

## Press Release

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# Nicox and Fera Pharmaceuticals to Focus on a Rare Disease Indication for Naproxcinod

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- Nicox and Fera Pharmaceuticals have amended their 2015 agreement for naproxcinod
  - Development, under the responsibility of Fera, will now focus on an undisclosed rare disease, which could potentially lead to an orphan drug designation for naproxcinod
  - Potential sales-based milestone increased to \$40 million if annual sales reach \$1 billion
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September 27, 2018 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, and Fera Pharmaceuticals, a privately-held, U.S. specialty pharmaceutical company, today announced that they have amended their 2015 license agreement, which granted Fera exclusive rights to develop and commercialize naproxcinod for the U.S. market. The development of naproxcinod will now focus on an undisclosed rare disease, for which Fera expects to seek an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA). Naproxcinod, a Cyclooxygenase-Inhibiting Nitric Oxide (NO)-Donating (CINOD) naproxen, is a non-steroidal anti-inflammatory product candidate originally discovered and developed by Nicox.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox, said,** “We are delighted that Fera intends to take the development of naproxcinod in a new direction, which could potentially lead to an Orphan Drug Designation for naproxcinod in a rare disease. Fera should benefit from the existing chemistry, manufacturing and control data and the extensive nonclinical and clinical safety database for naproxcinod to support a potentially accelerated clinical development program.”

**Frank DellaFera, Founder and President of Fera Pharmaceuticals, added** “Naproxcinod has the potential to become an FDA approved drug targeting an unmet medical need in a rare disease. Fera has conducted an extensive review and based on naproxcinod’s NO-donating activity, along with its pain-relieving properties, we are looking forward to its further development to potentially provide patients with an important new treatment option.”

Nicox and Fera have agreed that the collaboration will now be focused on an undisclosed rare disease. Fera may submit, subject to a successful completion by Fera of a preclinical Proof-of-Concept study, an application for an Orphan Drug Designation for naproxcinod to the FDA. Fera believes that naproxcinod may be able to enter directly into a clinical efficacy study if the Orphan Drug Designation is obtained.

Under the amended agreement, Nicox will now be eligible to potentially receive a single \$40 million, sales-based milestone if naproxcinod reaches \$1 billion yearly sales (for any indication) in the U. S. This milestone would be payable only once. The royalties remain unchanged at 7% of net sales of naproxcinod in the U.S. Other than as specified in the amendment, Fera remains responsible for all clinical development, manufacturing, regulatory and commercialization activities.

## About Naproxcinod

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Our product candidate naproxcinod is a non-steroidal anti-inflammatory drug (NSAID) that is a nitric oxide (NO)-donating naproxen. The NO-donating mechanism of action makes naproxcinod a cyclooxygenase inhibiting nitric oxide donator (CINOD), a class of drugs that are hoped to produce similar analgesic efficacy to traditional NSAIDs, but with an improved gastrointestinal and cardiovascular side effect profile. A broad clinical package already exists for naproxcinod in osteoarthritis, including three phase 3 studies with over 2,700 patients. Nicox submitted an NDA for naproxcinod for osteoarthritis in 2009 and received a Complete Response Letter in 2010 in which the FDA requested substantial additional long-term safety data.

## About Fera Pharmaceuticals

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Fera Pharmaceuticals is a privately held company. The company goal is to realize opportunities via acquisitions, in-licensing, developing and marketing abbreviated new drug applications (ANDAs), new drug applications (NDAs) and 505(b)(2) NDA products. Areas of interest include products that could benefit from lifecycle management with a special focus on niche markets. For more information visit [www.ferapharma.com](http://www.ferapharma.com).

## About Nicox

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Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio includes three programs in development based on our proprietary NO-donating research platform and on novel and proprietary formulations of well-established molecules that have previously been used in other indications and therapeutic areas as well as future generation stand-alone NO donors in formulation development and testing and other exploratory novel NO-donating compounds targeting ophthalmic conditions including glaucoma and ocular hypertension. In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017 as well as ZERVIA™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyeavance Pharmaceuticals. Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit: [www.nicox.com](http://www.nicox.com)

## Analyst coverage

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**Disclaimer**

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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 2017*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 19, 2018, which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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