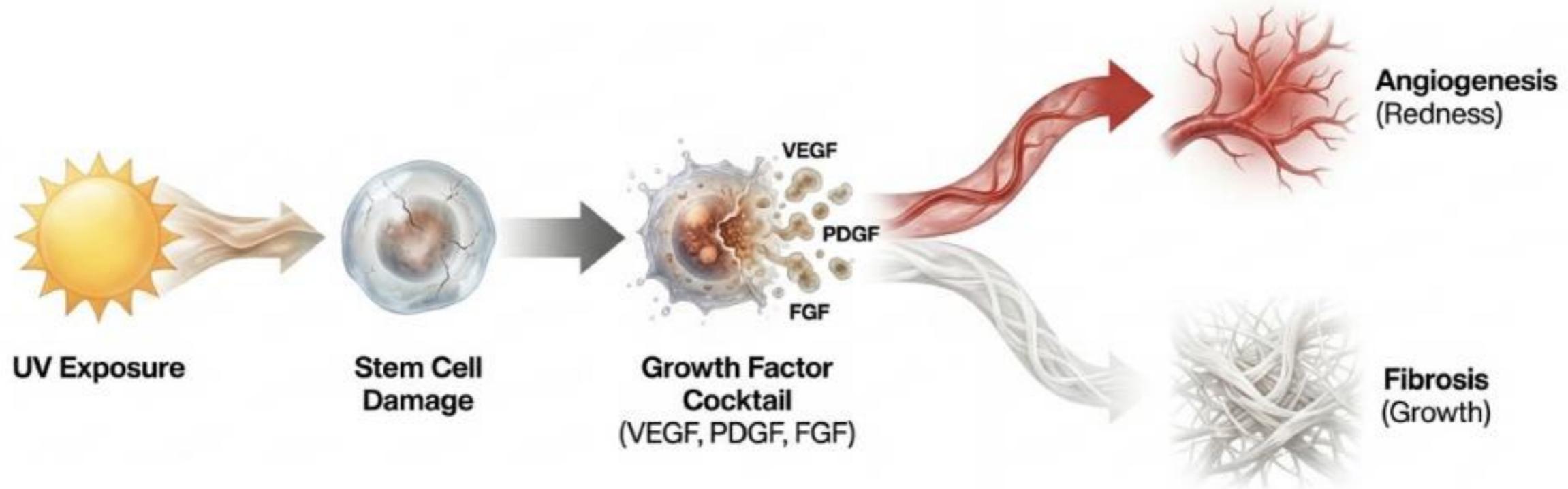
**3.7M** Diagnosed and treated as per ICD-10 by an ophthalmologist or medical optometrist

Most are treated for their symptoms using artificial tears, prescription dry eye products and/or NSAIDs and Corticosteroids *(all off-label and not impacting the root cause)*

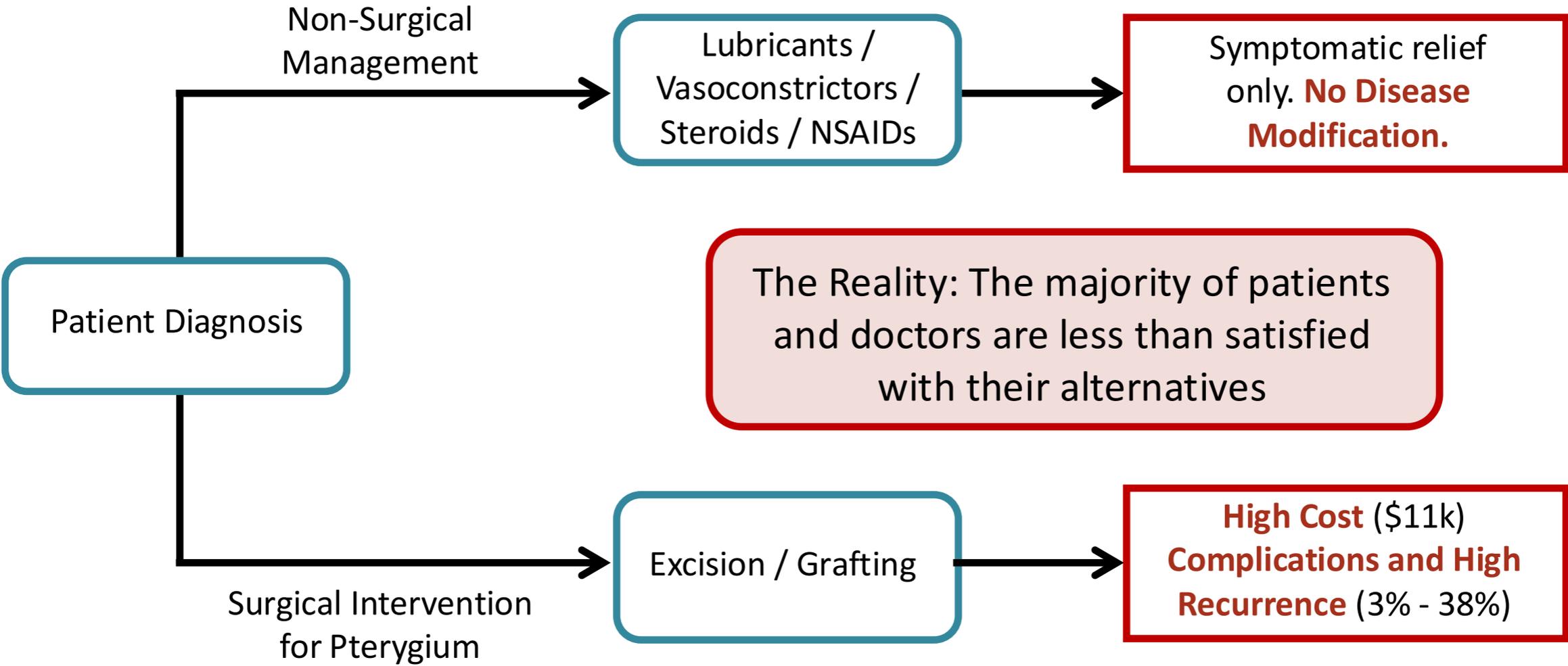
**100,000** Patients undergo surgery annually (Cost: \$11,500)

# Pterygium and Pinguecula are caused by abnormal fibro-vascular growth of a lesion on the surface of the eye

Environmental stress, such as excess UV light exposure, are thought to trigger the disease cascade



# Today, palliative treatment is all doctors can offer, short of surgery for pterygium



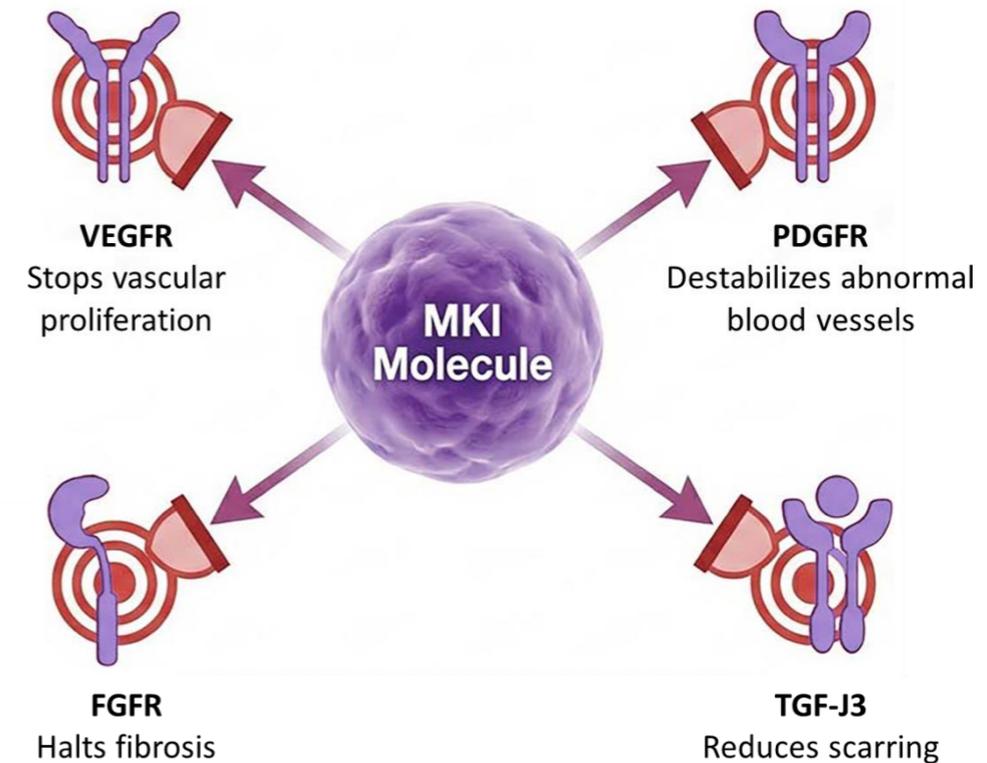
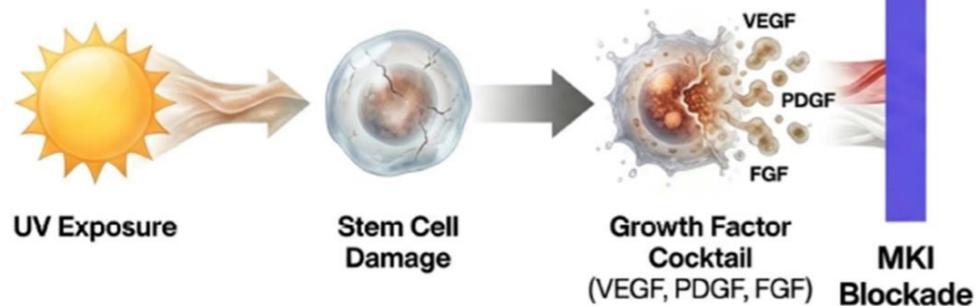
# Multi-kinase inhibitors are designed to address the root cause of these diseases

## Beyond Anti-VEGF:

Single-target drugs fail due to pathway redundancy.

**Mechanism of Action:** Simultaneous inhibition of multiple Receptor Tyrosine Kinases (RTKs).

MKIs are the only class that can interrupt both pathways simultaneously.



# CBT-001

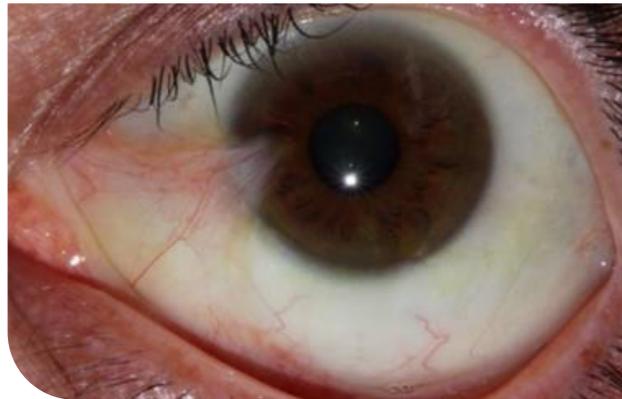
In a randomized, double-blind, placebo-controlled phase 2 clinical study, reduced pterygium vascularity, hyperemia score, and lesion length growth<sup>1</sup>

## A representative eye treated with CBT-001 (A137)



Day 1  
(grade 4)

↓ 50% Vascularity & Hyperemia Reduction in 4 Weeks



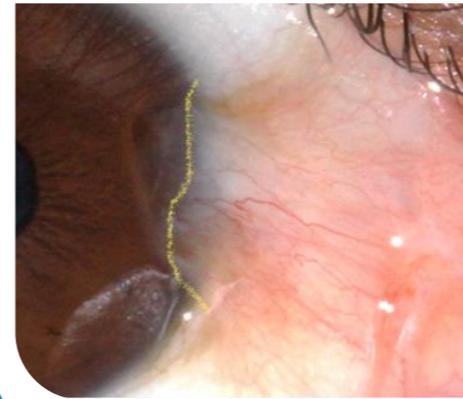
Week 4  
(grade 2)

## A representative eye treated with CBT-001 (A113)



Day 1

↓ 10% Corneal Lesion Length Reduction in 4 Weeks



Week 4

# CBT-001

Data read out from first phase 3 study expected 3Q 2026



Potential **first approved drug treatment for pterygium**, in late-stage clinical development for the reduction of hyperemia, bothersome symptoms, and stabilization or reduction in the lesion size

## Potential Advantages

**#1 First to Enter a Potential \$1 Billion Opportunity**  
 ✓ There are currently **no approved drug therapies** that address hyperemia/fibrosis and the pterygium lesion

**May delay or eliminate need for surgery**  
 ✓ Pharmacologically targeting the angiogenic and fibrovascular pathogenesis of pterygium with **promising clinical trial results**

**Desirable safety profile versus off-label options**  
 ✓ In clinical studies, no systemic effects and ocular AEs were mild and transient; may be used safely well beyond duration limits for corticosteroids

## On-going phase 3 MRCT

- Phase 3 MRCT is a multicenter, double-masked, randomized, vehicle-controlled 12-month (with a 12-month double-masked extension) parallel comparison study.
- Efficacy endpoints at **both Month 3 and Month 12**.
- Evaluate the **safety and efficacy of two different doses of CBT-001** emulsion dosed twice daily for 24 months compared to vehicle in reducing conjunctival hyperemia and preventing pterygium progression.

1Q '26	2Q '26	3Q '26	4Q '26	1Q '27	2Q '27	3Q '27	4Q '27	1Q '28	2Q '28	3Q '28	4Q '28
		▲									
		3-mos hyperemia and symptoms and 12-mos progression data (Study 1)									
▲					▲				▲		
				2-mos hyperemia (Study 2)				12-mos progression data (Study 2)			
							▲				▲
							Hyperemia NDA submission		Progression sNDA submission		

# Pterygium Market

Past examples of new market and drug class category creation in front-of-the-eye diseases



- Launched in 2003 as the first prescription dry eye product into a market that had previously been treated with OTC ocular lubricants
- Disease modifying rather than purely short-term symptom relief
- Created a new market and had no direct competition until the launch of Xiidra 14 years later
- Peak sales in 2017 of \$1.4 billion (\$1.8 billion in 2025 dollars)

- Launched in 2023 as the first prescription treatment for demodex mites
- Introduced a condition virtually unheard of by patients through a combination of doctor education and DTC advertising
- Treatment created new doctor revenue stream
- Sales in second full year expected to hit \$440 million with peak sales forecasted at \$885 million to over a billion

## Examples of Tactics Employed



Professional Education



Publications



Congresses



Disease Awareness



DTC Advertising



Digital Marketing

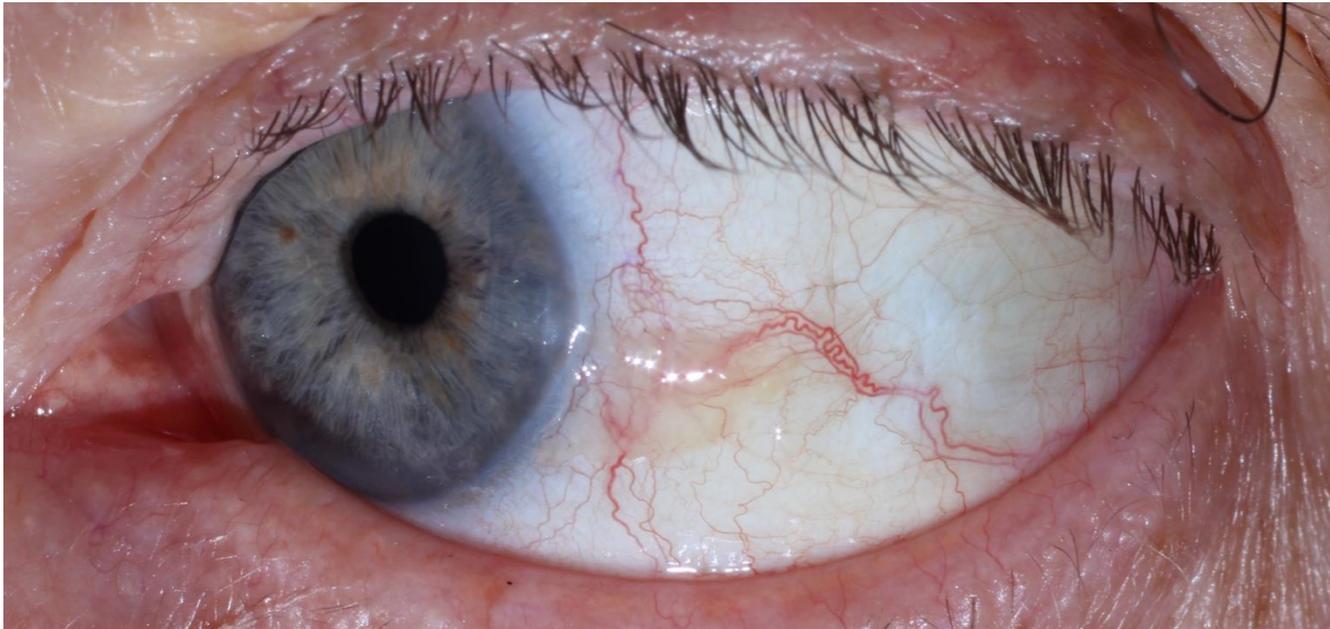
# Pinguecula

A disease impacting almost half of all adults in the US and with no FDA approved drug therapy



**Pinguecula** is characterized as a **round, yellowish, elevated growth** that develops on the conjunctiva adjacent to the cornea which is **prone to inflammation and vascularization**. It is **commonly caused by UV exposure** and can lead to redness, irritation and foreign body sensation and interfere with contact lens wear.

**Symptoms range from mild and painless, to very bothersome**



**50M**

People impacted by pinguecula in the U.S. alone

**15M**

**Patients** are seen by an eye doctor annually

**3.9M**

**Diagnosed and treated per the ICD-10 codes** by an ophthalmologist or medical optometrist

Most are treated for their symptoms using artificial tears, prescription dry eye product and/or NSAIDs and Corticosteroids *(all off-label and not impacting the root cause)*

# CBT-004

An MKI eye drop designed to address the vascularization and fibrosis of the pinguecula lesion



Potential **first approved drug treatment for pinguecula**, entering Phase 3 development for the reduction of hyperemia and bothersome symptoms caused by the lesion

## Potential Advantages

### First to enter a potential multi-billion market

- ✓ There are currently **no approved drug therapies** that address the basis of the pinguecula lesion

### Only option that is disease-modifying

- ✓ **Surgery is not typically an option; CBT-004 has demonstrated sustained effect** after dosing is stopped unlike off-label corticosteroids

### Desirable safety profile versus off-label options

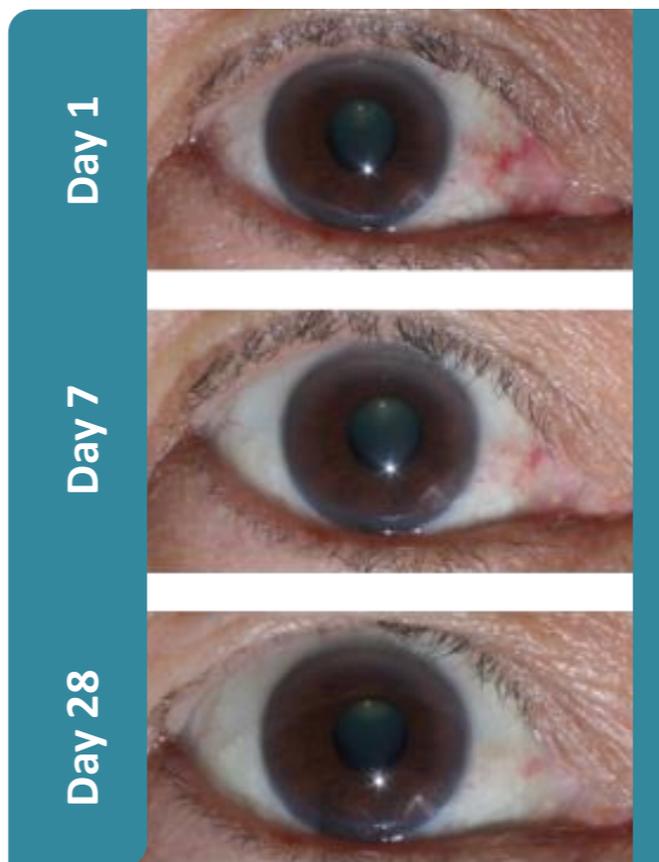
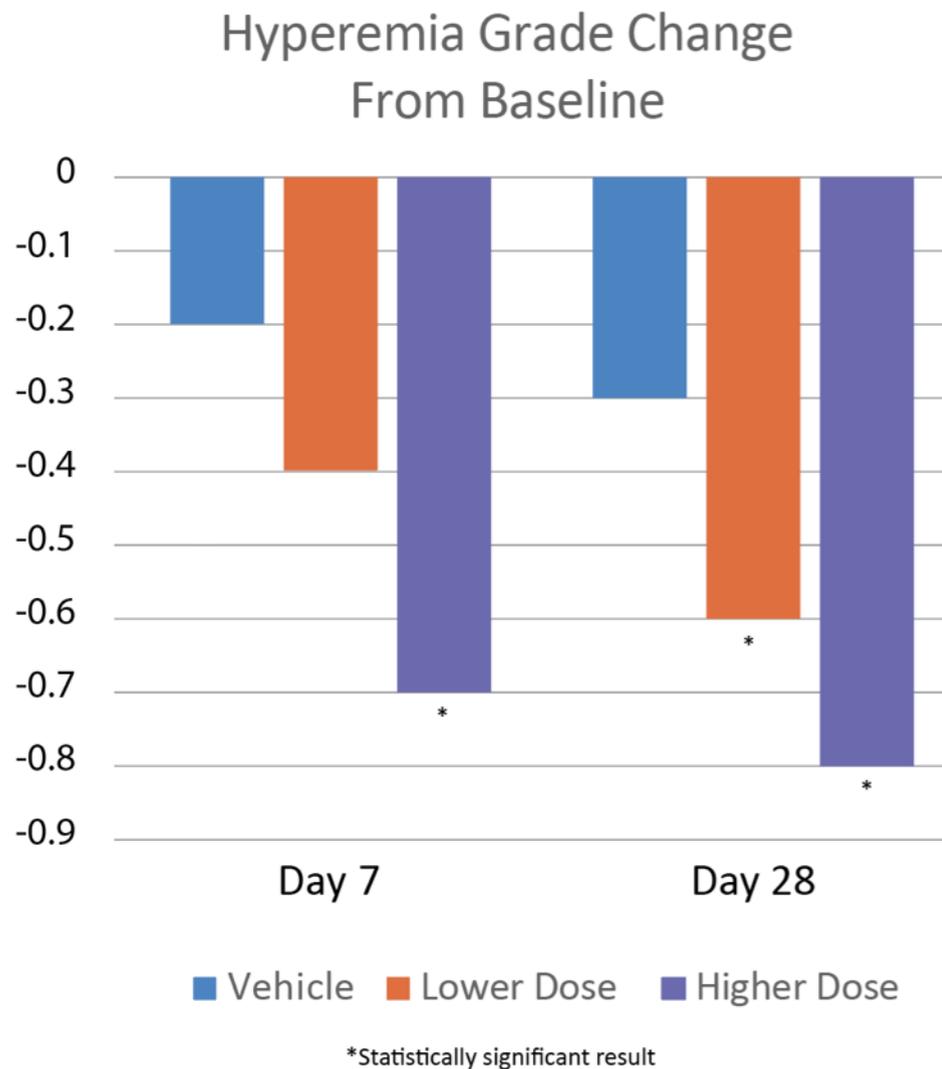
- ✓ In clinical studies, **no systemic effects** and ocular AEs were mild and transient; no treatment-limiting side effects (unlike corticosteroids)

## Development Timeline

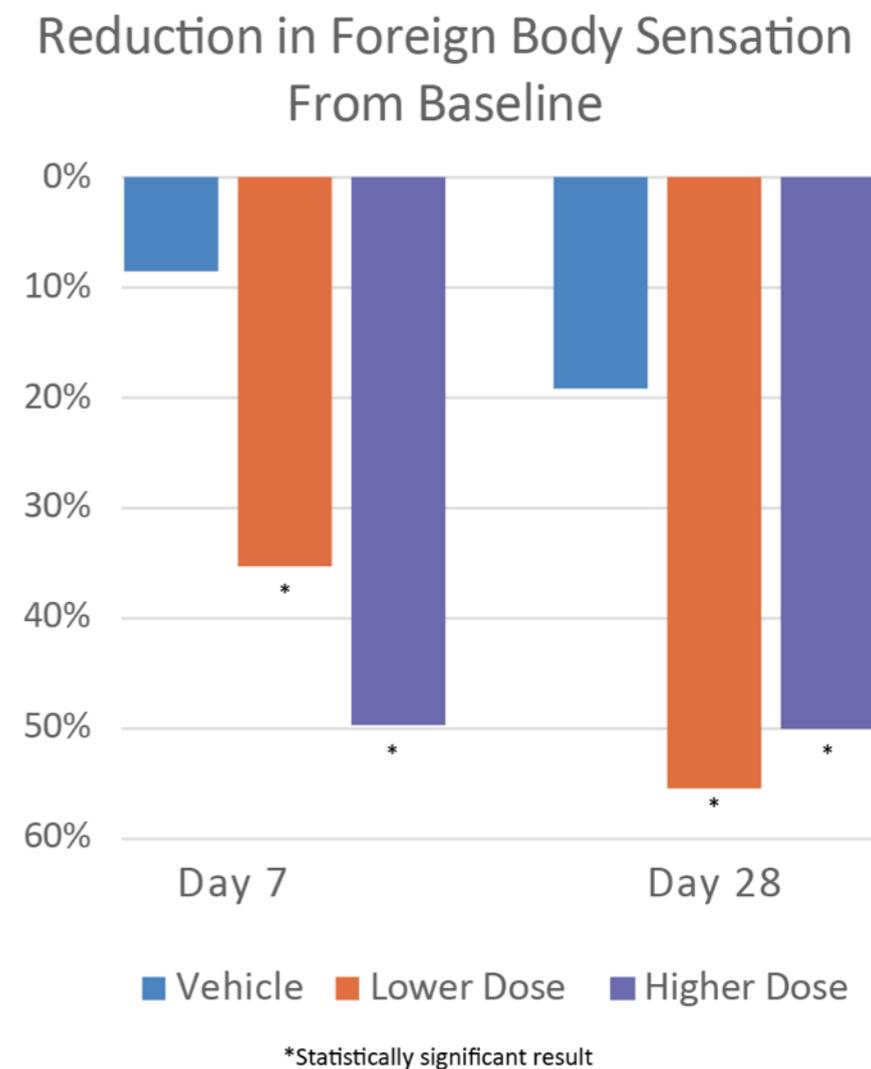
Q1 '26	Q2 '26	Q3 '26	Q4 '26	Q1 '27
▲ Start GLP Tox		▲ Complete GLP Tox		

1Q '27	2Q '27	3Q '27	4Q '27	1Q '28	2Q '28	3Q '28	4Q '28	1Q '29	2Q '29	3Q '29	4Q '29
▲ Phase 3 Study 1 FPI				▲ Phase 3 Study 1 Efficacy (3 mos) and Safety (12 mos) Data							
				▲ Phase 3 Study 2 FPI				▲ Phase 3 Study 2 Efficacy (3 mos) Data			
										▲ NDA submission	

# CBT-004: The first agent for treating the signs and symptoms of Pinguecula

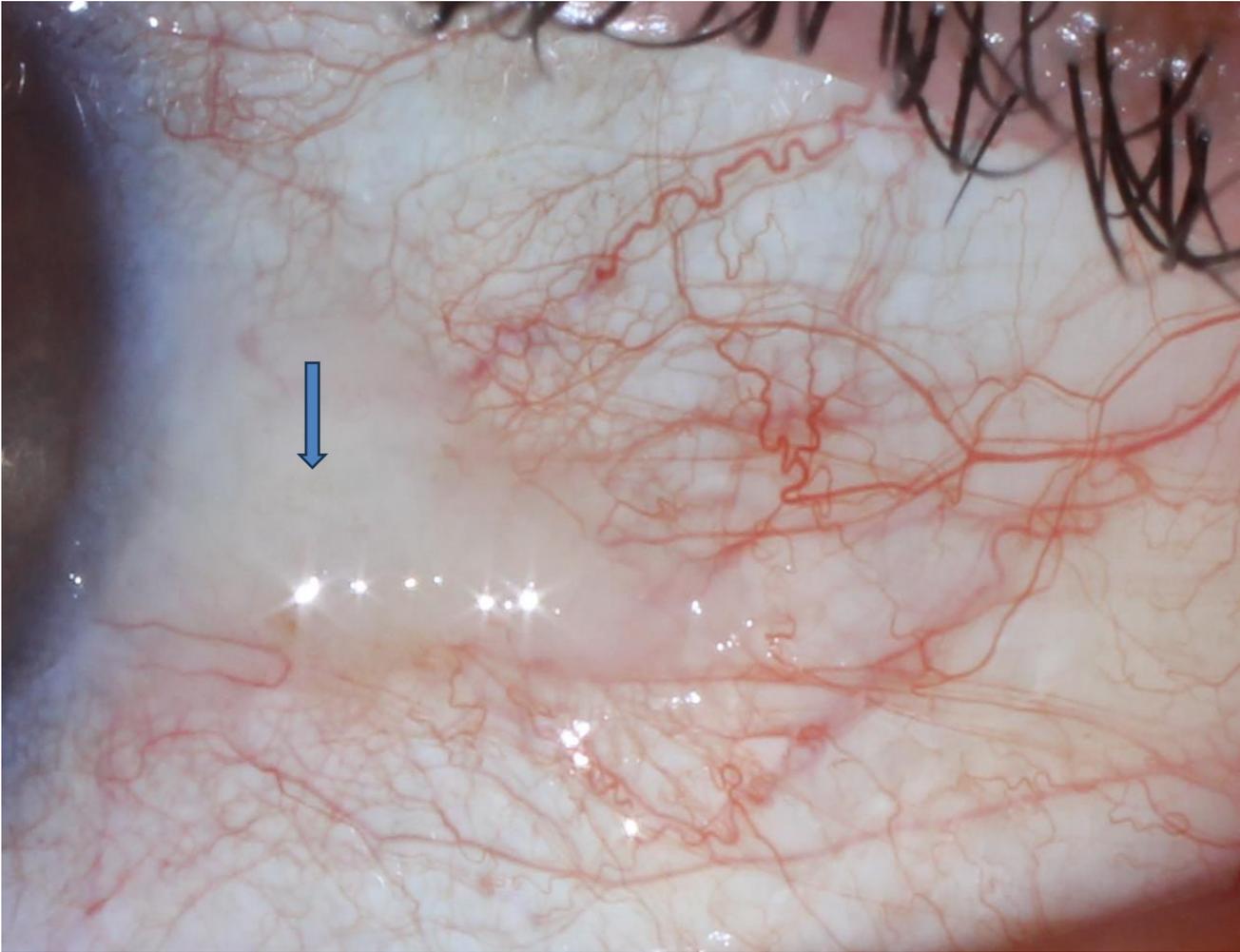


Representative subject dosed with higher-dose CBT-004

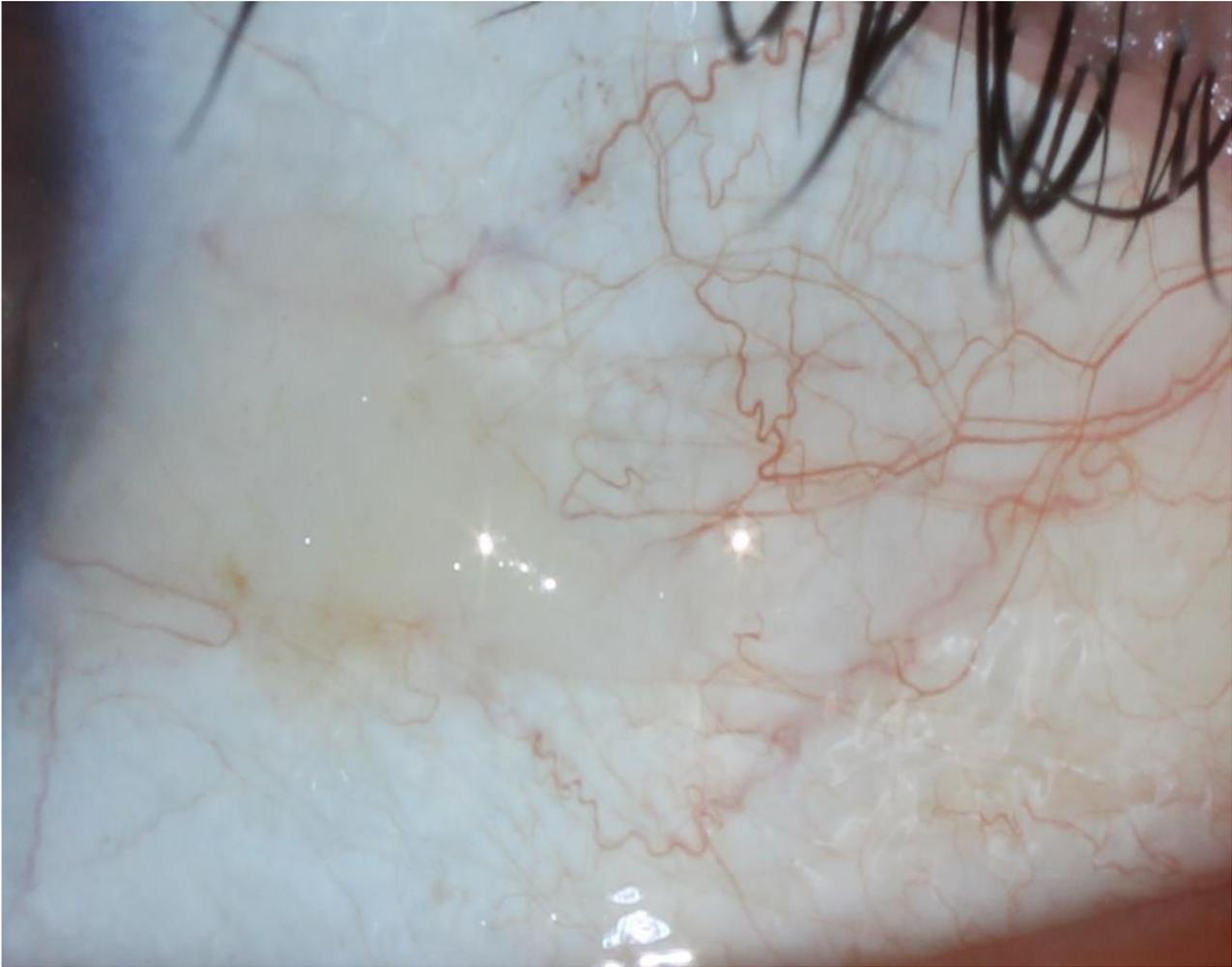


# CBT-004 in phase 2 trial

Vascularity substantially reduced and the lesion (arrow) became thinner and smoother at D28



Day1



Day28

# Positive output from recent FDA end of phase 2 meeting

Agreement on Indication and Trial Design for CBT-004



- **Phase 3** primary efficacy endpoints will include **conjunctival hyperemia as well as the key symptom of “foreign body sensation”**
- Both were statistically significant findings in the Phase 2 study with the dose included in the Phase 3 study
- This would make CBT-004, if approved, the only topical eye drug to:
  - Treat the **signs and symptoms** of pinguecula, and
  - The **only topical eye drug that is indicated to address both** of these important symptoms
- Clinical development plan is for two RCT's:
  - One three-month efficacy study (multi-regional)
  - One twelve-month study with 3-month efficacy and 12-month safety



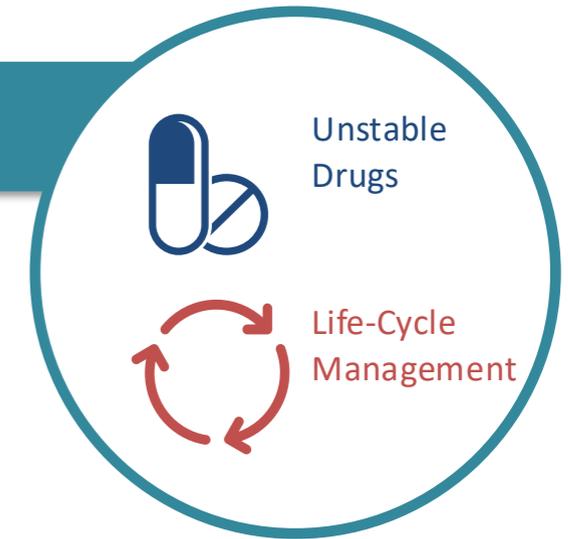


## Cloudbreak's proprietary SFA-Plus (SFA+) platform:

- **CBT-009:** myopia progression (Phase III ready)
- **CBT-199:** presbyopia (IND-filed)
- Broad patent-pending portfolio of **novel moieties** in the SFA+ platform
- Comfort, multi-dose, preservative free, convenience, and long shelf life

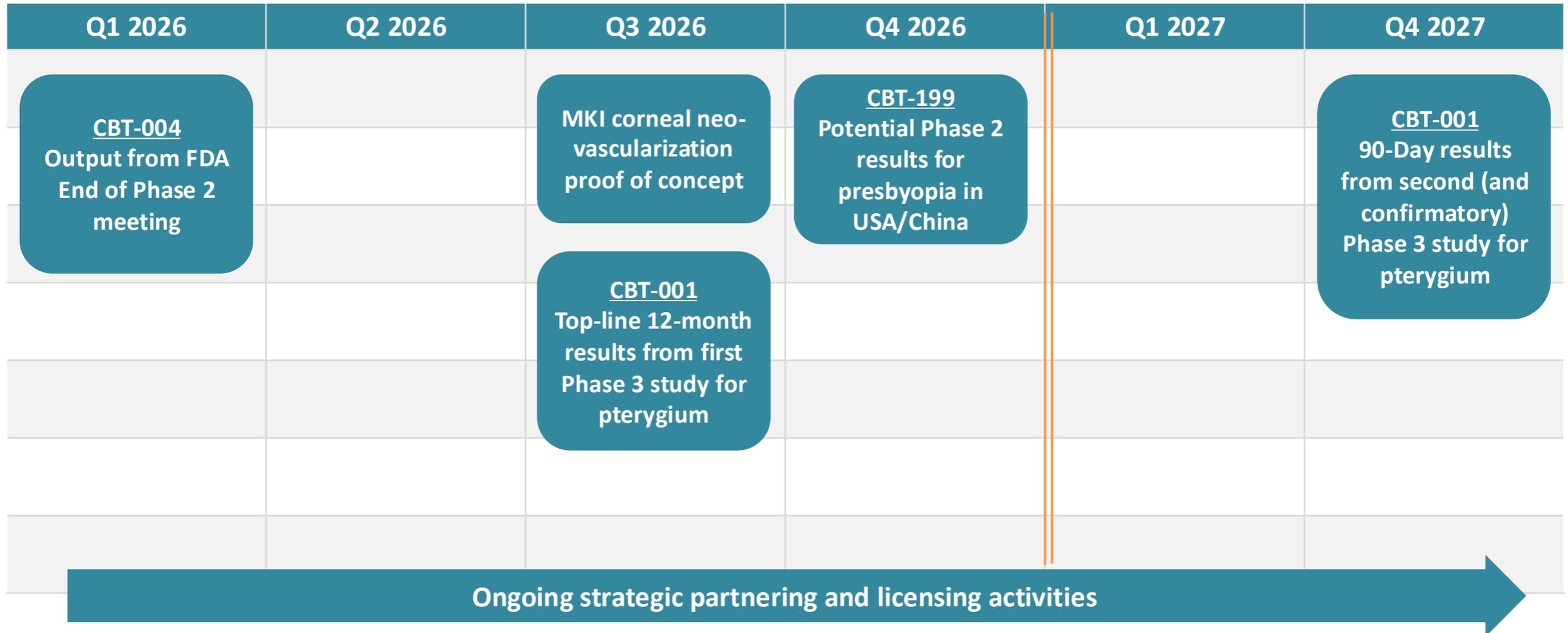
## Present numerous new product opportunities with SFA+ platform:

- Substantial improvement over existing or in-development products
  - Formulate stable eye drop product for “unstable” drug
  - Life-cycle management to enhance safety and comfort
- Enables novel non-aqueous drug design



# Cloudbreak Pharma

Multiple, near-term potential inflection points\*



\*Note – these are timing estimates and subject to change due to factors listed in “Forward Looking Statements”

**Key methods and  
formulation claims covered  
with multiple patents to  
2036 and beyond**

70 Global Patents Issued  
160+ Global Patents Pending

# Multiple commercialization partners<sup>1</sup>

Potential long-term income stream



## **Santen (4536.T)**

A global pharmaceutical company focusing on global R&D, manufacturing, and sales and marketing of eyecare products, headquartered in Japan.

### **CBT-001 Markets Covered**

Japan, South Korea, Southeast Asian (SEA) countries: Vietnam, Thailand, Malaysia, Philippines, Singapore and Indonesia



## **Grand Pharma (00512.HK)**

An **international pharmaceutical** company with a **strong marketing and sales capability** and a complete industrial chain, headquartered in China.

### **CBT-001 Markets Covered**

Greater China: mainland China, Hong Kong, Macau and Taiwan

License agreements with a total value of over \$100M in up-front and milestone payments plus potential royalties of over \$100M  
Ongoing discussions with multiple partners for multi-billion dollar opportunities in the U.S. and Europe

# The Investment Ask

Additional funding will speed development and raise value with potential strategic licensees



- **\$25 million equity investment** will be used to speed enrollment and reduce by six months the timeline for NDA's for both CBT-001 and CBT-004
  - Additional study sites and promotion
- The reduction in time **increases the projects value today** to potential partners and **reduces time to \$100 million in potential regulatory milestones**
  - CBT-001 moves up NDA filing by six months to middle of 2028
  - CBT-004 moves up NDA filing by nine months to beginning of 2029

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