



## NicOx reports results for the first three quarters of 2008

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**NicOx S.A.** (Euronext Paris: COX) today reported financial results for the nine months ended September 30, 2008.

### Key highlights of the third quarter of 2008:

- Positive top-line results from the 302 study for naproxcinod. The study met all three co-primary efficacy endpoints at week-13 ( $p < 0.001$ ) and naproxcinod 750 mg bid comfortably met the main secondary endpoint of non-inferiority to naproxen 500 mg bid at week-13 and 26. Blood pressure data from the 302 study also supported naproxcinod's non-detrimental effect on blood pressure.
- Good overall long term safety demonstrated for both doses of naproxcinod in the 301 extension study, with no unexpected safety findings. In addition, the patients' mean blood pressure remained stable for the 52 weeks following the completion of the 301 study, suggesting that naproxcinod does not increase blood pressure over time.
- Exclusive agreement signed with Capsugel, the leading producer of two-piece capsules, for the commercial manufacture of naproxcinod capsules. Capsugel will be responsible for the formulation and encapsulation of naproxcinod API.
- Enrollment of 417 osteoarthritis patients with controlled hypertension successfully completed in two Ambulatory Blood Pressure Monitoring (ABPM) trials, the 111 and 112 studies. These trials are designed to assess the 24-hour blood pressure profile of naproxcinod, in comparison to ibuprofen and naproxen.
- PF-03187207 demonstrated an improvement over Xalatan<sup>®</sup> 0.005% in a Japanese phase 2 study in glaucoma, although the primary endpoint at day 28 was not met. NicOx is currently discussing the rights to PF-03187207 with Pfizer to allow its potential continued development and commercialization, following Pfizer's decision not to launch a phase 3 program.

**Eric Castaldi, Chief Financial Officer at NicOx, said:** *"During the third quarter of 2008 we have achieved considerable success in the development of naproxcinod, while keeping the necessary control on expenses. We are very encouraged by the positive top-line results from the 302 phase 3 study, which comfortably met its efficacy endpoints and supported naproxcinod's non-detrimental effect on blood pressure, as well as by the good long term safety data observed in the 301 extension study.*

*We have also significantly advanced our pre-launch activities for naproxcinod, through the signature of an agreement for the manufacture of naproxcinod capsules for future commercialization, and are confident that the New Drug Application will be filed in mid 2009 as planned. We remain focused on the finalization of the clinical program for naproxcinod and look forward to the results of the 303 phase 3 study and the 111 and 112 Ambulatory Blood Pressure Monitoring studies in the coming months. As anticipated, our cash balance at the end of the third quarter is €124.8 million, which will enable us to fully finance the remaining clinical trials for naproxcinod and continue to advance the development of the other compounds in our portfolio."*

### Financial summary of the first nine months of 2008:

Revenues were €2.9 million for the nine months ended September 30, 2008, compared to €18.4 million during the same period in 2007. These revenues were due to the allocation of payments received from Pfizer Inc and Merck & Co., Inc. following the agreements signed with the two companies in the fields of ophthalmology and hypertension, respectively.

For the first nine months of 2008, operating expenses were €60.4 million, compared to €39.0 million for the corresponding period of 2007. As expected, the majority of these expenses were due to research and development costs related to naproxcinod, NicOx' lead investigational drug which is in late phase 3 studies for the treatment of the signs and symptoms of osteoarthritis.

For the nine months ended September 30, 2008, the net loss amounted to €49.7 million compared to €13.7 million for the first nine months of 2007. On September 30, 2008, the Company's current and non-current financial instruments and cash and cash equivalents were €124.8 million, compared to €172.8 million on December 31, 2007.

## **Review of the consolidated financial results for the nine months ended September 30, 2008 and 2007:**

### **Revenues**

NicOx' revenues totaled €2.9 million for the nine months ended September 30, 2008, compared to €18.4 million for the nine months ended September 30, 2007. This significant decrease is explained by the fact that the Company received €10.0 million from Merck and €1.0 million from Pfizer in 2007, which was entirely recognized as revenues in the first nine months of 2007.

For the first nine months of 2008, NicOx recognized the following amounts in revenues:

- €0.25 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
- €2.1 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 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. The remaining balance from the initial payment received from Merck was entirely recognized as revenues in the first semester of 2008.

### **Operating expenses**

For the nine months ended September 30, 2008, operating expenses totaled €60.4 million, compared to €39.0 million in the nine months ended September 30, 2007 (adjusted to reflect the reclassification of the research tax credit subsidies into other income as indicated below). During the first nine months of 2008, operating expenses were 86% attributable to research and development expenses and 14 % attributable to selling and administrative expenses, compared to 77% and 23% respectively during the same period in 2007.

Research and development expenses reached €52.0 million in the nine months ended September 30, 2008, compared to €30.2 million in the nine months ended September 30, 2007 (including €0.6 million allocated to cost of sales in the first nine months of 2008 and €1.6 million during the same period in 2007). This significant increase of 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. The Company anticipates that research and development expenses will remain at a high level during the fourth quarter of 2008, due to the end of phase 3 clinical studies on naproxcinod and the increase in the activities linked to the production of this compound. On September 30, 2008, the Company employed 98 people in research and development, compared to 79 people at the same date in 2007.

In the nine months ended September 30, 2008, administrative and selling expenses amounted to €8.4 million, compared to €8.8 million in the nine months ended September 30, 2007. During the first nine months of 2008, general and administrative expenses were €5.3 million compared to €5.6 million for the corresponding period of 2007 and represented mainly 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. For the first nine months of 2008, selling expenses totaled €3.1 million, compared to €3.2 million for the same period of 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 an increase in its selling expenses during the fourth quarter of 2008, due to activities linked to the commercial launch preparation for naproxcinod. On September 30, 2008, the Company employed 37 people in its selling, general, and administrative departments, compared to 32 people on September 30, 2007.

### **Other income**

During the nine months ended September 30, 2008, other income totaled €3.3 million, compared to €3.2 million on September 30, 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**

In the nine months ended September 30, 2008, the operating loss reached €54.2 million, compared to €17.4 million in the corresponding period of 2007. This situation is explained by the considerable increase in operating expenses during the first semester of 2008 and by the significant decrease in revenues recognized during the period as indicated above.

#### **Other results**

During the first nine months of 2008, net financial income totaled €4.6 million compared to €3.7 million in the corresponding period of 2007.

The income tax expense incurred by NicOx during the first nine months of 2008 relates to its subsidiaries and amounted to €0.2 million, compared to €0.03 million during the same period of 2007.

#### **Net result**

For the nine months ended September 30, 2008, the net loss amounted to €49.7 million compared to €13.7 million for the nine months ended September 30, 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 during this period.

#### **Balance sheet items**

The indebtedness incurred by NicOx is mainly short-term operating debt. On September 30, 2008, the Company's current liabilities amounted to €23.2 million, including €18.1 million in accounts payable to suppliers and external collaborators, €1.8 million in accrued compensation for employees, €1.6 million in deferred revenues due to payments received under collaboration agreements, €1.3 million in corporate taxes payable, €0.3 million for other liabilities and €0.1 million in current income tax payable.

In the first nine months of 2008, NicOx granted Archimica a loan amounting to €6.0 million, fully paid on September 30, 2008, as part of the financial terms of the manufacturing and supply agreement with this company.

On September 30, 2008, the Company's current and non-current financial instruments and cash and cash equivalents were €124.8 million, compared to €172.8 million on December 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 naproxcinod, which is currently in phase 3 clinical development.

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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 of naproxcinod, a proprietary NCE and the first compound in the Cyclooxygenase-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 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 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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*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

	Period of 9 months ended on	
	September 30, 2008	September 30, 2007
	(in thousands of € except for per share data)	
Revenues .....	2,943	18,398
Cost of goods and services sold .....	(620)	(1,647)
Research and development expenses.....	(51,348)	(28,501)
Administrative and selling expenses.....	(8,434)	(8,811)
Other products .....	3,267	3,180
<b>Operating loss .....</b>	<b>(54,192)</b>	<b>(17,381)</b>
Net financial income.....	4,649	3,703
<b>Loss before income tax .....</b>	<b>(49,543)</b>	<b>(13,678)</b>
Income tax expense.....	(198)	(27)
<b>Loss for the period.....</b>	<b>(49,741)</b>	<b>(13,705)</b>
Attributable to:		
- Equity holders of the Company .....	(49,741)	(13,705)
- minority interests .....	-	-
<b>Earnings per share for profit attributable to equity holders of the Company.....</b>	<b>(1.05)</b>	<b>(0.30)</b>
<b>Diluted .....</b>	<b>(1.05)</b>	<b>(0.30)</b>

## CONSOLIDATED BALANCE SHEET

	September 30, 2008	December 31, 2007
	(in thousands of €)	
<b>ASSETS</b>		
<b>Non current assets</b>		
Property plant & equipment .....	3,517	2,720
Intangible assets.....	788	464
Non-current financial instruments.....	4,692	14,402
Government subsidies receivable.....	8,477	5,264
Other financial assets .....	6,337	186
Deferred income tax assets .....	10	10
<b>Total non-current assets .....</b>	<b>23,821</b>	<b>23,046</b>
<b>Current assets</b>		
Trade receivables .....	2	2,224
Government subsidies receivable.....	-	133
Other current assets .....	1,648	2,564
Prepaid expenses .....	3,412	3,083
Current financial instruments .....	14,763	14,967
Cash and cash equivalents .....	105,345	143,444
<b>Total current assets .....</b>	<b>125,169</b>	<b>166,415</b>
<b>TOTAL ASSETS</b>	<b>148,991</b>	<b>189,461</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and Reserves attributable to equity holders of the Company.....</b>		
Share Capital .....	9,488	9,457
Other reserves .....	115,259	159,757
Minority interests .....	-	-
<b>Total Equity .....</b>	<b>124,747</b>	<b>169,214</b>
<b>Non-current liabilities</b>		
Provisions for other liabilities and charges .....	904	201
Deferred income tax liabilities .....	120	120
Finance lease .....	14	19
Other loans and non-current liabilities .....	1	-
<b>Total non-current liabilities.....</b>	<b>1,039</b>	<b>340</b>
<b>Current liabilities</b>		
Provisions for other liabilities and charges .....	-	-
Finance lease .....	6	10
Trade payables.....	18,124	13,858
Deferred revenue .....	1,539	1,481
Current income tax liabilities .....	128	51
Social security and other taxes.....	3,107	4,197
Other liabilities .....	300	310
<b>Total current liabilities.....</b>	<b>23,204</b>	<b>19,907</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>148,991</b>	<b>189,461</b>