



NicOx 2009 Financial Results

March 4, 2010. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (NYSE Euronext Paris: COX) today announced its financial results for full year 2009 and provided an overview of its activities, in particular those related to its lead compound naproxcinod, which is currently under review by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Michele Garufi, Chief Executive Officer of NicOx, commented: *"We are very pleased that we met our planned goal of submitting the marketing authorization applications for naproxcinod in the United States and in Europe in 2009 and that we have received the acceptance of both applications by the relevant health authorities. This is a very important step in the implementation of our strategy to grow NicOx into a specialty pharmaceutical company, which we began in 2008 through a targeted investment in our US based Commercial Affairs department. We have also had a very good start to 2010 with the recent signature of a major licensing agreement with Bausch + Lomb, confirming the potential of our innovative nitric oxide-donating R&D platform in the attractive field of ophthalmology."*

Key highlights 2009

- Significantly reinforced balance sheet with €148.3 million in cash and cash equivalents as of December 31st, 2009 following the successful completion of a two-step capital increase, raising total net proceeds of €94.6 million. The French Fonds Stratégique d'Investissement (FSI) was an important investor in this capital increase.
- Successful regulatory submissions of the naproxcinod New Drug Application (NDA) and Marketing Authorization Application (MAA) in the United States and in Europe, and acceptance for filing of the NDA by the FDA. These filings have been supported by data from a comprehensive development program of 35 clinical trials involving more than 6,500 patients.
- Improved production capacity for naproxcinod active pharmaceutical ingredient, through an additional agreement in late 2009 to invest in the dedicated manufacturing facilities of the leading supplier DSM, with which NicOx signed an initial agreement in 2008.
- Naproxcinod clinical results presented in key scientific and medical conferences as well as in peer-reviewed scientific journals.
- Positive results from the first-in-man clinical study with NCX 6560, an innovative nitric oxide (NO)-donating HMG-CoA Reductase Inhibitor. NCX 6560 has the potential to be developed as a new treatment to further reduce the risk of major adverse cardiac events (MACEs) in Coronary Heart Disease (CHD) patients.
- Acquisition of Nitromed's unlicensed patent estate covering novel NO-donating compounds.

Key highlights post-2009

- Signature of a licensing agreement with the leading eye health company Bausch + Lomb, granting it exclusive worldwide rights to develop and commercialize NCX 116, a NO-donating prostaglandin F2-alpha analog for the potential treatment of glaucoma and ocular hypertension (see NicOx press release of March 3, 2010).
- Validation of the naproxcinod MAA by the European health authorities in January 2010.

Eric Castaldi, Chief Financial Officer of NicOx, commented: *"In 2009, our total operating expenses decreased by €20.0 million, as a consequence of the completion of the pivotal phase 3 clinical development program of naproxcinod in 2008. Moreover, our investments have gradually shifted towards our Commercial Affairs team in the United States, the first country where naproxcinod is expected to be launched. Our successful financing has enabled NicOx to enter 2010 with a strong balance sheet, and we will continue this year to prepare for the future expected commercialization of naproxcinod, which includes optimizing the supply chain and preparing the establishment of our future expected first sales and marketing operations in the US."*

Financial summary of 2009

Revenues in 2009 were €1.1 million, compared to €3.4 million in 2008. The revenues in 2009 were due to NicOx's collaboration with Pfizer Inc in the field of ophthalmology, which was ended through a new agreement in August 2009, in which NicOx reacquired the full development and commercialization rights to NCX 116 (see NicOx press release of August 6, 2009).

Operating expenses totaled €66.7 million in 2009, lower than the €86.4 million spent in 2008. The majority of these costs were associated with research and development, including expenses related to the two regulatory submissions for naproxcinod.

As a consequence of the lower R&D expense following completion of naproxcinod phase 3 development, NicOx's net loss was €60.4 million for the full year 2009, compared to €73.9 million in 2008.

NicOx's balance sheet has been significantly reinforced in 2009, as the Company finished the year with cash and cash equivalents of €148.3 million. This compares with €104.7 million on December 31, 2008. This increase in cash was due to the successful completion of a two-step capital increase raising total net proceeds of €94.6 million toward the end of 2009. These proceeds will be mainly used to support the Company's efforts to prepare for the commercialization of naproxcinod.

Improved production capacity for naproxcinod

The activities planned by NicOx include the creation of dedicated commercial operations in the United States and the optimization of the supply chain for naproxcinod. The supply chain was originally put in place in 2008 with the signature of two agreements with DSM, one of the world's leading independent suppliers to the pharmaceutical industry, and Capsugel, the leading producer of two-piece capsules, for the commercial manufacture of naproxcinod active pharmaceutical ingredient (API) and capsules, respectively. In late 2009, NicOx has agreed to invest in DSM's infrastructure in order to increase the production capacity and flexibility. NicOx intends to continue investing in the naproxcinod supply chain in order to secure commercial supplies of an appropriate scale to support its successful launch.

Regulatory submissions for naproxcinod in the United States and in Europe

As planned, in 2009, NicOx has submitted regulatory dossiers for naproxcinod both in the United States and in Europe. A New Drug Application (NDA) was submitted to the US Food and Drug Administration (FDA) in September 2009 and accepted for filing in November 2009. NicOx is seeking approval for the relief of the signs and symptoms of osteoarthritis. Based on the Prescription Drug User Fee Act (PDUFA), the FDA will complete its review 10 months after submission and has set an action date of July 24, 2010.

A Marketing Authorization Application (MAA) was also submitted for naproxcinod to the European Medicines Agency (EMA) in December 2009. It was validated by the EMA in January 2010.

Naproxcinod clinical data continued to generate interest within the scientific community

In 2009, key naproxcinod data were presented at the following congresses:

- the American College of Cardiology (ACC) Annual Meeting,
- the American Society of Hypertension (ASH) Annual Scientific Meeting,
- the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) Annual International Meeting,
- the European League Against Rheumatism (EULAR) Congress,
- the European Meeting on Hypertension (annual meeting of the European Society of Hypertension, ESH),
- the World Congress on Osteoarthritis (annual congress of the Osteoarthritis Research Society International – OARSI)
- the American College of Rheumatology (ACR) and Association of Rheumatology Health Professionals (ARHP) Annual Scientific Meeting.

Moreover, an important scientific paper describing blood pressure results from the first phase 3 clinical trial for naproxcinod was accepted and published in the *American Journal of Cardiology*¹ in 2009.

Successful first-in-man study completed for NCX 6560

In November 2009, NicOx successfully completed a phase 1b clinical trial for NCX 6560, an innovative nitric oxide (NO)-donating HMG-CoA Reductase Inhibitor. NCX 6560 has the potential to be developed as a new treatment to further reduce the risk of major adverse cardiac events (MACEs) in Coronary Heart Disease (CHD) patients.

¹ White WB, Schnitzer T, Fleming R, Duquesroix B, Beekman M. Effects of the Cyclooxygenase Inhibiting Nitric Oxide Donator Naproxcinod Versus Naproxen on Systemic Blood Pressure in Patients with Osteoarthritis, *American Journal of Cardiology*, 2009, 104(6), 840-845.

This first-in-man study, versus placebo and Lipitor® (atorvastatin), met its primary and secondary objectives, with top-line results demonstrating very good safety and tolerability for all the tested doses of NCX 6560. The preliminary evaluation of the cholesterol-lowering effect in subjects with high LDL-cholesterol at baseline, the most important exploratory objective, showed strong activity for NCX 6560 with a dose-related LDL-cholesterol decrease. The highest dose tested achieved an approximate 60% reduction in LDL-cholesterol after only two weeks of treatment.

In light of these positive phase 1b results, NicOx is currently evaluating opportunities for the next steps of NCX 6560's clinical development.

Acquisition of Nitromed's NO-donating patents

In late April 2009, NicOx purchased Nitromed's unlicensed patent estate. 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 NO-donating technology worldwide, including a large number of new patents with potential uses in NicOx's core areas of inflammatory, cardiometabolic and ophthalmological disorders.

Worldwide licensing agreement with Bausch + Lomb announced in March 2010 for NCX 116. Phase 2 results presented at ARVO, a major ophthalmology meeting in 2009.

In March 2010, NicOx announced a licensing agreement with the leading eye health company Bausch + Lomb, granting it exclusive worldwide rights to develop and commercialize NCX 116 (see NicOx press release of March 3, 2010).

NCX 116 is a 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. In May 2009, preclinical and clinical results for NCX 116 were presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, a major ophthalmology meeting.

In August 2009, NicOx reacquired the full development and commercialization rights to NCX 116 from Pfizer (including the right to sublicense), as well as the entire current data-package and development information (see NicOx press release of August 6, 2009).

Consolidated financial results as of December 31, 2009 and 2008:

The 2009 consolidated financial statements, approved by the Board of Directors on March 4, 2010, have been certified by the statutory auditors.

Revenues

NicOx's revenues totaled €1.1 million in 2009, compared to €3.4 million in 2008. No revenues have been recorded in the last quarter of 2009.

In 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

In 2009, operating expenses amounted to €66.7 million, compared to €86.4 million in 2008. Of the 2009 figure, 78% was attributable to research and development expenses and 22% attributable to selling and administrative expenses, this compares with 87% and 13% respectively in 2008.

Research and development expenses totaled €51.7 million in 2009, compared to €75.0 million in 2008 (including €0.1 million allocated to cost of sales in 2009 and €0.8 million in 2008). In 2009, Research and development expenses correspond primarily to personnel expenses related to the activities performed for the preparation of the submission of a New Drug Application and a Marketing Authorization Application for naproxcinod to respectively the Food and Drug Administration and the European Medicines Agency; to expenses related to the completion of naproxcinod development;

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to expenses related to active ingredient purchases for the preparation of the commercialization of naproxcinod; and to a provision for asset impairment corresponding to the discounted acquisition value of the Nitromed patent portfolio. Excluding the impact of this provision, the research and development expenses decreased by €29.0 million in 2009, compared to 2008. This significant decrease 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 89 people in research and development on December 31, 2009, compared to 97 people at the same date in 2008.

In 2009, administrative and selling expenses totaled €15.0 million, compared to €11.4 million in 2008. General and administrative expenses were €6.4 million in 2009 compared to €6.6 million in 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. In 2009, selling and corporate development expenses reached €8.6 million, compared to €4.8 million in 2008. This increase was due to market research and analysis activities for naproxcinod, as well as the business development and communication activities of the Company. The increase in selling and corporate development expenses results principally from the activities linked to the preparation of the commercialization of naproxcinod. The Company employed 39 people in its selling, general and administrative departments on December 31, 2009, compared to 36 people on December 31, 2008.

Other income

In 2009, other income totaled €3.6 million, compared to €3.8 million 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 €62.0 million in 2009, compared to €79.2 million in 2008. This decrease in the operating loss results from the decrease in the development expenses incurred by the Company in 2009, following the completion of the phase 3 clinical development of naproxcinod at the end of 2008.

Other results

In 2009, the financial result amounted to €1.5 million, compared to €5.5 million in 2008, and represents mainly the returns on the financial investments of the Company's cash, cash equivalents.

The income tax revenue incurred by NicOx in 2009 relates to deferred tax from its US subsidiaries and totaled €0.2 million, compared to an income tax expense of €0.1 million during the same period in 2008.

Total comprehensive loss for the period

The total comprehensive loss amounted to €60.4 million in 2009, compared to €73.9 million in 2008. Notwithstanding the increase of selling expenses, the decrease in the total comprehensive loss in 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 December 31, 2009, the Company's current liabilities were €10.4 million, including €6.1 million in accounts payable to suppliers and external collaborators, €2.4 million in accrued compensation for employees, €1.5 million in taxes payable and €0.3 million for other liabilities.

On December 31, 2009, the Company's current and non-current financial instruments and cash and cash equivalents were €148.3 million, compared to €104.7 million on December 31, 2008. In late 2009, the Company completed a two step capital increase and received a total of €94.6 million corresponding to the net proceeds of the following operations: €29.4 million from a private placement of shares to institutional investors completed on November 23, 2009 and €65.2 million from a rights issue completed on December 23, 2009.

NicOx has the strategic objective of transforming itself into a specialty pharmaceutical company. As part of this strategy, NicOx will seek to enter into a partnership agreement with a pharmaceutical company for the promotion and marketing of naproxcinod to primary care physicians in the US, while retaining co-promotion rights for specialist prescribers. Expenses related to the preparation of the commercialization of naproxcinod are expected to increase in 2010. In the course of normal business, NicOx currently anticipates having sufficient cash to sustain operations beyond the projected launch of naproxcinod, even in the absence of a partnership agreement. This forecast assumes there will be no unexpected and substantial requests from the FDA and EMEA, which could potentially cause a delay in the projected launch dates.

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a pharmaceutical company focused on the research, development and future commercialization of drug candidates. NicOx is applying its proprietary nitric oxide-donating R&D platform to

develop an internal portfolio of New Molecular Entities (NME) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxcinod, a NME and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate 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 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in December 2009, following the successful completion of three pivotal phase 3 studies. The NDA for naproxcinod was accepted for filing by the FDA in November 2009 and the FDA has set a target date of July 24, 2010, for the completion of its review. The MAA was validated by the EMA in January 2010.

In addition to naproxcinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck & Co., Inc. and Bausch + Lomb, for the treatment of widespread eye diseases, cardiometabolic diseases, hypertension and dermatological disease.

NicOx S.A. is headquartered in France and is listed on 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 and its update filed with the AMF, which are 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 – DECEMBER 31, 2009

| | As of December 31, | |
|---|---|-----------------|
| | 2009 | 2008 |
| | Restated* | |
| | (in thousands of € except for per share data) | |
| Revenues..... | 1,119 | 3,362 |
| Cost of sales | (75) | (750) |
| Research and development expenses..... | (51,673) | (74,281) |
| Administrative expenses..... | (6,415) | (6,649) |
| Selling expenses..... | (8,582) | (4,709) |
| Other income..... | 3,641 | 3,814 |
| Operating loss | (61,985) | (79,213) |
| Finance income..... | 1,637 | 6,209 |
| Finance expense..... | (159) | (751) |
| Loss before income tax..... | (60,507) | (73,755) |
| Income tax expense..... | 157 | (132) |
| Net loss..... | (60,350) | (73,887) |
| Exchange differences on translation of foreign operations..... | (8) | - |
| Other comprehensive income (loss) for the period, net of tax | (8) | - |
| Total comprehensive income (loss) for the period, net of tax | (60,358) | (73,887) |
| Attributable to: | | |
| - Equity holders of the parent..... | (60,358) | (73,887) |
| - Minority interests | - | - |
| Basic and diluted loss per share attributable to equity holders of the parent..... | (1.20) | (1.56) |

* Compliant with IAS 1R

CONSOLIDATED STATEMENT OF FINANCIAL POSITION – DECEMBER 31, 2009

| | As of December 31, | |
|---|---------------------|---------|
| | 2009 | 2008 |
| | (in thousands of €) | |
| ASSETS | | |
| Non-current assets | | |
| Property, plant & equipment | 2,772 | 3,429 |
| Intangible assets | 797 | 835 |
| Financial instruments..... | - | 4,858 |
| Government subsidies receivable | 477 | - |
| Other financial assets | 238 | 201 |
| Deferred income tax assets | 156 | 21 |
| Total non-current assets..... | 4,440 | 9,344 |
| Current assets | | |
| Financial assets | - | 396 |
| Trade receivables | - | 6 |
| Government subsidies receivable | 2,597 | 9,004 |
| Other current assets | 1,329 | 3,310 |
| Prepaid expenses | 784 | 1,716 |
| Financial instruments | - | 9,912 |
| Cash and cash equivalents | 148,275 | 89,931 |
| Total current assets | 152,985 | 114,275 |
| TOTAL ASSETS | 157,425 | 123,619 |
| EQUITY AND LIABILITIES | | |
| Common shares | 14,434 | 9,498 |
| Other reserves | 128,444 | 92,571 |
| Minority interests | - | - |
| Total Equity | 142,878 | 102,069 |
| Non-current liabilities | | |
| Other contingencies and liabilities | 4,069 | 175 |
| Deferred income tax liabilities | 91 | 127 |
| Finance lease | 6 | 13 |
| Total non-current liabilities..... | 4,166 | 315 |
| Current liabilities | | |
| Finance lease | 7 | 6 |
| Trade payables..... | 6,136 | 16,232 |
| Deferred revenue | - | 1,119 |
| Current income tax payable | 19 | - |
| Social security and other taxes | 3,909 | 3,568 |
| Other liabilities..... | 310 | 310 |
| Total current liabilities..... | 10,381 | 21,235 |
| TOTAL EQUITY AND LIABILITIES | 157,425 | 123,619 |

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