Press Release

Nicox Completes NCX 470 New Drug Application Key Data Generation for Submission as Planned in H1 2026

- **All clinical trial and long-term stability data required for the preparation of the New Drug Applications (NDA) has been generated and analysed**
- **Pre-NDA meeting[1] with the U.S. Food and Drug Administration (FDA) in preparation; U.S. NDA submission on-track as planned in H1 2026**
- **Submission of NDA in China similarly on track for 2026**

December 16, 2025 – 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 successfully completed generation and analysis of all key data required to support the submission of New Drug Applications (NDAs) in the U.S. and China. Specifically, this includes all clinical trial and long-term stability data, compliant with International Council for Harmonisation (ICH[2]) guidelines, on batches of both the NCX 470 drug material and finished drug product. In addition to data from the NCX 470 clinical trials, these other elements are a standard part of an NDA submission and provide evidence to support the manufacturing and shelf-life of both the drug and the finished drug product, as well as investigating the drug metabolism. Nicox is now proceeding with the preparation of the NDA, which is being conducted at Kowa's cost.

"*We have achieved this milestone through close collaboration of our committed and dedicated team with our clinical and manufacturing partners and specialist research organisations. It marks a major step towards generating long-term value from NCX 470 and positioning Nicox for the future. Focus for the development team is now on accompanying our licensing partner for the U.S., Kowa, with preparation for our upcoming meeting with the Food and Drug Administration, and subsequent submission of the New Drug Application.*" said **Doug Hubatsch, EVP, Chief Scientific Officer of Nicox**.

Key Future Milestones

- **NCX 470 NDA submission in the U.S.:** expected in H1 2026
- **NCX 470 NDA submission in China:** expected shortly after U.S. submission
- **NCX 470 Phase 3 clinical program in Japan:** initiated in summer 2025. Managed and financed by Kowa.

[1] A pre-NDA meeting is a routine, standard step where a drug company meets with the FDA before submitting its New Drug Application. It serves as a final check to make sure the FDA will have everything it needs for the review.
[2] International Council for Harmonisation, http://www.ich.org, whose mission is "to achieve greater harmonisation worldwide to ensure that safe, effective and high-quality medicines are developed and registered."

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 U.S.	Yi Chen	New York,

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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Risks 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.

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