

# **Press Release**

# Nicox Provides Third Quarter 2017 Business Update and Cash Position

- ZERVIATE<sup>TM1</sup> U.S. Rights Licensed to Eyevance Pharmaceuticals Launch Expected Late 2018
- Two New Collaborations in Place for Development of Ophthalmic Sustained Release Pipeline Assets
- Cash Balance of €47.1 Million as of September 30, 2017

October 24, 2017 – release at 7:30 am CET Sophia Antipolis, France

**Nicox S.A.** (Euronext Paris: FR0013018124, COX), international ophthalmic company, today provided an update on its activities and cash balance as of September 30, 2017.

"We continued to execute on our strategy in the third quarter with a partnership for the U.S. commercialization of ZERVIATE<sup>TM</sup>, licensing the rights to Eyevance Pharmaceuticals. Eyevance is a newly created ophthalmic specialty pharmaceutical company backed by an investment group with a long track record of success in the creation and growth of U.S. specialty pharma companies. Eyevance is led by a seasoned, entrepreneurial leadership team with specific expertise in the commercialization of products in the U.S. ophthalmic market. We believe that the launch, planned for late 2018, will be a success for both Eyevance and Nicox." commented Michele Garufi, Chairman and Chief Executive Officer of Nicox.

"Our two mid-stage products, NCX 470 for IOP lowering and NCX 4251 for blepharitis, are progressing toward their IND submissions in H1 and H2 2018 respectively to enter directly into Phase 2. Moreover, we continue to pursue additional opportunities within our pipeline of early stage next generation stand-alone NO-donors through the recently announced research collaborations with pSivida and Re-Vana Therapeutics to evaluate the potential for sustained release delivery of our promising new compounds. We continue to focus on our strategy of becoming a fully-integrated pharmaceutical company focused on the discovery, development and commercialization of novel ophthalmic therapeutics and believe we are in a position to rapidly advance our clinical programs and realize the value of VYZULTA<sup>TM</sup> and ZERVIATE<sup>TM</sup> through our partnerships with Bausch + Lomb and Eyevance respectively."

# Third Quarter 2017 and Recent Business Development Highlights

- Earlier this month Nicox entered into two collaborations to explore the potential for sustained release formulations of Nicox's next generation of stand-alone nitric oxide (NO)-donors for the reduction of intraocular pressure (IOP), with Re-Vana Therapeutics concerning their EyeLief<sup>™</sup> long-acting photo-crosslinked biodegradable drug delivery platform and with pSivida Corp concerning their bioerodible sustained release drug delivery system.
- In September, Nicox entered into an exclusive licensing agreement with Eyevance Pharmaceuticals LLC, for the commercialization of ZERVIATE<sup>TM</sup> (cetirizine ophthalmic solution) 0.24%, in the US and received a non-refundable upfront payment of \$6 million.
- In September, Nicox and VISUfarma amended certain elements of their agreement relating to



the August 2016 transfer of Nicox's European and International commercial operations to VISUfarma. This amendment results in a net income of €2.8 million.

- In August, Nicox completed a financing through a reserved capital increase of ordinary shares of the Company with a specific category of investors. Gross proceeds from the financing were €26.3 million, and net proceeds were €24.5 million.
- In August, Nicox's licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) announced that it submitted a response to the U.S. Food and Drug Administration's (FDA) Complete Response Letter (CRL), also received in August, concerning the New Drug Application (NDA) for VYZULTA<sup>TM2</sup> (latanoprostene bunod ophthalmic solution), 0.024% for intraocular pressure lowering in patients with open angle glaucoma or ocular hypertension. The CRL from the FDA referred to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Florida. The NDA had been resubmitted to the FDA by Bausch + Lomb in February 2016 following receipt of a previous CRL. Neither CRL issued to Bausch + Lomb mentioned any efficacy or safety issues with respect to the NDA for VYZULTA, nor any additional clinical trials for the approval of the NDA.

### **Development Update**

Following an update on the manufacturing timelines for the NCX 4251 formulation, the IND application to support a Phase 2 clinical study is now expected to be submitted in H2 2018. NCX 4251 is a novel formulation of fluticasone propionate being developed for the first time as a topical treatment for acute exacerbation of blepharitis.

The IND application to support a Phase 2 clinical study with NCX 470 is expected to be submitted in H1 2018. NCX 470 is a novel NO-donating bimatoprost analog in development for reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

### **Q3 2017 Financial Highlights**

The Group had cash and cash equivalents of €47.1 million (including gross proceeds from the August 2017 financing) as of September 30, 2017, compared to €20.4 million as of June 30, 2017. The Group recorded no revenues for the third quarter 2017 because the non-refundable \$6 million payment received from Eyevance is not immediately recognizable as revenue accordingly to IFRS accounting principles.

#### Notes:

- 1. ZERVIATE<sup>™</sup> is the tradename approved for cetirizine ophthalmic solution, 0.24%
- VYZULTA™ is the provisionally approved tradename for latanoprostene bunod ophthalmic solution, 0.024%

All the figures of this press release are non-audited.

#### **About Nicox**

Nicox S.A. is an international ophthalmic company 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 one product at the review stage with the U.S. Food and Drug Administration (FDA), VYZULTA<sup>TM</sup> (latanoprostene bunod ophthalmic solution), 0.024%, licensed worldwide to Bausch + Lomb, and one product with an approved U.S. NDA, ZERVIATE<sup>TM</sup> (cetirizine ophthalmic solution) 0.24%, licensed in the U.S. to Eyevance. In addition, Nicox's promising drug-candidate 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 next-generation of stand-alone 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.



#### **Nicox Disclaimer**

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 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).

#### **Analyst coverage**

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Invest Securities

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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

November 23-24 Actionaria Paris, France

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