

Press Release

Nicox Fourth Quarter 2019 Business Update and Financial Highlights

- **NCX 470 for glaucoma in preparation to enter Phase 3 clinical development following positive Phase 2 results**
- **NCX 4251 demonstrated encouraging Phase 2 results in blepharitis, with promising efficacy in dry eye disease**
- **Q4 2019 net revenue of €0.6 million**
- **VYZULTA® prescriptions in Q4 2019 increased by 72% over Q4 2018**

January 21, 2020 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided Q4 2019 operational highlights, revenue and cash position for Nicox SA and its subsidiaries (the “Nicox Group”), as well as key expected milestones in 2020.

Key Expected Upcoming Milestones

- **NCX 470 Phase 3 clinical trial preparation:** End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) is scheduled in Q1 2020. Initiation of the first of the two U.S. Phase 3 clinical trials (“Mont Blanc”) is expected by the end of Q2 2020, comparing NCX 470 ophthalmic solution 0.065% and 0.1% vs. latanoprost ophthalmic solution 0.005% for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
- **NCX 4251:** Meeting with the U.S. FDA is scheduled in Q1 2020 to discuss the next steps of the development plan.
- **ZERVIAE™ U.S. launch:** Commercial launch of ZERVIAE™ (cetirizine ophthalmic solution), 0.24% in the U.S. is planned in H1 2020 by Nicox’s partner Eyeevance Pharmaceuticals, LLC.

Fourth Quarter 2019 and Recent Operational Highlights

- The total number of prescriptions¹ for VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, in the U.S. in the fourth quarter of 2019 increased by 12% compared to the third quarter 2019 and by 72% compared to the fourth quarter of 2018.
- Positive results were reported from the U.S., multicenter, Phase 2 safety and efficacy clinical trial (“[Dolomites](#)”) which evaluated 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. NCX 470 0.065% demonstrated non-inferiority and statistical superiority to latanoprost 0.005%, the U.S. market leader in prostaglandin analog prescriptions.
- Positive top-line results were reported from the Phase 2 clinical trial (“[Danube](#)”) of NCX 4251, a novel patented ophthalmic suspension of fluticasone propionate nanocrystals, which met the primary objective of the U.S. multicenter, dose escalating, first-in-human clinical trial which evaluated its safety and tolerability in patients with acute exacerbations of blepharitis. NCX 4251 0.1% once daily (QD) treatment was selected to advance into a larger Phase 2b clinical trial,

subject to the outcome of a meeting with the U.S. FDA scheduled in Q1 2020, and the necessary financial resources being secured. Selected dose also demonstrated promising efficacy in reducing signs and symptoms of dry eye disease.

- An exclusive license [agreement](#) was entered into with Samil Pharmaceutical Co., Ltd for the development and commercialization of ZERVIAE (cetirizine ophthalmic solution), 0.24% for the treatment of ocular itching associated with allergic conjunctivitis in South Korea.
- Global partner Bausch + Lomb, announced that VYZULTA, indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension, will be listed as a limited use product under the Ontario Drug Benefit Formulary, one of the principle drug benefit programs in Canada. VYZULTA is currently covered by most private insurance plans in Canada, and was launched in this market earlier this year.
- Global partner Bausch + Lomb also received approval of VYZULTA in [Mexico](#), [Hong Kong](#) and [Argentina](#).
- Future Nicox research activities will be focused on NO-donating phosphodiesterase-5 (PDE5) inhibitors projects for glaucoma, for which Nicox expects to be able to announce an Investigational New Drug (IND)-track candidate in 2020.

Changes in Management

Dr. Tomas Navratil, PhD, has been promoted to Executive Vice President, Head of R&D of the Nicox Group and General Manager of Nicox Ophthalmics Inc. as of January 1, 2020. In this expanded role, Dr. Navratil will be responsible for all research, non-clinical and clinical development, CMC and regulatory affairs activities for Nicox and general management of Nicox U.S. operations in Durham, North Carolina.

Fourth Quarter 2019 Financial Highlights

As of December 31, 2019, the Nicox Group had cash and cash equivalents of €28.0 million as compared with €17.4 million at September 30, 2019 and €22.1 million at December 31, 2018. The December 31, 2019 cash position does not include the last €8 million drawn down under the bond financing agreement with Kreos Capital. Net revenue² for the fourth quarter of 2019 was €0.6 million, compared to €3.3 million for the fourth quarter of 2018. Net revenue² for the full year 2019 was €6.9 million (€2.1 million in net royalties, €4.8 million in license payments), compared to €4.0 million (€1 million in net royalties and €3 million in license payments) for the full year 2018.

In November 2019, Nicox [raised](#) €12.5 million in gross proceeds through a private placement via the issuance of 3,315,650 new ordinary shares.

As of December 31, 2019, the Nicox Group had financial debt of €11.1 million in the form of a bond financing agreement with Kreos Capital [signed](#) in January 2019. Nicox has drawn down a total of €20 million under this bond financing agreement, as €8 million in January 2019, €4 million in October 2019 and €8 million in December 2019 received in January 2020. No further amounts can be drawn down under this bond financing agreement.

Only the figure related to the cash position of the Nicox Group as of December 31, 2018 is audited; all other figures of this press release are non-audited.

Notes

1. Bloomberg data, comparing the period of the weeks ending October 4, 2019 to December 27, 2019 with the period of the weeks ending July 5, 2019 to September 27, 2019 and October 5, 2018 to December 28, 2018
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

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive

portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio has three programs in development including NCX 470, a novel, second-generation NO-donating bimatoprost analog, for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with CycLERION). In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017, as well as ZERVIAE™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to EyeVance Pharmaceuticals, LLC.

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.

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 4th chapter of the 'Document de référence, rapport financier annuel et rapport de gestion 2018' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2019 which are available on Nicox's website (www.nicox.com).

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