

# **Press Release**

# Nicox Provides Second Quarter 2022 Financial and Business Highlights

- Enrollment completed in the NCX 470 Mont Blanc Phase 3 trial in glaucoma with topline results expected in November 2022
- Second quarter 2022 U.S. prescriptions for VYZULTA<sup>®</sup> increased by 35% over second quarter 2021
- Net revenue €0.7 million for second quarter 2022; cash of €31.6 million on June 30, 2022

July 20, 2022 – release at 7:30 am CET Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided financial and business highlights for second quarter 2022 for Nicox SA and its subsidiaries (the "Nicox Group") and updated on key upcoming milestones.

## **Key Upcoming Milestone**

• Mont Blanc Phase 3 clinical trial evaluating NCX 470 in patients with open angle glaucoma or ocular hypertension: Topline results expected in November 2022

# Second Quarter 2022 Financial Highlights

As of June 30, 2022, the Nicox Group had cash and cash equivalents of  $\in$ 31.6 million as compared with  $\in$ 42.0 million as of December 31, 2021 and  $\in$ 35.1 million as of March 31, 2022. The Company is financed until fourth quarter 2023, assuming the development of NCX 470 only. Net revenue<sup>1</sup> for the second quarter of 2022 was  $\in$ 0.7 million (consisting entirely of net royalty payments). Net revenue<sup>1</sup> for the second quarter of 2021 was  $\in$ 0.7 million (including  $\in$ 0.6 million of net royalty payments).

As of June 30, 2022, the Nicox Group had financial debt of €20.6 million consisting of €18.6 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2.0 million credit agreement guaranteed by the French State in August 2020 in the context of the COVID-19 pandemic.

# Second Quarter 2022 and Recent Operational Highlights

### Corporate

- Andreas Segerros joined Nicox as Chief Executive Officer on June 1, 2022. He has held executive positions (R&D, Marketing and Business Development) in the United States (U.S.), Europe and Japan, at Pharmacia, Pharmacia & Upjohn and Ferring, with a specific focus on specialty Pharma and ophthalmology. His venture capital experience comes from being Partner at the Scandinavian group Sunstone Capital, and as co-founder of Eir Ventures.
- Siobhan Garbutt has joined Nicox as Vice President and Head of Clinical Development, reporting to Doug Hubatsch, Executive Vice President, Chief Scientific Officer. Siobhan Garbutt holds a PhD. in ophthalmology and brings over 20 years of experience in clinical research and

<sup>1</sup> Net revenue consists of revenue from collaborations less royalty payments which corresponds to Net profit in the consolidated statements of profit or loss



development to Nicox. She most recently supported clinical operations in Santen Inc. and Lexitas Pharma Services Inc. Siobhan Garbutt will be based in Nicox's offices in North Carolina, U.S.

#### Commercial Out-licensed Product

VYZULTA<sup>®</sup> (latanoprostene bunod ophthalmic solution), 0.024% U.S. prescriptions<sup>2</sup> increased by 35% in the second quarter of 2022 compared to 2021. VYZULTA, exclusively licensed worldwide to Bausch + Lomb, was recently approved in Bahrain and Lebanon, meaning it is now approved in 18 countries, and commercialized in 7 of them. VYZULTA is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

### Product Candidates

- NCX 470, Nicox's lead clinical product candidate, is a novel, potential best-in-class, nitric oxide (NO)-donating prostaglandin eye drop currently in Phase 3 program for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The last patient in the Mont Blanc first Phase 3 clinical trial of NCX 470 has been enrolled and the topline results are expected in November 2022. The topline results of the second Phase 3 clinical trial, Denali, will not be available by the end of 2023 as previously communicated due to several hurdles (including the COVID-19 pandemic situation in the U.S. and China). The Company will announce a new date for availability of the Denali results when we have more visibility on the overall timelines of the trial.
- The results of the Dolomites Phase 2 clinical trial of NCX 470 in patients with open-angle glaucoma or ocular hypertension have been published by the Journal of Glaucoma, the official journal of the World Glaucoma Association. As previously reported, NCX 470 0.065% achieved statistical superiority compared to latanoprost 0.005% at all time-matched points measured on day 28, with a peak improvement in IOP lowering of 1.4 mmHg greater than latanoprost. All tested concentrations of NCX 470 were statistically non-inferior to latanoprost and the dose response of NCX 470 showed improved IOP lowering with each incremental concentration. NCX 470 was safe and well-tolerated with no drug-related serious adverse events and no evidence of treatment-related systemic side effects.
- The results from studies on the beneficial effects of NCX 470 in a nonclinical model of endothelin-1 -induced ischemia/reperfusion damage of the optic nerve head and retina have been published online in the peer-reviewed Journal of Ocular Pharmacology and Therapeutics.
- Poster presentations highlighting the effect of NCX 4251, a novel, patented, ophthalmic suspension of fluticasone propionate nanocrystals of Nicox, in patients with dry eye disease as well as new non-clinical data of neuroprotective activity on NCX 470 were made at the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting, one of the key scientific events in vision research.

Only the figure related to the cash position of the Nicox Group as of December 31, 2021 is audited; all other figures in this press release are non-audited.

#### 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 prostaglandin analog, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for dry eye disease. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of Southeast Asian markets.

Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

<sup>&</sup>lt;sup>2</sup> Bloomberg data, comparing the period of the weeks ending 8 April 2022 to 1 July 2022 with the period of the weeks ending 4 April 2021 to 2 July 2021 www.nicox.com



For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

#### Analyst coverage

Bryan, Garnier & Co Edison Investment Research H.C. Wainwright & Co Kepler Cheuvreux Dylan Van Haaften Pooya Hemami Yi Chen Arsene Guekam

Paris, France London, UK New York, U.S. Paris, France



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.

#### Nicox

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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 the 3rd chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2021' filed with the French Autorité des Marchés Financiers (AMF) on April 29, 2022 which is available on Nicox's website (www.nicox.com)

#### Nicox S.A.

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