

# **Press Release**

# Nicox and Kowa Enter into Agreement for NCX 470 Development and Commercialization in Japan

- ❸ million upfront payment and a total of a further potential €27.5 million in milestones
- Tiered royalties on net sales of 7% to 12%
- Kowa to be responsible for all development and commercialization costs for NCX 470 in Japan
- Upfront payment extends Nicox cash runway to September 2024

February 8, 2024 – release at 7:30 am CET Sophia Antipolis, France

**Nicox SA** (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced the signature of an agreement granting Kowa Company, Ltd., a Japanese company with a global pharmaceutical business engaged in ground-breaking research, development and marketing, exclusive Japanese rights to develop and commercialize NCX 470, Nicox's nitric oxide (NO)-donating bimatoprost eye drop, for the lowering of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension.

"We are very pleased to welcome Kowa as an exclusive partner for our lead asset, NCX 470, for the Japanese market. The interest of such an established ophthalmology player confirms the scientific and commercial opportunity for NCX 470 specifically for Japanese patients." said Emmet Purtill, Vice President of Business Development at Nicox. "Japan represents one of the largest regional markets for ophthalmic therapeutics and therefore this collaboration significantly strengthens the global potential revenue for NCX 470, which we estimate to be over \$300 million in peak annual net sales."

# **Terms of the Exclusive License Agreement**

Under the terms of the exclusive licensing agreement, Kowa has the rights to develop and commercialize NCX 470 in Japan. Kowa shall make a non-refundable upfront payment of €3 million to Nicox, with a further potential €10 million in development and regulatory milestones, €17.5 million in sales milestones and tiered royalties from 7% to 12% on net sales. Kowa shall be responsible for all development, regulatory and commercialization costs for NCX 470 in Japan.

The collaboration will be managed by a Joint Steering Committee. Kowa expects to conduct additional clinical trials in Japanese patients as required for regulatory approval of NCX 470 in Japan in addition to the development data from Nicox.

# **Nicox Corporate Status Update**

Including the upfront payment from the Japanese licensing deal for NCX 470, the Company estimates it is currently funded until September 2024, exclusively based on the development of NCX 470. The Company is pursuing business development discussions which could further extend the cash runway, exploring multiple strategic options and is also discussing with its creditors to restructure its debt.

# **About NCX 470**

NCX 470, a novel NO-donating bimatoprost eye drop, is currently in Phase 3 clinical development for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. Results of Mont Blanc, the first of the two Phase 3 clinical trials, were <u>announced</u> in October 2022. The second Phase 3 clinical trial, Denali, is currently ongoing, and the results are expected in 2025, based on current recruitment rates.



Mont Blanc and Denali 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 Therapeutics. In addition to the Japanese and Chinese licensees for NCX 470, Nicox is also looking for a commercial partner in the United States.

NCX 470 is protected worldwide by a composition of matter patent until 2029, with potential extension of up to 5 years in the U.S. and Europe, and by a patent covering the eye drops formulation until 2039 in the U.S., EU, Japan and China as well as other territories.

## **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 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) and is part of the CAC Healthcare index.

For more information www.nicox.com.

#### **Analyst coverage**

Bryan, Garnier & Co Eric Yoo Paris, France H.C. Wainwright & Co Yi Chen New York, U.S.



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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).

## Nicox S.A.

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