Press Release

Nicox Announces Positive Feedback from pre-NDA Meeting with U.S. FDA for NCX 470

- **U.S. NDA submission on track for summer 2026**
- **Nicox to receive milestone payment from Kowa upon submission of the NDA**
- **NDA submission based on Phase 3 clinical data showing NCX 470 lowered intraocular pressure by up to 10mmHg in patients with open-angle glaucoma or ocular hypertension**

February 16, 2026 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that it has received positive written feedback from its NCX 470 pre-NDA (New Drug Application) meeting with the U.S. Food and Drug Administration (FDA). The minutes confirm that the current data package and the proposed content and format of the proposed NDA application is generally acceptable for submission. The FDA requested complementary pharmacokinetic data, which will be generated in a small number of patients as part of an ongoing study in Japan, and will not impact any timelines. The NDA remains on track for submission in summer 2026. 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.

"The productive and collaborative pre-NDA meeting with the FDA was conducted with our partner Kowa. The outcome supports the finalisation of our registration dossier with its comprehensive data package, including positive results from two Phase 3 studies, and facilitates proceeding with submitting the NCX 470 New Drug Application to the U.S. Food and Drug Administration. Nicox will now transfer ownership of the application to Kowa to make the submission as planned in the summer of 2026," **said Doug Hubatsch, EVP and Chief Scientific Officer of Nicox.**

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.

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

Nicox
Gavin Spencer
Chief Executive Officer
T +33 (0)4 97 24 53 00
communications@nicox.com

Disclaimer

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

Risk factors which are likely to have a material effect on Nicox's business are presented in section 3 of the "*Rapport Annuel 2024*" and in section 4 of the "*Rapport semestriel* 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.

Nicox S.A.
Sundesk Sophia Antipolis, Bâtiment C, Emerald Square, Rue Evariste Galois, 06410 Biot, France
T +33 (0)4 97 24 53 00