

Nicox first quarter 2016 financial and business update

- Revenue of €3.5 million, with growth of over 60% in the first quarter 2016
- NDAs in the U.S. for latanoprostene bunod and AC-170 under review at the FDA

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May 10, 2016

Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic company, today reported its first quarter 2016 revenues and cash position and provided an update on its activities.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, stated, "We have successfully started 2016 with our strongest quarter revenue to date, €3.5 million, reflecting more than 60% growth. We also achieved the important development milestone of the submission last month of the AC-170 NDA for allergic conjunctivitis, for which we expect to hear shortly from the FDA concerning the Priority Review status. In addition, the recent ARVO ophthalmology congress in Seattle featured presentations by both our partner, Bausch + Lomb, on latanoprostene bunod, and the Nicox teams on our NO-donating pipeline, raising significant interest in the scientific community around the results of our new research projects. We look forward to communicating the FDA's feedback on the latanoprostene bunod and AC-170 NDAs in due course."

First-quarter financial highlights

The Group's revenues in the first three months of 2016 totaled €3.5 million and consisted exclusively of European and International product sales. These compare to €2.1 million in the first quarter of 2015, a growth of over 60%. Nicox is currently evaluating a number of strategic options for its European commercial business for which discussions remain ongoing.

The Group had cash, cash equivalents and financial instruments of €20.8 million as of March 31, 2016. The cash burn in the first quarter 2016 included €3.1 million of non-recurrent spending related to submission of the AC170 New Drug Application (NDA) and additional work so support the AC-170 NDA review.

First-quarter and post-reporting period operational highlights

 In January 2016, Nicox Ophthalmics, Inc. granted Ora Inc., the world's leading ophthalmic clinical research and product development firm, exclusive worldwide rights for the development and commercialization of the OTC asset AC-120, an innovative drug-candidate for morning eyelid swelling ("puffy eyes").

- Submission of AC-170 NDA to the U.S. Food and Drug Administration (FDA) on 18 April 2016, with a request for Priority Review, for the treatment of ocular itching associated with allergic conjunctivitis. This NDA has not yet been accepted for review by the FDA. The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing, and to confirm if the Priority Review has been granted. AC-170 is a novel formulation of cetirizine, the active ingredient in Zyrtec®¹, which has been developed for the first time for topical application in the eye for the treatment of ocular itching associated with allergic conjunctivitis.
- In May 2016, posters were presented by our partner Bausch + Lomb of clinical results for latanoprostene bunod and by Nicox on pipeline candidates NCX 667, NCX 1653, and NCX 4240 at the Association for Research in Vision and Ophthalmology (ARVO) 2016 Annual Meeting (see Press Release dated May 9, 2016).

Key Upcoming Milestones

- Q2 2016: Decision by the FDA on the Priority Review status for AC-170
- July 21, 2016: PDUFA date for latanoprostene bunod
- September 22, 2016: First-half results

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References

1. Zyrtec® is a trademark of UCB Pharma SA or GlaxoSmithKline.

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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, for which a New Drug Application (NDA) was submitted to the FDA by the Company's licensee Bausch + Lomb, Valeant Pharmaceuticals International, Inc.'s, wholly owned subsidiary. The Company's pipeline also features AC-170, for which the NDA was submitted to the FDA for the treatment of ocular itching associated with allergic conjunctivitis in April 2016, 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 has operations in Europe and the United States.

Nicox 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: www.nicox.com.

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Analyst coverage

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





Upcoming 2016 events

Financial and business conferences

May 10 Gilbert Dupont Forum Santé Paris, France May 17 SFAF Bio Day Paris, France May 19 European Mid Small Cap Forum London, UK BIO 2016 June 6-9 San Francisco, US June 28 SGCIB Healthcare & Biotechnology conference Paris, France July 12-13 Cantor Fitzgerald's 2nd Annual Healthcare conference New York, US

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This press release contains certain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements.

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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 2015' filed with the French Autorité des Marchés Financiers (AMF) on April 15, 2016, which is available on Nicox's website (www.nicox.com).