

PRESS RELEASE



## NicOx Provides Update on U.S. Regulatory Status of Naproxcinod

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April 4, 2012. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) today announces that it met with the United States Food and Drug Administration (FDA) on April 3, 2012, to discuss the proposed use of naproxcinod 375 mg twice daily (*bid*), for the treatment of signs and symptoms of osteoarthritis (OA) of the knee, under a proposed new NDA (New Drug Application) that would require additional clinical data prior to any such NDA submission.

The subject of the April 3, 2012 meeting was the required clinical data for the potential new NDA for naproxcinod 375 mg *bid*.

NicOx will assess the requirements for further clinical data discussed with the FDA and its impact on the overall development program of naproxcinod. NicOx intends to seek a partner to fund and manage any further development and potential commercialization of naproxcinod.

NicOx had previously submitted an NDA for naproxcinod 375 mg *bid* and 750 mg *bid* for the treatment of signs and symptoms of OA not limited to the knee. NicOx received a Complete Response Letter in July 2010 stating that the FDA did not approve that naproxcinod NDA. NicOx initiated a Formal Dispute Resolution process in July 2011 regarding that decision involving the previously submitted NDA. These were not the topic of the April 3, 2012 meeting.

NicOx is focused on becoming an international, late-stage development and commercial ophthalmology company in therapeutics, diagnostics and devices. NicOx intends to build a diversified, late-stage ophthalmology portfolio with a clear route to commercialization. The Company is currently evaluating a number of additional ophthalmic acquisition and in-licensing opportunities both in the United States and in Europe.

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### About NicOx

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is building an international late-stage development and commercial Ophthalmology Company based around therapeutics, diagnostics and devices. As of March 2012, NicOx holds an 11.8% stake in the UK-based ophthalmology company Altacor, with an option to acquire the remaining shares, as the first step of a transformation into a late-stage development and commercial ophthalmic Company.

NicOx is also developing an internal portfolio of New Molecular Entities (NMEs) through the application of its proprietary nitric oxide-donating R&D platform. The Company's pipeline includes several nitric oxide-donating NMEs for the potential treatment of ophthalmological, inflammatory and cardio-metabolic diseases, which are in development internally and with partners, who include Bausch + Lomb, Merck (known as MSD outside the United States and Canada) and Ferrer.

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



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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 2011* » filed with the French Autorité des Marchés Financiers (AMF) on February 29, 2012 and available on NicOx's website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).

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