

**PRESS RELEASE** 

## NicOx withdraws its Marketing Authorization Application for naproxcinod in Europe

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**NicOx S.A.** (NYSE Euronext Paris: COX) today announced its decision to withdraw the Marketing Authorization Application (MAA) for its osteoarthritis candidate naproxcinod from the centralized procedure in Europe. NicOx submitted the naproxcinod MAA to the European Medicines Agency (EMA) in December 2009.

The decision to withdraw the European MAA was made following the feedback at the April meeting of the Committee for Medicinal Products for Human Use (CHMP) that the CHMP would not adopt a formal positive opinion on the basis of the submitted information. NicOx has notified the EMA of its decision to withdraw the naproxcinod MAA, based on the CHMP considering that the data provided did not allow them to conclude on a positive benefit-risk balance. NicOx is now evaluating its options for the potential further development of naproxcinod in Europe, together with its advisors and with Grupo Ferrer Internacional S.A. which has an option for rights to naproxcinod in certain European countries (see NicOx press release dated March 18, 2011).

NicOx submitted a New Drug Application (NDA) for naproxcinod to the U.S. Food and Drug Administration (FDA) and received a Complete Response Letter in July 2010 stating that the FDA did not approve naproxcinod. NicOx has decided to appeal the FDA decision under the FDA's Formal Dispute Resolution process and is currently finalizing the submission of the supporting information for the appeal.

NicOx is developing a number of nitric oxide-donating New Molecular Entities (NMEs), both internally and with its partners Bausch + Lomb, Merck (known as MSD outside the United States and Canada) and Ferrer. The Company had €107.3 million in cash and cash equivalents as of December 2010 and is focused on a number of strategic priorities, including actively seeking appropriate M&A opportunities and new alliances on existing programs as well as targeting internal research resources on the most promising programs.

As per the EMA's guidelines, both a 'Question and Answer' document summarizing the CHMP evaluation and the public Assessment Report will be made available on the agency's website at a later date.

## About NicOx

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a pharmaceutical company focused on the research, development and future commercialization of drug candidates. NicOx is applying its proprietary nitric oxide-donating R&D platform to develop an internal portfolio of New Molecular Entities (NMEs) for the potential treatment of inflammatory, cardiometabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxcinod, an NME in development for the relief of the signs and symptoms of osteoarthritis. In addition to naproxcinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck (known as MSD outside the United States and Canada) and Bausch + Lomb, for the treatment of select cardiovascular indications, eye diseases and dermatological diseases.

NicOx S.A. is headquartered in France and is listed on Euronext Paris (Compartment B: Mid Caps).



This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the 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 2010* » filed with the French Autorité des Marchés Financiers (AMF) on February 25, 2011 and available on NicOx's website (<u>www.nicox.com</u>) and on the AMF's website (<u>www.amf-france.org</u>).

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