

# NicOx reacquires rights to PF-03187207 for glaucoma from Pfizer

August 6, 2009. Sophia Antipolis, France. www.nicox.com

**NicOx S.A.** (NYSE Euronext Paris: COX) today announced the signature of an agreement with Pfizer Inc to reacquire the full development and commercialization rights to PF-03187207, which has completed two phase 2 studies in patients with primary open angle glaucoma and ocular hypertension. As part of this agreement, Pfizer has granted NicOx the right to access and use certain proprietary Xalatan® (latanoprost) data.

"We are very pleased with this transaction with NicOx," said **David K. Rosen, Head of Out Licensing for Pfizer.** "The two companies have enjoyed a very good relationship throughout this collaboration and we look forward to supporting NicOx during the transition period. This agreement demonstrates our ongoing commitment to out-license and to allow partner companies to reacquire R&D programs that are no longer core to our strategy but could become important medicines for patients and physicians."

**Gavin Spencer, Vice President of Business Development at NicOx**, added: "We believe PF-03187207 has good potential to be registered for glaucoma and ocular hypertension and could represent an important new treatment option for the benefit of patients worldwide. We will evaluate opportunities for advancing PF-03187207 into phase 3, including possible third-party partnerships. We maintain an excellent relationship with Pfizer and understand its decision to conclude our previous agreements."

Under the new agreement and following Pfizer's announced strategic review process, NicOx is also regaining rights to a number of novel, research-stage, nitric oxide-donating compounds for the potential treatment of diabetic retinopathy and glaucoma. The compounds targeting diabetic retinopathy have produced positive results in a variety of models showing their potential benefit for the treatment of this prevalent eye disease, for which existing treatments are inadequate. The agreement announced today supersedes and concludes NicOx' previous August 2004 and March 2006 agreements with Pfizer and follows the receipt of the last annual research funding of €3 million by NicOx in March 2008.

## Terms of the new agreement on PF-03187207 and Xalatan® data access

Under the terms of the new agreement with Pfizer, NicOx is reacquiring the full development and commercialization rights to PF-03187207 (including the right to sublicense), as well as the entire current data-package and development information. NicOx can also access and use certain proprietary Xalatan® development information and cross-refer to Xalatan® regulatory filings, which could be important for the potential future development and regulatory filing of PF-03187207. Pfizer will also provide temporary technical support to help the transition to any further clinical program. In return, NicOx has agreed to pay Pfizer two undisclosed milestones (the first of which is linked to approval in the US, European Union and Japan, and the second on reaching predefined sales levels), in addition to royalties on future sales.

In the phase 2 studies conducted in the United States and Japan, the two highest doses of PF-03187207 showed an improvement over Xalatan® 0.005% of up to 12%, in terms of the diurnal intraocular pressure (IOP) reduction at day-28, compared to baseline. In both the Japanese and U.S. studies, PF-03187207 showed a 20% greater reduction in IOP at 20 hours post-dose compared to Xalatan® 0.005%, suggesting a more sustained IOP lowering effect. This difference was statistically significant in the U.S. study (p<0.05). PF-03187207 appeared to be safe and well tolerated in both studies, with adverse events being mild.

The results of the US phase 2 trial were presented in May 2009 by NicOx and Pfizer at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Fort Lauderdale, Florida, together with three other scientific communications on PF-03187207.

### NicOx regains rights to research stage compounds showing promise for diabetic retinopathy

Over the last 11 months, the research activities under the March 2006 agreement have been solely focused on the synthesis and characterization of compounds for the potential treatment of diabetic retinopathy. This research has identified a number of novel, nitric oxide-donating compounds, which have produced positive results in a variety of models showing their potential benefit for the treatment of diabetic retinopathy. Under the new agreement, Pfizer has relinquished its option to select a drug candidate for development from this research project. NicOx has also regained rights to a number of promising research stage compounds targeting glaucoma.

"The diabetic retinopathy research program we are receiving from Pfizer has produced compelling preclinical results and we intend to identify the best approach to advance it into development," declared **Pascal Pfister, Chief Scientific Officer and Head of Research and Development at NicOx.** "We are enthusiastic about the benefits of nitric oxide donation in ophthalmology and are glad to have regained full rights to our proprietary technology in this attractive therapeutic area."

#### About glaucoma

Glaucoma is a group of eye diseases which can lead to the loss of peripheral vision and eventually total blindness. Glaucoma is frequently linked to abnormally high pressure in the eye (intraocular pressure, IOP), due to blockage or malfunction of the eye's drainage system. Abnormally high IOP does not cause any symptoms itself, however it can lead to optic nerve damage and vision loss if left untreated. Drug therapy is used to reduce IOP and therefore prevent further vision loss, typically through increasing the drainage of intraocular fluid by relaxing certain muscles in the eye. Several large government trials have demonstrated that reducing IOP can prevent the progression of glaucoma in both early and late stages of the disease. A significant proportion of patients with elevated IOP require more than one medication to maintain their IOP within target levels, highlighting the need for more effective treatments.

## About diabetic retinopathy

Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness each year in the United States and represents the most common cause of blindness among adults aged 20 to 74 years. In the US, 40-45% of adults diagnosed with diabetes have some degree of diabetic retinopathy, which corresponds to 4.1 million adults (2004).

Diabetic retinopathy is retina damage due to diabetes. High blood sugar can damage ocular blood vessels, causing them to become blocked or leak fluid. Frequently a swelling of the retina or a build-up of protein deposits on the retina can be involved in the disease. In some cases there is a development of new, abnormal vessels, which can break and bleed into the center of the eye, inducing blindness. In addition to prevention through the management of blood sugar levels, the most established treatment for diabetic retinopathy is laser surgery.

**NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA)** is a product-driven biopharmaceutical company dedicated to the development and future commercialization of investigational drugs for unmet medical needs. NicOx is applying its proprietary nitric oxide-donating technology to develop an internal portfolio of New Chemical Entities (NCEs) in the therapeutic areas of inflammatory and cardio-metabolic disease.

Resources are focused on the development and pre-commercialization activities for naproxcinod, a proprietary NCE and a first-in-class Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent for the relief of the signs and symptoms of osteoarthritis. Naproxcinod has completed three pivotal phase 3 studies with positive results and regulatory submissions are projected for Q3 2009 for a New Drug Application (NDA) to the US Food and Drug Administration (FDA) and Q4 for a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA).

Beyond naproxcinod, NicOx has a pipeline containing multiple nitric oxide-donating NCEs, which are in development internally and with partners, including Merck & Co., Inc., for the treatment of prevalent and underserved diseases, such as atherosclerosis, hypertension, widespread eye diseases and respiratory diseases.

NicOx S.A. is headquartered in France and is listed on the NYSE 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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