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Bausch + Lomb Initiates Phase 3 Program for Glaucoma Drug Candidate Licensed from Nicox

January 29th, 2013.

Sophia Antipolis, France and Madison, NJ, USA.

Bausch + Lomb, the global eye health company, and **Nicox S.A.** (NYSE Euronext Paris: COX) today announced that Bausch + Lomb has initiated its Phase 3 clinical program of latanoprostene bunod (previously known as BOL-303259-X and NCX 116) for the reduction of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. Latanoprostene bunod is a nitric oxide-donating prostaglandin F2-alpha analog licensed by Nicox to Bausch + Lomb.

This pivotal Phase 3 program includes two separate randomized, multicentre, double-masked, parallel-group clinical studies, APOLLO and LUNAR, designed to compare the efficacy and safety of latanoprostene bunod administered once daily (QD) with timolol maleate 0.5% administered twice daily (BID) in lowering IOP in patients with open-angle glaucoma or ocular hypertension. The primary endpoint of both studies, which will include a combined total of approximately 800 patients, is the reduction in mean IOP measured at specified time points during three months of treatment. The Phase 3 studies are pivotal for U.S. registration and will be conducted in North America and Europe. Additional information about the studies can be found at www.clinicaltrials.gov.

"There is a need for more effective, safer and better tolerated therapies to lower IOP," said Robert N. Weinreb, M.D., chairman & distinguished professor of Ophthalmology, University of California San Diego and director, Shiley Eye Center and Hamilton Glaucoma Center. "The Phase 2b results for latanoprostene bunod were promising, so it is exciting that this potential new therapy is now in pivotal trials."

Bausch + Lomb's decision to proceed with a pivotal Phase 3 program followed positive results with latanoprostene bunod in a Phase 2b trial in 413 patients with elevated IOP due to glaucoma and ocular hypertension. This study showed that latanoprostene bunod consistently lowered IOP in a dose-dependent manner. All four doses tested in the Phase 2b trial showed greater IOP reduction compared with Xalatan® 0.005%, with the differences for two of the four doses reaching more than 1mmHg (statistical significance: p<0.01).

"Bausch + Lomb believes that latanoprostene bunod has the potential to become an important new treatment option for people suffering from elevated IOP due to glaucoma and ocular hypertension," said **Cal Roberts, M.D. executive vice president and chief medical officer, Bausch + Lomb**. "We look forward to completing this pivotal research program, and hope to develop an effective new treatment option to benefit physicians and the patients they serve."

"Latanoprostene bunod is a nitric oxide-donating compound which was discovered in our Research Laboratories in Milan and is the first Nicox program licensed to a partner to enter into Phase 3," said **Michele Garufi, chairman and CEO of Nicox.** "We are pleased with Bausch + Lomb's commitment to pursuing this program in an area of significant therapeutic need. The whole Nicox team has contributed to this important milestone which underlines the potential of our research platform in the ophthalmic field."

Nicox and Bausch + Lomb Worldwide Licensing Agreement

In March 2010, Bausch + Lomb signed a worldwide licensing agreement with Nicox for latanoprostene bunod, and made an initial license payment of \$10 million. In light of the positive results of the Phase 2b study completed in 2011, Bausch + Lomb made an additional \$10 million milestone payment in April 2012 following their decision to pursue further development of latanoprostene bunod. If certain regulatory, commercialization and sales milestones for latanoprostene bunod are met, Nicox stands to receive from Bausch + Lomb additional potential payments which, over time, could total \$162.5 million. Nicox will also receive tiered double-digit royalties on the sales of latanoprostene bunod and has the option to co-promote the product in the United States.

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 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.

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About Bausch + Lomb

forward-looking statements.

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Its core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, the company is headquartered in Rochester, NY, and employs roughly 11,000 people worldwide. Its products are available in more than 100 countries. More information is available at <u>www.bausch.com</u>.

About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is creating a new mid-sized international player in the ophthalmic market by building a diversified portfolio of innovative therapies and diagnostic tools. With a heritage of scientific, business development and commercial expertise, the Nicox team is focused on developing and marketing novel pharmaceuticals and diagnostic devices that can help people to enhance their sight. In the United States, Nicox markets AdenoPlus[™], a test for the differential diagnosis of acute conjunctivitis inlicensed from RPS®.

The Company's pipeline includes latanoprostene bunod, a novel drug-candidate based on Nicox's proprietary nitric oxide (NO)-donating R&D platform, developed in collaboration with Bausch + Lomb for the potential treatment of glaucoma and ocular hypertension. Further NO-donating compounds are under development in non-ophthalmic indications, notably through partners, including Merck (known as MSD outside the United States and Canada) and Ferrer.

Nicox S.A. is headquartered in France and is listed on Euronext Paris (Compartment B: Small Caps). For more information please visit <u>www.nicox.com</u>.

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

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 2011 » filed with the French Autorité des Marchés Financiers (AMF) on February 29, 2012 and available on Nicox's website (www.nicox.com) and on the AMF's website www.amf-france.org).

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