



Report of NicOx's financial results for the first three quarters of 2009

October 22, 2009. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (Euronext Paris: COX) today reported financial results for the nine months ended September 30, 2009.

Michele Garufi, Chairman and CEO of NicOx, declared: *"In the third quarter of 2009, we have achieved an important corporate milestone by submitting the NDA for naproxcinod on time to the US FDA and we have continued to drive our strategy to transform NicOx into a specialty pharmaceutical company through increasing the pre-commercialization activities for our lead compound, which is raising more and more interest from rheumatologists and cardiologists, as well as from the wider scientific community. We remain confident that naproxcinod has the potential to make a significant difference to osteoarthritis sufferers and are committed to participating in its expected commercial success. Moreover, our promising earlier stage pipeline is also progressing as planned and we look forward to announcing further clinical and pre-clinical milestones later this year."*

Key operational highlights of the third quarter of 2009:

- Submission of a New Drug Application (NDA) for naproxcinod to the United States Food and Drug Administration (FDA), seeking approval for an indication for the relief of the signs and symptoms of osteoarthritis (OA) – see press release of September 25, 2009. The NDA file contains data from three large pivotal phase 3 studies, all of which met their co-primary efficacy endpoints. NicOx plans to submit a Marketing Authorization Application (MAA) for naproxcinod to the European Medicines Agency (EMA) in Q4 2009.
- Publication of an important scientific article in the September issue of the *American Journal of Cardiology* which describes the blood pressure results from the 301 phase 3 study for naproxcinod in detail. The differentiated blood pressure profile of naproxcinod 750 mg bid and naproxcinod 375 mg bid, when compared to placebo and naproxen 500 mg bid on the systolic blood pressure (SBP) of patients with OA of the knee, was presented in the article.
- Three scientific presentations at the 2009 World Congress on Osteoarthritis (OARSI – annual congress of the Osteoarthritis Research Society International). The presentations included the efficacy results for naproxcinod from the 302 study completed in 2008 and the preclinical results obtained with two other CINOD compounds.
- Reacquisition of the full development and commercialization rights to NCX 116 (previously PF-03187207) from Pfizer, which has completed two phase 2 studies in patients with primary open angle glaucoma and ocular hypertension. As part of this agreement, Pfizer also granted NicOx the right to access and use certain proprietary Xalatan® (latanoprost) data. NicOx also regained rights to a number of novel, research-stage, nitric oxide-donating compounds for the potential treatment of diabetic retinopathy and glaucoma.

Eric Castaldi, CFO of NicOx added: *"As anticipated our operating expenses have decreased significantly as we have shifted our focus from clinical development to the pre-commercialization activities for naproxcinod. We have continued to invest in our Commercial Affairs team and are evaluating a range of opportunities to create an efficient commercial infrastructure in the United States in order to allow us to maximize naproxcinod's value."*

Financial summary of the first nine months of 2009:

Revenues were €1.1 million for the nine months ended September 30, 2009, compared to €2.9 million during the same period in 2008. These revenues were due to NicOx's collaboration with Pfizer Inc in the ophthalmology field.

For the first nine months of 2009, operating expenses were €45.7 million, compared to €60.4 million for the corresponding period of 2008, with this significant decrease being due to the completion of the phase 3 clinical program for naproxcinod in 2008. These operating expenses included the cost of pre-commercialization activities for naproxcinod.

For the nine months ended September 30, 2009, the total comprehensive loss amounted to €39.9 million compared to €49.7 million for the first nine months of 2008. On September 30, 2009, the Company's current and non-current financial instruments and cash and cash equivalents were €66.8 million, compared to €104.7 million on December 31, 2008.

Consolidated financial results as of September 30, 2009 and 2008:

Revenues

NicOx's revenues amounted to €1.1 million for the nine months ended September 30, 2009, compared to €2.9 million for the nine months ended September 30, 2008.

For the first nine months of 2009, NicOx recognized the following amounts in revenues:

- €0.1 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's proprietary technology in a drug discovery research program covering the field of ophthalmology
- €1.0 million corresponding to the funding of the research collaboration, pursuant to the above referenced agreement signed with Pfizer in March 2006

These amounts initially recorded as prepaid income were deferred over the estimated duration of NicOx's involvement in the research program provided for under the terms of the agreement with Pfizer. All revenues related to this agreement have been recognized. In August 2009, NicOx and Pfizer amicably terminated the March 2006 agreement.

Operating expenses

During the nine months ended September 30, 2009, operating expenses amounted to €45.7 million, compared to €60.4 million for the nine months ended September 30, 2008, of which 72.6% was attributable to research and development expenses and 27.4% attributable to selling and administrative expenses in the first nine months of 2009, compared to 86% and 14% respectively in the first nine months of 2008.

Research and development expenses totaled €33.2 million in the nine months ended September 30, 2009, compared to €52.0 million during the nine months ended September 30, 2008 (including €0.1 million allocated to cost of sales in 2009 and €0.6 million in 2008). Research and development expenses incorporate a provision for asset impairment of €5.7 million. This provision fully corresponds to the discounted acquisition value of the Nitromed patent portfolio. These assets were acquired mainly with a defensive objective, in order to give NicOx a preeminent intellectual property position in the nitric oxide-donating technology worldwide. However, considering the uncertainties linked to the financial resources to be allocated to these assets in the future and consequently the difficulties of estimating their recoverable value, the Company decided to fully impair these assets. The value of these assets will be subject to follow up. Any factor enabling a reassessment of their future recoverable value will be taken in consideration, as the case may be. Excluding the impact of this provision, the research and development expenses decreased by €24.5 million during the nine months ended September 30, 2009, compared to the same period in 2008. This significant decrease in research and development expenses results mainly from a reduction in the costs related to the clinical development of naproxinod. The cost of sales corresponds to the expenses incurred by NicOx in performing research activities under the contract signed with Pfizer. The Company employed 92 people in research and development on September 30, 2009, compared to 98 people on September 30, 2008.

Administrative and selling expenses totaled €12.6 million in the nine months ended September 30, 2009, compared to €8.4 million for the same period in 2008. General and administrative expenses were €5.1 million in the first nine months of 2009 compared to €5.3 million in the first nine months of 2008 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 reached €7.5 million in the nine months ended September 30, 2009, compared to €3.1 million during the same period in 2008, which correspond to the market analysis activities for naproxinod, as well as the business development and communication activities of the Company. This increase in selling and corporate development expenses results principally from the activities linked to the preparation of the commercialization of naproxinod. The Company employed 42 people in its selling, general and administrative departments on September 30, 2009, compared to 37 people on the same date in 2008.

Other income

In the nine months ended September 30, 2009, other income amounted to €3.2 million, compared to €3.3 million in the same period in 2008. Other income corresponds mainly to the operational subsidies from the research tax credits in France and for the first time in Italy.

Operating result

The operating loss was €41.3 million during the first nine months of 2009, compared to €54.2 million in the same period in 2008. This decrease in the operating loss results from the decrease in the development expenses incurred by the Company during the first nine months of 2009, following the completion of the phase 3 clinical development of naproxcinod at the end of 2008.

Other results

Net financial income amounted to €1.5 million in the nine months ended September 30, 2009, compared to €4.6 million in the nine months ended September 30, 2008, and represents mainly the returns on the financial investments of the Company's cash, cash equivalents and financial instruments.

The income tax expense incurred by NicOx during the first nine months of 2009 relates to its subsidiaries and totaled €0.1 million, compared to €0.2 million during the same period in 2008.

Total comprehensive loss for the period

The total comprehensive loss amounted to €39.9 million for the nine months ended September 30, 2009, compared to €49.7 million for the nine months ended September 30, 2008. Notwithstanding the increase of selling expenses, the decrease in the total comprehensive loss in the first nine months of 2009 corresponds to the reduction of development expenses due to the completion of the phase 3 clinical development of naproxcinod at the end of 2008.

Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On September 30, 2009, the Company's current liabilities were €14.9 million, including €11.3 million in accounts payable to suppliers and external collaborators, €2.1 million in accrued compensation for employees, €1.3 million in taxes payable and €0.2 million for other liabilities.

Other current assets totaled €7.9 million on September 30, 2009, compared to €3.3 million on December 31, 2008. These correspond to the advanced payments made to DSM, the active ingredient supplier of naproxcinod, to support the planned production of a pre-launch inventory of naproxcinod.

The Company's current and non-current financial instruments and cash and cash equivalents were €66.8 million on September 30, 2009, compared to €104.7 million on December 31, 2008 and to €124.8 million as of September 30, 2008.

The Company anticipates that its research and development expenses will be lower in 2009 compared to 2008, following the completion of the phase 3 clinical program for naproxcinod in 2008. NicOx has the strategic objective of transforming itself into a specialty pharmaceutical company. Expenses related to the preparation of the commercialization of naproxcinod are expected to increase over the coming financial years, as a result of the anticipated launch of naproxcinod. Overall, operating expenses are expected to decrease in 2009, compared to 2008.

Notwithstanding the increase of expenses related to the preparation of commercialization of naproxcinod, the Company's consumption of financial instruments and cash and cash equivalents is expected to decrease significantly in 2009 due to the reduction of development expenses, following the completion of the phase 3 clinical program for naproxcinod in 2008. NicOx currently anticipates having sufficient cash to sustain operations until the end of 2010. Certain scenarios to optimize the launch of naproxcinod would require more investments and would necessitate additional resources.

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a product-driven pharmaceutical 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.

NicOx's lead product is naproxcinod, a proprietary NCE and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory agent for the relief of the signs and symptoms of osteoarthritis. NicOx submitted a New Drug Application (NDA) for naproxcinod to the US Food and Drug Administration (FDA) in September 2009, following the successful completion of three pivotal phase 3 studies. The submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) is planned for Q4 2009.

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

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NicOx S.A. is headquartered in France and is listed on the Euronext Paris Stock Exchange (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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INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – SEPTEMBER 30, 2009

	Period of 9 months ended September 30,	
	2009	2008
	Restated*	
	(in thousands of € except for per share data)	
Revenues.....	1,119	2,943
Cost of sales	(75)	(620)
Research and development expenses.....	(33,079)	(51,348)
Selling and administrative expenses.....	(12,558)	(8,434)
Other income.....	3,244	3,267
Operating loss	(41,349)	(54,192)
Finance income (expense).....	1,513	4,649
Loss before income tax.....	(39,836)	(49,543)
Income tax expense.....	(108)	(198)
Net loss.....	(39,944)	(49,741)
Exchange differences on translation of foreign operations.....	(3)	(8)
Other comprehensive income (loss) for the period, net of tax	(3)	(8)
Total comprehensive income (loss) for the period, net of tax	(39,947)	(49,749)
Attributable to:		
- Equity holders of the parent.....	(39,947)	(49,749)
- Minority interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent.....	(0.84)	(1.05)

* Compliant with IAS 1R

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – SEPTEMBER 30, 2009

	September 30, 2009	December 31, 2008
	(in thousands of €)	
ASSETS		
Non-current assets		
Property, plant & equipment	3,224	3,429
Intangible assets	886	835
Non-current financial instruments	-	4,858
Government subsidies receivable	2,162	-
Other financial assets	199	201
Deferred income tax assets	18	21
Total non-current assets	6,489	9,344
Current assets		
Financial assets	-	396
Trade receivables	-	6
Government subsidies receivable	837	9,004
Other current assets	7,896	3,310
Prepaid expenses	953	1,716
Current financial instruments	-	9,912
Cash and cash equivalents	66,835	89,931
Total current assets	76,521	114,275
TOTAL ASSETS	83,010	123,619
EQUITY AND LIABILITIES		
Common shares	9,607	9,498
Other reserves	58,073	92,571
Minority interests	-	-
Total Equity	67,680	102,069
Non-current liabilities		
Other non-current liabilities and charges	340	175
Deferred income tax liabilities	125	127
Finance lease	7	13
Total non-current liabilities	472	315
Current liabilities		
Finance lease	7	6
Trade payables	11,271	16,232
Deferred revenue	-	1,119
Current income tax payable	-	-
Social security and other taxes	3,345	3,568
Other current liabilities	235	310
Total current liabilities	14,858	21,235
TOTAL EQUITY AND LIABILITIES	83,010	123,619