



FDA provides Complete Response Letter to NicOx's New Drug Application for naproxcinod

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NicOx S.A. (NYSE Euronext Paris: COX) today announced the receipt of a Complete Response Letter from the U.S. Food and Drug Administration (FDA) related to the New Drug Application (NDA) for naproxcinod. Naproxcinod is being developed for the relief of the signs and symptoms of osteoarthritis.

The FDA informed NicOx that its review of the NDA is complete and that it does not approve the naproxcinod application. The FDA has recommended conducting one or more long-term controlled studies to assess the cardiovascular and gastrointestinal safety of naproxcinod. Additional studies to demonstrate a clinically meaningful therapeutic benefit attributable to the nitric oxide donation were also recommended. No clinical efficacy studies were requested.

NicOx plans to discuss the Complete Response Letter and potential next steps as early as possible with the FDA.

The naproxcinod Marketing Authorization Application (MAA) submitted by NicOx in December 2009 is currently under review by the European Medicines Agency (EMA).

NicOx remains well funded and had cash, cash equivalents and financial instruments of €138.5 million at the end of March 2010. The Company will publish its financial results for the first half of 2010 on July 30, 2010. NicOx has no long-term debt and is constantly reviewing all aspects of its cost base to ensure careful conservation of its funds.

NicOx has a broad pipeline of nitric oxide (NO)-donating New Molecular Entities (NMEs) targeting the therapeutic areas of inflammatory, cardiometabolic and ophthalmological diseases. 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.

Risks factors which are likely to have a material effect on NicOx's business are presented in the 4th 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) and on the AMF's website (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 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, cardio-metabolic 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). In July 2010, the FDA provided a Complete Response Letter to the New Drug Application (NDA) for naproxcinod stating that it does not approve the naproxcinod application. The naproxcinod Marketing Authorization Application (MAA) submitted by NicOx in December 2009 is currently under review by the European Medicines Agency (EMA).

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, 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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