

PRESS RELEASE



## Posting of Briefing Documents for FDA Advisory Committee on NicOx's naproxcinod – Company to host conference calls on Thursday May 13

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May 11, 2010. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) announces today that the U.S. Food and Drug Administration (FDA) has published on its website both the FDA's briefing book and NicOx's briefing book ahead of the May 12 meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the New Drug Application (NDA) for naproxcinod. The briefing documents can be found at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/ucm203434.htm>.

Naproxcinod is currently under review by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and NicOx is seeking approval for the indication of the relief of the signs and symptoms of osteoarthritis.

The FDA Advisory Committee meeting is scheduled on Wednesday May 12 at 8:00 am EST (2:00 pm CET – 1:00 pm UK) in Washington.

The FDA Advisory Committee is a joint meeting with the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, two independent panels of experts which provide advice and recommendations to the FDA. The FDA uses committees and panels to obtain independent expert advice on scientific, technical, and policy matters to assist in its mission to protect and promote public health. FDA regulations indicate that, although the FDA will consider the recommendation of the panel, the final decision regarding the approval of an investigational drug product is made by the FDA.

The meeting will be webcast live by commercial organizations. It will be webcast neither on the FDA's website nor on NicOx's website.

### **NicOx will request the Company's stock trading to be halted during the FDA Advisory Committee meeting**

Considering that the FDA Advisory Committee is a public meeting, NicOx intends to request NYSE Euronext to suspend trading of the Company's common stock from Wednesday May 12 at 2:00 pm CET (8:00 am EST – 1:00 pm UK) until the conclusion of the meeting and to resume normal trading on Thursday May 13 at 9:00 am CET.

NicOx will issue a press release on the outcome of the FDA Advisory Committee meeting on Thursday May 13 before the opening of the market trading in France.

### **Conference calls on Thursday May 13**

NicOx will hold a conference call in French on Thursday May 13 at 3:00 pm CET (9:00 am EST – 2:00 pm UK) and another one in English at 4:00 pm CET (10:00 am EST – 3:00 pm UK) to discuss the outcome of the Advisory Committee meeting. Details of these conference calls will be available on the Company's website [www.nicox.com](http://www.nicox.com) on May 11, by 10:00 am CET.

### **About naproxcinod**

Naproxcinod is NicOx's lead investigational compound and the first in a new class of anti-inflammatory agents known as CINODs (Cyclooxygenase-Inhibiting Nitric Oxide Donators). The NDA file is supported by data from a large program of 35 clinical trials that involved more than 6,500 subjects. The program evaluated the efficacy of naproxcinod in relieving signs and symptoms of osteoarthritis, as well as its safety, with particular care given to its effect on blood pressure.

In September 2009, NicOx submitted an NDA for naproxcinod, seeking approval for the relief of the signs and symptoms of osteoarthritis, which was accepted for filing by the FDA in November 2009. Based on the Prescription Drug User Fee Act (PDUFA), the FDA has set an action date of July 24, 2010. In December 2009, NicOx submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), which was validated in January 2010.

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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 2009 » filed with the French Autorité des Marchés Financiers (AMF) on March 5, 2010 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)).

The Company notably draws the investors' attention to the following risk factors:

- *Risques liés à la dépendance de la Société à l'égard du naproxinod* (Risks related to the Company's dependence on the success of its lead product naproxinod)
- *Risques commerciaux et développements cliniques* (Clinical developments and commercial risk)
- *Risques liés aux contraintes réglementaires et à la lenteur des procédures d'approbation* (Risks linked to regulatory constraints and slow approval procedures)
- *Manque de capacités dans les domaines de la vente et du marketing* (Lack of sales and marketing capabilities)
- *Incertitude relative aux prix des médicaments et aux régimes de remboursement, ainsi qu'en matière de réforme des régimes d'assurance maladie* (Uncertainty on drug pricing and reimbursement policies and on the reforms of the health insurance systems)

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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 (NME) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxinod, an NME and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate developed for the relief of the signs and symptoms of osteoarthritis (OA), which is currently under review by regulatory authorities, following the submission and filing of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). The FDA has set an action date of July 24, 2010, under the Prescription Drug User Fee Act (PDUFA). The FDA and the EMA are evaluating the data submitted. NicOx does not wish to make any claims in regard to naproxinod's safety or efficacy prior to its potential approvals.

In addition to naproxinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck & Co., Inc. and Bausch + Lomb, for the treatment of hypertension, cardiometabolic diseases, widespread eye diseases and dermatological diseases.

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

*For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of NicOx S.A. to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Référence filed with the AMF, which is available on the AMF website (<http://www.amf-france.org>) or on NicOx S.A.'s website (<http://www.nicox.com>).*

**CONTACTS:** [www.nicox.com](http://www.nicox.com)

**NicOx: Gavin Spencer Vice President Business Development**  
Tel +33 (0)4 97 24 53 00 • [communications@nicox.com](mailto:communications@nicox.com)

**Media Relations      Financial Dynamics**

**Europe**      Guillaume Granier (France) • Tel: +33 (0)1 47 03 68 10 • [guillaume.granier@fd.com](mailto:guillaume.granier@fd.com)  
Stéphanie Bia (France) • Tel: +33 (0)1 47 03 68 10 • [stephanie.bia@fd.com](mailto:stephanie.bia@fd.com)  
Jonathan Birt (UK) • Tel +44 (0)20 7269 7205 • [jonathan.birt@fd.com](mailto:jonathan.birt@fd.com)

**United States**      Robert Stanislaro • Tel +1 212 850 5657 • [robert.stanislaro@fd.com](mailto:robert.stanislaro@fd.com)  
Irma Gomez-Dib • Tel +1 212 850 5761 • [irma.gomez-dib@fd.com](mailto:irma.gomez-dib@fd.com)