

Press Release

Nicox Highlights VYZULTA™ approval, Latest Corporate and Financial Developments, and Upcoming Pipeline Initiatives

- **VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% Approved by U.S. Food and Drug Administration (FDA); Bausch + Lomb to Launch by Year End**
- **Revenue Stream to Support Advancement of NCX 470 and NCX 4251 into Phase 2 Studies; Investigational New Drug (IND) applications to be submitted in 2018**

November 3, 2017 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), international ophthalmic company, today highlighted recent regulatory progress, with the approval in the United States of its partnered product, VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% announced yesterday and provided an overview of the Company's corporate and financial developments and upcoming pipeline initiatives.

Michele Garufi, Chairman and Chief Executive Officer of Nicox commented, *"We are delighted that VYZULTA™ has been approved by the U.S. FDA, giving Nicox two approved products. The launch of VYZULTA™ in the United States by our partner Bausch + Lomb, anticipated by year end, will mark a key milestone in our strategy for Nicox to become a fully-integrated pharmaceutical company, from discovery through commercialization. The revenue stream from this first commercialized product using our NO-donating technology, along with that of ZERVIA™ (cetirizine ophthalmic solution) 0.24%, expected to launch in late 2018, will help to support our pipeline programs, including advancing into Phase 2 clinical studies with our two mid-stage products: NCX 470, our second NO-donating product candidate, currently in development for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension; and NCX 4251, a novel formulation of fluticasone propionate for blepharitis. We are rapidly advancing our discovery and development programs to unlock the value in the Nicox pipeline and NO-donating technology."*

Product and Pipeline Highlights

- **VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% Approved by the U.S. Food and Drug Administration (FDA).** On November 2, 2017, Nicox and its licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) announced that the U.S. FDA approved the New Drug Application (NDA) for VYZULTA™, a prostaglandin analog indicated for the reduction of IOP in patients with open angle glaucoma or ocular hypertension. Following topical administration, VYZULTA™, a once daily monotherapy with a dual mechanism of action, works by metabolizing into two moieties, latanoprost acid, which primarily works within the uveoscleral pathway to increase aqueous humor outflow, and butanediol mononitrate, which releases NO to increase outflow through the trabecular meshwork and Schlemm's canal. The most common ocular adverse reactions with incidence ≥2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%). The U.S. launch of VYZULTA™ by Bausch + Lomb is expected by the end of 2017.

- **ZERVIAE™ (cetirizine ophthalmic solution), 0.24% Licensed to Eyevance Pharmaceuticals LLC for commercialization in the US.** Nicox recently announced its entry into an exclusive licensing agreement with Eyevance for the U.S. commercialization of ZERVIAE™, the first ocular formulation of the antihistamine cetirizine approved for the treatment of ocular itching associated with allergic conjunctivitis. Eyevance is a newly created ophthalmic specialty pharmaceutical company backed by an investment group with a long track record of success and led by a seasoned, entrepreneurial leadership team with specific expertise in the commercialization of products in the U.S. ophthalmic market. Nicox announced the approval of ZERVIAE™ in May 2017. ZERVIAE™ is planned to be launched in the United States by Eyevance in late 2018, coinciding with the fall allergy season.
- **NCX 470 in Development for the Reduction of Intraocular Pressure.** NCX 470 is a novel nitric-oxide (NO)-donating bimatoprost analog. Bimatoprost is a prostaglandin analog, a member of the most widely used class of IOP-lowering drugs. NCX 470 was designed to release both bimatoprost and NO following instillation into the eye, and, in non-clinical evaluations, the data suggest that it reduced IOP more than bimatoprost. Bimatoprost is generally regarded as more efficacious than latanoprost, and Nicox believes that, as a NO-donating analog of bimatoprost, NCX 470 has the potential to have better IOP lowering activity. Nicox plans to submit an IND application for NCX 470 to the FDA in the first half of 2018 to support a Phase 2 clinical study.
- **NCX 4251 in Development for the Treatment of Blepharitis.** NCX 4251, a novel formulation of fluticasone propionate, is being developed for the first time as a topical treatment for acute exacerbation of blepharitis, a common eye condition characterized by eyelid inflammation. Fluticasone propionate is a leading corticosteroid which has been marketed for more than 20 years for a number of indications, including asthma and allergic rhinitis, and has an approximately ten-fold greater affinity for the glucocorticoid receptor compared to dexamethasone, a corticosteroid frequently used in ophthalmology. Nicox plans to submit an IND application for NCX 4251 to the FDA in the second half of 2018 to support a Phase 2 clinical study.
- **Next Generation of Stand-alone NO-donors and of Novel NO-Donating Compounds.** Nicox has active research programs targeting NO donation in the eye and has discovered multiple novel compounds that release NO from pharmacologically active and non-pharmacologically active scaffolds. These novel chemical entities are thought to lower IOP by stimulating the primary fluid outflow mechanism from the anterior segment of the eye. The Company's next generation stand-alone NO-donors are designed to optimize NO dosing when administered alone or with current standard-of-care treatments to lower IOP in patients with open-angle glaucoma or ocular hypertension. Multiple candidates currently in the lead optimization stage of development have demonstrated IOP-lowering in animal models of ocular hypertension and are currently being investigated for extended release drug delivery. Nicox also recently announced its entry into two exploratory strategic collaborations, one with pSivida and one with Re-Vana Therapeutics, to evaluate biodegradable extended release formulations that may be appropriate for use with Nicox's NO-donating compounds.

Key Corporate and Financial Highlights

- Nicox's partnership with Bausch + Lomb for VYZULTA™ could lead to potential future milestone payments of up to \$145 million^{1,2} including a \$20 million milestone payable upon Bausch + Lomb reaching \$100 million sales (\$15 million to Pfizer^{3,4}). Bausch + Lomb will also make tiered royalty payments on net sales of 10% to 15% (6% to 11% net of payment to Pfizer⁵) on Bausch + Lomb global sales. Bausch + Lomb expects to launch VYZULTA™ by the end of 2017. Nicox estimates that the VYZULTA™ patent coverage could be extended to 2029-2030⁶.
- Nicox's collaboration with Eyevance could result in up to \$5 million in near-term manufacturing milestones and up to an additional \$37.5 million in potential future sales milestones, (including \$30 million triggered by annual sales targets of \$100 million and above) plus royalties of 8% to 15%. Nicox expects the launch of ZERVIAE™ to be in late 2018, and the product is protected by patents to 2030 and 2032.

- As of September 30, 2017, Nicox had cash and cash equivalents of €47.1 million.

Notes

1. \$15 million related to the development of a combination product involving latanoprostene bunod
2. Milestones relating to regulatory approvals, achievement of sales targets and future development steps
3. Per the terms of the contract signed with Pfizer in August 2009 by which Nicox recovered the rights to latanoprostene bunod
4. No further milestones payable to Pfizer
5. Net of royalty due to Pfizer per the agreement in note 3 above
6. Internal estimate based on 2025 patent expiry date

About Nicox

Nicox S.A. is an international ophthalmic company developing innovative solutions to help maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel drug candidates that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products with approved New Drug Applications, VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%, licensed worldwide to Bausch + Lomb, and ZERVIA™ (cetirizine ophthalmic solution) 0.24%, licensed in the U.S. to EyeVance. In addition, our promising drug-candidate pipeline includes clinical stage assets based both on our proprietary NO-donating research platform and on the repurposing of existing molecules as well as a next-generation of stand-alone nitric-oxide donors and exploratory novel NO-donating compounds with the potential to offer novel approaches to treat a range of ophthalmic conditions. 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.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
Invest Securities	Martial Descoutures	Paris, France
Gilbert Dupont	Damien Choplain	Paris, France



The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

Upcoming financial and business conferences

November 23-24	Actionaria	Paris, France
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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 2016*' filed with the French Autorité des Marchés Financiers (AMF) on March 29, 2017, and in the updated and additional risk factors as of August 14, 2017, which are available on Nicox's website (www.nicox.com).

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