



PRESS RELEASE

## NicOx 2011 Financial Results

February 29, 2012. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) today announces its financial results for the year ended December 31, 2011 and provides an overview of its activities.

### 2011 Operational Summary

- Discussions with potential M&A and in-licensing targets continuing to progress
- Continued reorganization of the structure of the Company to deliver strategic goals
- Phase 2b glaucoma study completed by Bausch + Lomb with preliminary results expected Q1 2012
- Preclinical and clinical results published and presented at international congresses
- Formal Dispute Resolution submitted to U.S. Food and Drug Administration (FDA) for naproxcinod
- Marketing Authorization Application for naproxcinod withdrawn in Europe
- Agreement granting Ferrer an option on rights to naproxcinod in selected European countries

### 2011 Financial Summary

Following the restructuring plan implemented by NicOx in late 2010, research and development costs and administrative and selling costs totalled €14.9 million in 2011, down sharply from €47.9 million in 2010.

In 2011, NicOx recorded a total net loss of €16.7 million, compared to a total net loss of €43.9 million in 2010. On December 31, 2011, the Company had cash and cash equivalents totalling €93.1 million, compared to €107.3 million on December 31, 2010.

No revenues were recorded in 2011, compared to €7.4 million in 2010, which related to the initial license payment received from Bausch + Lomb as part of the worldwide licensing agreement signed in March 2010.

**Eric Castaldi, Chief Financial Officer of NicOx**, commented, *"As a result of our reorganization and cost base reduction, our cash burn decreased significantly in 2011. We plan to continue our focus on cost control while ensuring the best strategic use of our resources, as we ended 2011 with cash and cash equivalents of more than €93 million."*

### Overall objective of building a specialist pharmaceutical company

The Company's overall objective is to become a late-stage development and commercial organization through potential M&A, product acquisition or in-licensing. The Company is targeting late-stage or marketed products in selected specialist areas presenting significant growth potential. Following a detailed screening and evaluation process, NicOx is now in advanced discussions with targets of interest.

In addition, NicOx is also continuing to explore alternative funding options to ensure the development of its early-stage programs in order to maximize the potential of its nitric oxide (NO)-donating research platform while preserving the Company's cash position for investment in new areas. These funding options could include spin offs, joint ventures and other forms of collaboration.

### Preliminary results from glaucoma study expected in Q1 2012

A phase 2b clinical trial was completed by NicOx's partner Bausch + Lomb with BOL-303259-X (previously called NCX 116 and PF-03187207) at the end of December 2011. Preliminary results are expected in the first quarter of 2012. BOL-303259-X is an NO-donating prostaglandin F2-alpha analogue which is thought to lower intraocular pressure (IOP) through a dual mechanism of action. It was licensed in March 2010 to Bausch + Lomb, a leading eye health company.

This phase 2b study is intended to identify the most effective dose of BOL-303259-X, administered in the evening, for the reduction of IOP. A total of approximately 400 patients with open-angle glaucoma or ocular hypertension were randomized to receive either BOL-303259-X (various concentrations) or Xalatan® 0.005% (latanoprost) for 28 days. The primary efficacy endpoint is the reduction in mean diurnal IOP at day 28.

## **Status of naproxcinod in the United States and in Europe**

Naproxcinod has been developed by NicOx for the potential relief of the signs and symptoms of osteoarthritis. In July 2011, NicOx submitted a formal appeal under the U.S. FDA's Formal Dispute Resolution process, regarding the decision issued in July 2010 by the FDA not to approve the naproxcinod New Drug Application (NDA) that NicOx had submitted in September 2009.

In March 2011, NicOx and Grupo Ferrer Internacional S.A., a subsidiary of Ferrer Grupo, signed an agreement granting Ferrer an option, which Ferrer could exercise following potential future regulatory approval of naproxcinod, to take exclusive distribution rights for naproxcinod in Greece and Portugal and co-marketing rights in Spain and Germany. NicOx retains the right to enter into co-marketing agreements with third parties in Spain and Germany, and full rights to naproxcinod in all other territories.

In April 2011, NicOx withdrew the Marketing Authorization Application (MAA) which had been submitted to the European Medicines Agency (EMA) in December 2009. The decision was made following feedback at the April 2011 meeting of the Committee for Medicinal Products for Human Use (CHMP) that the CHMP would not adopt a formal positive opinion on the basis of the submitted information. NicOx is still evaluating its potential options with its advisors and with Ferrer.

## **Publication and presentation of preclinical and clinical results**

In 2011, NicOx presented preclinical and clinical results in a number of peer-reviewed journals and international congresses:

- In the ophthalmology field, preclinical results obtained with BOL-303259-X<sup>(1)</sup> and NCX 434<sup>(2)(3)</sup> were published in international journals and were presented in several congresses, including the Association for Research in Vision and Ophthalmology (ARVO) and the European Society of Ophthalmology meetings.
- New preclinical data obtained with NCX 226, a prototype NO-donating compound developed in a research program targeting Pulmonary Arterial Hypertension (PAH), were presented at the annual European League Against Rheumatism (EULAR) congress and at the 10<sup>th</sup> World Congress on Inflammation.
- Clinical and preclinical results for NCX 6560 were also presented in several conferences, including the 40th European Muscle Conference (EMC), the Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) scientific sessions and the European Atherosclerosis Society (EAS) meeting.
- Results from the pooled analysis of the three pivotal phase 3 trials for naproxcinod (the 301, 302 and 303 studies) were published in the American Journal of Cardiology<sup>(4)</sup>.
- Preclinical results for NCX 1236, the lead prototype compound in a research program targeting neuropathic pain, were presented at the American Pain Society congress and in other conferences.

## **Collaborations with Ferrer and Merck**

Following the signature of an amendment to the dermatology agreement with Grupo Ferrer in October 2011, NicOx is now actively seeking a new partner for the development and marketing of NCX 1047 in the United States. NCX 1047 is an NO-donating anti-inflammatory drug developed for dermatology indications. Preclinical results obtained with NCX 1047 support the potential for a differentiated product profile.

Under the revised agreement signed in September 2010 between NicOx and Merck (known as MSD outside the United States and Canada), Merck has the right to develop novel compounds using a new approach to nitric oxide donation in certain cardiovascular indications. NicOx and Merck have agreed that no further announcements on the compounds developed by Merck under the collaboration are anticipated unless and until a drug-candidate advances into phase 2 clinical studies.

## **Board of Directors**

Birgit Stattin Norinder joined NicOx's Board in June 2011. Mrs Stattin Norinder has served as CEO and Chairman of Prolifix Ltd (UK), a biotechnology company targeting proliferative diseases. She brings significant experience in product development and regulatory affairs and has held several senior management positions in worldwide pharmaceutical companies, including Pharmacia & Upjohn and Glaxo Group Research Ltd.

Göran Ando stepped down as a director following expiry of his term of office on June 15, 2011. In August 2011, Jean-Luc Bélingard informed NicOx of his decision to step down from the Board because of his increased responsibilities at bioMérieux. The Company would like to thank Dr Ando and M. Bélingard for their support.

## **Review of the consolidated financial results as of December 31, 2011 and 2010**

The 2011 consolidated financial statements, as approved by the Board of Directors on February 28, 2012, have been certified by the statutory auditors.

## Revenues

NicOx did not record any revenues in 2011 compared to €7.4 million in 2010.

The revenues recognized in 2010 correspond to the initial license payment received from Bausch + Lomb following the signature of a licensing agreement in March 2010 that granted Bausch + Lomb exclusive worldwide rights to develop and commercialize BOL-303259-X (NCX 116). This amount was immediately recognized in revenues because the Company will not have continuing involvement in the future development of the compound which is the subject of this collaboration agreement.

## Research and development costs, general, administrative and selling costs

Research and development costs and general, administrative and selling costs decreased to €14.9 million in 2011 compared to €47.9 million in 2010. This significant reduction results from the restructuring of the Group's entities and activities announced in 2010. As part of the restructuring, the US offices of NicOx were closed in August 2010, the headcount of the French and Italian entities of the Group were significantly reduced, and the activities were redefined in order to protect the Company's cash and cash equivalents and refocus the Group's key strategic priorities. In the last quarter of 2011, the Group has implemented a planned reduction of its workforce by approximately one third in order to align its structure with the corporate strategy of creating a commercially-focused development organization. In 2011, 60% of these expenses were attributable to research and development and 40% to general, selling and administrative expenses compared to 73% and 27% in 2010, respectively.

Research and development expenses totaled €9.0 million in 2011, compared to €35.2 million in 2010. In 2011, research and development expenses primarily related to activities at the research center and ongoing regulatory activities for naproxinod. On December 31, 2011, the Group employed 36 people in research and development compared to 54 people at the same date in 2010.

In 2011, general and administrative expenses totaled €4.1 million compared to €5.4 million on December 31, 2010, and include personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers. In 2011, selling expenses were €1.8 million, compared to €7.4 million in 2010, and for 2011 relate to communication and business development activities (including the activities related to the evaluation of companies and products to acquire or in-license). In 2010, these expenses also included preparation for the potential future commercialization of naproxinod in the United States. On December 31, 2011, the Group employed 18 people in its selling, general and administrative departments compared to 23 people at the same date in 2010.

## Other income

Other income was €0.9 million in 2011, compared to €2.2 million in 2010. Other income corresponds to operational subsidies from research tax credits in France.

## Other expense

Other expense exclusively relates to restructuring costs. For 2011, other expense was €3.6 million and included notably (i) an accrual in an amount of €3.1 million corresponding to personnel expenses and additional estimated costs to be paid in 2012 and 2013 related to the most recent reduction in the Group's workforce as indicated above; (ii) an amount of €1.0 million corresponding principally to accelerated depreciation of fixed assets due to the restructuring; and (iii) an income of €0.5 million due to the cancellation of contingencies related to the restructuring of NicOx S.A previously recognized in 2010, which are no longer applicable in 2011.

For 2010, other expense was €5.7 million and included (i) €5.5 million of personnel expenses related to the overall restructuring plan of the Company and including notably an accrual in an amount of €2.6 million corresponding to additional estimated costs to be paid in 2011 and 2012 related to the reduction in workforce at the Company's head office in France and its Italian subsidiary, based on assumptions which may change; (ii) the cancellation of expenses previously booked in an amount of €1.5 million further to the cancellation of rights on stock options and free shares; and (iii) €1.7 million corresponding to the cost of the closure of the offices of NicOx Inc. in the U.S. excluding personnel expenses reported in (i) above.

## Operating result

The operating loss decreased to €17.6 million in 2011, compared to €44.0 million in 2010.

## Other results

Net financial income totaled €1.1 million in 2011, compared to €0.4 million in 2010, and mainly represents the returns on the financial investments of the Company's cash and cash equivalents.

The income tax expense incurred by NicOx in 2011 relates to tax from its US and Italian subsidiaries and totaled €0.05 million, compared to €0.3 million in 2010.

## Total net loss of the period

The total net loss was €16.7 million on December 31, 2011, compared to €43.9 million at the same date in 2010. This decrease is explained by the significant reduction in all the operating expenses following the restructuring implemented after the decision of the FDA not to approve naproxinod in July 2010.

## Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On December 31, 2011, the Company's current liabilities were €6.9 million, including €3.6 million in other contingencies and liabilities principally with respect to the restructuring cost accrued, €1.2 million in accounts payable to suppliers and external collaborators, €1.0 million in accrued compensation for employees, €0.9 million in taxes payable and €0.2 million for other liabilities.

The Company's cash and cash equivalents were €93.1 million on December 31, 2011, compared to €107.3 million on December 31, 2010.

- 
- (1) Krauss AH, Impagnatiello F, Toris CB, Gale DC, Prasanna G, Borghi V, Chiroli V, Chong WK, Carreiro ST, Ongini E, Ocular hypotensive activity of BOL-303259-X, a nitric oxide donating Prostaglandin F<sub>2α</sub> agonist, in preclinical models. *Exp Eye Res.* **2011**, 93: 250-255.
  - (2) Khoobehi B, Chiroli V, Ronchetti D, Miglietta D, Thompson H, Ongini E, Impagnatiello F, Enhanced Oxygen Saturation in Optic Nerve Head of Non-Human Primate Eyes Following the Intravitreal Injection of NCX 434, an Innovative Nitric Oxide-Donating Glucocorticoid. *J Ocul Pharmacol Ther.* **2011**, 27(2):115-21.
  - (3) Impagnatiello F, Giambene B, Lanzi C, Pini A, Somma T, Bastia E, Ongini E, Galassi F, Masini E. The nitric oxide (NO)- donating triamcinolone acetonide, NCX 434, does not increase intraocular pressure and reduces endothelin-1-induced biochemical and functional changes in the rabbit eye, *Br J Ophthalmol* **2012** (in press).
  - (4) White WB, Schnitzer TJ, Bakris GL, Frayssinet H, Duquesroix B, Weber M, Effects of Naproxinod on Blood Pressure in Patients With Osteoarthritis. *Am. J. Cardiol.* **2011**, 107(9): 1338-45.
- 

## About NicOx

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a pharmaceutical company focused on the research, development and future commercialization of drug candidates. NicOx is applying its proprietary nitric oxide-donating R&D platform to develop an internal portfolio of New Molecular Entities (NMEs) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

The Company's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, who include Merck (known as MSD outside the United States and Canada), Bausch + Lomb and Ferrer.

NicOx S.A. is headquartered in France and is listed on Euronext Paris (Compartment C: Small Caps).



---

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 2010 » filed with the French Autorité des Marchés Financiers (AMF) on February 25, 2011 and available on NicOx's website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).

---

## CONTACTS

**NicOx**                                 **Gavin Spencer • Vice President Business Development**  
+33 (0)4 97 24 53 00 • [communications@nicox.com](mailto:communications@nicox.com)  
[www.nicox.com](http://www.nicox.com)

**Media Relations**                     **FTI Consulting**  
Jonathan Birt • +44 (0)20 7269 7205 • [jonathan.birt@fticonsulting.com](mailto:jonathan.birt@fticonsulting.com)  
Stephanie Cuthbert • +44 (0)20 3077 0458 • [stephanie.cuthbert@fticonsulting.com](mailto:stephanie.cuthbert@fticonsulting.com)

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – DECEMBER 31, 2011

	As of December 31,	
	2011	2010
	(in thousands of € except for per share data)	
Revenues.....	-	7,423
Research and development expenses.....	(8,998)	(35,161)
Administrative expenses.....	(4,112)	(5,364)
Selling expenses.....	(1,817)	(7,389)
Other income.....	866	2,157
Other expense.....	(3,569)	(5,663)
<b>Operating loss .....</b>	<b>(17,630)</b>	<b>(43,997)</b>
Finance income .....	1,055	475
Finance expense.....	(6)	(95)
<b>Loss before income tax.....</b>	<b>(16,581)</b>	<b>(43,617)</b>
Income tax expense.....	(54)	(334)
<b>Net loss.....</b>	<b>(16,635)</b>	<b>(43,951)</b>
Exchange differences on translation of foreign operations.....	(25)	23
<b>Other comprehensive income (loss) for the period, net of tax</b>	<b>(25)</b>	<b>23</b>
<b>Total comprehensive income (loss) for the period, net of tax</b>	<b>(16,660)</b>	<b>(43,928)</b>
Attributable to:		
- Equity holders of the parent.....	(16,660)	(43,928)
- Non-controlling interests .....	-	-
<b>Basic and diluted loss per share attributable to equity holders of the parent.....</b>	<b>(0.23)</b>	<b>(0.61)</b>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION – DECEMBER 31, 2011**

	As of December 31,	
	2011	2010
	(in thousands of €)	
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant & equipment .....	843	2,130
Intangible assets .....	117	386
Other financial assets .....	263	247
Deferred income tax assets .....	65	39
<b>Total non-current assets</b> .....	<b>1,288</b>	<b>2,802</b>
<b>Current assets</b>		
Government subsidies receivable .....	866	1,509
Other current assets .....	367	909
Prepaid expenses .....	172	377
Cash and cash equivalents .....	93,136	107,335
<b>Total current assets</b> .....	<b>94,541</b>	<b>110,130</b>
<b>TOTAL ASSETS</b>	<b>95,829</b>	<b>112,932</b>
<b>EQUITY AND LIABILITIES</b>		
Common shares .....	14,563	14,509
Other reserves .....	69,761	85,979
Non-controlling interests .....	-	-
<b>Total Equity</b> .....	<b>84,324</b>	<b>100,488</b>
<b>Non-current liabilities</b>		
Other contingencies and liabilities .....	4,592	4,548
Deferred income tax liabilities .....	3	96
Finance lease .....	58	83
<b>Total non-current liabilities</b> .....	<b>4,653</b>	<b>4,727</b>
<b>Current liabilities</b>		
Other contingencies and liabilities .....	3,590	2,800
Finance lease .....	24	30
Trade payables .....	1,185	2,045
Current income tax payable .....	-	-
Social security and other taxes .....	1,890	2,627
Other liabilities .....	163	215
<b>Total current liabilities</b> .....	<b>6,852</b>	<b>7,717</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>95,829</b>	<b>112,932</b>

**NicOx S.A.**

Les Taissounières – Bât HB4 – 1681 route des Dolines – BP313 – 06906 Sophia Antipolis Cedex – France  
 Tel: +33 (0)4 97 24 53 00 • Fax: +33 (0)4 97 24 53 99