



Nicox Provides Update on Latanoprostene bunod and AC-170

- **Latanoprostene bunod: Bausch + Lomb anticipates launch mid-2017¹**
- **AC-170: Nicox to meet with the FDA concerning resubmission of AC-170 NDA and expects FDA feedback by early 2017**

November 9, 2016

Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today provided an update on the regulatory status of its key projects, latanoprostene bunod and AC-170.

Update on latanoprostene bunod

Valeant Pharmaceuticals International, Inc., has stated that Nicox's licensee for latanoprostene bunod, Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.), is currently addressing the issues identified by the U.S. Food and Drug Administration (FDA) and anticipates being ready for inspection by the end of the year. Bausch + Lomb also anticipates a launch mid-2017¹.

On July 21, 2016, Bausch + Lomb announced its receipt of a Complete Response Letter (CRL) from the FDA regarding the latanoprostene bunod NDA for the lowering of intraocular pressure in patients with open angle glaucoma or ocular hypertension. The CRL cited concerns pertaining to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Florida. The FDA's letter did not identify any efficacy or safety concerns with respect to the latanoprostene bunod NDA or additional clinical trials needed for the approval of the NDA.

Update on AC-170

On October 10, 2016, Nicox announced that it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for AC-170, its novel, proprietary, cetirizine eye drop formulation for the treatment of ocular itching associated with allergic conjunctivitis. The FDA's stated reason for the CRL pertains solely to a Good Manufacturing Practice (GMP) inspection at a third party facility producing the active pharmaceutical ingredient (API), cetirizine, and supplying it to the manufacturer of the finished product. The safety and efficacy data submitted by Nicox in

the AC-170 NDA have not resulted in the FDA requesting any further clinical or non-clinical testing for the approval of the AC-170 NDA. Furthermore, the CRL did not include any concerns related to the finished product manufacturing facility.

Since receiving the CRL, Nicox has remained in close contact with the relevant manufacturing parties who are actively working to address the FDA's concerns as soon as possible. Furthermore, Nicox expects to meet with the FDA during the fourth quarter of 2016 regarding the next steps for the resubmission of the AC-170 NDA and expects to receive feedback from the FDA by early 2017.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said: *"Taking into account these recent developments, we remain confident regarding the future approval of both latanoprostene bunod and AC-170. These two approvals have the potential to unlock significant value for Nicox and will help support our ongoing development programs. Furthermore, our solid cash position gives us financial runway through at least the end of 2018 and is sufficient to fund the proof of concept studies for both NCX 470 in glaucoma and NCX 4251 in blepharitis. The interactions with the FDA concerning the start of the clinical studies for these development programs will take place during the fourth quarter of 2016 and we plan to communicate the intended start dates for the clinical studies early next year."*

As a reminder, approval of the AC-170 NDA after 1st December 2016 would trigger a milestone payment of \$10 million in Nicox shares to ex-Aciex shareholders or \$35 million in Nicox shares if approval of the NDA is received before this date. The amount of the payments due will be reduced by \$3.2 million related to the costs incurred by Nicox in running the additional clinical safety study on AC-170. AC-170 was developed by Aciex Therapeutics, Inc., which became a wholly-owned subsidiary of Nicox in October 2014 and was subsequently renamed Nicox Ophthalmics, Inc.

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¹ Subject to regulatory approval. Bausch + Lomb will need to resubmit the NDA. Once the resubmission is filed, the FDA has 30 days to agree that the submission constitutes a complete response and is expected to complete its review within six months from the date of resubmission.

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About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an international R&D company focused on the ophthalmic market. For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

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November 14-15	Bryan Garnier & Co 4 th European Healthcare Conference	Paris, France
November 15-16	Stifel 2016 Healthcare Conference	New York, US
November 18-19	Actionnaria	Paris, France
November 21-23	Deutsches Eigenkapitalforum	Frankfurt, Germany
December 13	Guggenheim Securities 4th Annual Boston Healthcare Conference	Boston, US

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Contacts

Nicox **Gavin Spencer** | Executive Vice President Corporate Development
Tel +33 (0)4 97 24 53 00 | communications@nicox.com

Media Relations

United Kingdom **Jonathan Birt**
Tel +44 7860 361 746 | jonathan.birt@ymail.com

France **NewCap** | Nicolas Merigeau
Tel +33 (0)1 44 71 94 98 | nicox@newcap.eu

United States **Argot Partners** | Eliza Schleifstein
Tel +1 (917) 763-8106 | eliza@argotpartners.com

Investor Relations

Europe **NewCap** | Julien Perez | Valentine Bouchot
Tel +33 (0)1 44 71 94 94 | nicox@newcap.eu

United States **Argot Partners** | Melissa Forst
Tel +1 (212) 600-1902 | melissa@argotpartners.com

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