

## NicOx provides strategic update

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**NicOx S.A.** (NYSE Euronext Paris: COX) today provides an update on its strategy and activities following consultation with NicOx's Board of Directors this week.

Michele Garufi, Chief Executive Officer of NicOx, commented, "We remain confident about naproxcinod's medical value and in the strength of the data we have accumulated in our extensive clinical program. We look forward to hearing further feedback from the FDA. We also continue to work with the EMA in Europe, where naproxcinod was filed for approval in December 2009. NicOx is a well-funded company with more than €138 million in cash at the end of March 2010, no debt, a robust pipeline of nitric oxide-donating New Molecular Entities and a strong network of first-class partnerships, including Merck, Bausch + Lomb and Ferrer."

The Company will seek to continue discussions with the U.S. Food and Drug Administration (FDA) in the review of the New Drug Application (NDA) for naproxcinod following the May 12 FDA Joint Advisory Committee meeting, and looks forward to receiving the overall evaluation, including the Advisory Committee comments. The European Medicines Agency (EMA) is also currently reviewing the Marketing Authorization Application (MAA) for naproxcinod, which was submitted in December 2009 and validated in January 2010. The Company will evaluate opportunities for regulatory submissions for naproxcinod in other countries.

## Financial status

NicOx has a strong balance sheet, with cash, cash equivalents and financial instruments totaling €138.5 million on March 31, 2010, and the Company carries no long term debt. NicOx is reviewing all aspects of its cost base to ensure careful conservation of its funds. As a result, NicOx has decided to delay initiation of an in-house phase 2 study of NCX 6560, an innovative nitric oxide (NO)-donating HMG-CoA Reductase Inhibitor which achieved positive results in a first-in-man clinical study in 2009, until clarification of naproxcinod's regulatory position. The Company believes that NCX 6560 is a valuable asset in its pipeline and will now seek alternative funding options to develop NCX 6560 which will conserve NicOx's capital.

## **Partnerships**

NicOx has built a network of strong partnerships for the development of some of its promising lead compounds, including alliances with Merck & Co., Inc., Bausch + Lomb and Ferrer. We believe that these projects are a potential source of additional significant future value for the Company:

- The collaboration with Merck on NO-donating anti-hypertensive agents is an ongoing program to identify a phase 2 candidate.
- NicOx recently signed a worldwide licensing agreement with Bausch + Lomb for NCX 116, an NO-donating
  prostaglandin F2-alpha analog for the potential treatment of glaucoma and ocular hypertension. Both
  companies have already held an initial meeting to agree on the next steps for the development of NCX 116.
- Encouraging preclinical results have been obtained with Ferrer in the dermatology area. NicOx and Ferrer expect clinical studies for NCX 1047, the lead compound, to start in early 2011.

## **R&D Pipeline**

NicOx has a broad preclinical pipeline of NO-donating New Molecular Entities (NMEs) targeting the therapeutic areas of inflammatory, cardiometabolic and ophthalmological diseases. Preclinical results from several research programs will be presented at scientific and medical conferences in the next few months.

NicOx's R&D platform is supported by a strong intellectual property base, including over 700 granted and 500 pending patents, and continues to have significant potential to develop novel NO-donating compounds with unique properties.

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 (<u>www.nicox.com</u>) and on the AMF's website (<u>www.amf-france.org</u>).

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

- Risques liés à la dépendance de la Société à l'égard du naproxcinod (Risks related to the Company's dependence on the success of its lead product naproxcinod)
- 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)

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, cardiometabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxcinod, 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 naproxcinod's safety or efficacy prior to its potential approvals.

In addition to naproxcinod, 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).



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 Reference 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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