

# Nicox Provides Fourth Quarter 2020 Business Update and Financial Highlights

- **Initiated two large clinical trials: Denali, the second Phase 3 of NCX 470 in glaucoma, and Mississippi, a Phase 2b of NCX 4251 in blepharitis**
- **Phase 3 clinical trial of ZERVIA<sup>TM</sup> in allergic conjunctivitis initiated by partner Ocumension Therapeutics in China**
- **U.S. prescriptions for VYZULTA<sup>®</sup> in Q4 2020 increased by 29% over Q4 2019, and for ZERVIA<sup>TM</sup> by 56% over Q3 2020**
- **Q4 2020 net revenue of €5.8 million, full year 2020 net revenue of €8.9 million and cash of €47.8 million at December 31, 2020**

Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided a business update and financial highlights for Q4 2020 for Nicox SA and its subsidiaries (the “Nicox Group”), as well as key expected value-inflection milestones in 2021.

## Key Expected Milestones

- **NCX 470 first Phase 3 trial, Mont Blanc:** Nicox’s lead clinical product candidate, NCX 470 is a novel nitric oxide (NO) donating prostaglandin analog. Mont Blanc is a 3-month safety and efficacy trial evaluating 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 now prudently expected in H1 2022, instead of Q4 2021, given probable delays in recruitment due to COVID-19.
- **NCX 4251 Phase 2b trial, Mississippi:** NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals. Mississippi is evaluating once-daily dosing 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 enlarging the licensed territories and increasing potential future revenue.

#### **Fourth Quarter 2020 and Recent Operational Highlights**

##### *Innovative pipeline*

- [The second Phase 3 trial of NCX 470, Denali](#), for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, was initiated in the U.S. on November 9, 2020. Denali is a 3-month trial evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1% versus latanoprost ophthalmic solution, 0.005% and will also include a long-term safety extension. The trial is financed jointly and in equal parts by Nicox and its Chinese partner Ocumension. Top-line results are currently expected in Q4 2022.
- [The Phase 2b trial of NCX 4251, Mississippi](#), for the treatment of acute exacerbations of blepharitis was initiated in the U.S. on December 14, 2020. Top-line results are currently expected in Q4 2021.
- [A Phase 3 trial of ZERVIAE™](#) (cetirizine ophthalmic solution), 0.24%, for the treatment of ocular itching associated with allergic conjunctivitis, conducted and financed by Nicox's Chinese partner Ocumension, was initiated in China in December 2020. This trial will support the submission of a Chinese New Drug Application.
- [NCX 1728](#) was selected as the first development candidate in a new class of agents for IOP lowering where NO-mediated effects are enhanced by concomitant action of phosphodiesterase-5 (PDE5) inhibition within the same molecule. Further optimization of the ophthalmic formulations of NCX 1728 will continue prior to initiating formal pre-Investigational New Drug (IND) tests required for the filing of an IND application.

##### *Commercial products*

- The total number of prescriptions<sup>1</sup> for **VYZULTA®** (latanoprostene bunod ophthalmic solution), 0.024%, in the U.S. increased by 29% in the fourth quarter of 2020 compared to the fourth quarter of 2019 and by 16% compared to the third quarter of 2020 despite the challenging situation due to the COVID-19 pandemic. Along with the U.S., Canada and Argentina, VYZULTA has also been launched by Nicox's global partner Bausch + Lomb in Mexico and was recently approved in Colombia.
- **ZERVIAE™** (cetirizine ophthalmic solution), 0.24%, U.S. prescriptions<sup>2</sup> increased by 56% in the fourth quarter of 2020 over the third quarter of 2020. ZERVIAE has been commercialized in the U.S. since March 2020 by Nicox's U.S. partner Eyevance Pharmaceuticals, which was acquired in September 2020 by Santen Holdings U.S. Inc., a wholly owned subsidiary of Santen Pharmaceutical Co., Ltd of Japan, for \$225 million.

##### *Corporate*

- The Company completed a €15 million private placement with investors including long-term shareholder HBM Healthcare Investments alongside specialist institutional investors in the U.S. and Europe.
- The European Patent Office granted a formulation patent for NCX 470, extending the European exclusivity to 2039. The equivalent U.S. patent has already been granted, and NCX 470 is also covered by granted composition of matter patents.
- Fera Pharmaceuticals, Nicox's partner for naproxcinod, will evaluate naproxcinod as a potential adjuvant treatment for patients with COVID-19 infection. Fera plans to initiate pre-clinical proof-of-concept studies in models of COVID-19 infection in early 2021.

- Ora and Nicox have agreed to terminate their license agreement for the development of NCX 4280 targeting lid swelling, or morning eye congestion. All rights to NCX 4280 will return to Nicox and there are no current plans to continue the development.

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

#### **Fourth Quarter 2020 Financial Highlights**

As of December 31, 2020, the Nicox Group had cash and cash equivalents of €47.8 million as compared with €28.0 million at December 31, 2019 and €42.2 million at September 30, 2020. Net revenue<sup>3</sup> for the fourth quarter of 2020 was €5.8 million (consisting of €0.3 million of royalty payments and €5.5 million of license payments recognized from €14.0 million paid by Ocumension in March 2020 and initially recorded as prepaid income pursuant to accounting principles). Net revenue<sup>3</sup> for the fourth quarter of 2019 was €0.6 million and consisted entirely of royalty payments. Net revenue<sup>3</sup> for the full year 2020 was €8.9 million (€2.4 million in net royalties, €6.5 million in license payments), compared to €6.9 million (€2.1 million in net royalties, €4.8 million in license payments) for the full year 2019.

As of December 31, 2020, the Nicox Group had financial debt of €18.4 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, 2019 is audited; all other figures of this press release are non-audited.**

#### **Notes**

1. Bloomberg data, comparing the period of the weeks ending October 2, 2020 to January 1, 2021 with the periods of the weeks ending July 3, 2020 to September 25, 2020 and October 4, 2019 to December 27, 2019
2. Bloomberg data, comparing the period of the weeks ending October 2, 2020 to January 1, 2021 with the period of the weeks ending July 3, 2020 to September 25, 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