





# Forward-Looking Statements

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# Driving Innovation in Ophthalmology, Led by NCX 470 & an Experienced Team

Differentiated pipeline with positive NCX 470 pivotal Phase 3 clinical trial results

Lead asset NCX 470, with a potentially differentiated profile targeting glaucoma, leverages Nicox's proprietary Nitric Oxide (NO) donating research platform.

Positive topline results from the first Phase 3 trial (Mont Blanc)<sup>1</sup>.

Potential retinal benefits seen in nonclinical models<sup>2</sup>

Experienced Leadership, Board and Advisors with expertise to drive successful outcomes

Experienced team well positioned to bring NCX 470 to approval and to advance and build the pipeline to deliver future growth

Cash position enhanced by global partnerships and outlicensed commercial products

Cash balance of €21.4 million<sup>3</sup> expected<sup>4</sup> to fund operations until Q2 2024

Current and potential future revenue and value from global partnerships



Nicox Press release October 31, 2022

<sup>2.</sup> J Ocul Pharmacol Ther. 2022, 38: 496-504

<sup>3.</sup> As of March 31, 2023. Figure non audited

<sup>4.</sup> Based exclusively on the development of NCX 470



# Broad Global Leadership Experience



Andreas Segerros
Chief Executive Officer



Sandrine Gestin
VP, Finance



Doug Hubatsch

EVP, Chief Scientific Officer



Emmanuelle Pierry

General Counsel & Head, Legal



Gavin Spencer

EVP, Chief Business Officer &

Head, Corporate Development

**PHARMACIA** 























# Board Bringing Extensive Experience in Ophthalmology and Pharmaceuticals



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LES KAPLAN
Director





MICHELE GARUFI
Director





LAUREN SILVERNAIL
Director





ADRIENNE GRAVES
Director





LUZI VON BIDDER
Director







# U.S. Glaucoma Clinical Advisory Board with Leading Experts

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Professor and Chair of the Department of Ophthalmology at SUNY Upstate Medical University, Syracuse, NY

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Professor of Ophthalmology at Duke University in Durham, North Carolina, and Director of the Duke Eye Center of Cary and the Duke Glaucoma OCT Reading Center

#### DR. DONALD BUDENZ, MD MPH

Kittner Family Distinguished Professor and Chairman, Department of Ophthalmology, UNC Chapel Hill School of Medicine

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Vice-Chair, Senior Scientist, and Director of Glaucoma Services and Ophthalmic Clinical Trials for the Devers Eye Institute in Portland, Oregon. Clinical Professor of Ophthalmology at Oregon Health Science University

#### DR. TOM WALTERS, MD

President of Texan Eye P.A. and Medical Director of Eye LASIK Austin, Advanced Ophthalmic P.A., Keystone Clinical Research

#### DR. ROBERT N. WEINREB, MD

Distinguished Professor and Chair, Ophthalmology, Director of both the Shiley Eye Institute and the Hamilton Glaucoma Center, holder of the Morris Gleich, MD Chair in Glaucoma, and Distinguished Professor of Bioengineering





### **Unique Combination of Competencies**

Capable of bringing NCX 470 to approval and driving future growth



- International R&D Management with deep ophthalmology experience
- Corporate, Finance and Legal team have completed multiple transactions, restructuring and financing
- Board members with extensive experience in ophthalmology and pharmaceuticals from leading companies
- World-recognized Key Opinion Leaders on the Clinical Advisory Board







Novel molecule for intraocular pressure lowering, the leading cause of glaucoma

Positive pivotal Phase 3 topline results from the Mont Blanc trial<sup>1</sup>

Large and established market<sup>2</sup>:

\$5.9 billion worldwide

\$1.3 billion prostaglandin analog market in the U.S.

First non-combination product to demonstrate statistical non-inferiority to a prostaglandin analog in a pivotal trial, thereby meeting the efficacy requirements for approval in the U.S.



# NCX 470 Leads a Differentiated Ophthalmology Pipeline

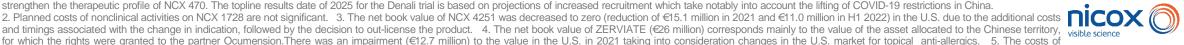
#### **Stages of Development**



<sup>1.</sup> In addition to our Chinese partner, the Company is actively looking for commercial partners in the U.S. and Japan, to maximize the value of NCX 470. The ongoing Denali trial is not financed beyond the current cash runway of Q2 2024. New Phase 3b clinical trials and nonclinical studies concerning the dual mechanism of action and the potential beneficial effects of NCX 470 on the retina are planned to report results in the next 12 to 18 months which may strengthen the therapeutic profile of NCX 470. The topline results date of 2025 for the Denali trial is based on projections of increased recruitment which take notably into account the lifting of COVID-19 restrictions in China.

2. Planned costs of nonclinical activities on NCX 1728 are not significant.

3. The net book value of NCX 4251 was decreased to zero (reduction of €15.1 million in 2021 and €11.0 million in H1 2022) in the U.S. due to the additional costs



development and commercialization of these products and product candidates are paid by the partner

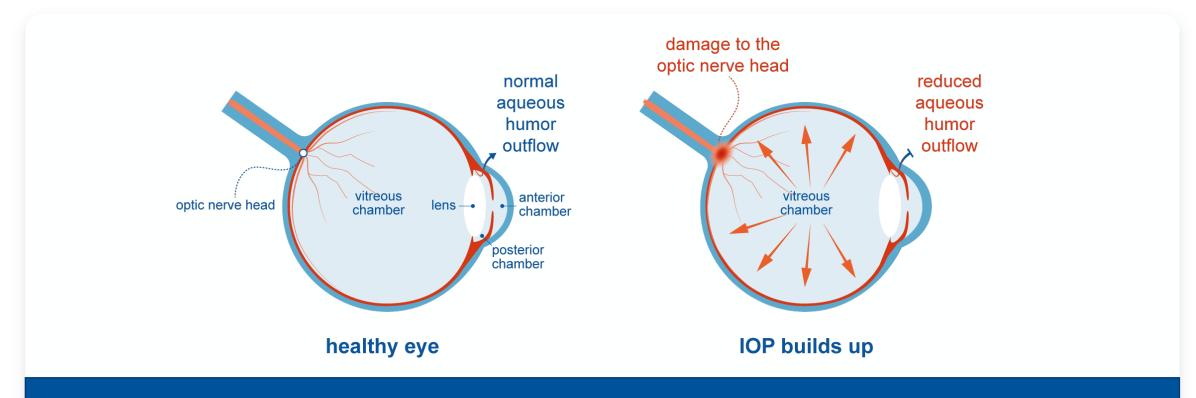






#### Glaucoma Snapshot

Elevated intraocular pressure (IOP) contributes to irreversible optic nerve damage, leading to progressive vision loss



As published in the landmark EMGT study "...each mmHg of decreased IOP was related to an approximately 10% lowering [of risk of vision loss progression]"

10% lowering [of risk of vision loss progression loss





#### Unmet Medical Need for Glaucoma Treatment

Despite having well established first line therapies, including the standard of care, latanoprost, patients do not react to glaucoma medications in the same way, and therefore eye care professionals need multiple treatment options

40% of patients do not achieve their target IOP on existing monotherapies1 requiring eye care professionals to adjust or change the medication used

Many patients require >1 medication which leads to compliance issues<sup>2,3</sup>

Tolerability issues with some medications lead to discontinuations and/or compliance issues4



Kass et al, Delaying treatment of ocular hypertension: the ocular hypertension treatment study. Arch Ophthalmol, 2010; 128:276-287

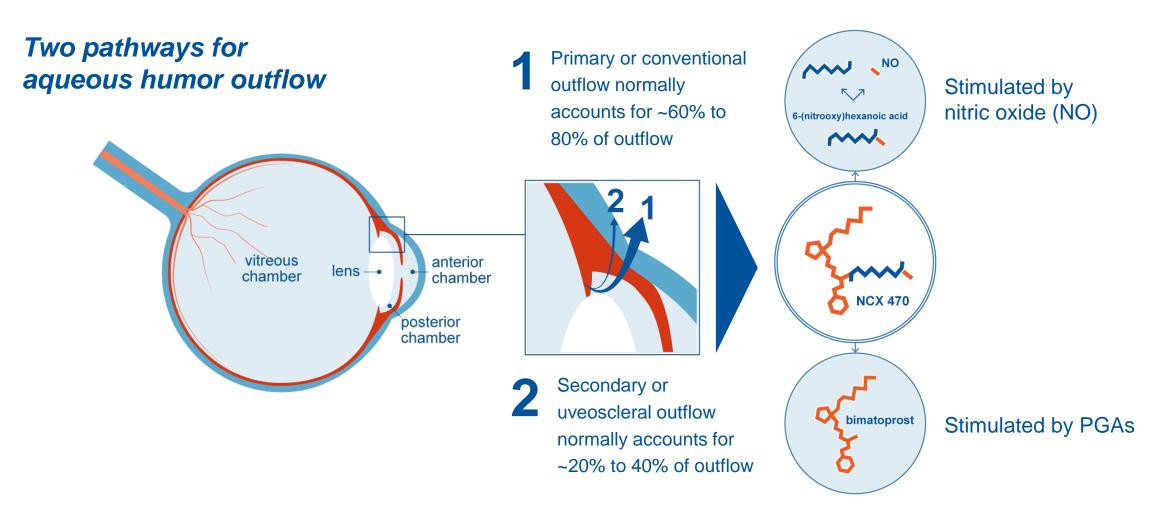
Robin AL et al, Does adjunctive glaucoma treatment therapy affect adherence to the initial primary therapy? Ophthalmology. 2005; 112:863-868

Robin et al. Adherence in glaucoma: Objective measurements of once-daily and adjunctive medication use. Am J Ophthalmol. 2007;144:533-540



# NCX 470 Acts Through A Dual Mechanism<sup>1</sup> for IOP Lowering

Nonclinical optic nerve/retinal damage models also demonstrate potentially beneficial retinal effects<sup>2</sup>





<sup>2.</sup> J Ocul Pharmacol Ther. 2022, 38: 496-504



PGAs = Prostaglandin Analogs;



# Positive Topline NCX 470 Mont Blanc Results<sup>1</sup>

Phase 3 program intended to support planned U.S. & China NDA submissions

Designed to demonstrate safety and efficacy of NCX 470 0.1% vs latanoprost 0.005%, defined by intraocular pressure reduction from time-matched baseline at pre-established time points

#### **MONT BLANC: Primary objective of non**inferiority achieved

N = 691

56 clinical sites in the U.S. & one site in China

Adaptive study design selected the 0.1%

Second efficacy objective, statistical superiority to latanoprost, was not achieved

NCX 470 was statistically superior to latanoprost in intraocular pressure reduction from baseline at 4 of the 6 timepoints, and numerically greater at all 6

#### **DENALI: Enrolling subjects**

N = ~670

~60 clinical sites in the U.S. & China

Includes a 12-month safety extension

Jointly conducted & equally financed with Chinese partner Ocumension Therapeutics

Topline results expected in 2025<sup>2</sup>





# Mont Blanc Phase 3 Efficacy Trial Design<sup>1</sup>

Designed to evaluate NCX 470 vs. established therapy, latanoprost

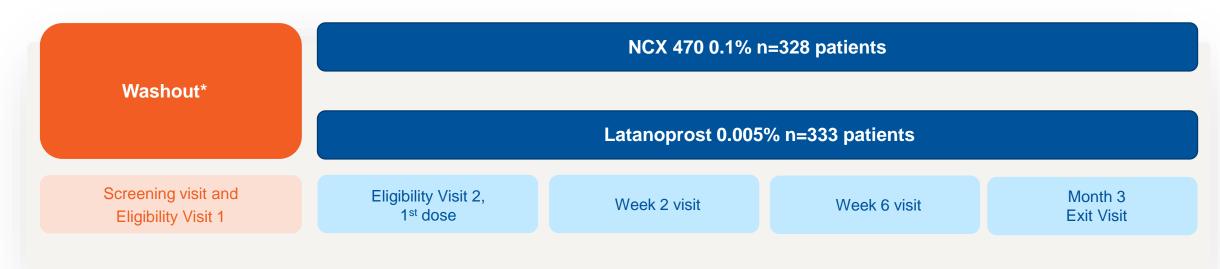
Randomized, controlled, double-masked, parallel design trial. Patients with open angle glaucoma or ocular hypertension were randomized 1:1 to once-daily treatment with NCX 470 0.1% or latanoprost 0.005%

#### **Primary Endpoint:**

Mean intraocular pressure reduction from time-matched baseline at 8 AM and 4 PM at the week 2, week 6 and month 3 visits

#### **Enrollment**:

The trial enrolled 691 patients across all arms (including ~30 patients on NCX 470 0.065% in the adaptive design part)







# Baseline Characteristics, Demographics and Disposition<sup>1</sup>

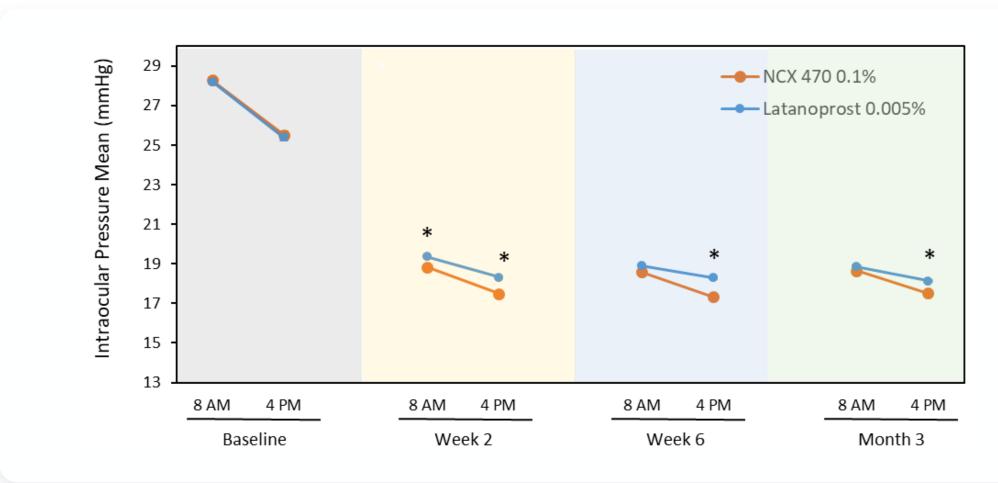
	NCX 470 0.1% N = 328	Latanoprost 0.005% N = 333
Mean Diurnal Baseline (8am+4pm) IOP, mmHg, Study Eye (SD)	26.9 (2.04)	26.8 (2.02)
Gender, n (%) Female Male	200 ( 61.0%) 128 ( 39.0%)	188 ( 56.5%) 145 ( 43.5%)
Age, Years (SD)	63.6 (10.12)	62.7 (11.73)
Completed the Study	314 (95.7%)	316 (94.9%)
Discontinued Prior to Study Completion	14 (4.3%)	17 (5.1%)
Reasons for Discontinuation		
Adverse Event	8 (57.1%)	6 (35.3%)
Lost to Follow-up	1 (7.1%)	4 (23.5%)
Physician Decision	0	0
Sponsor or IRB Decision	1 (7.1%)	2 (11.8%)
Protocol Violation	0	1 (5.9%)
Withdrawal by Subject	3 (21.4%)	3 (17.6%)
IOP greater than 36 mmHg	0	0
Other	1 (7.1%)	1 (5.9%)





# Significant, sustained IOP-lowering effects

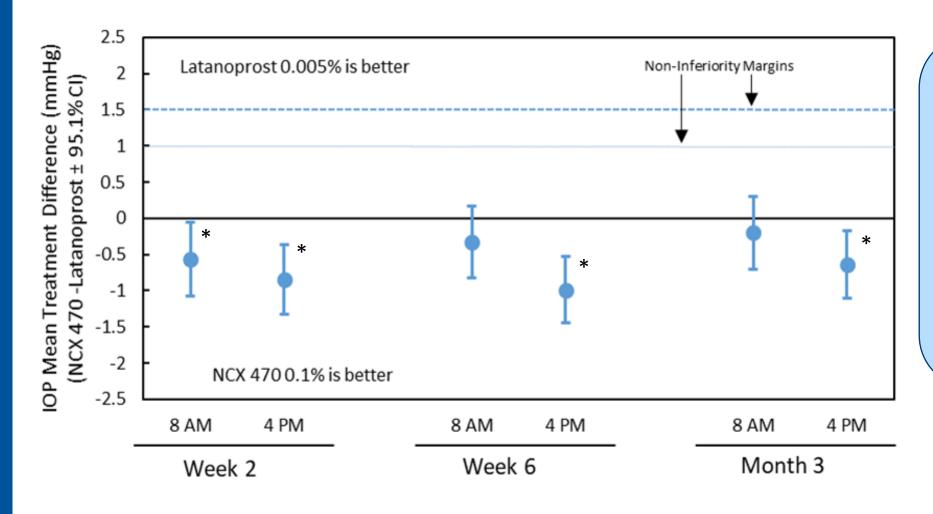
IOP-lowering effect from baseline was 8.0 to 9.7 mmHg for NCX 470 vs. 7.1 to 9.4 mmHg for latanoprost







# NCX 470 0.1% achieved non-inferiority and demonstrated an IOP Lowering greater than Latanoprost 0.005% of up to 1.0mmHg



# To be non-inferior, the treatment difference between NCX470 and latanoprost had to meet BOTH criteria:

- For all 6 timepoints, the upper limit of all confidence intervals (95.1%) were required to be less than or equal to 1.5 mmHg and
- At least 4 of the 6 timepoints were required to be less than or equal to 1.0 mmHg



<sup>\*</sup> Denotes statistically significant differences vs latanoprost (p<0.049)



# NCX 470 Topline Results Demonstrate Robust Efficacy and Safety<sup>1</sup>

All comparisons are based on NCX 470 0.1% and latanoprost 0.005%

IOP-lowering effect from baseline was 8.0 to 9.7 mmHg for NCX 470 vs. 7.1 to 9.4 mmHg for latanoprost

Statistical non-inferiority was met vs. latanoprost in the primary efficacy analysis

This trial therefore met the efficacy requirements for approval in the United States

While NCX 470 failed to meet statistical superiority to latanoprost in a pre-specified secondary efficacy analysis of time-matched change from baseline IOP, NCX 470 was numerically superior to latanoprost at all time points and statistically significant (p<0.049) at 4 of 6 timepoints

#### NCX 470 was well tolerated

The most common adverse event was ocular hyperemia in 11.9% of NCX 470 patients vs. 3.3% of latanoprost patients

There were no ocular serious adverse events and no treatment-related non-ocular serious adverse events

4.3% of patients on NCX 470 discontinued compared to 5.1% on latanoprost





# NCX 470 – Ophthalmology Conference Presentations 2023



#### NCX 470, a Nitric Oxide Donating Bimatoprost, Demonstrates Non-inferiority to Latanoprost in Phase 3 Mont Blanc Clinical Trial

RD Fechtner<sup>1</sup>, SL Mansberger<sup>1</sup>, J Branch<sup>2</sup>, J Mulaney<sup>2</sup>, S Ziebell<sup>3</sup> and K Lopez<sup>4</sup> (Nicox Consultant<sup>1</sup>, Investigator<sup>2</sup>, Contractor<sup>3</sup>, Employee<sup>4</sup>)

Purpose: To compare the safety and IOP-lowering efficacy of NCX 470 ophthalmic solution vs latanoprost ophthalmic solution in adult subjects with open-angle glaucoma or ocular

Methods: The trial was a randomized, doublemasked, multi-center, parallel group trial with an initial adaptive dose selection phase in which the higher dose, NCX 470 0.1%, was chosen for further evaluation.

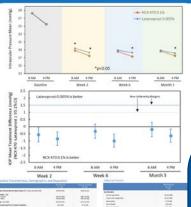
Medications were dosed once daily in the evening for 3 months.

Evaluated at 8AM and 4PM at week 2, week 6 and month 3.

Efficacy was based on mean IOP reduction from baseline at the 8AM and 4PM timepoints at week 2, week 6 and month 3.

The primary efficacy objective was to demonstrate non-inferiority, and the secondary objective was to demonstrate superiority to





Results: NCX 470 met the primary efficacy endpoint of non-inferiority to latanoprost. The IOP-lowering from baseline ranged from 8.0 to 9.7 mmHg for NCX 470 and 7.1 to 9.4 mmHg for latanoprost. IOP reductions for NCX 470 were numerically.

greater than those for latanoprost at all 6 timepoints, and statistically significant (pc/0,049) at 4 of the 6 timepoints. The secondary superiority endpoint required statistically significant results at all 6 time points, and this was not achieved.

NCX 470 was safe and well tolerated; the most common adverse event (AE) was coular hyperemia in 11.9% of the NCX 470 subjects vs. 3.9% of latanoprost subjects. There were no ocular serious AEs and no treatment-related non-ceular serious. AEs and no treatment-related non-ceular serious.

**ARVO**2**2**3 April 23 – 27 | New Orleans, La.

Poster presentation: NCX 470, a nitric oxide (NO)-donating bimatoprost, preserves rabbit eyes from biochemical and functional changes associated with endothelin-1 (ET-1)-induced ischemia/reperfusion injury of optic nerve head and retina





Poster Presentation: Effects of NCX 470, a Nitric Oxide (NO)-Donating Bimatoprost, in in vitro 3D-Human Trabecular Meshwork (TM) / Schlemm's Canal (SC) Co-Culture Tissue Model

Poster Presentation: NCX 470, a Nitric Oxide Donating Bimatoprost versus Latanoprost has Greater Proportion of Subjects Achieving ≥10 mmHg IOP Decrease in Phase 3 Trial

Poster Presentation: NCX 470, a Nitric Oxide Donating Bimatoprost Compared with Latanoprost - Adaptive Design Period Results from the Phase 3 Mont Blanc Clinical Trial





#### Retinal Benefits: A Potential Differentiator for NCX 470

Elevated IOP is the main risk factor in glaucoma, however a variety of IOP-independent risk factors, including ischemia, contribute to damage of the optic nerve head and the retina, ultimately causing vision loss

Initial exploratory studies generated encouraging results

Exploratory nonclinical studies in a well-defined model with optic nerve head and retina damage (ET-1-induced ischemia/reperfusion) investigated the NCX 470 effects beyond IOP lowering

The results<sup>1</sup> suggest that NCX 470 improves ocular perfusion and retinal function in damaged eyes compared to vehicle and may therefore have protective properties

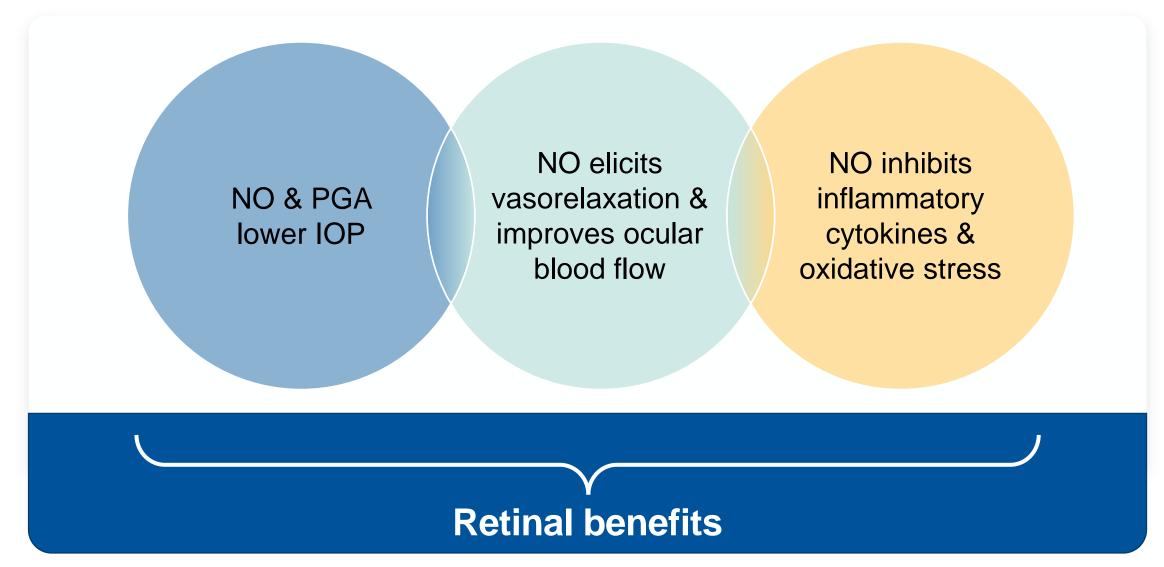
**Next Steps** 

Nonclinical studies and targeted clinical trials are planned to further explore NCX 470's dual mechanism of action and potential benefits on the retina, beyond its IOP lowering properties





# Why Nitric Oxide Could Generate Retinal Benefits



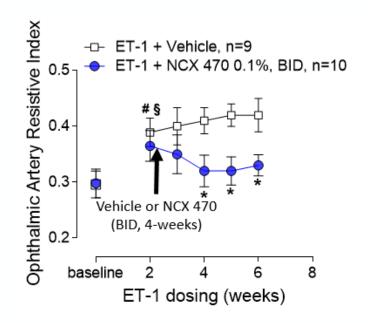




#### NCX 470 Shows Retinal Cell Protection in a Nonclinical Model<sup>1</sup>

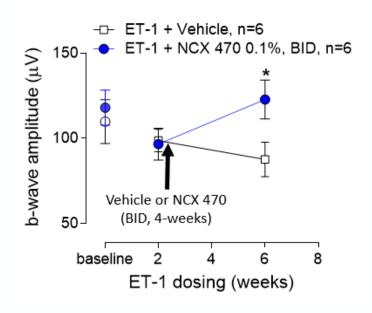
Improved ocular perfusion and retinal function in damaged eyes





Detrimental effect of ET-1 on ophthalmic artery hemodynamics was significantly reversed in eyes receiving NCX 470 0.1% bid (p<0.05 vs. vehicle at week 6)

# Retinal function (Scotopic Electroretinogram - rod/cone responses)



Photoreceptor response decline induced by ET-1 was almost completely reversed in eyes treated with NCX 470 0.1% bid (p<0.05 vs. vehicle at week 6)



#\$ p<0.05 vs. respective baseline. \* p<0.05 vs. vehicle at the same time point, Student's T-test



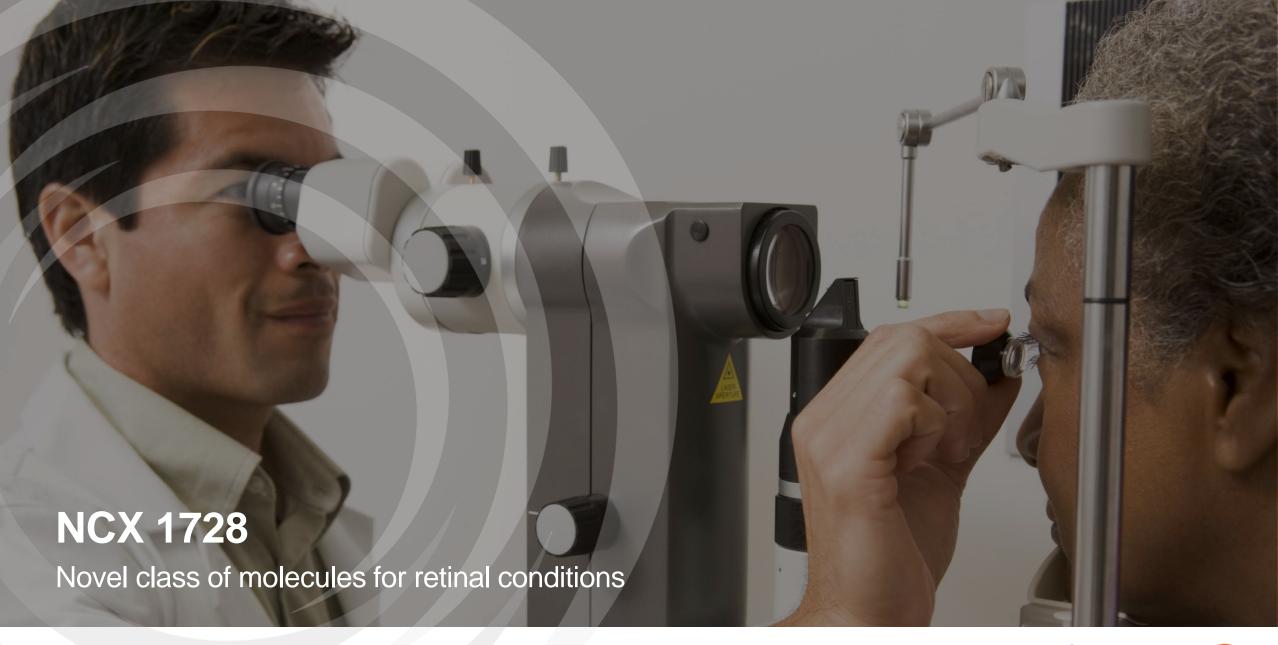
#### Phase 3b Trials to Further Evaluate NCX 470 Planned in H1 2023

**Episcleral Pressure Study**: Nitric oxide has been shown to induce vasodilation. NCX 470's ability to lower episcleral venous pressure as well as enhance outflow through the trabecular meshwork will be evaluated in a clinical trial

**OCT Study:** Retinal blood vessel density will be studied in a separate clinical trial using Optical Coherence Tomography (OCT)-angiography to fully understand the potential effects on retinal blood flow

Together, these trials are designed to validate NCX 470's dual mechanism of action in humans and potentially demonstrate some of the beneficial effects on the retina that have been observed in nonclinical models.









# NCX 1728: Lead Compound in a New Class of NO-donating Molecules

Combining NO-release with PDE5 Inhibition MOA for this novel class of molecules is based entirely on NO-mediated activity

NO-mediated effects are enhanced and prolonged by concomitant phosphodiesterase-5 (PDE5) inhibition within the same molecule

Potential in retinal conditions

NO plays a pivotal role in ocular blood flow which may be beneficial in a number of retinal conditions where dysfunctional ocular perfusion and neovascularization are key features in disease progression

Nonclinical program focused on evaluating MOA

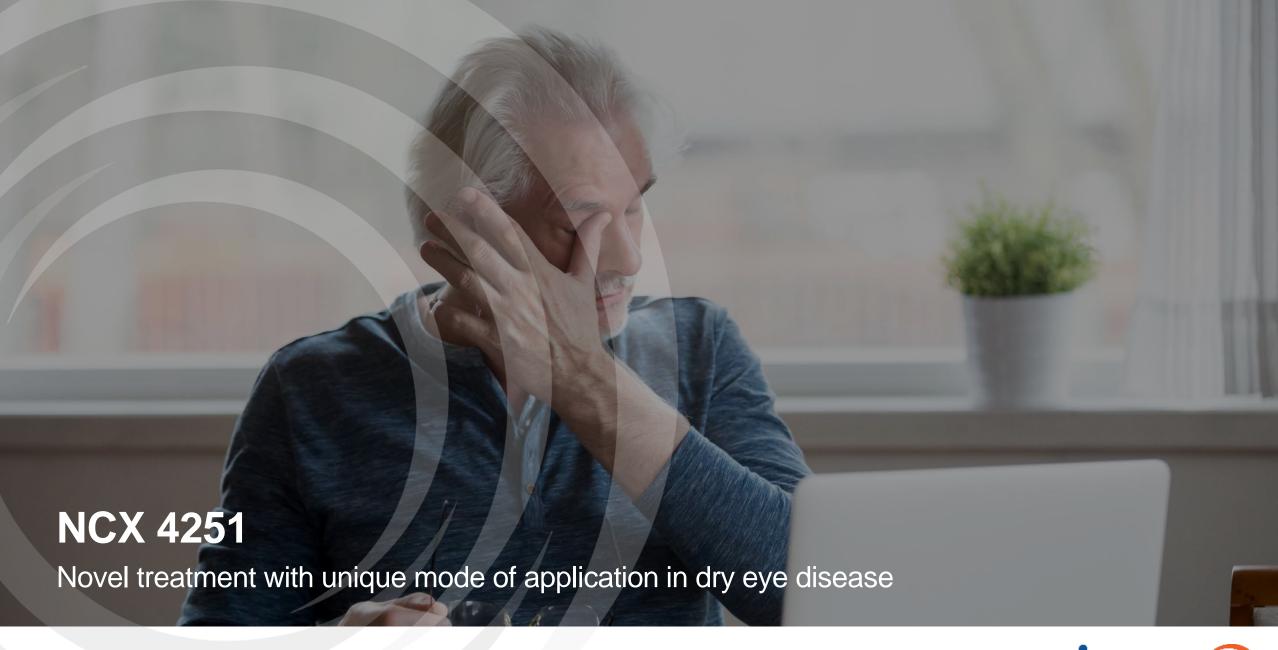
Nonclinical studies underway to further explore therapeutic potential of this molecule and its efficacy in disease progression

# NO-donating PDE5 inhibitor NO ← cell cytoplasm → cGMP [Ca++]

Muscle cell relaxation

- Vasorelaxation
- Enhancement of ocular blood flow
- Ocular tissues oxygenation
- Sparing of ONH & retinal damage









# NCX 4251: Novel Approach to Dry Eye Disease

Novel corticosteroid presentation leverages Nicox's unique formulation expertise

Novel, patented ophthalmic nanocrystal suspension of fluticasone propionate, a well-established corticosteroid. Fluticasone has 10x affinity for the glucocorticoid receptor vs. dexamethasone, commonly used in ophthalmology

Planned to be the first topical ophthalmic fluticasone product, a two-week, once-daily treatment leveraging Nicox's proprietary formulation technology

Targeting dry eye disease, a \$3.4 billion prescription market in the U.S.

Eye Care Professionals require improved short-term treatment for flares and bridging to chronic therapy

Unique delivery device applies drug directly to the eyelid margin, potentially reducing steroid sideeffects

Phase 2 trial supports potential clinical utility in dry eye disease

Post-hoc analysis of 224-subject Phase 2b Mississippi trial showed a statistically and clinically significant reduction in dry eye symptoms versus placebo

Nicox reached alignment with U.S. FDA on a 505(b)(2) development path for NCX 4251 and is currently looking for partnerships outside of China to advance development of this program

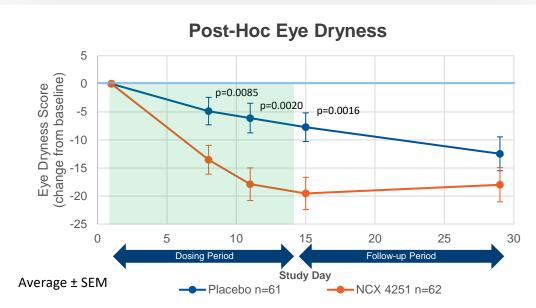




# Mississippi<sup>1</sup>: Phase 2b Post-Hoc Results Puts Dry Eye Disease in Sight



Unique eyelid margin application designed to minimize corticosteroid-induced ocular adverse events



Reduction from baseline in eye dryness score<sup>2</sup> in patients with inferior corneal fluorescein staining score of  $\geq 2$ 

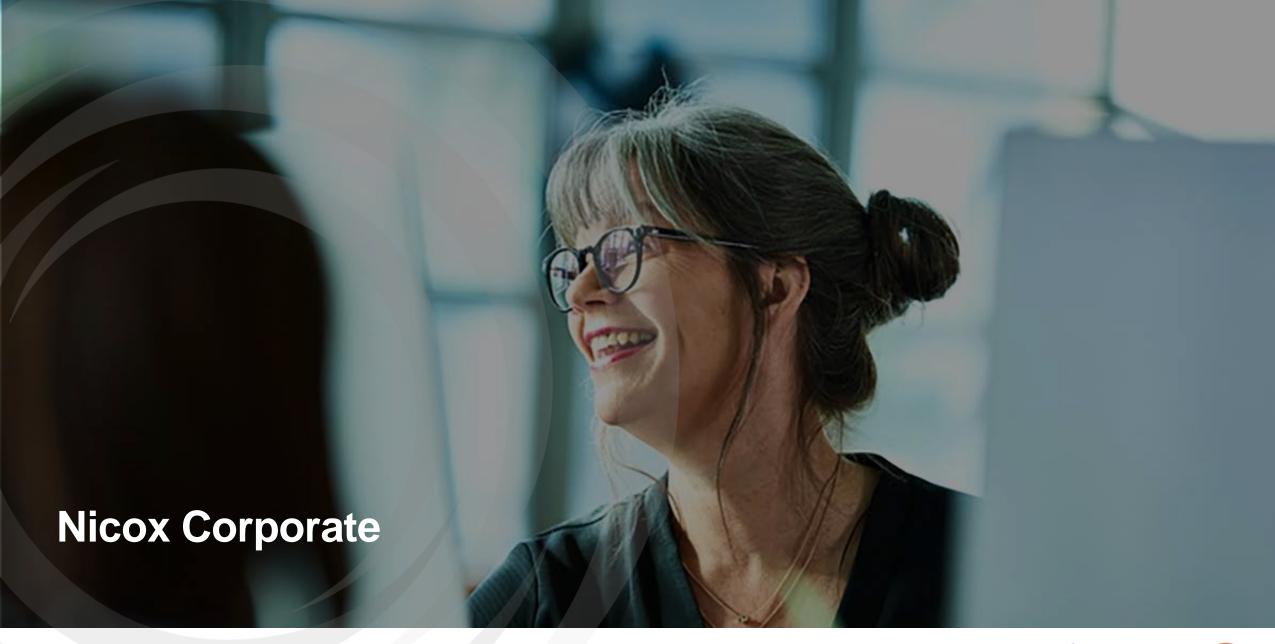
Overall Summary – The trial evaluated NCX 4251 in patients with acute exacerbations of blepharitis. NCX 4251 was found to be safe and well tolerated over 14 days with no serious adverse events (all events in the NCX 4251 arm were mild). Topline results of the trial did not meet primary endpoint

# Post-hoc results from the trial suggest NCX 4251 may be effective in dry eye disease:

 Patients with a baseline score of ≥ 2.0 (on a scale of 0 to 4) for fluorescein staining demonstrated a statistically significant difference in change from baseline vs. placebo for eye dryness score and several other symptoms



Mississippi: U.S. Multi-Center, Randomized, Double-Masked, Placebo-Controlled, Phase 2b Study Evaluating the Safety and Efficacy of NCX 4251 Ophthalmic Suspension, 0.1% QD for the Treatment of Acute Exacerbations of Blepharitis. ClinicalTrials.gov Identifier: NCT04675242







#### Mont Blanc Phase 3 Results May Bring NCX 470 Closer to U.S. Approval

Glaucoma: An established \$5.9Bn worldwide. \$2.9Bn U.S. market<sup>1</sup> Approximately 3 million patients in the U.S. with open angle glaucoma<sup>2</sup>

First line, prostaglandin-based therapies represent a \$1.3 billion opportunity in the U.S. alone<sup>1</sup> 40% of patients on existing monotherapies fail to reach target IOP, risking disease progression and vision loss

Positive Phase 3 results are a major milestone for Nicox First Phase 3 trial demonstrated non-inferiority of NCX 470 to latanoprost<sup>3</sup>

Statistical superiority to latanoprost was not achieved. However, NCX 470 was statistically superior to latanoprost in IOP reduction from baseline at 4 of the 6 timepoints, and numerically greater at all 6 timepoints

Next Steps on the path to NDA submission

Complete enrollment in the ~670 subjects/~60 sites (U.S.& China) Denali Phase 3 trial Denali topline results expected in 2025<sup>4</sup>

- https://www.cdc.gov/features/glaucoma-awareness/index.html
- Nicox Press Release 31 October 2022





# Partnering Deals Include Potential Future Payments & Royalties

NCX 470 OcuMen W 版 版 维

Potentially differentiated treatment for IOP lowering

6% to 12% royalties on future net sales<sup>1</sup> in China and Southeast Asia

Ocumension pays 50% of the Denali Phase 3 clinical trial costs

Nicox exploring commercial partnerships for both the U.S. and Japan



First eye drop for glaucoma approved in 20 years with a novel approach to reduce IOP Entitled to \$5 million net milestone at \$100 million net sales 6% to 12% net<sup>2</sup> royalties on global sales







First and only eye drop formulation of cetirizine for allergic conjunctivitis

NDA submitted in China by Ocumension<sup>3</sup> with approval and launch expected in 2024. Potential for up to \$17.2 million in sales milestones plus 5% to 9% royalties on net sales which are forecast by Ocumension to be over \$100 million annually within 7 years. Commercialized by Eyevance (a whollyowned subsidiary of Santen Pharmaceutical Co.) in the U.S.

NCX 4251



Novel treatment with unique mode of application in dry eye disease

Potential for up to \$11.3 million in future milestones plus 5% to 10% royalties on net sales in China by Ocumension<sup>4</sup>

Nicox looking for partnerships outside of China to advance development of this program

- 1. Ocumension has rights in Chinese, SE Asian markets and Korea
- 2. Net of royalties payable to Pfizer, per the terms of the contract signed with Pfizer in August 2009
- Ocumension has rights in Chinese and SE Asian markets
- 4. Ocumension has rights in Chinese markets





# Financial Highlights

#### Cash balance expected to support current operations through Q2 2024

#### Estimated Financial Position and Ownership as of March 31, 2023<sup>1</sup>

Cash, Cash Equivalents	€21.4 million	
Long term debt <sup>2</sup>	€22.8 million	
Cash runway <sup>3</sup>	Q2 2024	
Outstanding Shares <sup>4</sup>	50.1 million	
Management and Employees Ownership <sup>5</sup>	<2%	
Key Institutional Investors	Armistice Capital 5% HBM Healthcare Investments (Cayman) 5%	
Bryan Garnier	Eric Yoo	
Edison Investment Research	Pooya Hemami	
H.C. Wainwright	Yi Chen	
Kepler Cheuvreux	Arsene Guekam	
Edison Investment Research  H.C. Wainwright	Pooya Hemami Yi Chen	

<sup>1.</sup> Figures non audited.. 2. Includes Kreos Capital bond financing agreement (€1.8 million), a non-dilutive loan facility credit agreement (€1.7 million) guaranteed by the French state related to the COVID-19 pandemic and (€2.3 million) of present value attributed to the put option granted in the November 2022 equity financing. In the case of a merger by acquisition (*fusion par absorption*), merger (*fusion par création d'une nouvelle société*), division (*scission*), or a change of control within the meaning assigned in article L.233-3 I of the French commercial code (Code de commerce) where the consideration for such transaction is Nicox shares at a value of less than €1.70, the exercise price of the warrants, Armistice can request that Nicox purchases the warrants granted to Armistice at their Black Scholes value (using pre-defined terms). 3. Based exclusively on the development of NCX 470. 4. Existing outstanding shares as of March 20, 2023. 5.To the best of our knowledge, based on issued share capital as of March 20, 2023





# Value-Creating Milestones

#### Building a high-value ophthalmology pipeline



#### October 2022

NCX 470 Mont Blanc Phase 3 topline results

#### **April 2023**

ZERVIATE NDA in China submitted

#### **Throughout 2023**

Communication of Mont Blanc results at key ophthalmology congresses

#### 2024

New nonclinical and clinical data on NCX 470 MOA\* and potential beneficial effects on the retina

#### **2025**<sup>1</sup>

NCX 470 Denali Phase 3 (enrolling); topline results

#### H1 2023

Initiation of Phase 3b trials evaluating NCX 470 MOA\* and potential beneficial effects on the retina

#### 2024

Launch and approval of ZERVIATE in China





In progress



Future

\* MOA = mechanism of action





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