



NicOx reports first quarter 2009 financial results

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NicOx S.A. (NYSE Euronext Paris: COX) today reported financial results for the first three months of 2009 and provided an overview of the pre-commercialization activities for naproxcinod, a Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent, in the pre-registration phase for the treatment of the signs and symptoms of osteoarthritis.

Eric Castaldi, Chief Financial Officer of NicOx, declared: *"In the first quarter of 2009, we have continued to make good progress towards our two key goals of filing an NDA for naproxcinod with the FDA and transforming NicOx into a self-sustainable biopharmaceutical company. The new analyses of the phase 3 data presented at the annual meetings of the American College of Cardiology and the American Society of Hypertension further highlight naproxcinod's potential clinical advantages and have been supportive to our on-going partnering discussions."*

Business Overview for the first quarter of 2009

- In the first three months of 2009, NicOx' primary business focus has transitioned from the clinical development to the pre-commercialization and business development activities for naproxcinod. In parallel, NicOx is continuing to work on the preparation of the New Drug Application (NDA) file for naproxcinod.
- In late March, new analyses of the phase 3 data for naproxcinod were presented at the American College of Cardiology (ACC) Annual Meeting in Orlando, Florida. The presentation focused on blood pressure data for naproxcinod in osteoarthritis patients using antihypertensive therapies and included detailed assessments of the systolic blood pressure (SBP) changes from baseline in the overall population and in certain hypertensive sub-groups.
- During the quarter, NicOx announced the start of clinical development for NCX 6560, a novel, nitric oxide-donating compound which could become an improved treatment for serious cardiovascular diseases. The phase 1 proof-of-principal study is enrolling both healthy male volunteers and those with abnormally raised cholesterol and its initiation represents an important step in the development of NicOx' product pipeline.

Post-first quarter events 2009

In late April, NicOx announced the purchase of Nitromed's unlicensed patent estate covering nitric oxide-donating compounds, including a large number of new patents, with potential uses in NicOx' core areas of inflammatory and cardio-metabolic disorders. Under the terms of the agreement, NicOx has paid Nitromed €2 million at signature and will pay a further €4 million upon NicOx fulfilling certain future business criteria. Following the acquisition, the Company holds by far the most comprehensive intellectual property portfolio in this area.

In early May, new analyses of the phase 3 data for naproxcinod were presented at the American Society of Hypertension (ASH) Annual Scientific Meeting in San Francisco, California, including data on all hypertensive patients which were presented for the first time.

"Turning to our financial position, we expect cash burn to decrease significantly in 2009, following the completion of naproxcinod's phase 3 program," continued Eric Castaldi, CFO of NicOx. "Current budgetary estimates suggest our cash resources will finance the activities of the Company until the end of 2010. This projection does not include any possible upfront and milestone payments that could arise from a potential commercialization agreement for naproxcinod. As a result we are looking forward to the remainder of 2009 with confidence."

Financial summary of the first quarter of 2009:

Revenues were €0.4 million in the first quarter of 2009, compared to €1.4 million for the corresponding period of 2008. Revenues in the first quarter of 2009 were mainly due to research funding from Pfizer Inc.

Operating expenses were €13.7 million in the first quarter of 2009, compared to €17.5 million in the first quarter of 2008. The decline in operating expenses was due to the successful completion of the naproxcinod phase 3 clinical development program.

In the first quarter of 2009, NicOx recorded a total comprehensive loss for the period of €11.2 million. This compares to €13.0 million for the first quarter of 2008. On March 31, 2009, the Company had cash, cash equivalents and financial instruments of €84.6 million, compared to €104.7 million on December 31, 2008.

Review of the consolidated financial results for the three months ended March 31, 2009 and 2008

Revenues

NicOx' revenues totaled €0.4 million for the first three months ended March 31, 2009, compared to €1.4 million for the three months ended March 31, 2008.

In the first quarter of 2009, NicOx only recognized the following amounts in revenues:

- €0.04 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
- €0.36 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' involvement in the research program provided for under the terms of the agreement with Pfizer. The terms surrounding the duration of NicOx' involvement in this program are revised periodically, if necessary.

Operating expenses

For the three months ended March 31, 2009, operating expenses amounted to €13.7 million, compared to €17.5 million for the three months ended March 31, 2008, of which 73% was attributable to research and development expenses and 27% attributable to selling and administrative expenses in the first quarter of 2009, compared to 87% and 13% respectively in the first quarter of 2008.

Research and development expenses were €10.0 million during the first quarter of 2009, compared to €15.1 million during the first quarter 2008 (including €0.08 million allocated to cost of sales in 2009 and €0.5 million in 2008). This decrease in research and development expenses results mainly from a reduction in the costs related to the clinical development of naproxcinod. The cost of sales corresponds to the expenses incurred by NicOx in performing research activities under the contract signed with Pfizer. The Company employed 95 people in research and development on March 31, 2009, compared to 92 people at the same date in 2008.

Administrative and selling expenses reached €3.7 million during the first three months ended March 31, 2009 compared to €2.3 million during the same period in 2008. General and administrative expenses were €1.6 million in the first quarter of 2009 compared to €1.5 million in the first quarter of 2008 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. Selling expenses totaled €2.0 million during the three months ended March 31, 2009 compared to €0.8 million during the same period in 2008, and correspond to the market analysis activities for naproxcinod, as well as the business development and communication activities of the Company. This increase in selling expenses results from the activities linked to the commercial launch preparation for naproxcinod. The Company employed 39 people in its selling, general, and administrative departments on March 31, 2009, compared to 35 people on March 31, 2008.

Other income

Other income totaled €1.3 million in the three months ended March 31, 2009, compared to €1.6 million in the same period in 2008. Other income corresponds mainly to the operational subsidies from the research tax credits.

Operating result

The operating loss was €12.0 million during the first quarter of 2009, compared to €14.5 million in the first quarter of 2008. This decrease of the operating loss results from the decrease of development expenses incurred by the Company during the first quarter of 2009 following the completion of the phase 3 clinical development of naproxcinod at the end of 2008.

Other results

Net financial income totaled €0.8 million during the first quarter of 2009 compared to €1.6 million during the three months ended March 31, 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 quarter 2009 relates to its subsidiaries and amounted to €0.06 million compared to €0.07 million during the same period in 2008.

Total comprehensive loss for the period

The total comprehensive loss reached €11.2 million during the three months ended March 31, 2009, compared to €13.0 million during the three months ended March 31, 2008. Notwithstanding the increase of selling expenses, the decrease in the total comprehensive loss in the first quarter 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 (previously balance sheet)

The indebtedness incurred by NicOx is mainly short-term operating debt. On March 31, 2009 the Company's current liabilities amounted to €15.2 million, including €11.8 million in accounts payable to suppliers and external collaborators, €1.3 million in accrued compensation for employees, €1.3 million in taxes payable, €0.7 million in deferred revenues due to payments received under collaboration agreements and €0.1 million for other liabilities.

Other current assets were €6.7 million on March 31, 2009, compared to €3.3 million on December 31, 2008. They correspond to the advance payments made to DSM, the active ingredient supplier of naproxcinod, to support the planned production of a pre-launch inventory of naproxcinod. This item will continue to increase until the end of 2009.

The Company's current and non-current financial instruments and cash and cash equivalents were €84.6 million on March 31, 2009, compared to €104.7 million on December 31, 2008, and €153.7 million on March 31, 2008.

The Company anticipates that its research and development expenses will continue to decrease in 2009, following the completion of the phase 3 clinical program of naproxcinod in 2008. NicOx has the strategic objective of transforming itself into a self-sustainable biopharmaceutical company. Commercial expenses are 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 continue to decrease in 2009, compared to 2008.

Notwithstanding the increase of commercial expenses, the Company's consumption of financial instruments and cash and cash equivalents will continue to decrease significantly in 2009 due to the expected reduction of development expenses, 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 any 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 a 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, widespread eye diseases and respiratory diseases.

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 STATEMENT OF COMPREHENSIVE INCOME – MARCH 31, 2009

	End of the reporting period	
	Unaudited	Unaudited Restated
	March 31, 2009	March 31, 2008
	(in thousands of € except for per share data)	
Revenues.....	420	1,404
Cost of sales.....	(79)	(529)
Research and development expenses.....	(9,932)	(14,632)
Administrative and selling expenses.....	(3,681)	(2,312)
Other income.....	1,266	1,561
Operating result	(12,006)	(14,508)
Net financial income.....	823	1,617
Result before income tax	(11,183)	(12,891)
Income tax expense.....	(60)	(67)
Result for the period.....	(11,243)	(12,958)
Exchange differences on translation of foreign operations....	(2)	(12)
Other comprehensive income (loss) for the period, net of tax.	(2)	(12)
Total comprehensive income (loss) for the period, net of tax...	(11,245)	(12,970)
Attributable to:		
- Equity holders of the Company.....	(11,245)	(12,970)
- minority interests	-	-
Earnings per share for profit attributable to equity holders of the Company	(0.24)	(0.27)
Diluted	(0.24)	(0.27)

Commentary

IAS 1 R Presentation of Financial Statements

The consolidated financial statements of NicOx S.A. are presented in accordance with IAS 1 Presentation of Financial Statements (revised in 2003). IAS 1 Presentation of Financial Statements has been amended in September 2007 (IAS 1R) and is applicable for financial years beginning on or after 1 January 2009.

The previous version of IAS 1 used the titles "consolidated balance sheet" and "consolidated statement of operations" to refer to two of the financial statements considered to be part of the complete set. The revised standard refers to these statements as the "consolidated statements of financial position" and "consolidated statement of comprehensive income". NicOx Group has decided to change the titles and use the new terminology suggested by IAS 1R.

This standard also requires an entity to present all owner changes in equity and all non-owner changes either in one statement of comprehensive income or in two separate statements of income and comprehensive income. The previous standard required components of comprehensive income to be presented in the statement of changes in equity. The Group has elected to present all changes in equity in one statement of consolidated comprehensive income.

As of 31 March 2009, the exchange difference on translation of foreign operations is the only component of consolidated comprehensive income or (loss).

CONSOLIDATED STATEMENT OF FINANCIAL POSITION – MARCH 31, 2009

	Unaudited	
	March 31, 2009	December 31, 2008
(in thousands of €)		
ASSETS		
Non current assets		
Property, plant, & equipment	3,264	3,429
Intangible assets	869	835
Non-current financial instruments	-	4,858
Government subsidies receivable	1,370	-
Other financial assets	208	201
Deferred income tax assets	24	21
Total non-current assets	5,735	9,344
Current assets		
Financial assets	573	396
Trade receivables	-	6
Government subsidies receivable	8,875	9,004
Other current assets	6,676	3,310
Prepaid expenses	1,116	1,716
Current financial instruments	9,986	9,912
Cash and cash equivalents	74,617	89,931
Total current assets	101,843	114,275
TOTAL ASSETS	107,578	123,619
EQUITY AND LIABILITIES		
Capital and Reserves attributable to equity holders of the Company ...		
Ordinary shares	9,512	9,498
Other reserves	82,554	92,571
Minority interests	-	-
Total Equity	92,066	102,069
Non-current liabilities		
Provisions for other liabilities and charges	220	175
Deferred income tax liabilities	129	127
Finance lease	11	13
Total non-current liabilities	360	315
Current liabilities		
Finance lease	7	6
Trade payables	11,783	16,232
Deferred revenue	699	1,119
Current income tax payable	34	-
Social security and other taxes	2,552	3,568
Other liabilities	77	310
Total current liabilities	15,152	21,235
TOTAL EQUITY AND LIABILITIES	107,578	123,619