Nicox third quarter 2016 business update and cash position

October 11, 2016

Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today provided an update on its activities and cash position.

"We expect to further advance our position as a leading ophthalmic R&D company with the anticipated FDA decisions on latanoprostene bunod, which is licensed worldwide to Bausch + Lomb, and AC-170, as well as the planned commencement of Phase 2 clinical trials for both NCX 4251 and NCX 470," **commented Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"We are in close contact with the relevant parties for the resolution of GMP issues and we anticipate the resubmission of the NDAs as soon as these issues are resolved. We are pleased that none of the FDA's comments related to the products themselves, and we remain confident that both products will ultimately be approved by the FDA. This is an exciting time for Nicox, and we look forward to keeping you updated on our progress."*

Third-quarter financial highlights

Following the transfer of the European and International commercial operations to a new pan-European ophthalmic specialty company (now named "VISUfarma BV") Nicox did not record any revenues for the third quarter of 2016[1].

The Group had cash, cash equivalents and financial instruments of €32 million[2] as of September 30, 2016, compared to €12.3 million as of June 30, 2016.

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.

Nicox will resubmit the AC-170 NDA once the FDA's concerns have been addressed by the relevant manufacturing party.

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 monetary amount of the payments due will be reduced by the costs incurred by Nicox in running the additional clinical safety study on AC-170. Nicox estimates that this reduction will be $3.2 million, the maximum allowable under the terms governing the warrants associated with the share payments. 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.

Update on latanoprostene bunod

On July 21, 2016, latanoprostene bunod licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) announced its receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for the use of latanoprostene bunod for the treatment of glaucoma. 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. Bausch + Lomb has subsequently received written communication from FDA regarding the resubmission of the NDA for latanoprostene bunod to address issues raised in the CRL. Once the resubmission is filed, the FDA has 30 days to acknowledge its acceptance of the filing, and the FDA is expected to complete their review within six months.

Other third-quarter highlights

- In August 2016, Nicox completed the transfer of its European and International commercial operations to VISUfarma. The transaction was valued at up to €26 million and Nicox received a €9 million upfront cash payment and a minority stake in the new company.
- In July 2016, Nicox completed a financing through a reserved capital increase of ordinary shares of the Company with a specific category of investors. Gross proceeds from the financing were €18 million.

[1] Revenues, costs, assets and liabilities for the European commercial operations are treated as "Discontinued Operations" in accordance with IFRS 5

[2] Unaudited figures

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.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
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Upcoming financial and business conferences

November 14-15	Bryan Garnier & Co 4th 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

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 Brouchot
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