

## Press Release

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# Nicox first quarter 2017 business update and cash position

- **Vyzulta<sup>TM1</sup> PDUFA date set for August 24, 2017**
- **ZERVIAE<sup>2</sup> PDUFA date set for September 8, 2017**
- **NCX 4251 and NCX 470 on track to enter Phase 2**
- **Cash position of €25 million<sup>3</sup> as of March 31, 2017**

April 27, 2017  
Sophia Antipolis, France

**Nicox S.A.** (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today provided an update on its activities and cash position as of March 31, 2017.

*"With the PDUFA dates now set for both Vyzulta<sup>TM</sup> and ZERVIAE, we are focussing our resources on the partnering activities for ZERVIAE in the United States and on preparing for the initiation of the Phase 2 studies evaluating our promising pipeline candidates NCX 4251 in the fourth quarter of 2017 and NCX 470 in the first quarter of 2018," said Michele Garufi, Chairman and Chief Executive Officer of Nicox. "Subject to approval by the FDA, we expect to have two revenue-generating assets and have two candidates in the clinic within the next 12 months, which would put us in a strong position as a major R&D player with an extensive clinical and preclinical pipeline in the ophthalmic space."*

### First-quarter 2017 financial highlights

The Group had cash, cash equivalents and financial instruments of €25.0 million<sup>3</sup> as of March 31, 2017, compared to €28.9 million as of December 31, 2016. The Group recorded no revenues for the first quarter 2017.

### First-quarter 2017 and recent operational highlights

- Resubmission to the U.S. Food and Drug Administration (FDA) on February 24, 2017 by Nicox's licensee, Bausch + Lomb (a wholly-owned subsidiary of Valent Pharmaceuticals Inc.), of the New Drug Application (NDA) for Vyzulta<sup>TM</sup> (latanoprostene bunod ophthalmic solution) 0.024%. Latanoprostene bunod is an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma (OAG) or ocular hypertension (OHT). The FDA has set a PDUFA date of August 24, 2017 (see press release dated March 20, 2017).
- Resubmission to the U.S. FDA, by Nicox, on March 8, 2017 of the NDA for ZERVIAE (cetirizine ophthalmic solution) 0.24%, Nicox's novel, proprietary, cetirizine eye drop formulation for the treatment of ocular itching associated with allergic conjunctivitis. The FDA has set a PDUFA date of September 8, 2017 (see press release dated April 11, 2017).

### Key upcoming milestones

- August 24, 2017: Potential U.S. FDA approval of Vyzulta<sup>TM</sup> NDA
- September 8, 2017: Potential U.S. FDA approval of ZERVIAE NDA
- H2 2017: Expected launch of Vyzulta<sup>TM</sup> in the United States by Bausch + Lomb, subject to FDA approval

- Q4 2017: Expected start of Phase 2 clinical study for NCX 4251
- Q1 2018: Expected start of Phase 2 clinical study for NCX 470

**Notes:**

1. Vyzulta™ is the provisionally approved tradename for latanoprostene bunod ophthalmic solution, 0.024%
2. ZERVIATE is the tradename provisionally approved for cetirizine ophthalmic solution, 0.24%
3. Figures non audited

**About Nicox**

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Nicox is an international ophthalmic R&D company utilizing innovative science to maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel therapies that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products at the pre-approval stage with the U.S. Food and Drug Administration (FDA) and a promising pipeline including next-generation stand-alone nitric-oxide donors, with the potential to treat a range of ophthalmic indications. 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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**Upcoming financial and business conferences**

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May 3-4	Deutsche Bank 42 <sup>nd</sup> Annual Health Care Conference	Boston, US
May 22-23	BioEquity Europe	Paris, France
May 30	Gilbert Dupont 15 <sup>th</sup> Annual Healthcare Conference	Paris, France
June 19-22	2017 BIO International Convention	San Diego, US
September 25-27	Cantor Fitzgerald's 3 <sup>rd</sup> Annual Healthcare Conference	New York; US

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