

Press Release

Nicox Announces Positive Pre-submission Regulatory Feedback in China Supporting NDA filing for NCX 470

- **Exclusive licensee for China, Ocumension, received positive pre-submission regulatory feedback from the Chinese Center for Drug Evaluation (CDE) for NCX 470**
- **Based on this feedback, Ocumension intends to proceed with the New Drug Application (NDA) submission in China**
- **Submission should follow shortly after NCX 470 NDA to the U.S. Food and Drug Administration (FDA), expected summer 2026**

June 18, 2026 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that its exclusive licensee in China, Ocumension Therapeutics, has received positive pre-submission regulatory feedback from the Chinese Center for Drug Evaluation for NCX 470. Ocumension considers the feedback is sufficient to proceed with the submission of the dossier for marketing approval of NCX 470 to the Chinese National Institutes for Food and Drug Control. NCX 470 (bimatoprost grenod) is a novel nitric oxide-donating bimatoprost eye drop for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

“We congratulate our colleagues at Ocumension for the progress made on NCX 470 in China. This positive interaction with the Chinese Center for Drug Evaluation follows the recently announced successful NCX 470 pre-New Drug Application meeting with the U.S. FDA. With these two outcomes in hand, we are confident the respective submissions can be achieved shortly.” said Doug Hubatsch, Chief Scientific Officer of Nicox. “As previously communicated, we expect that our exclusive U.S. partner, Kowa, will submit the New Drug Application for NCX 470 in the U.S. this summer, and that the Chinese submission will follow shortly afterwards.”

NCX 470 is licensed globally to Kowa, except in the Chinese market, South Korea and Southeast Asia, where it is licensed to Ocumension Therapeutics. Nicox may receive regulatory and sales milestones and will be paid royalties on worldwide sales. All regulatory and commercialisation costs are borne by Kowa and Ocumension.

Key Future Milestones

- **NCX 470 NDA submission in the United States:** expected in summer 2026
- **NCX 470 NDA submission in China:** expected shortly after submission in the U.S.
- **NCX 470 Phase 3 clinical program in Japan:** initiated in summer 2025.

About Nicox

Nicox SA is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead late-stage development program 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 in the rest of the world. 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).

For more information www.nicox.com

Analyst coverage

H.C. Wainwright & Co

Yi Chen

New York, U.S.



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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 2025" which is available on Nicox's website (www.nicox.com).

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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