

## Press Release

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# Nicox Second Quarter 2020 Business Update and Financial Highlights

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- **NCX 470 Mont Blanc Phase 3 clinical trial initiated on schedule, more than 40 sites activated to enroll patients to date**
- **VYZULTA® prescriptions in Q2 2020 increased by 36% over Q2 2019**
- **Q2 2020 net revenue of €0.6 million and cash of €40.4 million as of June 30, 2020**
- **Recent divestment of VISUfarma stake further strengthens the July cash position by €5 million**

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

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided Q2 2020 operational highlights, revenue and cash position for Nicox SA and its subsidiaries (the “Nicox Group”), as well as updating key expected milestones for the remainder of 2020.

### Key Expected Upcoming Milestones

- **NCX 470 Mont Blanc Phase 3 clinical trial:** The adaptive design part of 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 on track to be completed in Q4 2020, facilitating both the start of the second Phase 3 “Denali” trial on schedule and the completion of the Mont Blanc trial where patients will then continue on the selected NCX 470 dose in the subsequent head-to-head 3-month safety and efficacy evaluation of NCX 470 vs. latanoprost.
- **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 Q4 2020. It will include clinical sites in both the U.S. and China, with the majority of the patients being in the U.S. The Denali trial was designed and is expected to be sufficient to support NDA filings in the U.S. and 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 the blepharitis or dry eye endpoints as the primary outcome of the trial. Timing and further trial design details will be announced in due course.
- **ZERVIA™ 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.

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

### Second 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 second quarter of 2020 increased by 36% compared to the second quarter of 2019 and was unchanged compared to the first quarter of 2020.

- **ZERVIA**<sup>™</sup> (cetirizine ophthalmic solution), 0.24%, U.S. prescriptions<sup>2</sup> totaled 1,389 in Q2 2020, the first full quarter of sales following launch in the U.S. in March 2020.
- We divested our shareholding in VISUfarma, a pan-European ophthalmic specialty pharmaceutical company, to a subsidiary of the main shareholder, GHO Capital, for €5 million.
- The first Phase 3 clinical trial, named Mont Blanc, evaluating **NCX 470** for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, was initiated on June 1, 2020, and currently has over 40 clinical sites initiated in the trial. NCX 470 is the company's novel, second-generation nitric oxide (NO)-donating bimatoprost analog. The Mont Blanc trial is a multi-regional, double-masked, 3-month, parallel group, adaptive design trial evaluating the efficacy and safety of NCX 470 ophthalmic solution, 0.065% and 0.1% compared to latanoprost ophthalmic solution, 0.005% in patients with open-angle glaucoma or ocular hypertension. In an adaptive portion of the trial, one NCX 470 dose will be selected to continue in the subsequent head-to-head 3-month efficacy and safety evaluation of NCX 470 vs. latanoprost. The primary efficacy evaluation is based on time-matched IOP at 8 AM and 4 PM at Week 2, Week 6 and Month 3. The trial is expected to randomize approximately 670 patients, primarily at approximately 50 clinical sites in the U.S. and at a small number of clinical sites in China.
- A successful Type C meeting with the U.S. FDA was held, with 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.
- 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.

## Second Quarter 2020 Financial Highlights

As of June 30, 2020, the Nicox Group had cash and cash equivalents of €40.4 million as compared with €28.0 million at December 31, 2019 and €45.2 million at March 31, 2020. This figure does not include the €5 million from the divestment of our VISUfarma shareholding in July. Net revenue<sup>3</sup> for the second quarter of 2020 was €0.6 million (consisting entirely of royalties), compared to €5.2 million (including €4.7 million of milestone and upfront payments) for the second quarter of 2019.

As of June 30, 2020, the Nicox Group had financial debt of €17.7 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 April 3, 2020 to June 26, 2020 with the period of the weeks ending January 3, 2020 to March 27, 2020 and April 5 2019 to June 28, 2019
2. Bloomberg data for the period of the weeks ending April 3, 2020 to June 26, 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 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<sup>™</sup> 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

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

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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