

Press Release

Nicox Provides Second Quarter 2021 Business and Financial Highlights and Strategic Update

- **Lead value drivers are 100% ownership of NCX 470 and NCX 4251 in the U.S., Europe and Japan**
- **VYZULTA® and ZERVIATE® prescriptions in the U.S. increased by 21% and 712% respectively in Q2 2021 compared to Q2 2020**
- **Cash of €36.5 million on June 30, 2021 sufficient for the Company to meet its current requirements for the next twelve months**

July 16, 2021 – 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 Q2 2021 for Nicox SA and its subsidiaries (the “Nicox Group”) as well as an update on its strategy and key expected value-inflection milestones today.

“Nicox has made strong progress in the second quarter of 2021, with timely completion of the in-patient part of the NCX 4251 Mississippi Phase 2b trial and continued clinical progress on NCX 470 where the first Phase 3 results are expected in the second quarter of 2022. Our strategy remains to retain the full revenue potential from our fully-owned, product candidates NCX 470 and NCX 4251 in the U.S. and Europe. We believe that this offers a higher potential return than licensing them to third parties and leaves multiple value-creating options open, including organic growth and corporate transactions. We will seek collaborations for NCX 470 and NCX 4251 in other key regions, including Japan, following the Mont Blanc and Mississippi trial results, respectively,” said **Michele Garufi, Chairman and Chief Executive Officer of Nicox.**

“Regarding our partnered commercial products, VYZULTA and ZERVIATE, we have seen significant prescription growth in both cases. While revenue growth has not yet caught up due to pricing and reimbursement mechanisms commonly experienced in the US market in the first years of launch, we expect to see that follow through shortly.” added **Gavin Spencer, Chief Business Officer of Nicox.**

Pipeline Update and Strategy

NCX 470 0.1% ophthalmic solution: Nicox’s lead clinical product candidate, NCX 470, a novel nitric oxide (NO)-donating prostaglandin analog (PGA), is currently in two multi-regional Phase 3 glaucoma clinical trials, with top-line results from the first Phase 3 clinical trial, Mont Blanc, expected in Q2 2022. Results from the second Phase 3 trial, Denali, are expected in 2023. Our objective with these two Phase 3 clinical trials is to demonstrate statistically superior efficacy for the lowering of intraocular pressure (IOP) with once-daily dosed NCX 470 0.1% ophthalmic solution over latanoprost ophthalmic solution 0.005% (first marketed as Xalatan), the most prescribed PGA in the U.S. No monotherapy has previously achieved approval in the U.S. based on trials demonstrating clinical proof of superior efficacy to a PGA, which, if achieved, would clearly differentiate NCX 470 from all other monotherapy products available on the market.

In the Dolomites Phase 2 clinical trial, NCX 470 0.065% ophthalmic solution, a lower dose than the one being tested in Phase 3, already demonstrated a statistically significant improvement in IOP lowering compared to latanoprost. We believe that the higher dose of 0.1% NCX 470, under evaluation in the ongoing Phase 3 trials, has the potential to demonstrate an even greater efficacy than that already observed in the Dolomites trial. Our ongoing Phase 3 program, planned and executed together with our Chinese partner, Ocumension Therapeutics, is expected to support NDA submissions in the U.S. and China, and will also provide data for countries accepting the same package for approval. Our market research suggests peak net sales potential for NCX 470 in the U.S. of over \$500 million, if approved and

depending on the results of the Phase 3 clinical trials, due to its unique efficacy and safety profile, as well as the choice of latanoprost as a comparator in these trials.

NCX 4251, our novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is currently being tested in the Mississippi Phase 2b clinical trial which evaluates a once-daily 0.1% dose versus placebo for the treatment of acute exacerbations of blepharitis. The in-patient part of the trial has been completed, and top-line results are expected in September 2021. The next steps and timelines in the development of NCX 4251, which are not currently financed, will be announced following an End-of-Phase 2 meeting with the U.S Food and Drug Administration, expected to take place at the beginning of 2022.

Second Quarter 2021 and Recent Operational Highlights

Innovative pipeline

- Over 443 out of the 670 patients planned to be included in the **NCX 470** Mont Blanc Phase 3 clinical trial have been randomized, and 318 patients have completed the 3-month efficacy evaluation.
- Results from the Dolomites Phase 2 trial on **NCX 470** in glaucoma were presented by Dr. David Wirta, one of the clinical investigators in the trial, at the World Glaucoma Congress 2021 (June 30 - July 3 2021).
- All patients have completed the treatment phase in the **NCX 4251** Mississippi Phase 2b blepharitis clinical trial.

Commercial products

- The number of prescriptions¹ for **VYZULTA**[®] in the U.S. increased by 21% in the second quarter of 2021 compared to the second quarter of 2020. The corresponding revenue increase has been lower due to pricing considerations in reimbursement.
- **VYZULTA** has been launched in Taiwan, and also approved in Qatar and the United Arab Emirates. VYZULTA is now commercialized by Nicox's exclusive worldwide partner Bausch + Lomb in the U.S. (2017), Canada (2019), Argentina (2020), Mexico (2020), Hong Kong (2020), and Taiwan (2021), and is now approved in six other territories – Brazil, Colombia, Qatar, South Korea, United Arab Emirates and Ukraine.
- The United States Patent and Trademark Office (USPTO) has determined that three U.S. composition of matter patents covering latanoprostene bunod, commercialized as **VYZULTA** (latanoprostene bunod ophthalmic solution), 0.024%, are eligible for patent term extension, potentially through to 2030. The USPTO has also issued a Notice of Allowance for the U.S. patent covering the use of latanoprostene bunod for the treatment of normal tension glaucoma.
- The number of **ZERVIAE**[®] U.S. prescriptions¹ increased by 712% in the second quarter of 2021 over the second quarter of 2020.
- Nicox entered into an exclusive license agreement with Laboratorios Grin, a wholly-owned subsidiary of Lupin Limited, for the registration and commercialization of **ZERVIAE**[™] (cetirizine ophthalmic solution), 0.24% for the treatment of ocular itching associated with allergic conjunctivitis in Mexico. Grin is a Mexican specialty pharmaceutical company engaged in developing, manufacturing and commercialization of branded ophthalmic products.

Corporate

- Nicox received \$2 million from Ocumension in full advance payment of the future development and regulatory milestones for **ZERVIAE** in China in consideration of amendments made to certain rights under non-financial clauses of the agreement.

- The Company added two new members to its Glaucoma Clinical Advisory Board, Robert N. Weinreb, M.D., Distinguished Professor and Chair, Ophthalmology and Director, Shiley Eye Institute, University of California San Diego, and Sanjay G. Asrani, M.D., Professor of Ophthalmology, Duke University.

Second Quarter 2021 Financial Highlights

As of June 30, 2021, the Nicox Group had cash and cash equivalents of €36.5 million as compared with €42.0 million at March 31, 2021 and €47.8 million at December 31, 2020. The cash at June 30, 2021 is sufficient for the Company to meet its current requirements for the next twelve months. Net revenue² for the second quarter of 2021 was €0.7 million (including €0.6 million of net royalty payments). Net revenue² for the second quarter of 2020 was €0.6 million (entirely composed of net royalty payments).

As of June 30, 2021, the Nicox Group had financial debt of €18.0 million consisting of €16.0 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, 2020 is audited; all other figures in this press release are non-audited.

Notes

1. Bloomberg data, comparing the period of the weeks ending 9 April 2021 to 25 June 2021 with the period of the weeks ending 10 April 2020 to 3 July 2020
2. Net revenue consists of revenue from collaborations less royalty payments, which corresponds to Net profit in the consolidated statements of profit and 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 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 ZERVIA[®] in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance 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.

Analyst coverage

Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	Paris, France

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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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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 3rd 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 which are available on Nicox's website (www.nicox.com).

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