



Nicox and Fera Pharmaceuticals sign exclusive license agreement for naproxcinod in the U.S.

Nicox eligible to receive up to \$35 million in commercial milestones, plus 7% royalties on future sales

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November 10, 2015

Sophia Antipolis, France and Locust Valley, New York

Nicox S.A. (Euronext Paris: FR0000074130, COX), the international ophthalmic company, and **Fera Pharmaceuticals**, a privately-held specialty pharmaceutical company, announced today that they have entered into an exclusive license agreement for the development and commercialization of Nicox's naproxcinod, a CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory candidate, in the United States.

Fera's initial focus will be the signs and symptoms of osteoarthritis. Fera plans to seek advice from the United States Food and Drug Administration (FDA) regarding the additional clinical work required before submitting a New Drug Application (NDA) for naproxcinod. Nicox already completed a broad clinical program for naproxcinod in osteoarthritis, including three phase 3 studies with over 2,700 patients.

Under the terms of the agreement, Nicox will be eligible to receive up to \$35 million in sales-based milestones, plus 7 percent royalties based on net sales of naproxcinod in the U.S. Fera will be responsible for, and will fully finance, all clinical development, manufacturing and commercialization activities. The agreement covers all indications excluding ophthalmology-related conditions and Duchenne Muscular Dystrophy (DMD), and Nicox will retain all rights for naproxcinod outside of the U.S. Fera is eligible to receive an undisclosed royalty should naproxcinod be approved and commercialized in any indication in any ex-U.S. territory using data generated by Fera. A joint steering committee will be put in place with representation from both companies to ensure that development of naproxcinod proceeds in accordance with the agreement.

"Fera has a long track record in the development and commercialization of specialty pharmaceuticals and recognizes the value of naproxcinod's unique product profile," said **Gavin Spencer, Executive Vice President, Corporate Development at Nicox**. "Following our alliance with Bausch + Lomb for latanoprostene bunod, this transaction further underscores the value of Nicox's nitric oxide-donating pipeline. If approved and commercialized, naproxcinod could become a meaningful treatment option for patients suffering from osteoarthritis and could bring royalties to Nicox that would provide important non-dilutive cash flow to support the development of our ophthalmology pipeline."

Frank DellaFera, Co-founder of Fera Pharmaceuticals, commented: "Nicox's nitric oxide-donating research platform places them at the forefront of innovation and we believe naproxcinod, which is supported by robust, late-stage clinical data, is a highly promising compound for patients suffering with pain associated

with osteoarthritis. We look forward to collaborating with Nicox and ensuring naproxcinod has the opportunity to display its full potential."

The U.S. intellectual property relating to this transaction is comprised of a patent for the naproxcinod S enantiomer which is protected until 2021 as well as a formulation patent.

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About Naproxcinod

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 additional long-term safety data.

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About Fera Pharmaceuticals

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.

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About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an international commercial-stage company focused on the ophthalmic market. With a heritage of innovative R&D, business development and marketing expertise, Nicox is building a diversified portfolio of ophthalmic products that can help people enhance their sight.

Nicox's advanced pipeline features latanoprostene bunod for the lowering of intra-ocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension, and for which a New Drug Application (NDA) was recently submitted to the FDA by the Company's licensee Valeant. Our pipeline also features AC-170, a pre-NDA candidate for the treatment of ocular itching associated with allergic conjunctivitis, as well as two pre-MAA candidates in Europe: AzaSite[®] for bacterial conjunctivitis and BromSite[™] for pain and inflammation after cataract surgery. Beyond these late-stage candidates, Nicox is developing a pipeline of next generation ophthalmology-focused candidates which utilize its proprietary nitric oxide (NO)-donating research platform. The Group operates directly in six countries, including the United States. It has proprietary commercial operations in Europe's five largest markets complemented by an expanding international network of distributors.

Nicox is headquartered in France and has more than 130 staff worldwide. It is listed on Euronext Paris (Category B: Mid Caps) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes. For more information on Nicox, its commercial products or pipeline, please visit <u>www.nicox.com</u>.

Upcoming 2015 events

Financial and business conferences

Nov. 12-13Bryan Garnier Healthcare ConferenceNov. 17-18Stifel Healthcare Conference 2015Nov. 20-21Actionaria 2015Nov. 24Natixis MidCap Conference

Scientific conferences

Nov. 14-17AAO – American Academy of OphthalmologyNov. 27-30SOI National Congress

Analyst coverage

Bryan, Garnier & Co Stifel Invest Securities Kepler Cheuvreux Hugo Solvet Max Herrmann Martial Descoutures Alexandra Ralli

Las Vegas, US Rome, Italy

Paris, France

Paris, France

Paris, France

New York, United States



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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.

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 2014*' filed with the French *Autorité des Marchés Financiers* (AMF) on April 10, 2015, which is available on Nicox's website (<u>www.nicox.com</u>).