

## Press Release

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# Nicox Provides Fourth Quarter 2021 Business and Financial Highlights

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- **Mont Blanc Phase 3 clinical trial of NCX 470 in glaucoma progressing rapidly with recruitment now at 90%**
- **VYZULTA® and ZERVIAE® fourth quarter U.S. prescriptions increased by 39% and 129%, respectively, in 2021 vs. 2020**
- **Net revenue of €3.5 million in the fourth quarter of 2021, €7.2 million for 2021; cash of €41.9 million on December 31, 2021**

January 21, 2022 – release at 7:30 am CET  
Sophia Antipolis, France

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

### Fourth Quarter 2021 Financial Highlights

As of December 31, 2021, the Nicox Group had cash and cash equivalents of €41.9 million as compared with €32.7 million at September 30, 2021 and €47.2 million at December 31, 2020. The Company is financed until fourth quarter 2023, financing development of NCX 470 only. Net revenue<sup>1</sup> for the fourth quarter of 2021 was €3.5 million (€0.5 million of net royalty payments, €3.0 million non-cash accounting adjustment initially recorded as deferred income following a licensing payment received from Ocumension in March 2020). Net revenue<sup>1</sup> for the fourth quarter of 2020 was €5.8 million (€0.3 million royalty payments, €5.5 million license payments).

Fourth quarter revenue for VYZULTA in 2021 was impacted by additional rebates due to year-end true-up calculations. In addition, Access and Medicare Part D coverage for VYZULTA expanded in 2021, which increases the level of rebates. Despite this, prescriptions for VYZULTA grew by 32% in 2021 compared to 2020. We believe the improved access will better position VYZULTA for growth.

As of December 31, 2021, the Nicox Group had financial debt of €18.3 million consisting of €16.3 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2.0 million credit agreement guaranteed by the French State in August 2020 in the context of the COVID-19 pandemic.

### Fourth Quarter 2021 and Recent Operational Highlights

#### *Corporate*

- The Company raised €15 million in a private placement and concurrently restructured the bond financing agreement with Kreos Capital, extending the cash runway to the fourth quarter of 2023.
- The Company has appointed Doug Hubatsch as Chief Scientific Officer to lead Nicox’s non-clinical and clinical development activities.

#### *Commercial Products*

- **VYZULTA®** (latanoprostene bunod ophthalmic solution), 0.024% United States (U.S.) prescriptions<sup>2</sup> increased by 39% in the fourth quarter of 2021 compared to 2020; **ZERVIAE®**

(cetirizine ophthalmic solution), 0.24% U.S. prescriptions<sup>2</sup> increased by 129% over the same period.

- Patent EP2408453, covering **ZERVIATE** in Europe until 2030 has been issued by the European Patent Office (EPO). The patent covers the formulation of ZERVIATE which is commercialized in the U.S. by our exclusive U.S. licensee Eyevance Pharmaceuticals, and the use of ZERVIATE in the treatment of the symptoms of allergic conjunctivitis or allergic rhinoconjunctivitis.

### *Product Candidates*

#### **NCX 470**

- 90% of the patients required to complete the Mont Blanc Phase 3 clinical trial on **NCX 470** in patients with open-angle glaucoma or ocular hypertension have been recruited into the trial.
- Patient enrollment has begun in China in the ongoing Denali Phase 3 clinical trial on **NCX 470** in patients with open-angle glaucoma or ocular hypertension, opening the way for New Drug Application (NDA) submissions in both the U.S. and China. Denali, which also includes a long-term safety extension, has been recruiting patients in the U.S. since November 2020. Approximately 670 patients are expected to be randomized at approximately 60 clinical sites in the U.S. and China, with approximately 80% of the patients to be recruited in the U.S. and the remaining 20% of the patients to be recruited in China.
- Nicox presented the results of responder analyses from the Dolomites Phase 2 clinical trial on **NCX 470** in patients with open-angle glaucoma or ocular hypertension at the American Academy of Ophthalmology 2021 (AAO) Annual Meeting. NCX 470 0.065% demonstrated both non-inferiority and superiority over latanoprost 0.005% with an IOP lowering effect for NCX 470 of 7.6 to 9.8 mmHg vs. 6.3 to 8.8 mmHg for latanoprost 0.005%. 27% of patients on NCX 470 showed  $\geq 3$  mmHg of IOP reduction at day 28 vs. latanoprost. 39%, 52% and 49% of NCX 470 patients had IOP  $< 18$  mmHg at 8AM, 10AM and 4PM vs 29%, 32% and 35% of latanoprost patients. NCX 470 was well tolerated with no drug-related serious adverse events and no evidence of treatment-related systemic effects.

#### **NCX 4251**

- Patent EP3769753, covering **NCX 4251** until 2040, has been issued by the EPO. NCX 4251 is being developed for ocular surface disease. The patent covers ophthalmic suspensions comprising a specific form of fluticasone propionate nanocrystals and the method for manufacturing the ophthalmic suspensions. Corresponding patent applications are under examination in the U.S., China, Japan and other territories.
- Positive post hoc results announced from the Mississippi Phase 2b clinical trial suggest that once-daily dosed **NCX 4251**, fluticasone propionate ophthalmic suspension 0.1%, is effective in reducing dry eye symptoms in a subgroup of patients. The results showed statistically significant improvements in a number of dry eye symptoms and improvements in one sign ( $p=0.0524$ ).

### **Key expected milestones**

- **NCX 470 in glaucoma:** Results from the Phase 3 clinical trials Mont Blanc and Denali to be communicated in first quarter 2023 and by the end of 2023, respectively.
- **NCX 4251 in ocular surface disease:** A meeting with the U.S. Food and Drug Administration is scheduled for early 2022 to discuss next development steps based on the Phase 2b Mississippi trial results.
- **ZERVIATE™ in allergic conjunctivitis (China):** The Phase 3 clinical trial intended to support an application for regulatory approval in China, conducted and financed by our partner Ocumension, has completed recruitment and results are expected shortly.

Only the figure related to the cash position of the Nicox Group as of December 31, 2020 is audited; all other financial figures in this press release are non-audited and subject to change on completion of audit procedures.

## Notes

1. Net revenue consists of revenue from collaborations less royalty payments, which corresponds to Net Profit in the consolidated statements of profit and loss
2. Bloomberg data, comparing the period of the weeks ending 8 October 2021 to 31 December 2021 with the period of the weeks ending 9 October 2020 to 1 January 2021

## About Nicox

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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 nitric oxide-donating prostaglandin 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 ZERVIAATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyeveance 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

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Bryan, Garnier & Co	Dylan van Haaften	Paris, France
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	Paris, France



*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 2020' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 and in the 2<sup>nd</sup> chapter of the amendment to the "Document d'Enregistrement Universel, rapport financier annuel et rapport de gestion 2020" filed with the AMF on December 9, 2021 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).



**Nicox S.A.**

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