## Press Release

# Nicox Recaps 2017 Achievements, Provides Update on Commercial Availability of VYZULTA™ and Outlines 2018 Activities

- **Nicox joins the select group of European R&D companies with U.S. FDA approved products, with two products approved in 2017**
- **Valeant Pharmaceuticals International, Inc.'s wholly owned subsidiary, Bausch + Lomb, a leading global eye health company, announced yesterday that it has begun distributing VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% to wholesale pharmaceutical distributors across the United States**
- **VYZULTA™ is the first approved product based on Nicox's NO-donating research platform**
- **Resources in 2018 will be focused on advancing Nicox's pipeline candidates NCX 470 and NCX 4251 towards mid-stage clinical development and on progressing its next generation of discovery-stage NO-donating compounds targeting glaucoma into preclinical development**

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December 19, 2017 - Release at 7:30 am CET
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), international ophthalmic company, today provided a review of the Company's 2017 achievements, along with an outline of 2018 activities. The Company also highlighted that its partner, Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International Inc.) has informed Nicox that as of December 18, 2017 VYZULTA™ is currently being shipped to U.S. wholesalers.

*"2017 was an exceptional year for Nicox. With the first approval, received by our licensee Bausch + Lomb, of a product based on our NO-donating research platform, we have now joined the select few European R&D companies who succeeded in having products based on their own research approved by the U.S. FDA."* **stated Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"VYZULTA™, which has just been launched by Bausch + Lomb, and ZERVIATE™ (cetirizine ophthalmic solution) 0.24%, expected to be launched in late 2018, should provide a sound financial foundation for our clinical programs and in-house proprietary research. With the anticipated revenues from VYZULTA and ZERVIATE, and an estimated cash balance of over €41 million at the end of November 2017, we are well positioned to advance our strategy of becoming a fully-integrated ophthalmic pharmaceutical company spanning discovery through commercialization."*

**Key 2017 Highlights and Planned 2018 Activities**

In 2017, both of Nicox's lead assets were approved by the U.S. Food and Drug Administration (FDA). Commercial rights to both VYZULTA™ and ZERVIATE™ have been out-licensed to Bausch + Lomb and Eyevance Pharmaceuticals respectively and the Company expects to begin receiving royalty revenue in 2018, along with potential sales and development milestones payments.

- **VYZULTA™ launched in the U.S. by Bausch + Lomb and shipping commenced**: Indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension, VYZULTA, the first prostaglandin analog with one of its metabolites being nitric oxide (NO), is the first approved product to utilize Nicox's proprietary nitric oxide (NO)-donating research platform. Bausch + Lomb holds exclusively licensed worldwide rights to VYZULTA. The current lead products in this market, Travatan Z[1] and Lumigan[2], had sales of $570 million and $687 million respectively in 2016[3]. Nicox estimates that the U.S. patents covering VYZULTA could be extended from 2025 to 2030.

- **ZERVIATE™ approved and partnered to Eyevance Pharmaceuticals**: Indicated for the treatment of ocular itching associated with allergic conjunctivitis, ZERVIATE is the first and only topical ocular formulation of cetirizine. Eyevance Pharmaceuticals, an ophthalmic specialty pharmaceutical company backed by a specialized investment group and led by a team experienced in the U.S. ophthalmic market, holds licensed rights to commercialize ZERVIATE in the $700 million U.S.[4] market of topical ocular allergy products. Eyevance plans to launch ZERVIATE in the U.S. in late 2018, coinciding with the fall allergy season. The product is protected by patents to 2030 and 2032. Nicox is currently exploring partnerships for ZERVIATE outside of the U.S.

Nicox continues to progress its two pipeline products towards mid-stage clinical development and is also advancing several innovative, discovery-stage assets at its research center of Bresso, Milan.

- **NCX 470 targeting IND submission for Phase 2 in 2018**: A novel NO-donating bimatoprost analog in development for the reduction of IOP in patients with open angle glaucoma or ocular hypertension. NCX 470 has the potential for an IOP lowering efficacy greater than VYZULTA™. Nicox is conducting IND-enabling nonclinical studies and, subject to their successful completion, currently plans to submit an Investigational New Drug (IND) application for NCX 470 to the U.S. FDA in the summer of 2018 to support a Phase 2 clinical study.

- **NCX 4251 targeting IND submission for Phase 2 in 2018**: A novel formulation of fluticasone propionate being developed for the first time as a targeted topical treatment administered directly to the eye lid for the treatment of acute exacerbation of blepharitis, a common eye condition characterized by eyelid inflammation and swelling. Annual revenues of anti-inflammatories, antibiotics and their combinations prescribed for blepharitis total more than $500 million[5] in the U.S. alone. Nicox is conducting formulation and IND-enabling non-clinical studies and, subject to their successful completion, currently plans to submit an IND application to the U.S. FDA in the winter of 2018 to support a Phase 2 clinical study.

- **Next Generation of Stand-alone NO-donors and Novel NO-Donating Compounds**: Nicox has active research programs targeting NO-donation in the eye and has discovered multiple novel compounds that release NO from pharmacologically active and non-active scaffolds. These novel chemical entities are thought to lower IOP by stimulating the primary fluid outflow mechanism from the anterior segment of the eye. The Company's next generation of stand-alone NO-donors is designed to optimize NO dosing when administered alone or with current standard-of-care treatments to lower IOP in patients with open-angle glaucoma or ocular hypertension. Multiple candidates currently in the lead optimization stage of development have demonstrated IOP-lowering in animal models of ocular hypertension. Some of these candidates are currently being investigated for extended release intraocular drug delivery as part of two exploratory strategic collaborations with **pSivida** and **Re-Vana Therapeutics.** The collaborations will evaluate whether these extended release technologies are suitable for use with Nicox's new NO-donating compounds.

**Notes:**

1. IMS Health Analytics 2016 reported sales and TRx (Total Prescriptions)
2. IMS Health Analytics 2016 reported sales and TRx (Total Prescriptions)
3. MS Health Analytics 2016 reported sales and TRx (Total Prescriptions)
4. IMS Health Analytics and TRx (Total Prescriptions), not including OTC products for ocular allergy
5. Internal estimate based on IMS Health Analytics data.

## About Nicox

Nicox S.A. is an international ophthalmic company, with two out-licensed commercial-stage products, developing innovative solutions to help maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide (NO) donation and other technologies, the Company is developing an extensive portfolio of novel drug candidates that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products approved for commercialization in the U.S., VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, licensed worldwide to Bausch + Lomb, and ZERVIATE™ (cetirizine ophthalmic solution) 0.24%, licensed in the U.S. to Eyevance Pharmaceuticals. In addition to VYZULTA and ZERVIATE, Nicox has a pipeline of development-stage assets designed using the Company's proprietary NO-donating technology, as well as candidates based on repurposed, clinically- and commercially-validated molecules. The Company's pipeline also includes its next-generation of stand-alone NO-donors and exploratory, novel NO-donating compounds with the potential to offer new therapeutic approaches for a range of ophthalmic conditions. 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

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|---|---|---|
| Bryan, Garnier & Co | Hugo Solvet | Paris, France |
| Invest Securities | Martial Descoutures | Paris, France |
| Gilbert Dupont | 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.*

## Upcoming financial and business conferences

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| March 20-21 | Oppenheimer's 28th Annual Healthcare Conference | New York, USA |
| April 8-10 | HC Wainwright Global Biotechnology Conference | Monaco, Principality of Monaco |

## Contacts


**Nicox**
Gavin Spencer,
EVP, Chief Business Officer
T +33 (0)4 97 24 53 00
communications@nicox.com

**Investor Relations**
Europe
Nicox
Corporate Communications Department
T +33 (0)4 97 24 53 00
communications@nicox.com

United States
Argot Partners
Melissa Forst
T +1 (212) 600-1902
melissa@argotpartners.com

**Media Relations**
United Kingdom
Jonathan Birt
T +44 7860 361 746
jonathan.birt@ymail.com

France
NewCap
Nicolas Merigeau
T +33 (0)1 44 71 94 98
nicox@newcap.eu

United States
Argot Partners
Eliza Schleifstein
T +1 (917) 763-8106
eliza@argotpartners.com

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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 2016*' filed with the French Autorité des Marchés Financiers (AMF) on March 29, 2017, and in the updated and additional risk factors as of August 14, 2017, which are available on Nicox's website (www.nicox.com).

**Nicox S.A.**
Drakkar 2
Bât D, 2405 route des Dolines
CS 10313, Sophia Antipolis
06560 Valbonne, France
T +33 (0)4 97 24 53 00
F +33 (0)4 97 24 53 99