



NicOx 2010 Financial Results

February 24, 2011. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (NYSE Euronext Paris: COX) today announced its financial results for the year ended December 31, 2010 and provided an overview of its activities.

Michele Garufi, Chief Executive Officer of NicOx, commented: *"In 2010, following the receipt of the Complete Response Letter from the FDA on naproxcinod in July, we moved quickly to restructure our organization and significantly reduce our costs. In parallel, we have intensified our strategic efforts in the evaluation of products and companies to acquire, with the aim of building a sustainable, specialist pharmaceutical company. We also continued to make good progress during the year in building high quality partnerships, broadening our collaboration with Merck and signing a worldwide agreement in ophthalmology with Bausch + Lomb for BOL-303259-X (NCX 116). Our ability to deliver on our growth strategy is underpinned by a strong balance sheet, a cash position of €107.3 million at the end of 2010, a significant reduction in the burn rate anticipated for 2011 and a continued scientific interest in the potential of our R&D platform."*

Operational summary 2010

- Signature of an exclusive worldwide licensing agreement with Bausch + Lomb for the glaucoma candidate BOL-303259-X (previously NCX 116), followed by the initiation by Bausch + Lomb of a phase 2b study.
- Complete Response Letter received from the U.S. Food and Drug Administration (FDA) stating that the FDA did not approve the New Drug Application (NDA) for naproxcinod.
- Implementation of a cash conservation and global restructuring plan, including the closure of the Company's U.S. headquarters in Warren, NJ, and workforce reductions in France and Italy.
- Scope of the licence agreement with Merck (known as MSD outside the United States and Canada) broadened to explore a novel approach to nitric oxide (NO) donation.
- Presentation of additional clinical data for naproxcinod and NCX 6560, and of preclinical results for NCX 434 and NCX 1236.
- Termination of the collaboration with TOPIGEN Pharmaceuticals Inc. as a result of its acquisition by Pharmaxis.

Eric Castaldi, Chief Financial Officer of NicOx, commented: *"NicOx had cash and cash equivalents of €107.3 million as of the end of December 2010. The measures we implemented in the second half of 2010 are anticipated to result in a significantly reduced cash burn rate for 2011. We currently expect that the 2011 cash burn rate for the Company, as the structure currently stands following the restructuring, should be around one third of the 2010 figure."*

Financial summary 2010

Revenues in 2010 were €7.4 million, compared to €1.1 million in 2009. These revenues correspond to the initial license payment received from Bausch + Lomb in the first quarter of 2010, as per the agreement signed in March.

Operating expenses totaled €53.6 million in 2010, compared to €66.7 million in 2009. These expenses relate principally to personnel costs linked to the regulatory processes for naproxcinod both in the United States and in Europe, investments in naproxcinod's supply chain, costs related to the anticipated cancellation of certain manufacturing and pre-commercial activities following the decision of the FDA not to approve naproxcinod and restructuring costs.

NicOx's net loss was €44.0 million for the full year 2010, compared to €60.4 million in 2009. On December 31, 2010, the Company's cash and cash equivalents totaled €107.3 million, compared to €148.3 million on December 31, 2009.

Phase 2b study underway in glaucoma under the new collaboration with Bausch + Lomb

In March 2010, NicOx and Bausch + Lomb signed a Worldwide Licensing Agreement granting Bausch + Lomb exclusive rights to develop and commercialize BOL-303259-X (NCX 116), an NO-donating prostaglandin F2-alpha analog for the potential 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 any future sales of BOL-303259-X.

In November 2010, a phase 2b study was initiated by Bausch + Lomb with BOL-303259-X. This study is intended to identify the most effective dose of BOL-303259-X, administered in the evening, for the reduction of intraocular pressure (IOP). A total of approximately 400 patients with open-angle glaucoma or ocular hypertension will be enrolled both in the United States and in Europe.

Naproxcinod regulatory status in the United States and in Europe

Naproxcinod is a New Molecular Entity (NME) in development for the relief of the signs and symptoms of osteoarthritis. 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). NicOx is planning to appeal the FDA decision on naproxcinod in the first quarter of 2011, under the FDA's Formal Dispute Resolution process. This process is made available by the FDA to request formal review of any Agency decision by raising the matter to the higher supervisory level.

In January 2010, the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for naproxcinod, which was submitted through the centralized procedure in December 2009. The Committee for Medicinal Products for Human Use (CHMP) opinion is expected by mid-2011, with the exact timing depending on the interactions needed with the health authorities in the last phase of the review process.

Restructuring of the Company's activities

Following the receipt of the FDA's Complete Response Letter in July 2010, NicOx decided to conserve its cash and refocus its key strategic priorities. These include actively seeking appropriate M&A opportunities and new alliances on existing programs; continuing to complete the European registration process; seeking potential marketing partners for naproxcinod in Europe and the rest of the world and targeting internal research resources on the most promising programs.

In the second half of 2010, NicOx initiated a global restructuring plan, with the closure of the U.S. headquarters in Warren, NJ, as of the end of August 2010. The restructuring also includes a workforce reduction of approximately 50% in the Company's head office in Sophia Antipolis, France, and of approximately 35% in the Italian subsidiary based in Bresso. As of February 28, 2011, the total headcount will stand at 63 compared with 128 on December 31, 2009.

Presentation of clinical and preclinical data for several drug candidates in international conferences and peer-reviewed papers

Detailed phase 3 results for naproxcinod were published in peer-reviewed journals in 2010: the 301 study was published in *Osteoarthritis and Cartilage*¹, the 302 study in *Seminars in Arthritis and Rheumatism*² and the 303 study in *Arthritis & Rheumatism*³. Clinical data for naproxcinod were also presented in May 2010 at the American Society of Hypertension Annual Scientific Meeting and Exposition in New York and in June 2010 at the European Meeting on Hypertension in Oslo and the Annual European Congress of Rheumatology in Rome.

Detailed results from the phase 1b first-in-man study for NCX 6560, an innovative NO-donating NME targeting patients with Acute Coronary Syndrome (ACS), were also presented in an oral session of the American Heart Association Scientific Sessions held in November 2010 in Chicago. NicOx is seeking potential partners to advance the clinical development of NCX 6560.

Additionally, preclinical results obtained with two of NicOx's NO-donating NMEs were presented in congresses in the first half of 2010. In May, preclinical findings obtained with NCX 1236, a lead compound for the potential treatment of Neuropathic Pain, were presented at the International Congress on Neuropathic Pain in Athens. Preclinical results for NCX 434, a potential preclinical candidate in Diabetic Macular Edema (DME), were presented in May at the Ocular Diseases & Drug Discovery conference in Boston and in June at the Retina International World Congress in Stresa. The Company is currently looking for new alliances for these two promising research projects.

Collaborations with Merck and Ferrer

In September 2010, NicOx agreed with its partner Merck, known as MSD outside the United States and Canada, to expand the scope of their worldwide license agreement, originally executed in 2006. This decision followed the discovery

¹ 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.

² Schnitzer TJ, Hochberg MC, Marrero CE, Duquesroix B, Frayssinet H, Beekman M. *Efficacy and Safety of Naproxcinod in Patients with Osteoarthritis of the Knee: A 53-Week Prospective Randomized Multicenter Study*, *Seminars in Arthritis and Rheumatism* **2011**, 40(4): 285-297.

³ Baerwald C, Verdecchia P, Duquesroix B, Frayssinet H, Ferreira T. *Efficacy, safety, and effects on blood pressure of naproxcinod 750 mg twice daily compared with placebo and naproxen 500 mg twice daily in patients with osteoarthritis of the hip: A randomized, double-blind, parallel-group, multicenter study*, *Arthritis & Rheumatism* **2010**, 62(12): 3635-3644.

of a new approach to NO donation during the course of the joint research program. Under the revised agreement, Merck has the right to develop NMEs using this new approach in certain cardiovascular indications. NicOx will have the right to develop product candidates in other 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.

The clinical program evaluating several NO-donating antihypertensive candidates from the original agreement in healthy volunteers and mild to moderate hypertensive patients has been completed and none of the compounds tested will be further advanced in development.

NicOx is also collaborating with the Spanish company Grupo Ferrer to develop novel NO-donating anti-inflammatory drugs for dermatology disorders. The start of clinical studies of NCX 1047, originally anticipated for early 2011, has been rescheduled by Ferrer and the new IND (Investigational New Drug) submission date has not yet been decided. Encouraging preclinical results were obtained with NCX 1047 and both companies remain committed to the continued collaboration.

Frank Baldino Jr, Director of NicOx

It was with great sadness that NicOx learned of death of Frank Baldino Jr, who passed away on December 16, 2010. Dr. Baldino led Cephalon from a privately held start-up company to one of the top ten biotechnology companies in the world and was a recognized pioneer in the biotechnology industry. He joined NicOx's Board in March 2001. Dr. Baldino was an invaluable and supportive member of the Board of NicOx over many years and brought his excellent knowledge of business and biotechnology as well as his personal energy and warmth to everything he did for the Company. He will be greatly missed.

Review of the consolidated financial results as of December 31, 2010 and 2009:

The 2010 consolidated financial statements, approved by the Board of Directors on February 23, 2011, have been certified by the statutory auditors.

Revenues

NicOx's revenues totaled €7.4 million in 2010, compared to €1.1 million in 2009.

This significant increase in revenues results from the recognition, 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 license agreement in March 2010 that granted Bausch + Lomb exclusive worldwide rights to develop and commercialize BOL-303259-X. This amount has been immediately recognized in revenues because the Company will not have continuing involvement in the future development of the compound subject of this collaboration agreement. No revenues have been recorded in the fourth quarter of 2010.

Research and development costs, general, administrative and selling costs

Research and development costs and general, administrative and selling costs totaled €47.9 million in 2010, compared to €66.7 million in 2009. This reduction of 28%, which occurred mainly during the second half of 2010, is a result of the decision of the FDA not to approve the marketing application for naproxinod in the US in July 2010. In 2010, 73% of these expenses were attributable to research and development compared to 78% in 2009, and 27% was attributable to selling and administrative expenses, compared to 22% in 2009.

Research and development expenses decreased by 32% to €35.2 million in 2010, compared with €51.7 million during 2009. In 2010, research and development expenses corresponded principally to (i) personnel expenses related to the naproxinod New Drug Application and Marketing Authorization Application submitted respectively in the US and in Europe; and (ii) investment expenses in dedicated facilities of DSM for the manufacture of the active ingredient of naproxinod to increase the supply chain capacity and flexibility. Following the decision in July 2010 of the FDA not to approve the naproxinod application, indemnities in an amount of €6.9 million relating to the cancellation of purchase orders placed with suppliers involved in the manufacturing of naproxinod have been booked as research and development expenses in 2010. The Company employed 54 people in research and development on December 31, 2010, compared to 89 people on December 31, 2009. The significant reduction of the research and development headcount results from the restructuring of the Company's activities in the second half of 2010, notably in its head office in France and in its Italian subsidiary.

General and administrative expenses were €5.4 million in 2010, compared to €6.4 million in 2009 and include personnel expenses in administrative and financial functions, as well as the remuneration and expenses of corporate officers, including stock options, free shares and warrant attributions. Selling expenses totaled €7.4 million in 2010, compared to €8.6 million in 2009 and correspond to market research and analysis activities performed in the first half of 2010 for naproxinod, as well as the business development and communication activities of the Company. The Company employed 23 people in its selling, general and administrative departments on December 31, 2010, compared to 39 people at the same date in 2009. The decrease of selling expenses and of the selling, general and administrative

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headcount is directly linked to the closure of the US headquarters of NicOx in August 2010, following the decision of the FDA not to approve naproxcinod.

Other income

Other income totaled €2.2 million in 2010 compared to €3.6 million in 2009. Other income corresponds mainly to the operational subsidies from the research tax credits in France and in Italy.

Other expense

Other expense, which concerns exclusively restructuring costs, was €5.7 million in 2010. Other expense includes (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 associated to the workforce reduction of 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 US excluding personnel expenses reported in (i).

Operating result

The operating loss amounted to €44.0 million in 2010, compared to €62.0 million in 2009.

Other results

Net financial income totaled €0.4 million in 2010, compared to €1.5 million in 2009, 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 2010 relates to tax from its US and Italian subsidiaries and totaled €0.3 million, compared to an income tax revenue of €0.2 million in 2009.

Total net loss of the period

The total net loss for the period was €44.0 million in 2010, compared to €60.4 million in 2009. Notwithstanding the payment of indemnities linked to the cancellation of certain manufacturing activities for naproxcinod, the cost of the closure of the US offices and the amounts accrued for the restructuring of the French and Italian entities, the decrease in net loss in 2010 as compared with 2009 is notably explained by (i) a significant increase in the revenues recognized during the period following the initial license payment received from Bausch + Lomb and (ii) by decisions not to commit to certain expected expenses linked to the preparation of the anticipated launch of naproxcinod in the United States following the decision of the FDA not to approve naproxcinod.

Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On December 31, 2010, the Company's current liabilities totaled €7.7 million, including €2.8 million in other contingencies and liabilities with respect to the restructuring cost accrued, €2.0 million in accounts payable to suppliers and external collaborators, €1.2 million in accrued compensation for employees, €1.5 million in taxes payable and €0.2 million for other liabilities.

On December 31, 2010, the Company's cash and cash equivalents were €107.3 million, compared to €148.3 million on December 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 (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.

NicOx's lead investigational compound is naproxcinod, an NME in development for the relief of the signs and symptoms of osteoarthritis. In addition to naproxcinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck (known as MSD outside the United States and Canada) and Bausch + Lomb, for the treatment of select cardiovascular indications, 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.

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 2009* » filed with the French Autorité des Marchés Financiers (AMF) on March 5, 2010 and available on NicOx's website (www.nicox.com) and on the AMF's website (www.amf-france.org).

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CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – DECEMBER 31, 2010

	As of December 31,	
	2010	2009
	(in thousands of € except for per share data)	
Revenues.....	7,423	1,119
Cost of sales.....	-	(75)
Research and development expenses.....	(35,161)	(51,673)
Administrative expenses.....	(5,364)	(6,415)
Selling expenses.....	(7,389)	(8,582)
Other income.....	2,157	3,641
Other expense.....	(5,663)	-
Operating loss	(43,997)	(61,985)
Finance income	475	1,637
Finance expense.....	(95)	(159)
Loss before income tax.....	(43,617)	(60,507)
Income tax expense.....	(334)	157
Net loss.....	(43,951)	(60,350)
Exchange differences on translation of foreign operations.....	23	(8)
Other comprehensive income (loss) for the period, net of tax	23	(8)
Total comprehensive income (loss) for the period, net of tax	(43,928)	(60,358)
Attributable to:		
- Equity holders of the parent	(43,928)	(60,358)
- Non-controlling interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent.....	(0.61)	(1.20)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION – DECEMBER 31, 2010

	As of December 31,	
	2010	2009
	(in thousands of €)	
ASSETS		
Non-current assets		
Property, plant & equipment	2,130	2,772
Intangible assets	386	797
Government subsidies receivable	-	477
Other financial assets	247	238
Deferred income tax assets	39	156
Total non-current assets	2,802	4,440
Current assets		
Government subsidies receivable	1,509	2,597
Other current assets	909	1,329
Prepaid expenses	377	784
Cash and cash equivalents	107,335	148,275
Total current assets	110,130	152,985
TOTAL ASSETS	112,932	157,425
EQUITY AND LIABILITIES		
Common shares	14,509	14,434
Other reserves	85,979	128,444
Non-controlling interests	-	-
Total Equity	100,488	142,878
Non-current liabilities		
Other contingencies and liabilities	4,548	4,069
Deferred income tax liabilities	96	91
Finance lease	83	6
Total non-current liabilities	4,727	4,166
Current liabilities		
Other contingencies and liabilities	2,800	-
Finance lease	30	7
Trade payables	2,045	6,136
Current income tax payable	-	19
Social security and other taxes	2,627	3,909
Other liabilities	215	310
Total current liabilities	7,717	10,381
TOTAL EQUITY AND LIABILITIES	112,932	157,425

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