



NicOx reports first quarter 2008 financial results

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NicOx S.A. (Eurolist: COX) today reported financial results for the first three months of 2008. On March 31, 2008, the Company had cash, cash equivalents and financial instruments of €153.7 million, compared to €201.2 million on March 31, 2007.

Revenues were €1.4 million in the first quarter of 2008, compared to €8.7 million for the corresponding period of 2007. The higher revenues achieved in Q1 2007 were principally due to two milestone payments from Merck & Co., Inc. and Pfizer Inc which were fully recognized during that period.

Operating expenses were €17.5 million in the first quarter of 2008, compared to €10.1 million in the first quarter of 2007. This increase in operating expenses was mainly due to the ongoing phase 3 clinical studies for naproxinod, NicOx' lead investigational drug and the first compound in the CINOD class, for the treatment of the signs and symptoms of osteoarthritis.

In the first quarter of 2008, NicOx recorded a net loss of €13 million. This compares to a net profit of €1.8 million for the first quarter of 2007.

Key operational highlights - first quarter 2008

- NicOx initiated two large Ambulatory Blood Pressure Monitoring (ABPM) studies for naproxinod in hypertensive patients with osteoarthritis. These two large clinical pharmacology studies in the United States will assess the blood pressure profile of naproxinod in comparison to ibuprofen and naproxen, using the Ambulatory Blood Pressure Monitoring (ABPM) technique. These two trials are 12 and 16 weeks in duration and together are expected to recruit around 420 osteoarthritis patients with controlled hypertension. Results of both studies are projected in the forth quarter of 2008
- Pfizer Inc signed an extension of its March 2006 ophthalmology research agreement with NicOx. This agreement grants Pfizer the exclusive right to apply NicOx' proprietary nitric oxide-donating technology to drug discovery research across the field of ophthalmology. The most advanced project under this agreement is focused on nitric oxide-donating prostaglandin analogs for the treatment of glaucoma and has produced encouraging results for various compounds in a validated *in vivo* model of abnormally high intraocular pressure (IOP), compared to a commonly used reference drug
- The Company continued to take the necessary steps to ensure the successful commercialization of naproxinod and signed an agreement for the commercial manufacture of naproxinod drug substance with the fine chemical company Archimica. The aim of this agreement is to ensure that commercial supplies of an appropriate scale will be available to ensure the successful launch of naproxinod
- In January, NicOx announced that Pfizer initiated phase 2 clinical development for PF-03187207 in Japan. PF-03187207 is an investigational nitric oxide-donating prostaglandin analog for the treatment of glaucoma. This dose ranging phase 2 study will recruit 120 patients and is expected to report results in the third quarter of 2008
- In May, following the end of the first quarter, NicOx announced the results of a U.S. phase 2 trial for PF-03187207. This dose ranging study conducted by Pfizer Inc, compared the safety and efficacy of PF-03187207 to Xalatan® (latanoprost) in patients with primary open-angle glaucoma and ocular hypertension. On the primary endpoint, PF-03187207 showed a 12% improvement over Xalatan® 0.005%, which did not reach statistical significance, although a statistically significant advantage over Xalatan® 0.005% was observed on a number of secondary endpoints ($p < 0.05$). Based on these results, Pfizer has taken the decision not to launch a global phase 3 development program for PF-03187207, although Pfizer has indicated that it would consider continuing the development of PF-03187207 for potential registration in Asia, including Japan, depending on the results of the ongoing Japanese phase 2 study
- In May, NicOx announced that Merck & Co., Inc. initiated the first in a series of planned clinical studies, in mild to moderate hypertensive patients, under the companies' collaborative agreement to develop new nitric oxide-donating antihypertensive agents using NicOx' proprietary technology. Three drug candidates have now been selected from the companies' joint research program, of which two have completed initial dose ranging studies in healthy volunteers, under the exploratory clinical study paradigm, with encouraging results.

Eric Castaldi, Chief Financial Officer of NicOx, declared: *"In the first quarter of 2008, we have continued to focus our efforts on completing the clinical development of naproxcinod and taking the initial steps necessary for the product's planned commercialization. An important part of our clinical development strategy is to confirm that naproxcinod has no detrimental impact on blood pressure in patients with osteoarthritis and the two new ABPM studies are designed to further highlight this key potential differentiating factor. Going forward we will be seeking partnership agreements for naproxcinod and we aim to retain certain commercialization rights in the US and selected EU markets, in order to fully exploit the drug's commercial and strategic value and to aid NicOx' planned transition to a fully integrated pharmaceutical business.*

As anticipated, we have seen our operating expenses increase significantly during the first three months of 2008 as we continue to invest in the clinical development and launch preparations for naproxcinod. We have finished the first quarter of 2008 with a cash balance of over €150 million, providing us with the resources needed to take naproxcinod through to regulatory filing."

Review of the consolidated financial results for the three months ended March 31, 2008 and 2007:

Revenues

For the three months ended March 31, 2008, NicOx' revenues reached €1.4 million, compared to €8.7 million for the three months ended March 31, 2007. This significant decrease is explained by the fact that the company received €5.0 million from Merck and €1.0 million from Pfizer in 2007, which was entirely recognized as revenues in the first quarter of 2007.

In the first quarter of 2008, NicOx only recognized the following sums, initially recorded as prepaid income, in revenues:

- €0.09 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 an exclusive worldwide license to develop and commercialize new drug candidates using NicOx' proprietary technology in the field of ophthalmology
- €0.75 million corresponding to the funding of the research collaboration, pursuant to the above referenced agreement signed with Pfizer in March 2006.
- €0.56 million corresponding to 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

The initial March 2006 payments from Pfizer and Merck, listed above, 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. The payments received from Pfizer for the funding of the research activities are deferred over a period of 12 months from the date of invoice.

Operating expenses

Consolidated operating expenses were €17.5 million for the three months ended March 31, 2008, compared to €10.1 million for the three months ended March 31, 2007 (adjusted to reflect the reclassification of the research tax credit subsidies into other income as indicated below), of which 87% was attributable to research and development expenses and 13 % to selling and administrative expenses in the first quarter of 2008, compared to 79% and 21% respectively in the first quarter of 2007.

Research and development expenses reached €15.1 million during the first quarter of 2008, compared to €8 million during the same period in 2007 (including €0.5 million allocated to cost of sales in 2008 and €0.6 million in 2007). These expenses are primarily due to the costs associated with the phase 3 development of naproxcinod, such as expenses related to contract research organizations and suppliers involved in naproxcinod's clinical development and manufacturing activities. At this time, the cost of sales principally corresponds to the expenses incurred by NicOx in performing research activities under the contracts signed with Pfizer and Merck. On March 31, 2008, the Company employed 92 people in research and development, compared to 72 people on March 31, 2007.

Administrative and selling expenses totaled €2.3 million in the first quarter of 2008, compared to €2.1 million in the first quarter of 2007. General and administrative expenses were €1.5 million during the three months ended March 31, 2008 and were primarily the result of personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers, including stock option, bonus share and warrant attributions. These expenses also included structural costs such as leases, property service charges and maintenance costs (excluding structural costs related to research and development activities), legal and accounting fees and other external administrative costs. Selling expenses reached €0.8 million during the three months ended March 31, 2008 and correspond to the market analysis activities for naproxcinod, as well as the business development and communication activities of the Company. On March 31, 2008, the Company employed 35 people in its selling, general, and administrative departments, compared to 28 people on March 31, 2007.

Other income

In the three months ended March 31, 2008, other income amounted to €1.6 million, compared to €1.9 million in the same period of 2007. Other income corresponds to the operational subsidies from the research tax credits which were previously deducted from research and development expenses until December 31, 2007.

Operating result

The operating loss amounted to €14.5 million during the first quarter of 2008, compared to an operating profit of €0.5 million in the first quarter of 2007. This situation is explained primarily by the strong increase in operating expenses during the first quarter of 2008 and by the considerable decrease in revenues recognized during the period as indicated above.

Other results

Net financial income amounted to €1.6 million during the first quarter of 2008, compared to €1.4 million during the three months ended March 31, 2007.

The income tax expense incurred by NicOx during the first quarter of 2008 relates principally to its Italian subsidiary and amounts to €0.1 million, compared to €0.1 million during the same period of 2007.

Net result

The net loss reached €13 million during the first quarter of 2008, compared to a net profit of €1.8 million in the three months ended March 31, 2007. As indicated above, this situation results from the strong increase in operating expenses during the first quarter of 2008 and from the considerable decrease in the revenues recognized during this period.

Balance sheet items

The indebtedness incurred by NicOx is mainly short-term operating debt. On March 31, 2008, the Company's current liabilities amounted to €15.9 million, including €9.9 million in accounts payable to suppliers and external collaborators, €3.1 million in deferred revenues due to payments received under collaboration agreements, €1.6 million in taxes payable, €1.1 million in accrued compensation for employees, €0.1 million in corporate taxes payable and €0.1 million for other liabilities.

In the first quarter of 2008, NicOx granted Archimica a loan totaling €6 million, payable in 9 monthly installments, as part of the financial terms of the manufacturing and supply agreement with this company. On March 31, 2008, the amount paid by NicOx under this agreement was €2.6 million.

On March 31, 2008, the Company's current and non-current financial instruments and cash and cash equivalents amounted to €153.7 million, compared to €201.2 million on March 31, 2007. The Company uses its liquid assets principally to cover research and development expenses, expenses relating to the development of relationships with pharmaceutical companies, with a view to encouraging new partnerships, and corporate expenses related to general and administrative and promotional activities. NicOx expects its operating expenses to continue to increase very strongly over the coming financial years, as a result of the anticipated expenses related to the clinical development and the launch preparation activities for its drug candidate naproxinod, currently in phase 3 clinical development.

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) 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 of naproxinod, a proprietary NCE and the first compound in the COX-Inhibiting Nitric Oxide-Donating (CINOD) class of anti-inflammatory agents, which is in phase 3 clinical studies for the treatment of the signs and symptoms of osteoarthritis, with final phase 3 results anticipated in 2008.

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, glaucoma and Chronic Obstructive Pulmonary Disease (COPD).

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

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NicOx SA – IFRS FINANCIAL CONSOLIDATED STATEMENTS
CONSOLIDATED STATEMENT OF OPERATIONS

	For the period ended March 31	
	2008	2007
	(in thousands of €)	
Revenues	1,404	8,746
Cost of sales.....	(529)	(598)
Research and development expenses.....	(14,632)	(7,353)
Administrative and selling expenses.....	(2,312)	(2,152)
Other income.....	1,561	1,866
Operating result	(14,508)	509
Net financial income.....	1,617	1,354
Result before income tax.....	(12,891)	1,863
Income tax expense.....	(67)	(68)
Net Result.....	(12,958)	1,795

NicOx SA – IFRS FINANCIAL CONSOLIDATED STATEMENTS
CONSOLIDATED BALANCE SHEET

	For the period ended	
	March 31 2008	Dec 31 2007
	(in thousands of €)	
ASSETS		
Non-current assets		
Property, plant & equipment	3,027	2,720
Intangible assets.....	681	464
Non-current financial instruments.....	14,397	14,402
Loan	2,613	0
Government subsidies receivable.....	6,828	5,264
Other financial assets.....	184	186
Deferred income tax assets.....	10	10
Total non-current	27,740	23,046
Current assets		
Trade receivables.....	2,222	2,224
Government subsidies receivables.....	133	133
Other current assets.....	1,574	2,564
Prepaid expenses.....	2,724	3,083
Current financial instruments.....	15,066	14,967
Cash and cash equivalents.....	124,280	143,444
Total current assets.....	145,999	166,415
TOTAL ASSETS	173,739	189,461
EQUITY		
Capital and Reserves attributable to equity holders of the Company		
Ordinary shares.....	9,458	9,457
Other reserves.....	148,056	159,757
Minority interests in equity.....	0	0
Total Equity	157,514	169,214
LIABILITIES		
Non-current liabilities		
Provisions for other liabilities and charges.....	212	201
Deferred income tax liabilities.....	120	120
Finance lease.....	17	19
Total non-current	349	340
Current liabilities		
Provisions for other liabilities and charges.....	0	0
Finance lease.....	6	10
Trade payables.....	9,842	13,858
Deferred revenue	3,077	1,481
Current Income tax payable.....	114	51
Social security and other taxes	2,738	4,197
Other liabilities.....	99	310
Total current liabilities.....	15,876	19,907
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	173,739	189,461