



## NicOx reports first quarter 2010 financial results

May 7, 2010. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) today reported financial results for the first three months of 2010 and provided an overview of its activities, in particular those related to its lead compound naproxcinod which is currently under review by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

*"The first quarter of 2010 was marked by the signature of the Worldwide Licensing Agreement with the leading eye health company Bausch + Lomb for our glaucoma candidate NCX 116," declared Michele Garufi, Chief Executive Officer of NicOx. "Moreover, with naproxcinod under review by the relevant Authorities both in the United States and in Europe, the entire Company has been fully committed and engaged by continuous interactions with the FDA and the EMA and, in particular, in the preparation of the upcoming FDA Advisory Committee meeting of May 12<sup>th</sup>."*

### Key highlights for the first quarter of 2010

- In March 2010, NicOx and Bausch + Lomb signed a Worldwide Licensing Agreement granting Bausch + Lomb exclusive rights to develop and commercialize NCX 116, a nitric oxide-donating prostaglandin F2-alpha analog for the treatment of glaucoma and ocular hypertension. Under the terms of this agreement, NicOx received an initial license payment of \$10 million and stands to receive potential milestones totaling \$169.5 million, as well as tiered double-digit royalties on the sales of NCX 116.
- The US Food and Drug Administration (FDA) announced in the beginning of March that the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would meet on May 12, 2010, to discuss the New Drug Application (NDA) for naproxcinod.
- The European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for naproxcinod in January 2010.
- NicOx and TOPIGEN Pharmaceuticals Inc. have mutually terminated their collaboration for TPI 1020, as a result of the acquisition of TOPIGEN by Pharmaxis announced on January 11.

### Post-first quarter events 2010

- Blood pressure results from the pre-specified pooled analysis of the three pivotal phase 3 trials for naproxcinod (the 301, 302 and 303 studies) were presented on May 2 at the American Society of Hypertension (ASH) Annual Scientific Meeting and Exposition in New York, by Professor William B. White. In addition, detailed results from the 301 study have been published in the May issue of *Osteoarthritis and Cartilage*<sup>1</sup>.

**Eric Castaldi, Chief Financial Officer of NicOx**, commented: *"In the first quarter of 2010, NicOx received a \$10 million payment from Bausch + Lomb as per the terms of the licensing agreement signed in March. This further reinforces our balance sheet and supports our confidence in the potential of NicOx's nitric oxide (NO)-donating research platform. We are now preparing for the future potential commercialization of naproxcinod and are therefore increasingly investing in the activities of our Commercial Affairs team in Warren, New Jersey."*

### Financial summary of the first quarter of 2010:

Revenues were €7.4 million in the first quarter of 2010, compared to €0.4 million for the corresponding period of 2009. This significant increase results from €7.4 million initial license payment received from Bausch + Lomb as per the agreement signed in March 2010.

Operating expenses were €16.2 million in the first quarter of 2010, compared to €13.7 million in the first quarter of 2009. These expenses correspond principally to research and development activities in relation with the regulatory submissions for naproxcinod in the US and in Europe and to investment expenses in the naproxcinod supply chain.

<sup>1</sup> Schnitzer TJ, Kivitz A, Frayssinet H, Duquesroix B. Efficacy and Safety of Naproxcinod in the Treatment of Patients with Osteoarthritis of the Knee: A 13 Week Prospective, Randomized, Multicenter Study, *Osteoarthritis and Cartilage*, 2010, 18(5), 629-639.

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

In the first quarter of 2010, NicOx recorded a total comprehensive loss for the period of €7.2 million compared to €11.2 million for the first quarter of 2009. On March 31, 2010, the Company had cash, cash equivalents and financial instruments of €138.5 million, compared to €148.3 million on December 31, 2009.

## **Review of the consolidated financial results for the three months ended March 31, 2010 and 2009.**

### **Revenues**

NicOx's revenues reached €7.4 million for the first three months ended March 31, 2010 compared to €0.4 million for the three months ended March 31, 2009.

This significant increase results from the recognition as revenues during the first quarter of 2010 of €7.4 million corresponding 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 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 subject of this collaboration agreement.

### **Operating expenses**

For the three months ended March 31, 2010, operating expenses amounted to €16.2 million, compared to €13.7 million for the three months ended March 31, 2009, of which, 76% was attributable to research and development expenses and 24% attributable to selling and administrative expenses in the first quarter of 2010, compared to 73% and 27% respectively in the first quarter 2009.

Research and development expenses totaled €12.3 million during the first quarter of 2010, compared to €10.0 million during the first quarter 2009 (including €0.08 million allocated to cost of sales in 2009). In the first quarter of 2010, research and development expenses correspond principally to personnel expenses related to the activities performed in relation with the naproxinod New Drug Application and Marketing Authorization Application submitted respectively in the US and in Europe and to investment expenses in dedicated manufacturing facilities of its active ingredient supplier DSM in order to increase the naproxinod supply chain capacity and flexibility. The cost of sales recognized in the first quarter 2009 corresponds to the expenses incurred by NicOx in performing research activities under the contract signed with Pfizer. The Company employed 80 people in research and development on March 31, 2010, compared to 95 people at the same date in 2009.

General and administrative expenses totaled €1.6 million in the first quarters of 2010 and 2009 and include personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers, including stock option, free share and warrant attributions. Selling and corporate development expenses were €2.2 million during the first three months ended March 31, 2010 compared to €2.0 million during the same period in 2009 and correspond to market research and analysis activities for naproxinod, as well as the business development and communication activities of the Company. The Company employed 46 people in its selling, general and administrative departments on March 31, 2010, compared to 39 people on March 31, 2009.

### **Other income**

During the first quarter of 2010, other income totaled €1.8 million compared to €1.3 million in the first quarter of 2009. Other income corresponds mainly to the operational subsidies from the research tax credits in France and in Italy.

### **Operating result**

The operating loss was €7.0 million in the three months ended March 31, 2010, compared to €12.0 million in the same period in 2009. This significant decrease in the operating loss results from the strong increase of the revenues recognized in the first quarter of 2010.

### **Other results**

Net financial income amounted to €0.1 million during the first three months of 2010, compared to €0.8 million during the first quarter of 2009, and represents mainly the returns on the financial investments of the Company's cash, cash equivalents.

The income tax expense incurred by NicOx during the first quarter of 2010 relates to tax from its US and Italian subsidiaries and totaled €0.2 million, compared to €0.06 million during the same period in 2009.

## Total comprehensive loss for the period

The total comprehensive loss amounted to €7.2 million during the first quarter of 2010, compared to €11.2 million during the same period in 2009. This decrease in the total comprehensive loss results from the strong increase of the revenues recognized in the first quarter of 2010 following the initial license payment received from Bausch + Lomb as explained above.

## Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On March 31, 2010, the Company's current liabilities totaled €8.5 million, including €5.6 million in accounts payable to suppliers and external collaborators, €1.4 million in accrued compensation for employees, €1.3 million in taxes payable, €0.1 million in current income tax payable and €0.1 million for other liabilities.

The Company's financial instruments and cash and cash equivalents were €138.5 million on March 31, 2010, compared to €148.3 million on December 31, 2009 and €84.6 million on March 31, 2009. In late 2009, the Company completed a two step capital increase and received a total of €94.6 million corresponding to the net proceeds of the following operations: €29.4 million from a private placement of shares to institutional investors completed on November 23, 2009 and €65.2 million from a rights issue completed on December 23, 2009.

NicOx has the strategic objective of transforming itself into a specialty pharmaceutical company. As part of this strategy, NicOx will seek to enter into a partnership agreement with a pharmaceutical company for the promotion and marketing of naproxinod to primary care physicians in the US, while retaining co-promotion rights for specialist prescribers. Expenses related to the preparation of the commercialization of naproxinod are expected to increase in 2010. In the course of normal business, NicOx currently anticipates having sufficient cash to sustain operations beyond the projected launch of naproxinod, even in the absence of a partnership agreement. This forecast assumes there will be no unexpected and substantial requests from the FDA and EMA, which could potentially cause a delay in the projected launch dates.

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 2009 » filed with the French *Autorité des Marchés Financiers* (AMF) on March 5, 2010 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)).

The Company notably draws the investors' attention to the following risk factors:

- *Risques liés à la dépendance de la Société à l'égard du naproxinod* (Risks related to the Company's dependence on the success of its lead product naproxinod)
- *Risques commerciaux et développements cliniques* (Clinical developments and commercial risk)
- *Risques liés aux contraintes réglementaires et à la lenteur des procédures d'approbation* (Risks linked to regulatory constraints and slow approval procedures)
- *Manque de capacités dans les domaines de la vente et du marketing* (Lack of sales and marketing capabilities)
- *Incertitude relative aux prix des médicaments et aux régimes de remboursement, ainsi qu'en matière de réformes des régimes d'assurance maladie* (Uncertainty on drug pricing and reimbursement policies and on the reforms of the health insurance systems)

---

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 (NME) for the potential treatment of inflammatory, cardiometabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxinod, an NME and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate developed for the relief of the signs and symptoms of osteoarthritis (OA), which is currently under review by regulatory authorities, following the submission and filing of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). The FDA has set an action date of July 24, 2010, under the Prescription Drug User Fee Act (PDUFA).

In addition to naproxinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck & Co., Inc. and Bausch + Lomb, for the treatment of hypertension, cardiometabolic diseases, widespread eye diseases and dermatological diseases.

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.*

*For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of NicOx S.A. to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Reference filed with the AMF, which is available on the AMF website (<http://www.amf-france.org>) or on NicOx S.A.'s website (<http://www.nicox.com>).*

**CONTACTS:** [www.nicox.com](http://www.nicox.com)

**NicOx: Gavin Spencer Vice President Business Development**

**Tel +33 (0)4 97 24 53 00 • [communications@nicox.com](mailto:communications@nicox.com)**

**Media Relations      Financial Dynamics**

**Europe**

Guillaume Granier (France) • Tel: +33 (0)6 32 65 79 28 • [guillaume.granier@fd.com](mailto:guillaume.granier@fd.com)

Stéphanie Bia (France) • Tel: +33 (0)6 79 44 66 55 • [stephanie.bia@fd.com](mailto:stephanie.bia@fd.com)

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

**United States**

Robert Stanislaro • Tel +1 212 850 5657 • [robert.stanislaro@fd.com](mailto:robert.stanislaro@fd.com)

Irma Gomez-Dib • Tel +1 212 850 5761 • [irma.gomez-dib@fd.com](mailto:irma.gomez-dib@fd.com)

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – MARCH 31, 2010**

	End of the reporting period	
	Unaudited	Unaudited Restated*
	March 31, 2010	March 31, 2009
(in thousands of € except for per share data)		
Revenues.....	7,423	420
Cost of sales .....	-	(79)
Research and development expenses.....	(12,331)	(9,932)
Administrative expenses.....	(1,627)	(1,640)
Selling expenses.....	(2,230)	(2,041)
Other income.....	1,753	1,266
<b>Operating loss .....</b>	<b>(7,012)</b>	<b>(12,006)</b>
Finance income.....	93	852
Finance expense.....	(34)	(29)
<b>Loss before income tax.....</b>	<b>(6,953)</b>	<b>(11,183)</b>
Income tax expense.....	(213)	(60)
<b>Net loss.....</b>	<b>(7,166)</b>	<b>(11,243)</b>
Exchange differences on translation of foreign operations.....	12	(2)
<b>Other comprehensive income (loss) for the period, net of tax</b>	<b>12</b>	<b>(2)</b>
<b>Total comprehensive income (loss) for the period, net of tax</b>	<b>(7,154)</b>	<b>(11,245)</b>
Attributable to:		
- Equity holders of the parent.....	(7,154)	(11,245)
- Non-controlling interests .....	-	-
<b>Basic and diluted loss per share attributable to equity holders of the parent.....</b>	<b>(0.10)</b>	<b>(0.24)</b>

\* Compliant with IAS 1R

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION – MARS 31, 2010**

	<b>Unaudited</b>	
	<b>March 31, 2010</b>	<b>December 31, 2009</b>
	<b>(in thousands of €)</b>	
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant & equipment .....	2,652	2,772
Intangible assets .....	759	797
Government subsidies receivable .....	1,388	477
Other financial assets .....	251	238
Deferred income tax assets .....	108	156
<b>Total non-current assets</b> .....	<b>5,158</b>	<b>4,440</b>
<b>Current assets</b>		
Government subsidies receivable .....	2,964	2,597
Other current assets .....	1,039	1,329
Prepaid expenses .....	1,892	784
Cash and cash equivalents .....	138,539	148,275
<b>Total current assets</b> .....	<b>144,434</b>	<b>152,985</b>
<b>TOTAL ASSETS</b> .....	<b>149,592</b>	<b>157,425</b>
<b>EQUITY AND LIABILITIES</b>		
Common shares .....	14,480	14,434
Other reserves .....	122,373	128,444
Non-controlling interests .....	-	-
<b>Total Equity</b> .....	<b>136,853</b>	<b>142,878</b>
<b>Non-current liabilities</b>		
Other contingencies and liabilities .....	4,129	4,069
Deferred income tax liabilities .....	92	91
Finance lease .....	4	6
<b>Total non-current liabilities</b> .....	<b>4,225</b>	<b>4,166</b>
<b>Current liabilities</b>		
Finance lease .....	7	7
Trade payables .....	5,632	6,136
Current income tax payable .....	136	19
Social security and other taxes .....	2,621	3,909
Other liabilities .....	118	310
<b>Total current liabilities</b> .....	<b>8,514</b>	<b>10,381</b>
<b>TOTAL EQUITY AND LIABILITIES</b> .....	<b>149,592</b>	<b>157,425</b>