Press Release

Nicox Announces NCX 470 NDA in China Accepted for Review

- **Acceptance of the NCX 470 dossier initiates the review process**
- **Regulatory decision expected within 12-18 months from the August submission**
- **Q&A on Ocumension available on Nicox's website**

September 11, 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 confirmation from China's National Medical Products Administration (NMPA) that the NCX 470 (also referred to as OT-301 by Ocumension) New Drug Application (NDA) in China has been accepted for review. This acceptance initiates the review of the NDA by the NMPA. Nicox had previously announced the submission of the NCX 470 NDA in China as a treatment to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

"The acceptance for review of the NCX 470 NDA in China initiates the examination process and is another key step towards its commercialisation in this territory. We look forward to continuing to work with the Ocumension team as they prepare for a future launch." said **Gavin Spencer, Chief Executive Officer of Nicox.**

Ocumension's Press release is here.

Ocumension has paid Nicox license fees of €18 million for the rights to develop and commercialise NCX 470 in the Chinese, Korean and Southeast Asian markets, contributed 50% of the Denali clinical trial costs and is one of Nicox's principal shareholders. Nicox will receive tiered royalties on sales of NCX 470 made by Ocumension ranging from 6% to 12%. Ocumension already has an ophthalmology sales force in place throughout China and is therefore well-positioned for a rapid launch of NCX 470.

There is no fixed period for approval of a pharmaceutical product in China, however the review process typically takes 12 to 18 months following submission. The decision on NCX 470 in China is expected after the decision by the U.S. FDA, who have assigned the PDUFA date[1] for 30 April 2027.

Key Upcoming NCX 470 Milestones

- **Japan Phase 3 clinical trials results:** trials ongoing
- **NDA approval in the U.S.:** PDUFA date 30 April 2027
- **U.S. Launch:** expected in H2 2027, subject to NDA approval

[1] A PDUFA date is the target date by which the U.S. Food and Drug Administration (FDA) aims to complete its review and issue a decision on a New Drug Application (NDA) under the Prescription Drug User Fee Act (PDUFA).

- **NDA decision in China:** Submission made in August 2026, accepted for review on 10 September 2026

About NCX 470

NCX 470 is a novel nitric oxide (NO)-donating bimatoprost eye drop that leverages the potent intraocular pressure (IOP)-lowering effects of NO and prostaglandin analogs (PGAs). NCX 470 incorporates Nicox's proprietary NO-donating research platform and bimatoprost in a single molecule. NCX 470 is designed to release bimatoprost and NO into the eye to lower IOP by two different pathways in patients with open-angle glaucoma or ocular hypertension. NO is a well-known small, naturally occurring signalling molecule that plays a key role in the regulation of IOP through activation of soluble guanylate cyclase (sGC). NO brings additional IOP-lowering efficacy by enhancing aqueous humor drainage from the eye via a different mechanism of action to that of PGAs.

NCX 470 has completed two Phase 3 clinical trials designed to fulfil the regulatory requirements for safety and efficacy to support NDA submissions in the U.S. and China, Mont Blanc and Denali. Both trials were positive and met the efficacy endpoints necessary for submission of a New Drug Application in the United States and China. NDAs for NCX 470 have been submitted in the U.S. and China. NCX 470 is an investigational product and has not yet been approved by the FDA.

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.

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.

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Disclaimer

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 are 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.

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