Press Release

Nicox Expects to Fully Repay Financial Debts with NCX 470 De-Risked and Globally Licensed

- **Company expects to fully repay existing financial debts in 2026**
- **NCX 470 NDA submissions in U.S. (H1 2026) and subsequently in China**
- **Milestones payable on U.S. NDA submission and on approval**
- **Glaukos extends NCX 1728 research agreement**
- **Future strategic options under consideration including collaborations or business combinations**
- **Q&A for shareholders available on the Nicox website: Q&A**

September 4, 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 expects to be able to fully repay all existing financial debts in 2026 and provided an update on its portfolio and financial situation. This follows the recent announcements of the licensing of NCX 470 to Kowa, completing our global coverage, and the positive results from our second pivotal Phase 3 clinical trial, Denali. NCX 470 has met the requirements for New Drug Applications (NDA) in the U.S. and China, with NDA submission expected in H1 2026 in the U.S., and subsequently in China. Based on these submissions, the Company expects to have recurrent revenue from 2027, in addition to milestone payments on NDA submission and approval. Costs of the NDA submissions are the responsibility of our partners.

"*Nicox is a revenue generating biotech with a deep and proven expertise in ophthalmology development, transactions and corporate operations. Following the recent announcement of the licensing deal for NCX 470 with Kowa, which fulfils our global licensing plans, we have also completed the second pivotal Phase 3 clinical trial, Denali, for NCX 470 in the U.S. and China. Our team will be supporting our partners, Kowa and Ocumension, in submitting the NCX 470 New Drug Applications and ensuring broad communication of the product profile and data."* said **Gavin Spencer, Chief Executive Officer of Nicox**. "*We have demonstrated that Nicox can deliver on both the development of major clinical assets and the associated financing, whilst simultaneously implementing commercial solutions. In doing so, we have created long-term revenue streams for the Company, addressed our short-term financial needs and expect to fulfil our obligations to creditors. We believe we are now in a strong position to explore strategic options, including collaborations or business combinations."*

Key Future Milestones

- **NCX 470 New Drug Application (NDA) filing in the United States:** expected in H1 2026.
- **NCX 470 New Drug Application (NDA) filing in China:** expected after submission in the U.S.
- **Results from NCX 470 Phase 3 clinical program in Japan:** Program initiated in summer 2025. Managed and financed by Kowa.

Financial Update

NCX 470 is now licensed globally, with milestone payments expected in 2026 and 2027. Royalties on net sales are expected from 2027. Based on the expected upcoming milestones and the repayment of all existing financial debts, the Company is financed into Q3 2026. The Company remains committed to cost control, optimizing resource allocation while maintaining the capabilities required to support our strategic objectives. If any of the assumptions around estimated income or costs change, this may impact the cash runway of the Company.

Portfolio update

NCX 470, Nicox's lead product candidate, is licensed globally to two top-tier pharma partners, Kowa and Ocumension Therapeutics. The first two Phase 3 trials, Mont Blanc and Denali, have met the requirements for submission of NDAs in the U.S. and China.

- U.S. – based on Nicox's projections, an NDA with the U.S. Food and Drug Administration (FDA) is expected to be submitted in H1 2026. Kowa is responsible for the costs of the NDA submission.
- China – an NDA is expected to be filed with the Chinese regulatory authorities by our partner, Ocumension, after the U.S. submission. The costs of filing the NDA are the responsibility of Ocumension.
- Japan – a Phase 3 confirmatory efficacy and a Phase 3 safety trial have been initiated in Japanese patients. Kowa is responsible for managing the trials, at their cost, and expect to be able to file for a marketing authorisation in Japan based on these trials.
- Europe – the regulatory strategy is being evaluated.

NCX 1728, an NO-donating PDE-5 inhibitor, is being evaluated in a pre-clinical research program exploring indications for the treatment of glaucoma, including neuroprotection, and in the treatment of retinal diseases, under an exclusive research and option to license agreement with Glaukos. Glaukos has paid an extension fee to prolong the period of evaluation of NCX 1728 for the treatment of glaucoma. Evaluation for retinal conditions is also continuing, and is subject to different option conditions.

ZERVIATE® (cetirizine ophthalmic solution), 0.24%, is currently commercialized through exclusive licensing agreements in the U.S. by Harrow, Inc. and in China by Ocumension Therapeutics for ocular itching associated with allergic conjunctivitis.

VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, is exclusively licensed worldwide to Bausch + Lomb. Nicox sold the royalty revenue from VYZULTA to Soleus Capital in October 2024.

NCX 4251: Changes in the U.S. dry eye market suggest that the investment in development may not be justified. NCX 4251 remains available for licensing outside the Chinese market.

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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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 (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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