



NicOx first half 2009 financial results: naproxcinod nearing regulatory submissions in US and Europe

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NicOx S.A. (NYSE Euronext Paris: COX) today reported its financial results for the six months ended June 30, 2009 and provided a business update highlighting its activities for naproxcinod, NicOx' lead compound and the first-in-class Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent.

Michele Garufi, Chairman and CEO of NicOx, declared: *"With naproxcinod nearing US and European regulatory submissions, we are now focused on the next phase of NicOx' transformation into a self-sustainable biopharmaceutical company. As we have outlined previously, we aim to play a very active role in naproxcinod's future sales and marketing, through retaining select co-commercialization rights to specialist doctors. Our goal is to sign one or more commercialization agreements covering the major pharmaceutical markets by the time of launch, in order to maximize the revenues of our lead product. In parallel, we are continuing to evaluate potential acquisitions which could provide us with complementary products to market alongside naproxcinod and allow us to achieve critical mass for our planned commercial operations."*

Key highlights of the first six months of 2009:

- In the first six months of 2009, NicOx' primary business focus has transitioned from the clinical development to the pre-commercialization and business development activities for naproxcinod. NicOx is holding discussions with a range of potential commercialization partners and these interactions have reinforced NicOx' view on the value and consistency of the naproxcinod data.
- NicOx is nearing the completion of the files for the submission 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) for naproxcinod. NicOx will request an indication for the relief of the signs and symptoms of osteoarthritis (OA) for naproxcinod. The NDA submission is expected within Q3, with the MAA submission anticipated in Q4.
- Oral presentations and posters on important clinical results for naproxcinod were presented at key rheumatology and cardiology congresses. The results presented focused on the blood pressure profile of naproxcinod.
- A phase 1b proof-of-principle clinical study has been initiated for NCX 6560, an innovative investigational drug which could represent a global therapeutic approach for reduction of cardiovascular risk.
- NicOx has acquired Nitromed's unlicensed patent estate covering novel nitric oxide (NO)-donating compounds, which further strengthens its intellectual property (IP) leadership in this exciting approach to drug discovery.

"During the first half of the year we have continued to invest in the pre-commercialization activities for naproxcinod and to strengthen our Commercial Affairs team in Warren, New Jersey," added **Eric Castaldi, CFO of NicOx.** *"Despite this important investment, the financial results for the first six months of 2009 show a significant decrease in research and development expenses, resulting in a substantial reduction in cash burn. Considering these first half results, which are in-line with our estimates, we expect cash burn to decrease significantly in 2009."*

Financial summary for the first half of 2009:

Revenues for the first half of 2009 were €1.1 million, compared to €2.2 million during the same period in 2008. These revenues were due to NicOx' collaboration with Pfizer Inc in the field of ophthalmology.

For the first six months of 2009, operating expenses were €32.7 million, compared to €40.6 million for the same period in 2008, with this significant decrease being due to the completion of the phase 3 program for naproxcinod. These operating expenses included the cost of pre-commercialization activities for naproxcinod.

The Company recorded a total comprehensive loss of €27.2 million for the first six months of 2009, compared to a corresponding loss of €33.1 million for the same period in 2008. On June 30, 2009, NicOx had cash, cash equivalents and current and non-current financial instruments of €76.8 million, compared to €104.7 million on December 31, 2008.

Review of the first six months of 2009:

The preparation of a New Drug Application (NDA) submission to the US Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for naproxcinod for the relief of the signs and symptoms of osteoarthritis is nearing completion. NicOx expects to submit the NDA within the next two months and the MAA in Q4.

“NicOx was present at numerous scientific and medical congresses in the first half of 2009, which gave us the opportunity to share naproxcinod’s clinical results with leading experts in the fields of rheumatology and cardiology,” added Pascal Pfister, Chief Scientific Officer and Head of Research and Development at NicOx. “These interactions, as well as those with potential partners, have reinforced our confidence in the clinical merits of naproxcinod. We are currently concentrating our time and efforts on finalizing the NDA submission in the United States. Given the importance of this filing, we are taking the time required to ensure we deliver a dossier of the highest quality.”

During the first half of 2009, NicOx presented important clinical data for naproxcinod to the scientific and medical community:

- Pr. William White MD, from the University of Connecticut School of Medicine, gave two presentations on the blood pressure results from the 301 study at major cardiology congresses: the American College of Cardiology (ACC) Annual Meeting in Orlando in March and the American Society of Hypertension (ASH) Annual Scientific Meeting in San Francisco in May.
- Detailed blood pressure results from the 111 Ambulatory Blood Pressure Monitoring (ABPM) study were presented by Pr. Raymond Townsend, from the University of Pennsylvania, at the European Meeting on Hypertension (annual meeting of the European Society of Hypertension – ESH) in Milan in June and at the American Society of Hypertension (ASH) Annual Scientific Meeting in San Francisco in May.
- Quality of life and utility data were presented at the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) Annual International Meeting in Orlando in May and at the European League Against Rheumatism (EULAR) Congress in Copenhagen in June.
- A publication was also issued in the *Journal of Rheumatology* (J. Karlsson *et al.*) on additional results from the phase 2 ZEST study with naproxcinod and the COX-2 inhibitor rofecoxib.

Acquisition of Nitromed’s NO-donating patents

The purchase of Nitromed’s unlicensed patent estate, which was announced in late April, has consolidated NicOx’ leading position in the field of NO donation. Under the terms of the agreement, NicOx has paid Nitromed €2.0 million at signature and will pay a further €4.0 million upon NicOx fulfilling certain future business criteria. This acquisition gives NicOx by far the strongest intellectual property position on the NO-donating technology worldwide, including a large number of new patents with potential uses in NicOx’ core areas of inflammatory and cardiometabolic disorders.

Initiation of clinical development for NCX 6560

NicOx announced in March 2009 the initiation of clinical development for NCX 6560, a novel NO-donating compound which could represent a global therapeutic approach for reduction of cardiovascular risk. The first-in-man study is enrolling both healthy and hypercholesterolemic male volunteers and is comparing NCX 6560 to placebo and atorvastatin (Lipitor®), with a preliminary evaluation of activity, safety and tolerability. Top-line results for this study are expected in the fourth quarter of 2009.

Through the sustained release of NO, NCX 6560 has the potential to inhibit multiple steps in the development of atherosclerosis and could therefore be developed in cardiovascular indications which go beyond lipid lowering. In the first quarter, NCX 6560 was identified as one of the five most promising drugs entering phase 1 clinical trials by the Thomson Reuters ‘The Ones to Watch’ Pharma Matters Report, which is based on the strategic data and insight of Thomson Pharma®.

Ongoing collaboration with Merck & Co., Inc. to develop novel nitric oxide-donating antihypertensive agents

Merck is in the process of evaluating a number of nitric oxide-donating antihypertensive agents in a series of clinical studies in mild to moderate hypertensive volunteers. Merck plans to complete this program prior to the potential selection of a compound to be advanced into phase 2. These compounds are covered by Merck's March 2006 exclusive worldwide agreement with NicOx.

Clinical and scientific communications on PF-03187207 for glaucoma co-presented at ARVO with Pfizer Inc

In May, preclinical and clinical results for PF-03187207 were co-presented by NicOx and Pfizer at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, a major ophthalmology meeting. PF-03187207 is an NO-donating prostaglandin F2-alpha analog, which completed two phase 2 studies in the United States and Japan during 2008, in patients with primary open angle glaucoma and ocular hypertension. Pfizer is currently in active discussions with NicOx regarding the worldwide rights to this compound.

Consolidated financial results as of June 30, 2009 and 2008

Revenues

NicOx' revenues amounted to €1.1 million for the first six months ended June 30, 2009, compared to €2.2 million for the six months ended June 30, 2008.

During the first semester of 2009, NicOx only 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' 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' involvement in the research program provided for under the terms of the agreement with Pfizer.

Operating expenses

For the six months ended June 30, 2009, operating expenses totaled €32.7 million, compared to €40.6 million for the six months ended June 30, 2008, of which 77% was attributable to research and development expenses and 23% attributable to selling and administrative expenses in the first semester of 2009, compared to 86% and 14% respectively in the first semester of 2008.

Research and development expenses amounted to €25.1 million during the first semester of 2009, compared to €34.8 million during the first semester of 2008 (including €0.1 million allocated to cost of sales in 2009 and €0.5 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 €15.4 million during the first semester of 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 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 93 people in research and development on June 30, 2009, compared to 94 people on the same date in 2008.

Administrative and selling expenses amounted to €7.6 million during the six months ended June 30, 2009, compared to €5.8 million during the same period in 2008. General and administrative expenses were €3.2 million in the first semester of 2009 compared to €3.6 million in the first semester 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 expenses reached €4.4 million in the six months ended June 30, 2009, compared to €2.2 million during the same period in 2008, which 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 preparations for naproxcinod. The

NicOx S.A.,

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Company employed 39 people in its selling, general and administrative departments on June 30, 2009, compared to 35 people on June 30, 2008.

Other income

Other income was €3.1 million in the six months ended June 30, 2009, compared to €2.4 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 amounted to €28.5 million during the first semester of 2009, compared to €36.0 million in the first semester of 2008. This decrease in the operating loss results from the decrease in the development expenses incurred by the Company during the first six months of 2009, following the completion of the phase 3 clinical development of naproxcinod at the end of 2008.

Other results

Net financial income was €1.3 million during the first semester of 2009, compared to €3.0 million during the six months ended June 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 semester of 2009 relates to its subsidiaries and amounted to €0.1 million, compared to €0.1 million during the same period in 2008.

Total comprehensive loss for the period

The total comprehensive loss totaled €27.2 million for the six months ended June 30, 2009, compared to €33.1 million for the six months ended June 30, 2008. Notwithstanding the increase of selling expenses, the decrease in the total comprehensive loss in the first semester 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 June 30, 2009, the Company's current liabilities were €16.0 million, including €12.7 million in accounts payable to suppliers and external collaborators, €1.8 million in accrued compensation for employees, €1.3 million in taxes payable and €0.2 million for other liabilities.

Other current assets totaled €8.1 million on June 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. 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 €76.8 million on June 30, 2009, compared to €104.7 million on December 31, 2008 and to €141.6 million as of June 30, 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 for naproxcinod in 2008. NicOx has the strategic objective of transforming itself into a self-sustainable biopharmaceutical company. Commercial expenses are expected 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.

Notwithstanding the increase of commercial expenses, the Company's consumption of financial instruments and cash and cash equivalents will decrease significantly in 2009 due to the reduction of development expenses, following the completion of the phase 3 clinical program for naproxcinod in 2008. Based on current budgetary estimates, NicOx anticipates having sufficient cash to finance the activities of the Company until the end of 2010. This projection includes the continuation of ongoing activities linked to the potential commercial launch preparations for naproxcinod. NicOx is currently assessing various strategic options to optimize the production and the planned commercial launch of naproxcinod. For example, the above cash burn projection does not include any possible upfront and milestone payments which could arise from a potential commercialization agreement for naproxcinod. Certain other scenarios would require more investments and would generate a higher cash burn. Therefore, these cash flow projections could alter due to strategic options which could be chosen and potential opportunities which may arise before the end of the second semester of 2009.

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 naproxinod, a proprietary NCE and the first-in-class Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent for the relief of signs and symptoms of osteoarthritis. Naproxinod has completed three pivotal phase 3 studies with positive results and regulatory submissions are projected for Q3 2009 for a New Drug Application (NDA) to the US Food and Drug Administration (FDA) and Q4 for a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

Beyond naproxinod, 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 conditions.

NicOx S.A. is headquartered in France and is listed on the NYSE Euronext Paris (Compartment B: Mid Caps).

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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 – JUNE 30, 2009

	For the period ended June 30,	
	2009	2008
	Restated*	
	(in thousands of € except for per share data)	
Revenues.....	1,119	2,243
Cost of sales	(75)	(537)
Research and development expenses.....	(25,031)	(34,298)
Administrative and selling expenses.....	(7,637)	(5,780)
Other income.....	3,130	2,376
Operating result	(28,494)	(35,996)
Net financial income.....	1,334	3,025
Result before income tax	(27,160)	(32,971)
Income tax expense.....	(77)	(129)
Result for the period.....	(27,237)	(33,100)
Exchange differences on translation of foreign operations.....	(1)	4
Other comprehensive income (loss) for the period, net of tax.	(1)	4
Total comprehensive income (loss) for the period, net of tax..	(27,238)	(33,096)
Attributable to:		
- Equity holders of the Company	(27,238)	(33,096)
- minority interests	-	-
Earnings per share for the period for profit attributable to equity holders of the Company.....	(0.57)	(0.70)
Diluted for the period.....	(0.57)	(0.70)

* Commentary

IAS 1 R Presentation of Financial Statements

The interim 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 30 June 2009, the exchange difference on translation of foreign operations is the only component of consolidated comprehensive income or (loss).

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 30, 2009

	June 30, 2009	December 31, 2008
	(in thousands of €)	
ASSETS		
Non current assets		
Property, plant, & equipment.....	3,101	3,429
Intangible assets	781	835
Non-current financial instruments.....	-	4,858
Government subsidies receivable	1,996	-
Other financial assets	201	201
Deferred income tax assets	20	21
Total non-current assets	6,099	9,344
Current assets		
Financial assets	842	396
Trade receivables	-	6
Government subsidies receivable	1,205	9,004
Other current assets	8,146	3,310
Prepaid expenses.....	1,488	1,716
Current financial instruments	-	9,912
Cash and cash equivalents	76,846	89,931
Total current assets	88,527	114,275
TOTAL ASSETS	94,626	123,619
EQUITY AND LIABILITIES		
Capital and Reserves attributable to equity holders of the Company		
Ordinary shares.....	9,578	9,498
Other reserves	68,611	92,571
Minority interests	-	-
Total Equity	78,189	102,069
Non-current liabilities		
Provisions for other liabilities and charges	268	175
Deferred income tax liabilities	127	127
Finance lease	9	13
Total non-current liabilities	404	315
Current liabilities		
Finance lease	7	6
Trade payables	12,740	16,232
Deferred revenue	-	1,119
Current income tax payable	-	-
Social security and other taxes	3,131	3,568
Other liabilities	155	310
Total current liabilities	16,033	21,235
TOTAL EQUITY AND LIABILITIES	94,626	123,619