

## Press Release

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# Nicox First Quarter 2020 Business Update and Financial Highlights

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- **Expanded collaboration with Ocumension Therapeutics in China allows NCX 470 to enter two Phase 3 glaucoma clinical trials**
- **ZERVIAE™ launched in the U.S. by partner Eyevance Pharmaceuticals**
- **Q1 2020 net revenue of €1.7 million and cash of €45.2 million as of March 31, 2020**
- **VYZULTA® prescriptions in Q1 2020 increased by 60% over Q1 2019**

April 17, 2020 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided Q1 2020 operational highlights, revenue and cash position for Nicox SA and its subsidiaries (the “Nicox Group”), as well as updating key expected milestones in 2020.

### Key Expected Upcoming Milestones

- **NCX 470 Mont Blanc Phase 3 clinical trial:** The first Phase 3 clinical trial of NCX 470 for lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension is currently expected to start by the end of Q2 2020, with top-line results expected in Q3 2021. The Mont Blanc trial will be conducted principally in clinical sites in the U.S. and will include a small number of Chinese clinical sites. The trial will be initiated with 0.065% and 0.1% doses of NCX 470 vs. latanoprost 0.005%, with only one dose of NCX 470 being selected through an adaptive design to complete the trial.
- **NCX 470 Denali Phase 3 clinical trial:** The second Phase 3 glaucoma clinical trial, jointly managed and equally funded by Nicox and Ocumension, is currently expected to start in H2 2020. It will include clinical sites in both the U.S. and China, with the majority of the patients being in the U.S. to support the U.S. New Drug Application (NDA) filing. A sufficient number of patients from China will be included in the Denali trial to support an NDA filing in China.
- **NCX 4251 Phase 2b clinical trial:** This Phase 2b trial will include both blepharitis and dry eye endpoints with the option of declaring either acute exacerbations of blepharitis endpoint or dry eye endpoints as the primary outcome of the trial. Timing and further trial design details will be announced in due course.
- **ZERVIAE China:** A Phase 3 clinical trial for approval in China, to be conducted and financed by Ocumension, is currently expected to start by Q4 2020.

Nicox continues to closely watch the spread of COVID-19 and its impact around the world. We do not currently anticipate delays to our clinical timelines but we are monitoring the situation and will provide updates in due course if there is an impact on our development projects and timelines.

### First Quarter 2020 and Recent Operational Highlights

- The total number of prescriptions<sup>1</sup> for **VYZULTA®** (latanoprostene bunod ophthalmic solution), 0.024%, in the U.S. in the first quarter of 2020 increased by 11% compared to the fourth quarter of 2019 and by 60% compared to the first quarter of 2019.

- Successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and agreement on the design for the **NCX 470** Phase 3 program, as well as nonclinical and CMC plans supporting submission of an NDA in the U.S. NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, is Nicox's lead clinical development program.
- Successful Type C meeting with the U.S. FDA and agreement on Phase 2b trial designs for **NCX 4251** in both acute exacerbations of blepharitis and the reduction of signs and symptoms of dry eye disease. NCX 4251, a novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is Nicox's second product candidate in clinical development. The timing of the future program for NCX 4251 is subject to securing the financial resources to advance its development.
- **ZERVIAE** (cetirizine ophthalmic solution), 0.24%, launched in the U.S. by our partner, Eyevance, creating an additional recurrent revenue stream. ZERVIAE is the first novel prescription-only treatment for allergic conjunctivitis in over 10 years and is being marketed by the Eyevance commercial team, which currently covers 40 key territories in the U.S.
- Amendment of NCX 470 agreement with Ocumension where Ocumension paid €15 million (in replacement of the totality of the milestones in the original agreement), gained additional exclusive rights to NCX 470 for Korea and Southeast Asia and will pay 50% of the costs of the second glaucoma Phase 3 clinical trial of NCX 470 ('Denali'). The two companies will jointly manage the Denali trial in the U.S. and China.
- Amendment of ZERVIAE license agreement with Ocumension, extending the exclusive rights to include the majority of the Southeast Asian region.
- Following results from *in vivo* primary pharmacodynamics studies of naproxcinod in models of sickle-cell disease, U.S. partner Fera Pharmaceuticals decided to focus its development of naproxcinod on the treatment of painful vaso-occlusive crisis in sickle-cell disease. Fera plans to conduct further studies and other development activities in preparation for entering directly into a clinical efficacy trial of naproxcinod in sickle-cell patients, subject to being granted an ODD.
- Approval from the U.S. Patent and Trademark Office and from the Japanese Patent Office of a formulation patent for NCX 470, extending the patent coverage to 2039 in those countries.
- Exclusive global partner Bausch + Lomb received approval for VYZULTA® in Argentina, Mexico, Hong Kong and Taiwan, bringing the total number of countries or territories where VYZULTA is approved for commercialization to six.

### First Quarter 2020 Financial Highlights

As of March 31, 2020, the Nicox Group had cash and cash equivalents of €45.2 million as compared with €28.0 million at December 31, 2019. Net revenue<sup>2</sup> for the first quarter of 2020 was €1.7 million (including €1.0 million of the milestone from Ocumension), compared to €0.4 million for the first quarter of 2019. €14 million of the milestone received from Ocumension is classified as deferred income due to Nicox's ongoing involvement in the development of NCX 470.

As of March 31, 2020, the Nicox Group had financial debt of €18.1 million in the form of a bond financing agreement with Kreos Capital signed in January 2019.

**Only the figure related to the cash position of the Nicox Group as of December 31, 2019 is audited; all other figures of this press release are non-audited.**

#### Notes

1. Bloomberg data, comparing the period of the weeks ending January 3, 2020 to March 27, 2020 with the period of the weeks ending October 4, 2019 to December 27, 2019 and January 1, 2019 to March 27, 2019
2. 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 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, second-generation nitric oxide-donating bimatoprost 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™ in allergic conjunctivitis, licensed in multiple geographies, including to Eyevence Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and 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.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	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

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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 2019' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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