

## Press Release

---

# Nicox Announces Third Quarter 2020 Business Update and Financial Highlights

---

- **Selection of 0.1% dose of NCX 470 enables the second part of Mont Blanc Phase 3 trial in glaucoma and the initiation of the second Phase 3 trial, Denali, expected by end 2020**
- **Q3 2020 net revenue of €0.8 million and cash of €42.2 million as of September 30, 2020**
- **VYZULTA® U.S. prescriptions in Q3 2020 increased by 45% over Q3 2019**
- **ZERVIAE™ U.S. prescriptions in Q3 2020 increased by 176% over Q2 2020, the first full quarter of sales**

October 20, 2020 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced a business update and financial highlights for Q3 2020 for Nicox SA and its subsidiaries (the “Nicox Group”), as well as an update on key expected milestones.

### Key Expected Upcoming Milestones

- **NCX 470 Mont Blanc Phase 3 clinical trial:** Top-line results from Mont Blanc, the first Phase 3 trial of NCX 470 for lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension are currently expected in Q4 2021. Mont Blanc is a 3-month safety and efficacy evaluation of NCX 470 ophthalmic solution, 0.1%, against latanoprost ophthalmic solution, 0.005%.
- **NCX 470 Denali Phase 3 clinical trial:** The second Phase 3 trial in glaucoma, Denali, which is funded equally by Nicox and our Chinese partner Ocumension, is expected to start by the end of 2020 and will evaluate NCX 470 ophthalmic solution, 0.1%, versus latanoprost ophthalmic solution, 0.005%. The Denali trial will include clinical sites in both the U.S. and China, with the large majority of the patients to be recruited in the U.S. The Denali trial was designed to fulfill the regulatory requirements to support New Drug Application (NDA) filings in the U.S. and China.
- **NCX 4251 Mississippi Phase 2 clinical trial:** A Phase 2 trial, Mississippi, for the treatment of acute exacerbations of blepharitis is targeted to be initiated in December 2020. This trial will include primary and secondary efficacy endpoints for blepharitis and dry eye disease respectively. Top-line results are currently expected in Q4 2021. If successful in meeting the primary endpoint for blepharitis previously agreed upon with the U.S. Food and Drug Administration (FDA), the trial could represent the first of two pivotal trials needed to support an NDA in the U.S.
- **ZERVIAE™ China:** A Phase 3 clinical trial intended to support an application for regulatory approval in China is expected to start by the end of 2020, conducted and financed by our partner Ocumension.
- **Nitric oxide (NO)-donating phosphodiesterase-5 (PDE5) inhibitors** for IOP lowering: IND-track candidate expected to be announced shortly.

We continue to closely watch the spread and impact of the COVID-19 pandemic. We do not currently anticipate delays in our clinical timelines but we are monitoring the situation and will provide an update when needed.

### Third Quarter 2020 and Recent Operational Highlights

- The 0.1% dose of **NCX 470** was selected in the adaptive design portion of the Mont Blanc Phase 3 clinical trial. This dose continues in the second part of Mont Blanc, a multi-regional, double-masked, 3-month, parallel group trial evaluating the efficacy and safety of NCX 470 ophthalmic solution, 0.1%, compared to latanoprost ophthalmic solution, 0.005%, in patients with open-angle glaucoma or ocular hypertension. The 0.1% dose will also be used in the Denali trial, the second Phase 3 glaucoma trial of NCX 470.
- Nicox's partner, Ocumension Therapeutics, received approval from China's Center for Drug Evaluation of the National Medical Products Administration to carry out Phase 3 clinical trials with **ZERVIAE™** (ophthalmic solution of cetirizine), 0.24% for the treatment of ocular itching associated with allergic conjunctivitis, paving the way for a Chinese Phase 3 trial, expected to start in Q4 2020.
- The total number of prescriptions<sup>1</sup> for **VYZULTA®** (latanoprostene bunod ophthalmic solution), 0.024%, in the U.S. in the third quarter of 2020 increased by 45% compared to the third quarter of 2019 and by 17% compared to the second quarter of 2020. VYZULTA has also been approved in Ukraine, bringing the total number of countries or territories where VYZULTA is approved to market to seven.
- **ZERVIAE™** (cetirizine ophthalmic solution), 0.24%, U.S. prescriptions<sup>2</sup> in Q3 2020 increased by 176% over Q2 2020, which had been the first full quarter of sales following launch in the U.S. in March 2020.
- We entered into an exclusive agreement with ITROM Pharmaceutical Group for the registration and commercialization of **ZERVIAE™** for the treatment of ocular itching associated with allergic conjunctivitis in Gulf and Arab markets.
- Our partner Fera has informed us that the application with the U.S. FDA for an Orphan Drug Designation (ODD) for **naproxcinod** in sickle-cell disease has been refused but that Fera is reviewing how to respond to the points raised by the FDA and is also considering alternative indications for the development of naproxcinod.

### Third Quarter 2020 Financial Highlights

As of September 30, 2020, the Nicox Group had cash and cash equivalents of €42.2 million as compared with €28.0 million at December 31, 2019 and €45.5 million at June 30, 2020 (including €5 million from the divestment of our VISUfarma shareholding in July). Net revenue<sup>3</sup> for the third quarter of 2020 was €0.8 million (consisting of ZERVIAE and VYZULTA royalties and upfront payments from ITROM), compared to €0.5 million (consisting entirely of royalty payments) for the third quarter of 2019.

As of September 30, 2020, the Nicox Group had financial debt of €19.2 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2 million credit agreement, granted by Société Générale and LCL and guaranteed by the French State, 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, 2019 is audited; all other figures of this press release are non-audited.**

#### Notes

1. Bloomberg data, comparing the period of the weeks ending July 3, 2020 to October 2, 2020 with the period of the weeks ending April 3, 2020 to June 29, 2020 and July 5, 2019 to September 27, 2019
2. Bloomberg data, comparing the period of the weeks ending July 3, 2020 to October 2, 2020 with the period of the weeks ending April 3, 2020 to June 29, 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

---

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, 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 Eyeavance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East 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.*

## Contacts

---

### 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

---

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)).

### 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