

# Nicox first quarter 2015 financial and business update

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April 17, 2015.

Sophia Antipolis, France.

**Nicox S.A.** (Euronext Paris: FR0000074130, COX), the international ophthalmic company, today reported its first quarter 2015 revenues and cash position and provided an update on its activities.

"We enjoyed an excellent start to 2015 across the different business activities of our Group" said Michele Garufi, Chairman and CEO of Nicox. "The successful financing completed in March demonstrated support for our strategy from international specialist investors, and in particular for Vesneo™ and AC-170, both of which have the possibility to be approved in the US by the end of 2016. In addition, we have just launched a new product from our internal development program in Europe, under our own brand Zared, and we look forward to further product launches and sales growth through the rest of 2015."

## First-quarter financial highlights

The Group's revenues in the first three months of 2015 totaled €2.1 million and consisted exclusively of European and International product sales. These compare to €0.9 million in the first quarter of 2014<sup>1</sup>, showing a strong progress over the same period of the previous year. The Company expects a continuous progression and growth of the revenues throughout the rest of 2015.

The Group had cash, cash equivalents and financial instruments of €48.4 million as of March 31, 2015.

## First-quarter operational highlights

- Financing successfully completed in March 2015 with the participation of major institutional investors specialized in life sciences, mainly from the US. The gross proceeds of the financing are approximately €27 million.
- Two positive pre-NDA (New Drug Application) meetings held with the US Food and Drug Administration (FDA) regarding AC-170, cetirizine ophthalmic solution developed for the treatment of ocular itching associated with allergic conjunctivitis. Nicox's objective is to obtain FDA approval by the end of 2016.
- Exclusive license agreement signed with InSite Vision for AzaSite<sup>®</sup> (azithromycin ophthalmic solution for bacterial conjunctivitis) and BromSite<sup>™</sup> (bromfenac ophthalmic solution for pain and inflammation

after cataract surgery) in Europe, Middle East and Africa. Nicox plans to file both European Marketing Authorization Applications (MAAs) by Q1 2016.

- Orphan Drug Designation (ODD) granted by the FDA to naproxcinod for the treatment of Duchenne Muscular Dystrophy (DMD). Naproxcinod is currently under evaluation by an undisclosed financial partner for potential clinical development in DMD, with an update expected mid-2015.
- Presentation of Vesneo<sup>™</sup> (latanoprostene bunod ophthalmic solution for glaucoma and ocular hypertension) data at two major glaucoma conferences:
  - Poster entitled "Effect of Latanoprostene Bunod Compared with Timolol Maleate on Ocular Perfusion Pressure in Subjects with Open-Angle Glaucoma or Ocular Hypertension (CONSTELLATION)" presented by Liu et al.<sup>2</sup> at the 25<sup>th</sup> American Glaucoma Society (AGS) Annual Meeting, held from February 26 to March 1, 2015 in Coronado (California, United States). This poster presented some interesting new data obtained in the phase 2 study CONSTELLATION.
  - Oral presentation entitled "First NO-donating compound for IOP lowering in patients with Glaucoma and Ocular Hypertension" made by Baldo Scassellati Sforzolini, VP Development Eyecare at Bausch + Lomb, at the Glaucoma 360 conference, held from February 5 to 7, 2015 in San Francisco (California, United States).

Bausch + Lomb (Valeant group) plans to submit an NDA for Vesneo™ to the US FDA in Q2 2015.

# Post-first quarter events

- In April 2015, Nicox launched a new product from its internal development program, a fortified food combining antioxidants and zinc (zinc contributes to the maintenance of normal vision) marketed under the Company's brand Zared. The new Zared product is being launched directly in the top five European markets and in a number of International markets through distribution agreements. Additional product launches are planned in 2015 and in the next few years.
- Jerry St Peter, Executive Vice President and General Manager of Aciex Therapeutics, a US subsidiary of Nicox, has decided to leave the Company to join another international specialty pharmaceutical company. Jerry joined Nicox in March 2012 and played an important part in the transformation of Nicox into an internationally recognized ophthalmology company, helping to build a successful diagnostics business which is now part of Valeant and to strengthen Nicox's therapeutic pipeline through the integration of Aciex. The Company is grateful for his contribution and wishes him every success in his future role.

## 2015 financial calendar

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## References

 In accordance with IFRS5, the first-quarter 2014 revenues of €0.9 million do not include Nicox Inc., which was divested to Valeant in November 2014.

2. Liu JHK et al. Invest Ophthalmol Vis Sci 2014;55:E-abstract 3549.



#### **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, we are building a diversified portfolio of ophthalmic products that can help people to enhance their sight.

Nicox's advanced pipeline features two pre-NDA candidates (Vesneo<sup>™</sup> for glaucoma, partnered with Bausch + Lomb / Valeant and AC-170 for allergic conjunctivitis) as well as two pre-MAA candidates (AzaSite<sup>®</sup> for bacterial conjunctivitis and BromSite<sup>™</sup> for pain and inflammation after cataract surgery). The Group operates directly in six countries, including the United States. It has proprietary commercial operations in Europe's five largest markets complemented by an expanding international network of distributors.

Nicox is headquartered in France and has more than 120 staff worldwide. It 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.

#### Upcoming events

### Financial and business conferences

May 21	Gilbert Dupont Forum Santé	Paris, France
June 16	Gilbert Dupont Forum Small & Midcaps	Paris, France
June 25	Kepler Biotech Day	Paris, France

#### Scientific conferences

May 9-12	Société Française d'Ophtalmologie (SFO)	Paris, France	Booth PO2
May 3-7	Association for Research in Vision and Ophthalmology (ARVO)	Denver, US	
May 14-16	Sociedad Española de Cirugía Ocular Implanto Refractiva (SECOIR)	Gran Canaria, Spain	Booth tbc
May 19-21	Royal College of Ophthamologists (RCO)	Liverpool, United Kingdom	Booth 33
June 6-9	European Society of Ophthalmology (SOE)	Vienna, Austria	
June 28-30	MaculArt	Paris, France	Booth tbc

#### Analyst coverage

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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 forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 4<sup>th</sup> 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).