

Nicox reports strong revenue growth in 2015 and provides corporate update

• 2015 annual revenues grew by 65% to €9.9 million

NDA filing for AC-170 expected in early Q2 2016

February 25, 2016

Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic company, today reported the unaudited revenues and cash position for the full year 2015 and provided an update on its corporate activities.

"Revenues from our European commercial operations continued to grow throughout 2015. We ended the year with €30 million in cash and are entering 2016 with strong sales momentum," commented **Michele Garufi, Chairman and Chief Executive Officer of Nicox.** "We continue to see strong interest from potential partners in our European commercial business, and we are in active discussions with several parties that we believe could ensure the future growth and success of the business. Regarding our R&D pipeline, we are anticipating two potential product approvals this year, for latanoprostene bunod, which is licensed to Bausch + Lomb, and also for our proprietary cetirizine eye drop, AC-170, if a Priority Review is granted. We are also making significant progress with the advancement of our internal pipeline candidates."

2015 estimated revenue and cash position

Nicox revenues amounted to approximately €9.9 million for the full year 2015, an increase of 65% over 2014, with both 2014 and 2015 sales comprised exclusively of European and International product sales.

Cash, cash equivalents and financial instruments at December 31, 2015 totaled approximately €29.6 million.

The Group's full 2015 financial results will be released on April 15, 2016.

U.S. and global development programs

- Latanoprostene bunod, licensed to Bausch + Lomb (a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.), is currently under review by the U.S. Food and Drug Administration (FDA) as an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma or ocular hypertension. The FDA has set an action date of July 21, 2016 to finalize its review, as per the Prescription Drug User Fee Act (PDUFA).
- Nicox expects to submit a New Drug Application (NDA) to the U.S. FDA for AC-170 early in the second quarter 2016. AC-170 is a novel cetirizine eye drop formulation developed for the treatment of ocular itching associated with allergic conjunctivitis. The Company is planning to seek Priority Review for AC-170, which, if obtained, could result in an approval by the end of 2016 based on PDUFA performance goals.
- NCX 4251, a novel form of fluticasone propionate being developed for blepharitis, is now in formulation studies, with the goal of entering directly into Phase 2.
- NCX 470, a novel nitric-oxide donating bimatoprost, is now advancing through pre-IND development prior to entering first-in-man clinical studies.

European development programs

As previously reported in December 2015 (see Nicox Press Release December 3, 2015), Nicox is currently evaluating a number of strategic options for the European commercial business with different potential partners. Nicox's European pipeline could potentially be included in these strategic discussions.

- AzaSite[®] for bacterial conjunctivitis and BromSite[™] for pain and inflammation after cataract surgery are currently being prepared for European Marketing Authorization Application (MAA) submission, the date of which will be communicated in due course.
- NCX 4240, an innovative Carragelose[®] eye drop in development for viral conjunctivitis, is expected to be launched in mid 2018.
- The development of AAT (RPS-AP), a diagnostic test for the combined detection of adenoviral and allergic conjunctivitis, which was in-licensed from RPS[®], has been discontinued, based on unsatisfactory clinical results obtained by RPS. Nicox continues to market AdenoPlus[®] in more than 15 markets.

.....

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, and for which a New Drug Application (NDA) was submitted to the FDA by the Company's licensee Valeant. The Company's pipeline also features AC-170, a pre-NDA candidate for the treatment of ocular itching associated with allergic conjunctivitis, 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.

.....

Analyst coverage

Bryan, Garnier & Co
Invest Securities

Martial Descoutures
Gilbert Dupont

Hugo Solvet
Paris, France
Paris, France
Paris, France
Paris, France



Upcoming 2016 events

Financial and business conferences

April 12-13 Needham Healthcare Conference New York, US
May 17 SFAF Bio Day Paris, France
June 6-9 BIO 2016 San Francisco, 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

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.

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 2014' filed with the French Autorité des Marchés Financiers (AMF) on April 10, 2015, which is available on Nicox's website (www.nicox.com).