

# **Press Release**

# Nicox and Kowa Sign Key Agreement worth up to €191.5 million for Exclusive Rights to Glaucoma Treatment NCX 470 in U.S. and all Unlicensed Territories

- €7.5 million upfront, with total potential development and commercial milestones, depending on Denali trial results, of up to €191.5 million
- Tiered royalties of up to 20% in the U.S., starting at a minimum of 8%, with tiered high single to double digit royalties elsewhere
- Kowa will assume full responsibility for the preparation and filing costs of the U.S. NDA for NCX 470, and all future development and commercial costs
- Provides flexibility for Nicox to explore future growth options

### July 17, 2025 – release at 7:30 am CET Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced the signing of a major new agreement concerning NCX 470 with Kowa Company, Ltd., a Japanese company with a global pharmaceutical business engaged in ground-breaking research, development and marketing. The agreement, worth up to €191.5 million, grants Kowa exclusive rights to develop and commercialize NCX 470, Nicox's nitric oxide (NO)-donating bimatoprost eye drop, for the lowering of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension in the U.S. and all other territories of the world excluding Japan, China, Korea and Southeast Asia. Kowa <u>already</u> has a license to NCX 470 for Japan, where it is preparing to enter a Phase 3 clinical trial. NCX 470 is also licensed to Ocumension Therapeutics for China, Korea and Southeast Asia.

Under the terms of the agreement, Nicox will receive an upfront payment of  $\in$ 7.5 million on signing. Additional near-term milestones payments are due on positive topline results from the Denali clinical trial, expected mid-August to mid-September 2025, and on submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), which is currently expected in H2 2026. The total potential development and sales milestones payments will be either  $\in$ 127 million or  $\in$ 191.5 million, depending on the outcome of the Denali clinical trial, plus royalties up to 20% in the U.S.

"This new agreement with our existing partner, Kowa, is a major endorsement of NCX 470's potential in glaucoma and marks a major step forward in strengthening Nicox's financial position. With NCX 470 now globally licensed, we are focused on delivering the Denali Phase 3 results, which we anticipate releasing mid-August to mid-September." said **Gavin Spencer, Chief Executive Officer of Nicox.** "The revenue stream we expect from NCX 470 gives us the flexibility to pursue future growth opportunities, leveraging our expert U.S. ophthalmology development team."



"Expanding our collaboration with Kowa, who now becomes our key commercial partner for NCX 470 in the U.S and other major territories, is based on a very successful history of working together. We believe that Kowa has recognised the significant market potential of NCX 470, which we expect to be confirmed with the upcoming results from the Denali Phase 3 trial." said **Emmet Purtill, VP Business Development of Nicox.** "We look forward to continuing to work with Kowa as well as our partner for the Chinese market, Ocumension, to bring NCX 470 to glaucoma patients worldwide."

# **Details of the Agreement**

Under the terms of the exclusive licensing agreement, Kowa is granted rights to develop and commercialize NCX 470 worldwide, excluding the territories already licensed to Ocumension (China, Korea and Southeast Asia) and to Kowa itself (Japan). The collaboration will be managed by a Joint Steering Committee. Key terms include:

# Milestone Payments

Nicox will receive an upfront payment of €7.5 million upon signing the agreement. Additional near-term milestones payments are due on positive topline results from the Denali Phase 3 clinical trial, expected mid-August to mid-September 2025 and upon submission of an NDA to the FDA, which is currently expected in H2 2026. The total potential development and sales milestones payments will be either €127 million or €191.5 million, depending on the outcome of the Denali clinical trial.

# Royalty Payments

Kowa will pay Nicox tiered royalties in the U.S. which could reach 20% of net sales. Depending on the results of the Denali clinical trial, royalties due in the U.S. will initially be 8% or 10%. Outside of the U.S., Nicox will receive tiered royalties ranging from single-digit to double-digit percentages.

### Nicox Obligations

Nicox is responsible, at its cost, for generating the remaining development data necessary for the NDA submission to the FDA (principally pharmacokinetic studies) and will support Kowa in preparation of the NDA.

### Kowa Obligations

Other than the activities for which Nicox is responsible, Kowa is responsible, at its cost, for all development, regulatory and commercialization activities for NCX 470 in the licensed territories.

# Cash Runway and Debt Repayment

As disclosed in the amended bond agreement <u>announced</u> on 14 October 2024, 70% of the upfront payment from Kowa will be used to partially reimburse Nicox's debt, reducing the total debt to  $\in$ 9.6 million. Based on the current cash position (estimated<sup>1</sup> at  $\in$ 5.9 million as of 30 June 2025) expected revenue and anticipated milestone payments, Nicox forecasts that it has over 12 months of cash at the date of signature of this agreement.

<sup>&</sup>lt;sup>1</sup> Non-audited figure www.nicox.com



### **Glaucoma Pharmaceutical Market**

The glaucoma pharmaceutical market is estimated at over \$7 billion<sup>2</sup>, with the U.S. market accounting for around 40%, growing globally at around 3% to 5% CAGR and the number of patients globally is estimated to be around 80 million<sup>3</sup>.

### About NCX 470

NCX 470, Nicox's lead clinical product candidate, is a novel NO-donating bimatoprost eye drop, currently in Phase 3 clinical development in the U.S., China and Japan (clinical trial authorisation granted for Japan) for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. Results of Mont Blanc, the first of the Phase 3 clinical trials, have been extensively <u>published</u> and are available on our website. The second Phase 3 clinical trial, Denali, is currently ongoing. The last patient in Denali has completed their final visit, and the results are expected mid-August to mid-September 2025. Mont Blanc and Denali have been designed to fulfil the regulatory requirements for safety and efficacy Phase 3 trials to support NDA submissions in both the U.S. and in China. All remaining NDA-enabling pharmacokinetic and non-clinical studies necessary to support the U.S. NDA filing are on track. A separate Phase 3 program is underway to support Japanese approval, with the first patient expected to be enrolled in H2 2025. NCX 470 is exclusively licensed to Ocumension Therapeutics in China, Korea and Southeast Asia, and to Kowa in the rest of the world.

### About Nicox

Nicox SA is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470 (bimatoprost grenod), a novel nitric oxide-donating bimatoprost eye drop, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension, licensed to Ocumension Therapeutics for the Chinese, Korean and Southeast Asian markets and to Kowa elsewhere. Nicox also has a preclinical research program on NCX 1728, a nitric oxide-donating phosphodiesterase-5 inhibitor, with Glaukos. Nicox's first product, VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, is available commercially in the U.S. and over 15 other territories. Nicox generates revenue from ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Harrow, Inc. in the U.S., and Ocumension Therapeutics in the Chinese and in the majority of Southeast Asian markets.

Nicox, headquartered in Sophia Antipolis, France, is listed on Euronext Growth Paris (Ticker symbol: ALCOX) and is part of the CAC Healthcare index.

For more information www.nicox.com

Analyst coverage

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The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

### Contacts

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<sup>&</sup>lt;sup>2</sup> Antiglaucoma Drug Market Size, Trends, Growth Report 2034; Glaucoma Therapeutics Market Report by Drug Class (Prostaglandin Analogs, Beta Blockers, Alpha Adrenergic Agonists, Carbonic Anhydrase Inhibitors, Combination Drugs, and Others), Indication (Open Angle Glaucoma, Angle Closure Glaucoma, and Others); Glaucoma Therapeutics Market Size, Growth, Analysis - 2031 <sup>3</sup> World Glaucoma Association website: World Glaucoma Association » What is glaucoma?



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Risks factors which are likely to have a material effect on Nicox's business are presented in section 3 of the "*Rapport Annuel 2024*" which is available on Nicox's website (<u>www.nicox.com</u>).

Finally, this press release may be drafted in the French and English languages. If both versions are interpreted differently, the French language version shall prevail.

### Nicox S.A.

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