

# **Press Release**

# Nicox Highlights Recent Progress with Key Programs and Activities

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Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided a business update and highlighted recent progress with key programs and activities.

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"As expected, the first half of 2018 has seen important progress with our primary research and development projects," said Michele Garufi, Chairman and Chief Executive Officer of Nicox. "In addition, we know that Bausch + Lomb are putting significant efforts into the marketing of VYZULTA in the United States, with May prescriptions exceeding 4,400 scripts<sup>1</sup>. The manufacturing and scale-up of ZERVIATE is proceeding on track to support a fall 2018 commercial launch in the United States."

"Preparations for the clinical studies evaluating NCX 470 for patients with glaucoma and NCX 4251 for patients with blepharitis are progressing as planned to support IND submissions during the third quarter of this year and first quarter of next year, respectively. Moreover, we have initiated our collaboration with Ironwood Pharmaceuticals, Inc. focused on combining Ironwood's expertise in soluble guanylate cyclase (sGC) and our proprietary NO-donating research platform to generate new molecules with therapeutic potential; as well as progressed in our collaboration with Re-Vana. We are therefore optimistic about the evolution of our entire pipeline in the near future."

## **Key Upcoming Milestones**

- July 2018: Revenue update for Q2 2018
- Q3 2018: Planned U.S. Investigational New Drug (IND) submission for NCX 470 for the treatment of patients with glaucoma
- Fall 2018: Expected ZERVIATE<sup>™</sup> U.S. commercial launch
- Q1 2019: Planned U.S. IND submission for NCX 4251 for the treatment of patients with blepharitis

### **Progress on Key Activities**

- Commercialization of VYZULTA<sup>™</sup> in the United States. The product has now been in the market for over 6 months and Q2 2018 revenue for Nicox is expected to be announced in mid-July.
- ZERVIATE<sup>™</sup> expected to be launched in the U.S. by our partner Eyevance Pharmaceuticals during fall of 2018. Indicated for the treatment of ocular itching associated with allergic conjunctivitis, ZERVIATE<sup>™</sup> is the first and only topical ocular formulation of cetirizine.
- NCX 470 U.S. IND submission enabling Phase 2 clinical study in glaucoma patients planned in Q3 2018. NCX 470 is a novel second generation NO-donating prostaglandin analog



in development for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension.

- Additional pre-IND meeting held on NCX 4251 supporting the U.S. IND submission enabling Phase 2 clinical study in blepharitis patients planned in Q1 2019. In June 2018, an additional pre-IND meeting, which addressed specific questions on the potential primary endpoints for the Phase 2 study, was held with the U.S. FDA. Based on the FDA comments from this and previous meetings, we are finalizing the design of a first in human Phase 2 clinical trial. NCX 4251 is a novel, patented ophthalmic suspension of fluticasone propionate which is being developed for the first time as a targeted topical treatment of the eyelids for patients with acute exacerbation of blepharitis.
- Research Collaboration with Ironwood Pharmaceuticals, Inc. In June 2018, we announced that we had entered into a research collaboration agreement with Ironwood Pharmaceuticals, Inc., a commercial biotechnology company, focused on combining Ironwood's expertise in soluble guanylate cyclase (sGC) and our proprietary nitric oxide (NO)-donating research platform to generate novel compounds in order to identify potential new therapeutics for the treatment of certain ophthalmic conditions.
- Increasing the focusing of collaboration in extended release intraocular drug delivery for stand-alone NO-donors. We have decided to focus on our collaboration with Re-Vana Therapeutics concerning biodegradable extended release technologies and have discontinued the collaboration with Eyepoint Pharmaceuticals (previously pSivida) in this area.

#### **Change to Nicox Board of Directors**

Birgit Stattin Norinder, after seven years as member of Nicox's Board of Directors, has decided to step down from the Board of Directors to pursue other projects, with effect as of 20 June 2018. The entire Nicox team would like to thank Birgit Stattin Norinder for her valuable contribution.

#### Reference

1. Bloomberg – June 27. 2018

#### 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 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 with approved U.S. New Drug Applications, VYZULTA<sup>™</sup> (latanoprostene bunod ophthalmic solution), 0.024%, licensed worldwide to Bausch + Lomb, and ZERVIATE<sup>™</sup> (cetirizine ophthalmic solution), 0.24%, licensed worldwide to Bausch + Lomb, and ZERVIATE<sup>™</sup> (cetirizine ophthalmic solution), 0.24%, licensed in the U.S. to Eyevance. In addition, our promising pipeline includes clinical stage assets based both on our proprietary NO-donating research platform and on the repurposing of existing molecules as well as a future generation of standalone nitric-oxide donors and exploratory novel NO-donating compounds with the potential to offer novel approaches to treat 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

Bryan, Garnier & Co Invest Securities Gilbert Dupont Jam

Hugo Solvet Martial Descoutures Jamina El-Bougrini Paris, France Paris, France 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

October 1-3 November 22-23 Cantor Global Healthcare Conference Bryan, Garnier 6<sup>th</sup> Annual Healthcare Conference New York, USA 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 2017* filed with the French Autorité des Marchés Financiers (AMF) on March 19, 2018, which is available on Nicox's website (www.nicox.com).

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