

## Press Release

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# Nicox: Third Quarter 2019 Business Update and Financial Highlights

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- **Positive topline results from Dolomites Phase 2 clinical trial of NCX 470 in glaucoma**
- **VYZULTA prescriptions exceeded 3,000 per week for the first time<sup>1</sup>**
- **Q3 2019 net revenue of €0.5 million**

October 16, 2019 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox S.A.** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided a Q3 2019 business update and financial 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,** “*The encouraging topline results from the Dolomites Phase 2 clinical trial of NCX 470 confirm the potential of both this product candidate and of our research platform, and set the stage for the next phase of Nicox’s development. Together with the NCX 4251 blepharitis trial, results of which we expect later in the fourth quarter, Nicox would have two advanced clinical programs in 2020.*”

### Key Upcoming Milestones

- **NCX 4251 Phase 2 results:** Clinical trial in patients with acute exacerbations of blepharitis continuing on track for topline data in Q4 of this year.
- **NCX 470 Phase 3:** End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) expected in early 2020.

### Third Quarter 2019 Business update

- Nicox announced positive topline results of the [Dolomites trial](#), its multicenter, U.S. Phase 2 safety and efficacy clinical study evaluating **NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog**, in patients with open-angle glaucoma or ocular hypertension. The 0.065% dose of NCX 470 demonstrated non-inferiority and statistical superiority to latanoprost 0.005%, the U.S. market leader in prostaglandin analog prescriptions.
- The total number of prescriptions<sup>1</sup> for VYZULTA in the U.S. exceeded 3,000 per week for the first time, with scripts in the third quarter of 2019 increasing by 10% compared to second quarter 2019 and by 127% compared to third quarter 2018.
- Nicox amended its [bond financing agreement with Kreos Capital](#) and drew down €4 million in additional debt. Under the amended agreement, Nicox may draw down a further €3 million or €8 million on December 31, 2019 subject to notice to Kreos prior to December 16, 2019. Apart from the amended notice dates, payment dates and amounts mentioned here, all other contractual terms remain unchanged.
- Nicox entered into an exclusive license [agreement with Ocumension Therapeutics](#) for the development and commercialization of **NCX 4251, a novel, patented ophthalmic suspension of**

**fluticasone propionate nanocrystals**, in the Chinese market and received a €2.0 million upfront payment in July 2019.

- In July 2019 we received a \$3.0 million [milestone payment](#) from U.S. partner Eyeavance Pharmaceuticals linked to completion by Nicox of regulatory and manufacturing responsibilities concerning **ZERVIAE (cetirizine ophthalmic solution), 0.24%** in the U.S. From now on, all manufacturing and regulatory responsibilities, together with decisions on launch timing, lie with Eyeavance. Eyeavance has informed Nicox that the commercial launch of ZERVIAE in the U.S. is currently projected in the first half of 2020.
- We strengthened our Management in CMC Development by appointing Dr. Ramesh Krishnamoorthy, Ph.D., to the newly-created position of Senior Director and Head, Late Stage CMC and Quality Control, effective September 1, 2019. Dr. Krishnamoorthy brings to Nicox over 24 years of experience in CMC, pharmaceutical development, and quality control aspects of sterile ophthalmic products. Dr. Krishnamoorthy holds an M.S. degree in pharmaceuticals and Ph.D. in industrial and physical pharmacy.

### Third Quarter 2019 Financial Highlights

As of September 30, 2019, the Nicox Group had cash and cash equivalents of €17.4 million, as compared with €17.3 million at June 30, 2019 and €22.1 million at end December 31, 2018. Including the cash from the recent bond financing and the research tax credit payments related to years 2017 and 2018 received in October, the cash available is €22.6 million. Net revenue for the third quarter of 2019 was €0.5 million versus €0.4 million in the third quarter of 2018.

As of September 30, 2019, the Nicox Group had financial debt of €7.4 million in the form of a bond financing agreement with Kreos Capital signed in January 2019.

**Only figures at 31 December 2018 are audited. All figures of this press release are non-audited.**

#### Notes

1. Bloomberg data, comparing the period of the weeks ending 5 July 2019 to 27 September 2019 with the periods of the weeks ending 5 April 2019 to 28 June 2019 and 6 July 2018 to 28 September 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 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 Cycleron). 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 Eyeavance 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

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Bryan, Garnier & Co  
H.C. Wainwright & Co  
Oppenheimer & Co

Hugo Solvet  
Yi Chen  
Hartaj Singh

Paris, France  
New York, U.S.  
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 Conferences

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Bryan, Garnier & Co European Healthcare Conference	12 - 13 November, 2019	Paris
Actionaria	21 - 22 November, 2019	Paris

## Contacts

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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 4<sup>th</sup> 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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