

## Press Release

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# Nicox Provides First Quarter 2021 Business Update and Financial Highlights

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- **NCX 470 Phase 3 trials in glaucoma on track for top-line results in Q2 2022 (Mont Blanc) and Q4 2022 (Denali)**
- **NCX 4251 Mississippi Phase 2b trial in blepharitis on track for top-line results in Q4 2021**
- **U.S. prescriptions for VYZULTA® in Q1 2021 increased by 10.6% over Q1 2020, and for ZERVIAE® by 29.1% over Q4 2020**
- **Q1 2021 net revenue of €0.6 million and cash of €42.0 million at March 31, 2021**

April 19, 2021 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided a business update and financial highlights for Q1 2021 for Nicox SA and its subsidiaries (the “Nicox Group”), and updated key expected value-inflection milestones.

### Key Expected Milestones

- **NCX 470 Phase 3 program in glaucoma:** Nicox’s lead clinical product candidate, NCX 470, is a novel nitric oxide (NO)-donating prostaglandin analog currently in two multi-regional Phase 3 trials for the evaluation of the safety and efficacy of NCX 470 ophthalmic solution, 0.1%, against latanoprost ophthalmic solution, 0.005%, for lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Top-line results are currently expected in Q2 2022 for Mont Blanc and in Q4 2022 for Denali.
- **NCX 4251 Phase 2b trial, Mississippi in blepharitis:** NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals. Mississippi is evaluating once-daily dosed NCX 4251 0.1% versus placebo for the treatment of acute exacerbations of blepharitis. Top-line results are currently expected in Q4 2021.
- We expect to enter into additional agreements for **ZERVIAE®** (cetirizine ophthalmic solution), 0.24%, further expanding the licensed territories and increasing potential future revenue.
- Bausch + Lomb is planning to launch **VYZULTA®** (latanoprostene bunod ophthalmic solution), 0.024%, in Taiwan in 2021 and in South Korea in 2022.

### First Quarter 2021 and Recent Operational Highlights

#### *Innovative pipeline*

- 50% of patients in the **NCX 470** Mont Blanc Phase 3 glaucoma clinical trial have now been randomized with top-line results currently on track to be announced during Q2 2022.
- Ocumension Therapeutics, Nicox’s partner for **NCX 470** in China and Southeast Asia, received approval from China’s Center for Drug Evaluation of the National Medical Products Administration to conduct the Chinese part of the ongoing NCX 470 Denali Phase 3 trial for the lowering of IOP in patients with open angle glaucoma or ocular hypertension. Ocumension is also currently evaluating **ZERVIAE** in a confirmatory Phase 3 clinical trial in China, which was initiated in

December 2020 to support a New Drug Application there for the treatment of ocular itching associated with allergic conjunctivitis.

- Pre-clinical IOP-lowering results on a new class of non-prostaglandin analog, NO-donating compounds, were published in the Journal of Ocular Pharmacology and Therapeutics, a leading scientific journal. Elevated IOP is one of the principal risk factors of open-angle glaucoma. The NO-mediated IOP-lowering effect in this new class of compounds is enhanced by concomitant action of phosphodiesterase type-5 inhibition within the same molecule. **NCX 1728** is the first in this new class of compounds to be selected for development.

### Commercial products

- **VYZULTA** has been approved in Brazil, the largest market in Latin America. VYZULTA is commercialized by Nicox's exclusive worldwide partner Bausch + Lomb in the U.S. (2017), Canada (2019), Argentina (2020), Mexico (2020) and Hong Kong (2020), and is now approved in 5 other territories – Brazil, Colombia, South Korea, Taiwan and Ukraine.
- The number of prescriptions<sup>1</sup> for **VYZULTA** in the U.S. increased by 10.6% in the first quarter of 2021 compared to the first quarter of 2020.
- **ZERVIAE** U.S. prescriptions<sup>2</sup> increased by 29.1% in the first quarter of 2021 over the fourth quarter of 2020. ZERVIAE has been commercialized in the U.S. since March 2020 by Nicox's U.S. partner Eyevance Pharmaceuticals. Eyevance has entered into a partnership with Hikma Pharmaceuticals for the co-promotion of ZERVIAE in the U.S. who will be responsible for promoting ZERVIAE to U.S. healthcare professionals working outside the eyecare specialty, with all sales continuing to be booked by Eyevance, and on which Nicox will receive royalties.

### Corporate

- Nicox amended its bond financing agreement with Kreos Capital, introducing an additional one-year period of interest-only payments on the outstanding principal starting on February 1, 2021, and an extension of the overall period of the loan by 6 months to July 2024. The new one-year interest-only period is expected to provide approximately €5.5 million of additional flexibility for investment in development activities in 2021. The interest rate of the bonds remains unchanged as a result of this amendment.

*We continue to closely watch the spread and impact of the COVID-19 pandemic and we will provide an update of any delays.*

### First Quarter 2021 Financial Highlights

As of March 31, 2021, the Nicox Group had cash and cash equivalents of €42.0 million as compared with €47.8 million at December 31, 2020. Net revenue<sup>3</sup> for the first quarter of 2021 was €0.6 million (entirely composed of net royalty payments). Net revenue<sup>3</sup> for the first quarter of 2020 was €1.7 million (including €0.7 million of net royalty payments).

As of March 31, 2021, the Nicox Group had financial debt of €17.8 million consisting of €15.8 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2 million credit agreement with Société Générale and LCL, guaranteed by the French State, and granted in August 2020 in the context of the COVID-19 pandemic.

**Only the figure related to the cash position of the Nicox Group as of December 31, 2020 is audited; all other figures of this press release are non-audited.**

### Notes

1. Bloomberg data, comparing the period of the weeks ending 8 January 2021 to 2 April 2021 with the period of the weeks ending 3 January 2020 to 3 April 2020
2. Bloomberg data, comparing the period of the weeks ending 8 January 2021 to 2 April 2021 with the period of the weeks ending 2 October 2020 to 3 April 2020

3. Net revenue consists of revenue from collaborations less royalty payments, which corresponds to Net profit in the consolidated statements of profit or loss

## About Nicox

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Nicox S.A. 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 glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIA TE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyeveance 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.

For more information on Nicox, its products or pipeline, please visit: [www.nicox.com](http://www.nicox.com).

## Analyst coverage

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Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	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.*

## Contacts

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### Nicox

Gavin Spencer  
Executive Vice President, Chief Business Officer  
& Head of Corporate Development  
T +33 (0)4 97 24 53 00  
[communications@nicox.com](mailto:communications@nicox.com)

**Investors & Media**  
United States & Europe  
LifeSci Advisors, LLC  
Mary-Ann Chang  
T +44 7483 284 853  
[mchang@lifesciadvisors.com](mailto:mchang@lifesciadvisors.com)

**Media**  
France  
LifeSci Advisors, LLC  
Sophie Baumont  
M +33 (0)6 27 74 74 49  
[sophie@lifesciadvisors.com](mailto:sophie@lifesciadvisors.com)

## Forward-Looking Statements

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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 3<sup>rd</sup> chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2020' filed with the French Autorité des Marchés Financiers (AMF) on March 1, 2021 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

### Nicox S.A.

Drakkar 2  
Bât D, 2405 route des Dolines  
CS 10313, Sophia Antipolis



06560 Valbonne, France  
T +33 (0)4 97 24 53 00  
F +33 (0)4 97 24 53 99