

PRESS RELEASE



## NicOx provides update on FDA Advisory Committee Meeting for naproxcinod

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May 13, 2010. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) announced today that the Joint Advisory Committees of the U.S. Food and Drug Administration (FDA), including the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, voted by 16 to 1 with 1 abstention that they did not have sufficient evidence at this time to support the approval of naproxcinod for the relief of the signs and symptoms of osteoarthritis.

Chair Dr Kathleen O'Neil MD, Associate Professor of Pediatrics, University of Oklahoma College of Medicine, Division of Rheumatology, summarized the findings of the Advisory Committee meeting, saying there was enthusiasm for the potential of naproxcinod but more data was required from additional safety studies.

The FDA Arthritis Drugs Advisory Committee and Drug Safety and Risk Management Committee based their recommendation on a review of data from the naproxcinod clinical development program, which included 35 clinical studies involving more than 6,500 subjects. The New Drug Application (NDA) file contains data from three large pivotal phase 3 studies, all of which met their co-primary efficacy endpoints.

The FDA is not bound by the recommendations of the Advisory Committee but may take their advice into consideration when evaluating the NDA for naproxcinod. The FDA is expected to make a decision on whether to approve naproxcinod by July 24, 2010.

NicOx submitted a Marketing Authorization Application (MAA) for naproxcinod to the European Medicines Agency (EMA) in December 2009.

### 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 are available on the Company's website [www.nicox.com](http://www.nicox.com).

### 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.

### About osteoarthritis

Osteoarthritis (OA), the most common type of arthritis, is a widespread degenerative disease which affects the joints and causes moderate to severe chronic pain. OA mainly occurs in the weight-bearing joints of the hips and knees and is associated with the breakdown of cartilage, a material which covers the ends of bones in normal joints. OA is most commonly seen in older people, especially women, and its exact cause is unknown, although heredity factors, previous joint damage and obesity appear to play a role. According to a Datamonitor estimate published in December 2009, OA is estimated to have afflicted over 81 million people in 2009 in the seven major markets (US, Japan, France, Germany, Italy, Spain and the UK), including approximately 29 million in the United States alone. Symptomatic treatments commonly used by OA patients include traditional non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors.

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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>).*

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