





### Forward-Looking Statements

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Risk factors which are likely to have a material effect on Nicox SA's business are presented in the 3<sup>rd</sup> chapter of the "Document d'Enregistrement Universel, rapport financier annuel et rapport de gestion 2021" filed with the French Autorité des Marchés Financiers (AMF) on April 29, 2022 under number D.22-0392 available on Nicox SA' website (www.nicox.com).

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

Differentiated pipeline with recent, 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) announced October 31, 2022. Potential retinal benefit seen in preclinical models<sup>1</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 €25.6 million<sup>2</sup> expected<sup>3</sup> to fund operations until mid-November 2023

Current and potential future revenue and value from global partnerships



<sup>1.</sup> J Ocul Pharmacol Ther. 2022, 38: 496-504

<sup>2</sup> As of Sentember 30, 2022

<sup>2.</sup> As or September 30, 2022



### Broad Global Leadership Experience



Andreas Segerros
Chief Executive
Officer

**PHARMACIA** 







Sandrine Gestin
VP, Finance





Doug Hubatsch

EVP, Chief Scientific Officer









Emmanuelle Pierry

General Counsel & Head,

Legal

Former member of the Paris Bar



Gavin Spencer

EVP, Chief Business Officer &

Head, Corporate Development









## Board Bringing Extensive Experience in Ophthalmology and Pharmaceuticals



JEAN-FRANÇOIS LABBE Chairman of the Board





LES KAPLAN
Director





MICHELE GARUFI
Director





LAUREN SILVERNAIL Director







ADRIENNE GRAVES
Director





LUZI VON BIDDER
Director







## **Unique Combination of Competencies**

### Capable of bringing NCX 470 to approval and driving future growth



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







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

Positive pivotal Phase 3 topline results from the Mont Blanc trial announced October 31, 2022

Large and established market<sup>1</sup>:

\$5.9 billion worldwide

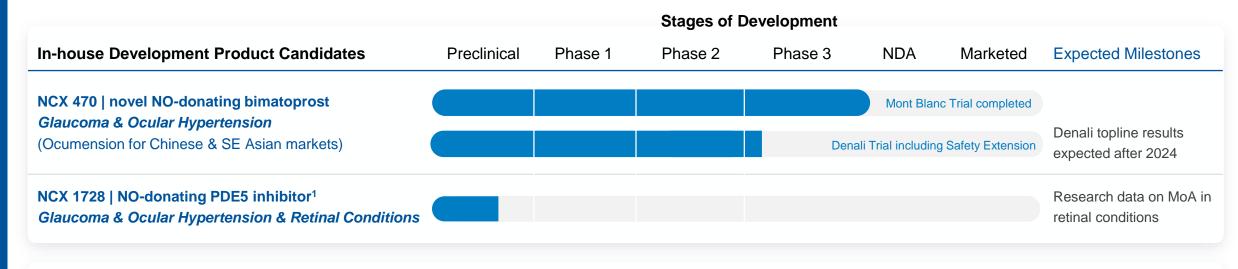
\$1.3 billion prostaglandin analog market in the United States

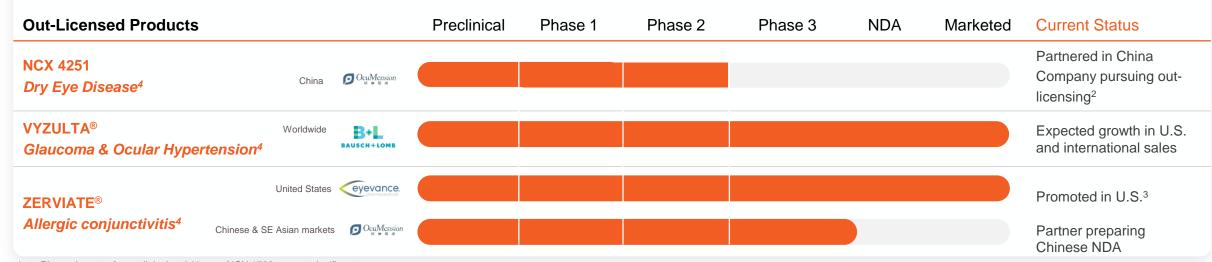
First non-combination product to demonstrate statistical non-inferiority to a prostaglandin analog in a pivotal trial, thereby meeting the efficacy requirements for approval in the United States





## NCX 470 Leads a Differentiated Ophthalmology Pipeline





- 1. Planned costs of non-clinical activities on NCX 1728 are not significant
- 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 United States due to the additional costs and timings associated with the change in indication, followed by the decision to out-license the product
- The net book value of ZERVIATE corresponds mainly to the value of the asset allocated to the Chinese territory, for which the rights were granted to the partner Ocumension, following an impairment (€12.7 million) to the value in the United States taking into consideration changes in the U.S. market for topical anti-allergics
- 1. The costs of development and, as the case may be, commercialization, of these products and product candidates are paid by the partner



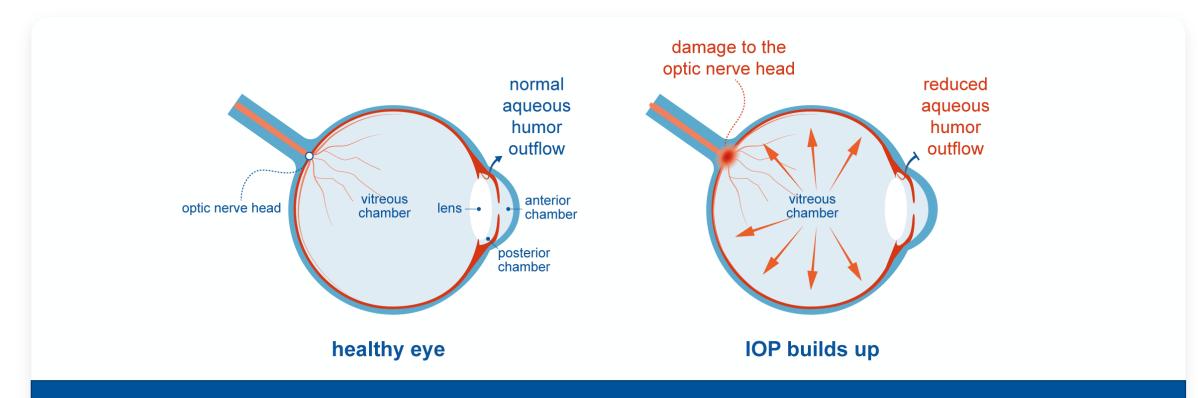






### Glaucoma Snapshot

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]"





### 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 leads 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

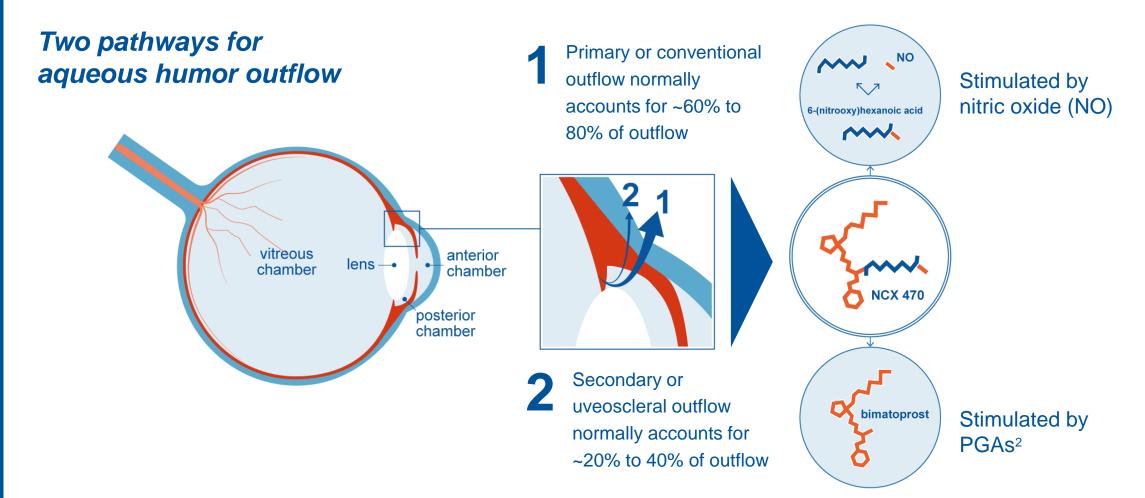
Robin AL et al, Does adjunctive glaucoma treatment therapy affect adherence to the initial primary therapy? Ophthalmology. 2005; 112:863-868

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



## NCX 470 Targets the Two Key Outflow Pathways for IOP Lowering

Proven dual mechanism of action<sup>1</sup>



Nonclinical optic nerve/retinal damage models demonstrate potentially beneficial retinal effects<sup>3</sup>



<sup>1.</sup> Same mechanism of action as Nicox's first commercialized NO-donating product, latanoprostene bunod

<sup>2.</sup> PGAs = Prostaglandin Analogs;

<sup>3.</sup> J Ocul Pharmacol Ther. 2022. 38: 496-504



## Positive Topline NCX 470 Mont Blanc Results Released October 31, 2022

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 noninferiority achieved

N=691

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

Adaptive study design selected the 0.1% dose for the duration of the trial

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 after 2024





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

### Designed to Evaluate NCX 470 vs. Established Therapy, Latanoprost

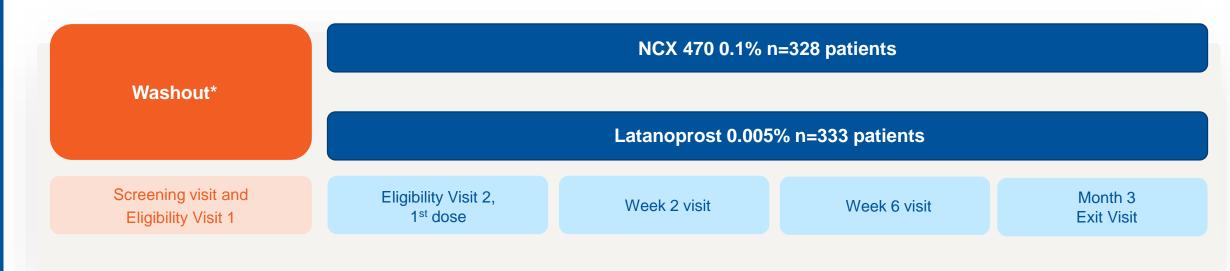
Randomized, controlled, double-masked, parallel design trial. Patients with open angle glaucoma or ocular hypertension were randomized 1:1 to once-daily treatment with NCX 470 0.1% or latanoprost 0.005%

#### **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







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

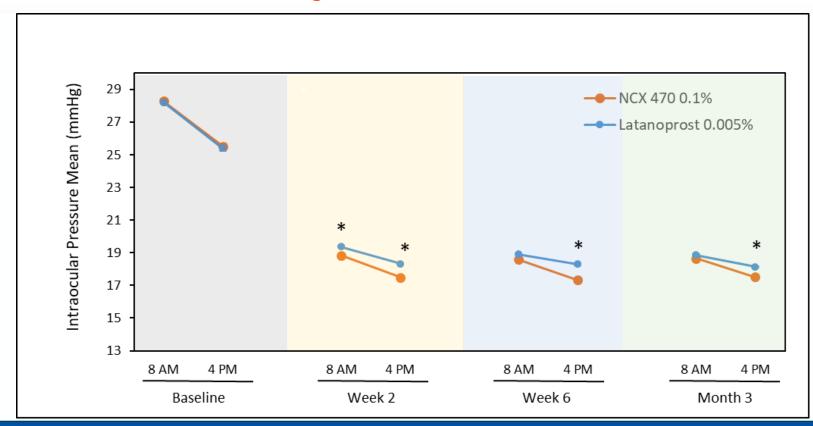
	NCX 470 0.1% N = 328	Latanoprost 0.005% N = 333
Mean Diurnal Baseline (8am+4pm) IOP, mmHg, Study Eye (SD)	26.9 (2.04)	26.8 (2.02)
Gender, n (%) Female Male	200 ( 61.0%) 128 ( 39.0%)	188 ( 56.5%) 145 ( 43.5%)
Age, Years (SD)	63.6 (10.12)	62.7 (11.73)
Completed the Study	314 (95.7%)	316 (94.9%)
Discontinued 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%)





### NCX 470 0.1% IOP Lowering Compared to Latanoprost 0.005%

Significant, sustained IOP-lowering effects



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

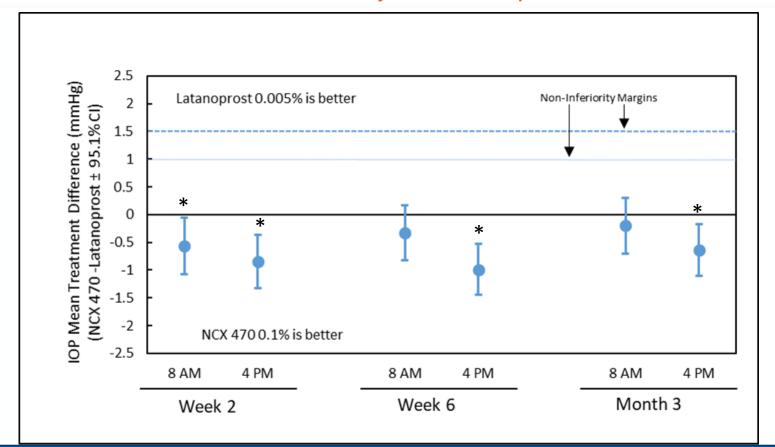
IOP-lowering effect from baseline was 8.0 to 9.7 mmHg for NCX 470 0.1% vs. 7.1 to 9.4 mmHg for latanoprost (reduction from baseline in time-matched IOP at 8 AM and 4 PM across the week 2, week 6 and month 3 visits)





## NCX 470 0.1% IOP Lowering Compared to Latanoprost 0.005%

NCX 470 0.1% Achieved Non-inferiority vs. Latanoprost 0.005%



Non-inferiority criteria: The upper limit of all 6 95.1% confidence intervals were required to be ≤1.5 mmHg and at least 4 of 6 were required to be ≤1.0 mmHg

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

NCX 470 0.1% demonstrated an IOP lowering effect greater than latanoprost 0.005% of up to 1.0 mmHg





## 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

Measured by a change from baseline in time-matched IOP at 8 AM and 4 PM across the week 2, week 6 and month 3 visits

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

The upper limit of the 95.1% confidence limit on the difference in the treatment effect between NCX 470 and latanoprost in change from baseline in time-matched IOP to the follow-up visits (week 2, week 6, and month 3) was ≤1.5 mmHg at 6 of 6 timepoints and ≤1.0 mmHg at 6 of 6 timepoints

**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 the 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





### Positive NCX 470 Phase 3 Results a Milestone for Nicox

Novel dual action compound designed to leverage PGA and NO for a differentiated profile

NCX 470 was designed to leverage both PGA and NO mechanisms of action to safely and effectively deliver a differentiated profile in IOP lowering for patients with openangle glaucoma or ocular hypertension

NCX 470 reduced IOP by 8.0 to 9.7 mmHg in the 691-patient Mont Blanc trial

NCX 470 was statistically noninferior to latanoprost

The secondary efficacy objective, statistical superiority to latanoprost, was not achieved, however, NCX 470 was statistically superior at 4 out of the 6 timepoints

Well tolerated with no ocular serious adverse events and no treatment-related non-ocular serious adverse events

Mont Blanc Phase 3 results may bring NCX 470 closer to U.S. approval

First non-combination product to demonstrate statistical noninferiority to a prostaglandin analog in a pivotal trial

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

Phase 3 program designed to support NDA submission in U.S. and China





### 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 of ischemia/reperfusion that results in injury to the optic nerve investigated the potential protective effects of NCX 470 on the retina and the optic nerve head

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<sup>2</sup> are planned to further explore NCX 470's effects of the retina, beyond its IOP lowering properties





### Planned NCX 470 Clinical Trials to Evaluate Potential Retinal Benefit<sup>1</sup>

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

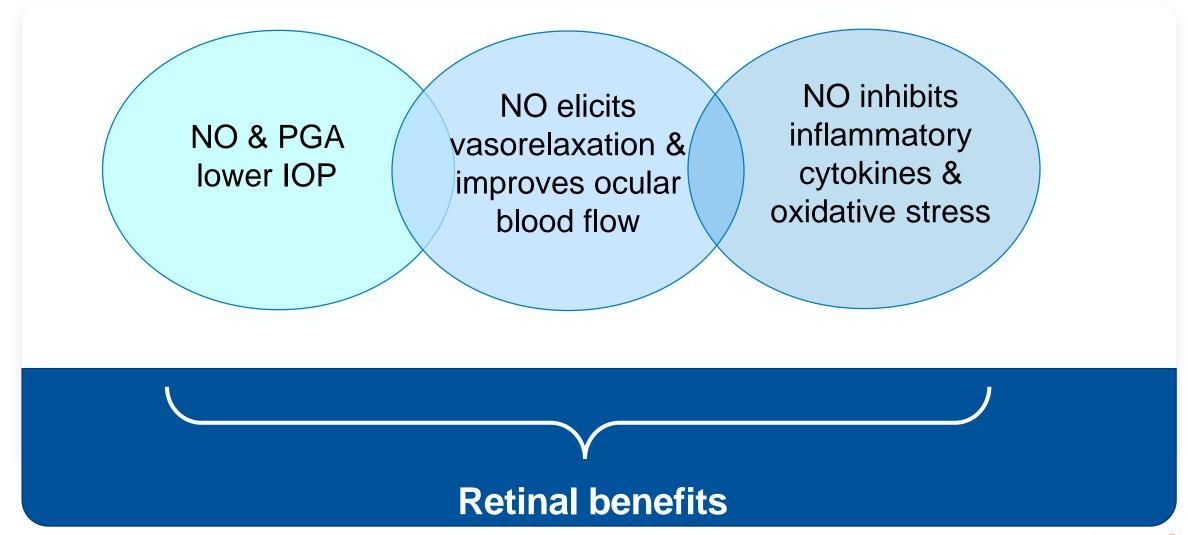
Retinal blood vessel density will be studied in a separate clinical trial using Optical Coherence Tomography (OCT)-angiography to fully understand the potential effects on retinal blood flow

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.





### Why Nitric Oxide Could Generate Retinal Benefits

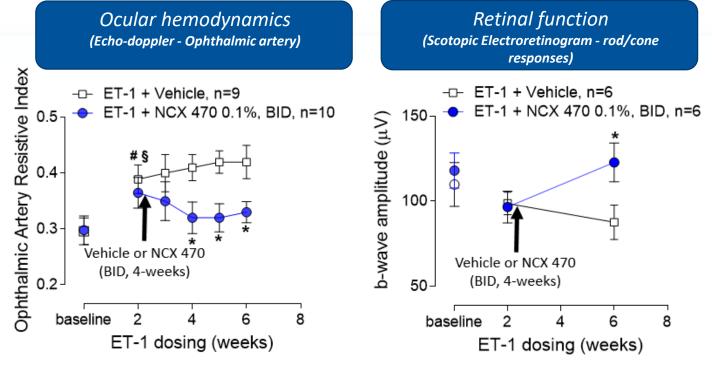






### NCX 470 Shows Retinal Cell Protection in a Nonclinical Model<sup>1</sup>

Improved ocular perfusion and retinal function in damaged eyes Potential therapeutic properties beyond IOP lowering



#\$ p<0.05 vs respective baseline; \* p<0.05 vs vehicle at the same time point, Student's t-Test

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)

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)



### Commercial Landscape of the United States Glaucoma Market

#### NCX 470 Profile<sup>1</sup>

#### Mont Blanc Phase 3 results

- 8-9.7 mmHg IOP reduction
- Non-inferior to latanoprost
- Whilst statistical superiority was not met, NCX 470 was numerically up to 1.0 mmHg better than latanoprost at certain timepoints
- NCX 470 was statistically superior to latanoprost at 4 of 6 timepoints
- Good tolerability

#### A space in the market

~\$200 million - estimated potential peak net sales in the U.S. for a product with 1.25 mmHg superior to latanoprost<sup>3</sup>

~\$100-150 million - estimated potential peak net sales range for recently launched branded products in the PGA market<sup>2</sup>

#### **Potential growth levers**



Data to be developed supporting non-IOP benefits



Commercial strength of the U.S. marketing partner is required<sup>4</sup>

For new entrants, including NCX 470 (if approved), obtaining reimbursement and getting on the formularies are critical elements to market access and successful commercialization and [significant] commercial investment by a strong marketing partner is required.



<sup>1.</sup> Profile based on Mont Blanc Phase 3 results only; The design of the efficacy part of the Denali trial is identical to that of Mont Blanc, however there is no guarantee that the results will be the same

<sup>2.</sup> Management estimates based on IQVIA Forecast Link. Data on sales of recently launched branded products in the PGA market using a 55% gross-net calculation

<sup>3.</sup> Nicox sponsored market research 2019 and 2021 (the forecast includes estimations about the future growth of the market and assumes an appropriate level of reimbursement is available)







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

Combining NO-release with PDE5

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 IOP lowering and retinal conditions

In addition to IOP lowering, NO has a role in ocular perfusion which may be beneficial in a number of orphan retinal conditions for which there is no standard treatment

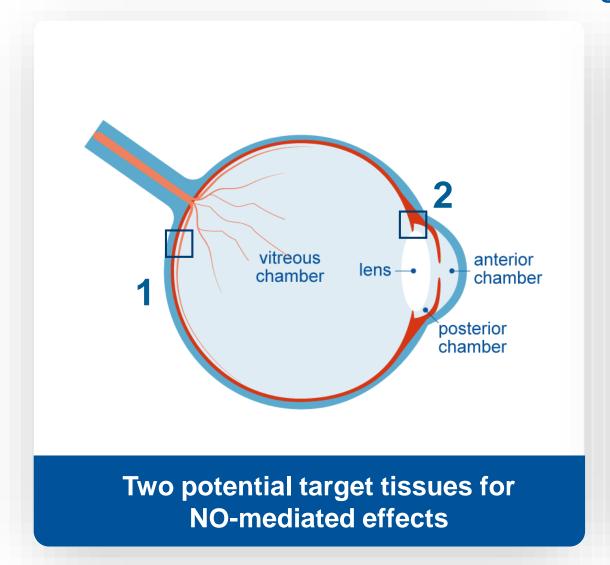
Nonclinical program focused on evaluating MoA

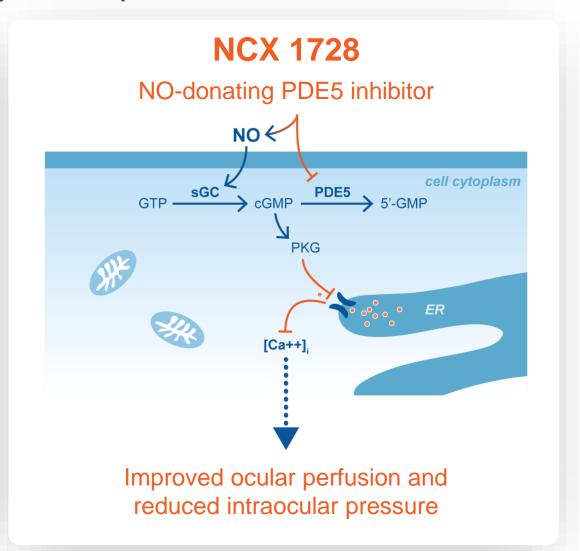
Nonclinical studies underway to evaluate the mechanism of action in models of orphan retinal conditions



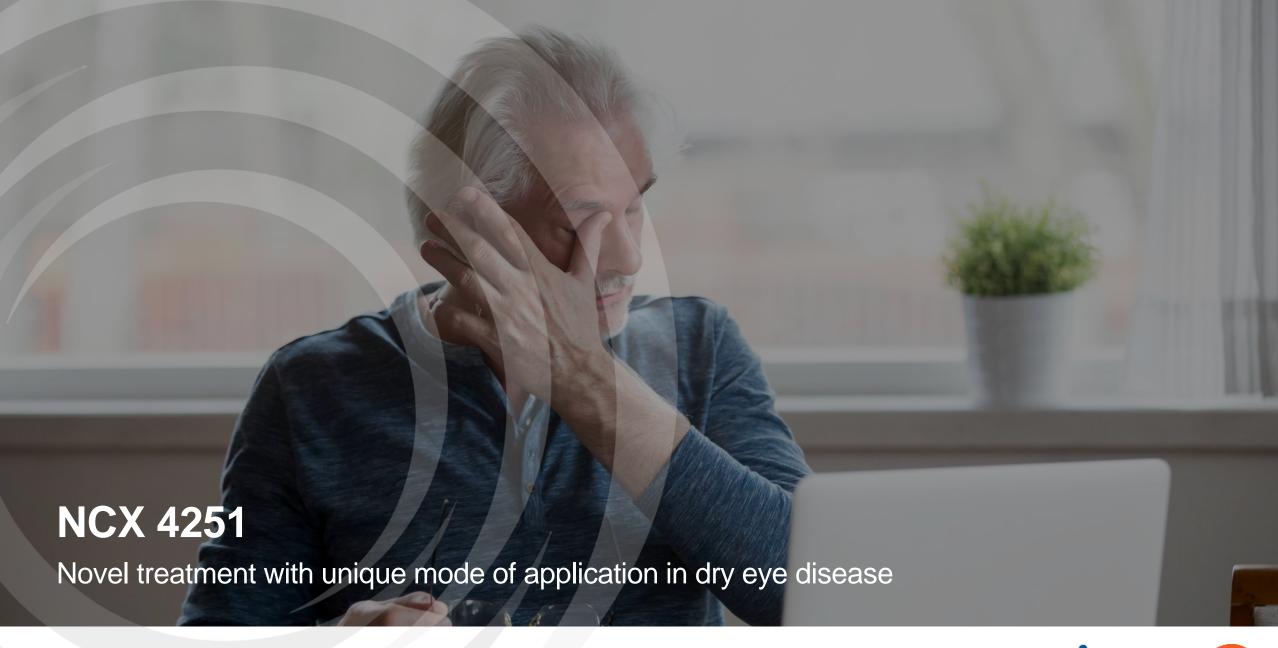


## NCX 1728: NO-Mediated IOP Lowering and Improved Ocular Perfusion













## 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

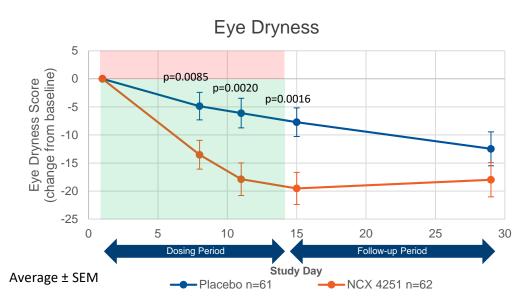




## Mississippi: Post-Hoc Results Puts Dry Eye Disease in Sight



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



Reduction from baseline in eye dryness score<sup>1</sup> in patients with inferior corneal fluorescein staining score of  $\geq 2$ 

### Phase 2 Mississippi<sup>2</sup> Trial Summary

The trial evaluated NCX 4251 in patients with acute exacerbations of blepharitis. Topline results of the trial did not meet primary endpoint of difference between NCX 4251 and placebo in the proportion of patients with complete cure of eyelid redness, debris, and discomfort

Positive post-hoc results from the Mississippi Phase 2 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

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)



<sup>.</sup> Eye dryness measured on a visual analog scale (0 to 100)

<sup>2.</sup> 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 analysis of the Mont Blanc trial data

Complete enrollment in the ~670 subjects/~60 sites (U.S. & China) Denali trial

Denali topline results expected after 2024



IQVIA Analytics Link 2021

<sup>2.</sup> https://www.cdc.gov/features/glaucoma-awareness/index.html

Nicox Press Release 31 October 2022



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

#### DR. ROBERT D. FECHTNER, MD, CHAIRMAN

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

#### DR. SANJAY G. ASRANI, MD

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

#### DR. STEVEN MANSBERGER, MD MPH

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





### Partnering Deals Include Potential Future Payments & Royalties

NCX 470



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

VYZULTA BAUSCH+LOMB

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

Phase 3 completed by Ocumension<sup>3</sup> in China: Potential for up to \$17.2 million in sales milestones plus 5% to 9% royalties on net sales

Commercialized by Eyevance (a wholly-owned 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>

Company pursuing out-licensing outside China

- Ocumension has rights in Chinese, SE Asian markets and Korea
- 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 mid-November 2023

#### Estimated Financial Position and Ownership as of September 30, 2022<sup>1</sup>

Cash, Cash Equivalents	€25.6 million
Long term debt <sup>2</sup>	€20.6 million
Cash runway <sup>3</sup>	mid-November 2023
Outstanding Shares <sup>4</sup>	43.2 million
Management and Employees Ownership <sup>5</sup>	<2%
Key Institutional Investor	HBM Partners 7.0%

#### **Analyst Coverage**

Bryan Garnier	Eric Yoo
Edison Investment Research	Pooya Hemami
H.C. Wainwright	Yi Chen
Kepler Cheuvreux	Arsene Guekam

<sup>.</sup> Unaudited results



<sup>2.</sup> Includes Kreos Capital bond financing agreement (€18.6 million) and a non-dilutive loan facility credit agreement (€2 million) guaranteed by the French state related to the COVID-19 pandemic

<sup>.</sup> Based on the development of NCX 470 alone. The company estimates it would be financed to mid-December 2023 if the option to extend the interest-only period of the Kreos loan was exercised. This option was conditional upon NCX 470 being non-inferior to latanoprost in the Mont Blanc trial. This condition was met in the Mont Blanc trial.

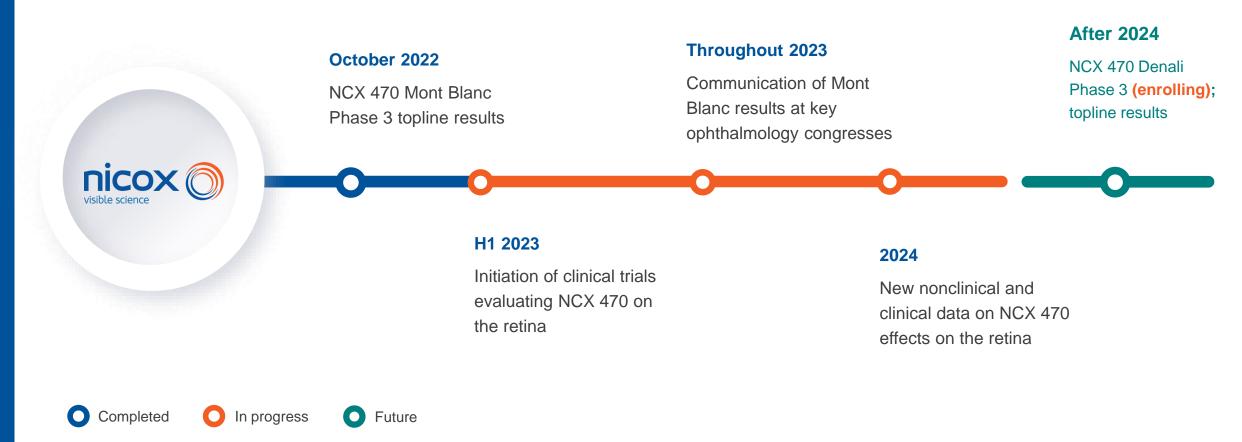
Existing outstanding shares as of September 30, 2022

<sup>.</sup> To the best of our knowledge, based on issued share capital



## Value-Creating Milestones

### Building a high-value ophthalmology pipeline







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