

# NicOx first half 2011 financial results

July 29, 2011. Sophia Antipolis, France. www.nicox.com

**NicOx S.A.** (NYSE Euronext Paris: COX) today reported its financial results for the six months ended June 30, 2011, and provided an update on its activities.

Michele Garufi, Chairman and CEO of NicOx, commented: "The Company has maintained a solid cash position as of the end of June and the first half results demonstrate a substantial reduction in our cost base, as a result of the restructuring measures implemented. We continue to explore ways of creating value by transforming NicOx into a commercial organization through the acquisition of complementary businesses and late-stage products. We are also seeking to identify innovative alternatives to maximize the potential of our nitric oxide-donating research platform. We look forward to updating the market on our progress in the second half of 2011."

#### Financial summary for the first half of 2011

Following the restructuring of the Group's entities and activities, research and development costs and administrative and selling costs were €8.8 million for the six months ended June 30, 2011, compared to €36.4 million for the same period in 2010.

NicOx recorded a total net loss for the period of €7.8 million for the first six months of 2011, compared to a corresponding net loss of €27.5 million for the same period in 2010. On June 30, 2011, NicOx had cash and cash equivalents of €97.2 million, compared to €107.3 million on December 31, 2010.

No revenues were recorded for the first half of 2011, compared to revenues of €7.4 million for the same period of 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: "NicOx had cash and cash equivalents of €97.2 million on June 30, 2011. As anticipated, our expenses for the first half of 2011 show a significant reduction compared to the same period in 2010. As part of our priorities, we are committed to efficiently managing our cash resources with the aim of creating long-term value for the Company and its shareholders."

#### Strategy

To achieve its overall objective of becoming a commercial organization, NicOx is focusing its resources on a number of priorities, including the evaluation of companies and products to acquire or in-licence. The Company is targeting late-stage or marketed products in select specialist areas and is reviewing a number of potential opportunities. NicOx's goal is to create an organization with strong growth potential in today's rapidly transforming market environment.

The Company is also looking at a number of alternative funding options to ensure the development of promising early-stage programs, which could include spin offs, joint ventures and other forms of collaboration. These could cover programs targeting Neuropathic Pain, Diabetic Macular Edema (DME) and Pulmonary Arterial Hypertension (PAH) and the phase 1b candidate NCX 6560. The Company is evaluating select cardiovascular indications for NCX 6560, where nitric oxide contribution may bring the greatest therapeutic benefits.

### Regulatory status of naproxcinod

Naproxcinod is a New Molecular Entity (NME) developed for the relief of the signs and symptoms of osteoarthritis. 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 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 now evaluating its options for the potential further development of naproxcinod in Europe, together with its advisors and its commercial partner Ferrer.

In July 2010, NicOx received a Complete Response Letter from the FDA informing NicOx that it did not approve the naproxcinod New Drug Application (NDA) submitted by the Company in September 2009. In July 2011, NicOx formally appealed the FDA decision, under the FDA's Formal Dispute Resolution process. This process enables companies to request a formal review of any Agency decision. NicOx will not comment further on the appeal until the process is completed.

#### Signature of an option agreement with Ferrer for naproxcinod

NicOx and Grupo Ferrer Internacional S.A., a subsidiary of Ferrer Grupo, signed an option agreement for naproxcinod in March 2011. Under the terms of the agreement, Ferrer has been granted an option, which it 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.

If Ferrer exercises the option under this agreement, NicOx could receive potential regulatory and commercial milestones from Ferrer of up to €7.0 million. NicOx would supply naproxcinod capsules to Ferrer at an agreed transfer price which would result in a financial return to NicOx equivalent to a royalty. NicOx has agreements for the manufacture and supply of naproxcinod active pharmaceutical ingredient (API) and capsules, with DSM and Capsugel respectively.

#### Alliances with Bausch + Lomb, Merck and Ferrer

A phase 2b clinical trial is currently being conducted by NicOx's partner Bausch + Lomb with BOL-303259-X (previously called NCX 116 and PF-03187207). BOL-303259-X is a nitric oxide (NO)-donating prostaglandin F2-alpha analog developed for the potential treatment of glaucoma and ocular hypertension, which was licensed to Bausch + Lomb in March 2010. Results from this phase 2b study are expected in the fourth quarter of 2011.

Under the revised agreement signed between NicOx and Merck (known as MSD outside the United States and Canada) in September 2010, 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.

NicOx is also collaborating with the Spanish company Grupo Ferrer to develop novel NO-donating anti-inflammatory drugs for dermatology disorders. The date for the initiation of clinical studies with NCX 1047, the candidate selected for development, has not been decided.

#### Scientific communications

During the first half of 2011, NicOx presented scientific 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</sup> were published in the first half of the year. The NCX 434 data were also presented in several congresses, including the Association for Research in Vision and Ophthalmology (ARVO) and the European Society of Ophthalmology meetings.

NicOx also presented the first preclinical data obtained with NCX 226 in the cardiovascular field. NCX 226 is a prototype NO-donating compound developed in a research program targeting Pulmonary Arterial Hypertension (PAH). Preclinical results 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 Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) Scientific Sessions and the European Society of Atherosclerosis 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>3</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 in May 2011.

#### **Board of Directors**

NicOx is pleased to welcome Birgit Stattin Norinder as a new member of its Board. 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 from the Board following the expiry of his term of office on June 15, 2011. The Company would like to thank Dr Ando, who has been an active member of NicOx's Board of Directors since 2004, for his valuable contribution to NicOx's development.

Review of the consolidated financial results for the six months ended June 30, 2011 and 2010.

#### Revenues

NicOx did not record any revenues for the six months ended June 30, 2011, compared to €7.4 million for the same period of 2010.

The revenues recognized during the first half of 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 has been 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

For the first six months of 2011, research and development costs and general, administrative and selling costs were significantly reduced as compared with that of 2010; amounting to €8.8 million for 2011, compared to €36.4 million for 2010. This significant reduction results from the restructuring of the Group's entities and activities following the decision of the FDA not to approve the marketing application for naproxcinod in the US in July 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.

As of June 30, 2011, 60% of these expenses concerned research and development costs and 40% general, administrative and selling costs, compared to 74% and 26%, respectively, in the first half of 2010.

During the first half of 2011, research and development expenses totaled €5.2 million, compared to €26.9 million during the first six months of 2010. In the first semester of 2011, research and development expenses correspond mainly to personnel expenses for the activities performed in relation to the naproxcinod MAA submitted in Europe. The Group employed 40 people in research and development on June 30, 2011, compared to 79 people at the same date in 2010.

General and administrative expenses totaled €2.6 million in the first six months of 2011, compared to €3.2 million in the first half of 2010 and include personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers. Selling expenses were €1.0 million during the first six months ended June 30, 2011, compared to €6.2 million during the same period in 2010, and correspond for 2011 to the communication and business development activities (including the activities related to the evaluation of companies and products to acquire or in-licence). In 2010, these expenses also included preparations for the potential future commercialization of naproxcinod in the United States. On June 30, 2011, the Group employed 19 people in its selling, general and administrative departments, compared to 48 people on June 30, 2010.

#### Other income

Other income totaled €0.5 million in the first half of 2011, compared to €1.6 million in the first half of 2010. Other income corresponds to the operational subsidies from the research tax credit in France.

#### Other expense

Other expense, which concerns exclusively restructuring costs, was an income of €0.1 million in the first six months of 2011 due to the cancellation of contingencies, related to the restructuring of NicOx S.A. in 2010, which are no longer applicable.

#### Operating results

In the first six months ended June 30, 2011, the operating loss amounted to €3.2 million, compared to €27.4 million in the first semester of 2010.

### Other results

Net financial income amounted to €0.4 million during the first half of 2011, compared to €0.1 million during the same period in 2010, and represents mainly the returns on the financial investments of the Company's cash and cash equivalents.

The income tax expense incurred by NicOx in the first six months of 2011 relates principally to tax from its subsidiaries and totaled €0.08 million, compared to €0.3 million during the first half of 2010.

#### Total net loss for the period

The total net loss was €7.8 million for the first six months ended June 30, 2011, compared to €27.5 million during the same period in 2010. This decrease is explained by the significant reduction of all the operating expenses following the restructuring implemented after the decision of the FDA not to approve naproximod in July 2010.

The indebtedness incurred by NicOx is mainly short-term operating debt. On June 30, 2011, the Company's current liabilities totaled €4.2 million, including €1.2 million in accounts payable to suppliers and external collaborators, €1.1 million in accrued compensation for employees, €0.9 million in taxes payable, €0.9 million in other contingencies and liabilities with respect to the restructuring cost accrued, and €0.1 million for other liabilities.

The Company's cash and cash equivalents were €97.2 million on June 30, 2011, compared to €107.3 million on December 31, 2010 and €128.4 million on June 30, 2010.

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- White WB, Schnitzer TJ, Bakris GL, Frayssinet H, Duquesroix B, Weber M, Effects of Naproxcinod 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, cardiometabolic 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 B: Mid 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 (<a href="www.nicox.com">www.nicox.com</a>) and on the AMF's website (<a href="www.nicox.com">www.nicox.com</a>).

#### **CONTACTS**

NicOx Gavin Spencer • Vice President Business Development

Tel +33 (0)4 97 24 53 00 • communications@nicox.com

www.nicox.com

Media Relations Financial Dynamics

Europe Guillaume Granier (France) • Tel: +33 (0)1 47 03 68 10 • guillaume.granier@fd.com

Stéphanie Bia (France) • Tel: +33 (0)1 47 03 68 10 • stephanie.bia@fd.com

Jonathan Birt (UK) • Tel: +44 (0)20 7269 7205 • jonathan.birt@fd.com

United States Robert Stanislaro • Tel: +1 212 850 5657 • robert.stanislaro@fd.com

Irma Gomez-Dib • Tel: +1 212 850 5761 • irma.gomez-dib@fd.com

## INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – JUNE 30, 2011

-	For the period of six months ended June 30,	
	2011	2010
- -	(in thousands of €except for per share data)	
Revenues	-	7,423
Research and development expenses	(5,250)	(26,924)
Administrative expenses	(2,562)	(3,214)
Selling expenses	(976)	(6,241)
Other income	532	1,600
Other expense	102	-
Operating loss	(8,154)	(27,356)
Finance income	471	183
Finance expense	(39)	(70)
Loss before income tax	(7,722)	(27,243)
Income tax expense	(83)	(257)
Net loss of the period	(7,805)	(27,500)
Exchange differences on translation of foreign operations	47	(38)
Other comprehensive income (loss) for the period, net of tax	47	(38)
Total comprehensive income (loss) for the period, net of tax	(7,758)	(27,538)
Attributable to:		
- Equity holders of the parent	(7,758)	(27,538)
- Non-controlling interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent	(0.11)	(0.38)

## INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 30, 2011

As of Ju	,	As of December 31,
	2011 2010	
	(in thousands of €)	
S		
rrent assets		
, plant & equipment	304	2,130
le assets	99	386
nancial assets	35	247
l income tax assets	-	39
on-current assets 2,3	38	2,802
t assets		
nent subsidies receivable	91	1,509
urrent assets	15	909
expenses	58	377
d cash equivalents	207	107,335
irrent assets	,201	110,130
ASSETS 102,	,539	112,932
Y AND LIABILITIES		
n shares	562	14,509
serves	730	85,979
ntrolling interests	-	-
quity	292	100,488
rrent liabilities		
ontegencies and liabilities	36	4,548
d income tax liabilities	)6	96
lease	1	83
on-current liabilities 5,0	13	4,727
t liabilities		
ontingencies and liabilities	56	2,800
	6	30
ayables		2,045
ecurity and other taxes		2,627
abilities 12		215
urrent liabilities 4,2		7,717
102	,539	112,932
LEQUITY AND LIABILITIES 102,	,539	

#### 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