

Press Release

Nicox Updates on Corporate, Pipeline and Financing Perspectives and Will Hold a Webcast on March 18, 2024

- **Focusing resources on the clinical development of Nicox's lead program NCX 470 in glaucoma**
- **NCX 470 Denali Phase 3 trial in patients with open-angle glaucoma or ocular hypertension on track to generate topline results in H2 2025**
- **Objective of securing financing to support clinical development of NCX 470**
- **Implementing cost reductions and exploring developing other assets through collaborations**
- **Webcast (in French) to be held on March 18, 2024 at 6:00 pm CET; additional details to follow**

March 13, 2024 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today provided an update on its corporate and development strategy, in the context of its debt restructuring and the appointment of Gavin Spencer as Chief Executive Officer and announced it will be holding a Webcast (in French) on March 18, 2024 at 6:00 pm CET. Further details on the webcast will be sent shortly.

*"Nicox is focusing its resources on the Denali Phase 3 pivotal trial of its lead asset NCX 470 in glaucoma. This trial, which we are conducting with our long-term Chinese partner Ocumension Therapeutics, is on track with 80% of the target number of patients already randomized. We expect topline results in H2 2025 and expect that these will be supportive of future regulatory approval and partnering in the U.S. and other territories. We are reducing costs, including the size of the organization, and are exploring advancing NCX 1728, through collaborations. Our licensed, marketed products, VYZULTA and ZERVIATE, are generating royalty revenues for Nicox. With an experienced team delivering on the Denali trial, we are also focused on putting financing in place to complete the debt restructuring and to deliver on the promise of our innovative treatment NCX 470," said **Gavin Spencer, Chief Executive Officer of Nicox**. "We maintain constructive relationships with potential licensing and strategic partners for NCX 470 in the U.S. and other territories outside of those already partnered and continue to update them on the status."*

Update on Development Pipeline

- NCX 470, our lead clinical asset, is a novel nitric oxide-donating bimatoprost eye drop. The Denali Phase 3 clinical trial evaluating NCX 470 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, being conducted in the U.S. and China, is on track to generate topline results in H2 2025. 80% of the target number of patients have been randomized in the trial and completion of recruitment of U.S. patients is expected in Q4 2024. Supportive development data required for the preparation of the U.S. New Drug Application (NDA) is expected to be available on or before the completion of the Denali trial. The database from the trial will not be locked until after the last patient has completed their final trial visit in China, which drives the timing of the Denali results.

The Whistler Phase 3b trial investigating the dual mechanism of action of NCX 470 in IOP lowering is underway and results are expected in Q1 2025. The Phase 3b optical coherence tomography (OCT) trial to investigate the potential benefits of NCX 470 on the retina is not included in the current plan, however this development will be revisited when finances allow. Neither of the two Phase 3b trials are required for an NDA submission in either the U.S. or China. The potential of NCX 470 has been validated by our established partnerships with Ocumension and more recently with Kowa, for China and Japan respectively. With the completion of the Denali trial, Nicox expects to be in a position to partner NCX 470 for commercialization in the U.S. and potentially other territories. Mont Blanc and Denali trials have been designed to fulfill the regulatory requirements for safety and efficacy Phase 3 trials to support NDA submissions in both the U.S. and in China, where NCX 470 is exclusively licensed to Ocumension.

- NCX 1728, an NO-donating phosphodiesterase-5 (NO-PDE5) inhibitor, is a preclinical asset with potential for development in retinal conditions. The United States Patent Office (USPTO) recently issued the Notice of Allowance for the patent covering NO-PDE5 inhibitors including NCX1728, with an expiry date in 2039. Nonclinical data have demonstrated potential for the development of NCX 1728 in a number of ophthalmic conditions and we are exploring continuing the development of this product candidate through partnerships.
- NCX 4251, a novel suspension of fluticasone propionate nanocrystals, is at development stage for dry eye disease. The Company has agreed a development plan with the U.S. Food and Drug Administration (FDA) for a Phase 3 program in dry eye disease, and this asset is available for partnering outside China. NCX 4251 is licensed to Ocumension in China who are currently reviewing the pharmaceutical development activities which would be needed to enter in clinical trials in China.

Update on Revenue Generating Products

- Historically, Nicox has been generating and reporting royalty revenues from the sales of its products by its partners, primarily Bausch + Lomb for the commercialization of VYZULTA®, and from upfront and milestone payments from its licensing agreements. We expect to add to this the royalty revenue from Ocumension from the commercialization of ZERVIAE® in China this year and, in the future, from the commercialization of NCX 470 by Ocumension and Kowa, by its future partners in the U.S. and potentially other territories. Nicox estimates annual global net sales of NCX 470 could be over \$300 million¹ within 8 years of the date of launches in the U.S. and China.
- VYZULTA – Nicox continues to receive royalties on net sales of VYZULTA. Bausch + Lomb, exclusive worldwide partner of Nicox, reported 35% revenue growth for VYZULTA in 2023. VYZULTA is commercialized by Bausch + Lomb in more than 15 countries and territories, including the U.S., and is also approved in a number of other countries. VYZULTA is indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension.
- ZERVIAE – Our forecasts assume that the majority of the ZERVIAE revenue will come from the sales of ZERVIAE in China by our exclusive Chinese partner Ocumension. ZERVIAE is expected to be approved in China shortly, following submission of the NDA there in April 2023. Ocumension forecasts peak annual net sales of over \$100 million within 7 years of launch in China. ZERVIAE is also currently commercialized in the U.S. for ocular itching associated with allergic conjunctivitis by Harrow, Inc. In January 2024, Nicox expanded the territory of the exclusive licensing agreement with Harrow, Inc., to include Canada. No payment was associated with the extension of the territory, and Nicox would receive royalties on any net sales of ZERVIAE in Canada. ZERVIAE forms part of Harrow's recent [agreement](#) with Apotex for Canada.

Update on Cash Runway

The Company is financed to at least November 2024, based on focusing exclusively on the development of NCX 470. The Company is pursuing business development discussions, including the sale or license of certain assets, and exploring multiple strategic options which could further extend the cash runway. The Company is evaluating all options for financing and will use the most appropriate at the time.

¹ See [Press Release](#) of 10 July 2023
www.nicox.com

As of February 28, 2024, Nicox had a total amount of debt² of €18.2 million consisting of €16.9 million debt outstanding from Kreos Capital VI (UK) Limited (an affiliate of BlackRock) and a €1.3 million of non-dilutive loan facility credit agreement guaranteed by the French state related to the COVID-19 pandemic.

About Nicox

Nicox SA is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470, a novel nitric oxide-donating bimatoprost eye drop, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIAE® 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) and is part of the CAC Healthcare index.

For more information www.nicox.com.

Analyst coverage

Bryan, Garnier & Co
H.C. Wainwright & Co

Eric Yoo
Yi Chen

Paris, France
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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Forward-Looking Statements

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.

Risks factors which are likely to have a material effect on Nicox's business are presented in section 2.7 of the "Rapport Annuel 2022" and in section 4 of the "Rapport semestriel financier et d'activité 2023" which are available on Nicox's website (www.nicox.com).

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² This figure is the contractual amount of the debt which is different from that reported under accounting standards. It does not include the premium of €2.4 million due to BlackRock upon repayment of the non-amortizing, non-convertible bond, which would be paid on January 1st, 2026 at the earliest. Nor does it include the Armistice put option granted in the November 2022 equity financing, payable in the case of a merger by acquisition (*fusion par absorption*), merger (*fusion par création d'une nouvelle société*), division (*scission*), or a change of control within the meaning assigned in article L.233-3 I of the French commercial code (Code de commerce) where the consideration for such transaction is Nicox shares at a value of less than €1.70, the exercise price of the warrants, Armistice can request that Nicox purchases the warrants granted to Armistice at their Black Scholes value (using pre-defined terms). This figure will no longer be reported following the Company's decision to change from Consolidated Financial Statements under IFRS to statutory financial statements under French Gaap.