



Financial results for full year 2008: NicOx in a unique position to deliver significant shareholder value

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NicOx S.A. (NYSE Euronext Paris: COX) today announced its financial results for full year 2008 and provided an overview of the development and pre-commercialization activities for naproxcinod, its lead investigational drug for the treatment of the signs and symptoms of osteoarthritis (OA).

Michele Garufi, Chief Executive Officer of NicOx, commented: *"We believe NicOx has entered 2009 in its strongest strategic position to date. We intend to use the excellent platform that we have developed over the last several years to transform NicOx into a self-sustainable biopharmaceutical company. Central to our ambition is to maximize the strategic and economic value of naproxcinod by signing the most appropriate commercial deal for this unique new product. Our intention is to retain select commercialization rights to naproxcinod to enable the creation of our own sales and marketing operations. Therefore, in parallel with our on-going discussions with potential naproxcinod partners, we are accelerating our search for marketed or late-stage clinical products for in-licensing or acquisition to leverage our future commercial infrastructure. We are confident we will achieve these key near term milestones, which should position NicOx to deliver sustainable profitability in the mid-term."*

Key highlights 2008:

- Successful completion of the phase 3 clinical program for naproxcinod in OA patients, with all three studies (301, 302 and 303) achieving highly statistically significant results on all three co-primary efficacy endpoints (the WOMAC™ pain and function subscales and patients' overall rating of disease status).
- Positive results on naproxcinod's blood pressure profile from a prospectively designed statistical analysis of the pooled Office Blood Pressure Measurement (OBPM) data from the phase 3 program (304) and two Ambulatory Blood Pressure Monitoring (ABPM) studies (111 and 112), which showed naproxcinod's favorable 24-hour blood pressure profile.
- Signature of two commercial supply agreements for naproxcinod with world leading manufacturing companies: DSM for the production of active pharmaceutical ingredient (API) and Capsugel for the production of naproxcinod capsules.
- Further progress in the collaboration with Merck & Co., Inc., following the initiation of a series of phase 1b studies in mild to moderate hypertensive volunteers, which have the aim of selecting the most appropriate compound to advance into phase 2.
- Two phase 2 studies for PF-03187207 in glaucoma patients conducted by Pfizer Inc demonstrated an improvement over Xalatan® 0.005%, in terms of intraocular pressure lowering, but did not reach statistical significance on the primary endpoint.

Eric Castaldi, Chief Financial Officer of NicOx, commented: *"As planned, we successfully completed the phase 3 clinical program for naproxcinod in 2008. We believe that the attractive profile of naproxcinod achieved in the phase 3 program should ensure our compound's future commercial success. Our balance sheet has enabled us to continue to expand the pre-commercialization activities for naproxcinod in parallel with the ongoing partnering discussions. We project cash burn will substantially decline throughout 2009, following the completion of the phase 3 program, and we currently believe we have sufficient cash to finance the activities of the Company until the end of 2010. This projection does not include the possible upfront and milestone payments we expect from a potential commercialization agreement for naproxcinod."*

Financial summary of 2008

Revenues for the full year 2008 were €3.4 million, compared to €20.6 million in 2007. These revenues were due to payments received in previous years from NicOx' partnered programs with Merck & Co., Inc. in the antihypertensive field and Pfizer Inc in ophthalmology.

Operating expenses totaled €86.4 million in 2008, compared to €61.8 million in 2007. The majority of these expenses were associated with the phase 3 clinical program for naproxcinod in osteoarthritis (OA) patients, which was successfully completed in the second half of 2008. Naproxcinod is the first Cyclooxygenase-Inhibiting Nitric Oxide Donator (CINOD) and a New Drug Application (NDA) submission to the US Food and Drug Administration (FDA) is projected for mid-2009. NicOx' net loss was €73.9 million for the full year 2008, compared to €32.1 million in 2007.

On December 31, 2008, NicOx had cash, cash equivalents and financial instruments of €104.7 million, compared to €172.8 million on December 31, 2007.

Considerable progress made in naproxcinod pre-commercialization activities

In 2008, NicOx signed two major manufacturing agreements to prepare the commercial launch of naproxcinod. In September, an agreement was signed with Capsugel, for the commercial manufacture and supply of naproxcinod capsules and in December, an agreement was signed with DSM for the commercial manufacturing and supply of naproxcinod drug substance (Active Pharmaceutical Ingredient, API). The aim of these agreements is to ensure sufficient commercial supplies of naproxcinod to underpin its successful market launch.

NicOx is currently in discussions with a number of companies regarding a potential commercialization agreement for naproxcinod. NicOx aims to retain certain commercialization rights for naproxcinod, in order to fully exploit the drug's commercial and strategic value and aid the Company's planned transition to a self-sustainable pharmaceutical business.

Completed phase 3 program confirms naproxcinod's efficacy and achieves target product profile

In 2008, NicOx successfully completed the phase 3 clinical program for naproxcinod in patients with OA of the knee (the 301 and 302 studies) and hip (the 303 study), with all three studies achieving highly statistically significant results on all three co-primary efficacy endpoints (the WOMAC™ pain subscale, WOMAC™ function subscale and subject's overall rating of disease status), as well as good overall safety and tolerability.

- In July, the top-line results of the 52-week safety extension of the 301 study were reported, which revealed no unexpected safety findings and showed a good overall long term safety for both doses of naproxcinod.
- The 302 study reported top-line results in 1020 knee-OA patients in September 2008. In addition to meeting the three co-primary endpoints at 13 weeks ($p < 0.001$), both doses of naproxcinod (750 mg and 375 bid) were statistically non-inferior to naproxen 500 mg bid at 26 weeks, in terms of the mean change from baseline in the WOMAC™ pain and function subscales.
- Top-line results from the 303 study in 810 patients with OA of the hip were reported in November. Naproxcinod 750 mg bid met all three co-primary efficacy endpoints with high statistical significance ($p < 0.001$).

During 2008, NicOx successfully completed an extensive database describing naproxcinod's blood pressure profile in more than 3,000 patients, using Office Blood Pressure Measurements (OBPM) and Ambulatory Blood Pressure Monitoring (ABPM).

Naproxcinod shows positive blood pressure results in phase 3 pooled analysis

In December 2008, NicOx announced the top-line results of the pooled blood pressure analysis from the phase 3 program (304). OBPM measurements were taken in a rigorous and standardized manner in each of the phase 3 studies (301, 302 and 303), at baseline and at weeks 2, 6 and 13. This OBPM data was pooled and analyzed according to a prospectively designed statistical plan, the objective of which was to evaluate the blood pressure profile of naproxcinod 375 mg bid, naproxcinod 750 mg bid, naproxen 500 mg bid and placebo, in a large OA population.

Both doses of naproxcinod showed a similar blood pressure profile to placebo, as indicated by one-sided 95% confidence intervals (CIs). Naproxen 500 mg bid raised systolic blood pressure (SBP) by 2.0 mmHg compared to placebo, in terms of the mean change between baseline and the average over weeks 2, 6 and 13. Further analyses on these pooled data are ongoing and NicOx plans to disclose more detailed results at leading medical conferences and in peer reviewed scientific publications during 2009 and 2010.

Two additional ABPM studies provided critical, complementary data to the phase 3 program

In November and December, NicOx announced the top-line results of the 111 and 112 clinical pharmacology studies in OA patients with controlled hypertension. These trials were designed to assess the 24-hour blood pressure profile of naproxcinod and two of the most widely used non-steroidal anti-inflammatory drugs (NSAIDs), ibuprofen and naproxen. The state of the art ABPM technique was used, providing critical, complementary data to the phase 3 OBPM data.

- In the 111 study, 118 patients were randomized to receive naproxcinod or naproxen, with escalating doses every three weeks (375, 750 and 1125 mg bid for naproxcinod, 250, 500 and 750 mg bid for naproxen). Over the whole study period, naproxcinod lowered SBP by 2.3 mmHg from baseline and naproxen raised it by 1.5 mmHg from baseline.
- In the 112 study, 299 patients were randomized to receive naproxcinod 375 mg bid, naproxcinod 750 mg bid, naproxen 250 mg bid, naproxen 500 mg bid, or ibuprofen 600 mg tid. At week 13, naproxcinod 750 mg bid showed a reduction in SBP of 2.7 mmHg compared to naproxen 500 mg bid and naproxcinod 375 mg bid showed a reduction in SBP of 1.1 mmHg compared to naproxen 250 mg bid. NicOx believes that the 112 trial is a key study for characterizing the blood pressure profile of naproxcinod, as it used the gold standard ABPM technique to provide data at 13 weeks, in OA patients with hypertension.

Further analyses on the 111 and 112 studies will form the basis of presentations at leading medical conferences and peer reviewed scientific publications during 2009 and 2010.

Interactions with clinical and scientific advisors

In 2008, NicOx organized 11 Advisory Boards to discuss naproxcinod's clinical results with world-famous experts in the fields of rheumatology, cardiology, nephrology and gastroenterology. Clinical advisors were consulted about various topics such as cardiovascular and blood pressure concerns related to traditional NSAIDs and COX-2 inhibitors, blood pressure and gastrointestinal results observed with naproxcinod and nitric oxide's mechanism of action.

The Company also attended 9 scientific congresses in 2008 and sponsored 3 symposia: at the American Heart Association (AHA) annual meeting in New Orleans, the European League Against Rheumatism (EULAR) annual meeting in Paris, and the Osteoarthritis Research Society International (OARSI) congress in Rome. All these events gave NicOx' scientists and clinicians the opportunity to seek advice regarding naproxcinod data from many leading advisors.

Initiation of a series of phase 1b studies by Merck & Co., Inc. in the hypertension field

In May 2008, Merck initiated a series of clinical studies in volunteers with mild to moderate hypertension. This program is part of the March 2006 agreement to develop new nitric oxide-donating antihypertensive drugs and is testing a number of compounds with single and multiple ascending dosing, prior to the selection of a candidate to be advanced into phase 2. The main objectives of these studies are to assess the efficacy, safety, tolerability and pharmacokinetics of these compounds.

Ophthalmology agreements with Pfizer Inc

NicOx and Pfizer are currently in discussions regarding the rights to PF-03187207 for glaucoma (PF-03187207 is covered by the companies' August 2004 agreement). This follows the results of two phase 2 studies in the US and Japan, which demonstrated an improvement over Xalatan® 0.005% that did not reach statistical significance on the primary endpoint. The March 2006 agreement granted Pfizer the exclusive right to apply NicOx' nitric oxide-donating technology across the entire field of ophthalmology and current research activities are focused on compounds for the potential treatment of diabetic retinopathy.

Results of a phase 2 study for TPI 1020 in COPD

In December, NicOx and its partner Topigen Pharmaceuticals Inc. announced the results of a phase 2 study for TPI 1020 in patients with Chronic Obstructive Pulmonary Disease (COPD). TPI 1020 did not obtain the differentiated activity required to be advanced into further development in this indication. Topigen and NicOx are currently exploring other possible therapeutic opportunities for TPI 1020 in the respiratory field.

Financial consolidated results on December 31, 2008 and 2007:

Revenues

NicOx' revenues totaled €3.4 million in 2008, compared to €20.6 million in 2007. This significant decrease is explained principally by the fact that the Company received €10.0 million from Merck and €1.0 million from Pfizer in 2007, which were entirely recognized as revenues in 2007.

In 2008, NicOx recognized the following amounts in revenues:

- €0.3 million corresponding to the initial payment of €5.0 million from Pfizer, as a technology exclusivity fee, following the March 2006 agreement that granted Pfizer rights to apply NicOx' proprietary technology in a drug discovery research program covering the field of ophthalmology

- €2.5 million corresponding to the funding of the research collaboration, pursuant to the above referenced agreement signed with Pfizer in March 2006
- €0.6 million corresponding to the balance of the spreading of the initial payment of €9.2 million received from Merck following the signature of a collaboration agreement for new antihypertensive drug candidates in March 2006

These amounts initially recorded as prepaid income were deferred over the estimated duration of NicOx' involvement in the research and development programs provided for under the terms of the corresponding agreements. The terms surrounding the duration of NicOx' involvement in these programs are revised periodically, if necessary.

Operating expenses

In 2008, operating expenses amounted to €86.4 million, compared to €61.8 million in 2007 (adjusted to reflect the reclassification of the research tax credit subsidies into other income as indicated below). During 2008, operating expenses were 87% attributable to research and development expenses and 13% attributable to selling and administrative expenses, compared to 82% and 18% respectively in 2007.

Research and development expenses reached €75.0 million in 2008, compared to €50.4 million in 2007 (including €0.8 million allocated to cost of sales in 2008 and €2.2 million in 2007). This significant increase in research and development expenses results mainly from the costs related to the phase 3 development of naproxcinod, such as expenses associated with contract research organizations and suppliers involved in naproxcinod's clinical development and manufacturing activities. At this time, the cost of sales corresponds to the expenses incurred by NicOx in performing research activities under the contracts signed with Pfizer and Merck. On December 31, 2008, the Company employed 97 people in research and development, compared to 84 people at the same date in 2007.

In 2008, administrative and selling expenses totaled €11.4 million compared to €11.3 million in 2007. General and administrative expenses were €6.6 million in 2008 compared to €6.8 million in 2007 and include personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers, including stock option, bonus share and warrant attributions. In 2008, selling expenses totaled €4.8 million, compared to €4.5 million in 2007, and correspond to the market analysis activities for naproxcinod, as well as the business development and communication activities of the Company. The Company anticipates a significant increase in its selling expenses in the future, due to activities linked to the commercial launch preparation for naproxcinod. On December 31, 2008, the Company employed 36 people in its selling, general, and administrative departments, compared to 33 people on December 31, 2007.

Other income

Other income totaled €3.8 million in 2008, compared to €3.9 million in 2007. Other income corresponds mainly to the operational subsidies from the research tax credits which were previously deducted from research and development expenses until December 31, 2007.

Operating result

In 2008, the operating loss totaled €79.2 million, compared to €37.2 million in 2007. This situation is explained by the considerable increase in operating expenses during 2008 and by the significant decrease in revenues recognized in 2008 as indicated above.

Other results

In 2008, net financial income amounted to €5.5 million compared to €5.2 million in 2007 and represents mainly the returns on the financial investments of the Group's cash, cash equivalents and financial instruments.

The income tax expense incurred by NicOx in 2008 relates to its subsidiaries and amounted to €0.1 million, identical to 2007.

Net result

The net loss reached €73.9 million in 2008 compared to €32.1 million in 2007. As indicated above, this very significant increase in net loss in 2008 is due to the strong increase of research and development expenses associated with naproxcinod and from the considerable decrease in the revenues recognized in 2008.

Balance sheet items

The indebtedness incurred by NicOx is mainly short-term operating debt. On December 31, 2008, the Company's current liabilities amounted to €21.2 million, including €16.2 million in accounts payable to suppliers and external collaborators, €2.1 million in accrued compensation for employees, €1.5 million in taxes payable, €1.1 million in deferred revenues due to payments received under collaboration agreements and €0.3 million for other liabilities.

In 2008, NicOx granted to Archimica a loan of €6.0 million as part of the financial terms of the manufacturing and supply agreement with this company. Following the termination of the agreement in November 2008, €5.0 million out of the €6.0 million loan were forgiven in accordance with the terms of the agreement and Archimica remains liable to NicOx, as of December 31, 2008, of an amount of €0.9 million with regards to this loan. Considering there is a risk for the recovery of this sum, the Company has decided to depreciate partially this asset and has booked as of December 31, 2008 a contingency provision for an amount of €0.5 million.

On December 31, 2008, the Company's current and non-current financial instruments and cash and cash equivalents were €104.7 million, compared to €172.8 million on December 31, 2007.

The Company anticipates a significant decrease in its research and development expenses for 2009, following the completion of the phase 3 clinical program for naproxcinod in 2008. NicOx has the strategic objective of transforming itself into a self-sustainable biopharmaceutical company. Commercial expenses would be expected to continue to increase strongly over the coming financial years, as a result of the anticipated launch preparation activities for naproxcinod. Overall, operating expenses are expected to decrease in 2009, compared to 2008.

The Company's consumption of financial instruments and cash and cash equivalents is expected to decrease significantly in 2009, following the completion of the phase 3 clinical program for naproxcinod in 2008. Current budgetary estimates suggest NicOx has sufficient cash to finance the activities of the Company until the end of 2010. This projection does not include the possible upfront and milestone payments that could arise from a potential commercialization agreement for naproxcinod.

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a product-driven biopharmaceutical company dedicated to the development and future commercialization of investigational drugs for unmet medical needs. NicOx is applying its proprietary nitric oxide-donating technology to develop an internal portfolio of New Chemical Entities (NCEs) in the therapeutic areas of inflammatory and cardio-metabolic disease.

Resources are focused on the development and pre-commercialization activities for naproxcinod, a proprietary NCE and the first Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent for the treatment of the signs and symptoms of osteoarthritis. Naproxcinod has completed three pivotal phase 3 studies with positive results and the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) is projected for mid-2009.

Beyond naproxcinod, NicOx has a pipeline containing multiple nitric oxide-donating NCEs, which are in development internally and with partners, including Pfizer Inc and Merck & Co., Inc., for the treatment of prevalent and underserved diseases, such as atherosclerosis, hypertension and widespread eye diseases and respiratory conditions.

NicOx S.A. is headquartered in France and is listed on the NYSE 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>).

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CONSOLIDATED INCOME STATEMENT

	Fiscal year ended December 31	
	2008	2007
	(in thousands of € except for per share data)	
Revenues.....	3,362	20,620
Cost of sales	(750)	(2,151)
Research and development expenses.....	(74,281)	(48,278)
Administrative and selling expenses.....	(11,358)	(11,322)
Other income.....	3,814	3,933
Operating loss	(79,213)	(37,198)
Net financial income.....	5,458	5,183
Loss before income tax	(73,755)	(32,015)
Income tax expense.....	(132)	(129)
Loss for the period	(73,887)	(32,144)
Attributable to:		
- Equity holders of the Company.....	(73,887)	(32,144)
- minority interests	-	-
Earnings per share for profit attributable to equity holders of the Company	(1.56)	(0.69)
Diluted.....	(1.56)	(0.69)

CONSOLIDATED BALANCE SHEET

	December 31, 2008	December 31, 2007
	(in thousands of €)	
ASSETS		
Non current assets		
Property, plant, & equipment	3,429	2,720
Intangible assets	835	464
Financial instruments	4,858	14,402
Government subsidies receivable	-	5,264
Other financial assets	201	186
Deferred income tax assets	21	10
Total non-current assets	9,344	23,046
Current assets		
Financial assets	396	-
Trade receivables	6	2,224
Government subsidies receivable	9,004	133
Other current assets	3,310	2,564
Prepaid expenses	1,716	3,083
Current financial instruments	9,912	14,967
Cash and cash equivalents	89,931	143,444
Total current assets	114,275	166,415
TOTAL ASSETS	123,619	189,461
EQUITY AND LIABILITIES		
Capital and Reserves attributable to equity holders of the Company		
Ordinary shares	9,498	9,457
Other reserves	92,571	159,757
Minority interests	-	-
Total Equity	102,069	169,214
Non-current liabilities		
Provisions for other liabilities and charges	175	201
Deferred income tax liabilities	127	120
Finance lease	13	19
Total non-current liabilities	315	340
Current liabilities		
Finance lease	6	10
Trade payables	16,232	13,858
Deferred revenue	1,119	1,481
Current income tax payable	-	51
Social security and other taxes	3,568	4,197
Other liabilities	310	310
Total current liabilities	21,235	19,907
TOTAL EQUITY AND LIABILITIES	123,619	189,461