

## Press Release

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# Nicox First Quarter 2019 Business Update and Financial Highlights

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- **Total VYZULTA® prescriptions for the first quarter 2019 increased by 18% compared to the fourth quarter 2018 and by 360% compared to the first quarter 2018**
  - **NCX 470 Phase 2 clinical trial in glaucoma over 85% enrolled**
  - **NCX 4251 Phase 2 clinical trial initiated in blepharitis**
  - **ZERVIATE multiple licensing discussions ongoing ex-U.S.**
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April 18, 2019 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided Q1 2019 operational highlights, revenue and cash position for Nicox and its subsidiaries (the “Nicox Group”), as well as key upcoming milestones.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said, *“With two exciting programs in advanced clinical development and two products approved in the U.S. we are continuing apace to fully leverage our scientific, clinical, and commercial assets. Enrollment has now reached over 85% in the NCX 470 glaucoma clinical trial, and both this and the NCX 4251 blepharitis trial should generate topline results in Q4 of this year. We expect our recurrent revenues to ramp up as Bausch + Lomb progresses the international rollout of VYZULTA, and with the launch by Eyevance of ZERVIATE in the U.S. In addition, our ongoing discussions for ZERVIATE outside of the U.S. could result in agreements in the near future with further upfront, milestone and royalty payments.”*

### Key Upcoming Milestones

- **NCX 470 Phase 2 results:** Top-line data from the NCX 470 Phase 2 clinical trial for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension expected in Q4 of this year.
- **NCX 4251 Phase 2 results:** Phase 2 clinical trial in patients with acute exacerbations of blepharitis ongoing with top-line data expected in Q4 of this year.
- **ZERVIATE U.S. launch:** Commercial launch of ZERVIATE (cetirizine ophthalmic solution), 0.24% in the U.S. planned by our partner Eyevance Pharmaceuticals for summer of this year. Nicox eligible for up to \$3 million of a potential future milestone payment from Eyevance related to certain regulatory and near-term manufacturing objectives, which are expected to be received prior to the U.S. launch.
- **ZERVIATE ex-US partnering:** Multiple discussions ongoing for potential new licensing agreements in significant markets.
- **Nicox’s ophthalmology programs** to be presented at key scientific conferences including the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting.

## First Quarter 2019 and Recent Operational Highlights

- The total number of prescriptions for VYZULTA in the U.S. in the first quarter of 2019 increased by 18% compared to Q4 2018<sup>1</sup> and by 360% compared to the first quarter 2018<sup>1</sup>.
- On March 19, 2019, we announced the initiation of a Phase 2 clinical trial evaluating NCX 4251, our novel patented ophthalmic suspension of fluticasone propionate nanocrystals, being developed as the first targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. We expect to report top-line results from this Phase 2 trial in the fourth quarter of 2019.
- On March 15, 2019, we announced that we had entered into an exclusive license agreement with Ocumension Therapeutics for the development and commercialization of Nicox's product ZERVIAE (cetirizine ophthalmic solution), 0.24% for the treatment of allergic conjunctivitis for the Chinese market.
- On January 25, 2019, we announced that we had entered into a bond financing for up to €20 million from Kreos Capital. The financing is structured as three tranches of which only the first tranche of €8 million has been drawn down. The exercise of the two other tranches is at Nicox's sole discretion.
- On January 8, 2019 we announced that we had reached the 50% patient enrollment threshold of our multicenter, U.S. Phase 2 clinical trial evaluating our lead product candidate, NCX 470, ahead of schedule. NCX 470 is a novel, second-generation nitric oxide (NO)-donating prostaglandin analog for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension that has demonstrated 2 to 3 mmHg superior IOP lowering vs. the U.S. market leader LUMIGAN in head-to-head preclinical evaluations.
- Also in January, our global partner, Bausch + Lomb, a leading global eye health company and wholly owned subsidiary of Bausch Health Companies, Inc., received approval in Canada of VYZULTA (latanoprostene bunod ophthalmic solution), 0.024%. VYZULTA is indicated for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension.

## First Quarter 2019 Financial Highlights

As of March 31, 2019, the Nicox Group had cash and cash equivalents of €23.5 million as compared with €22.0 million at December 30, 2018. Net revenue<sup>2</sup> for the first quarter of 2019 was €0.430 million versus €0.075 million in the first quarter of 2018.

**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 4 January 2019 to 29 March 2019 with the periods of the weeks ending 5 October 2018 to 28 December 2018 and 5 January 2018 to 30 March 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

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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 includes three programs in development including NCX 470 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 Ironwood). 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 ZERVIA™ (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](http://www.nicox.com).

## Analyst coverage

Bryan, Garnier & Co    Hugo Solvet                    Paris, France  
H.C. Wainwright & Co    Yi Chen    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.*

## Upcoming financial and business conferences

May 16	European MidCap Event	Copenhagen, Denmark
June 2-6	BIO 2019	Philadelphia, U.S.
June 18-19	European MidCap Event	Paris, France
June 19-20	JMP Securities Healthcare Conference	New York, U.S.
June 24-25	HealthTech Investor Day	Paris, France

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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](http://www.nicox.com)).

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