



NicOx first half 2010 financial results

July 30, 2010. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (NYSE Euronext Paris: COX) today reported its financial results for the six months ended June 30, 2010 and provided a business update on its activities.

Michele Garufi, Chairman and CEO of NicOx, declared: *"This has been both an active and a challenging first half for NicOx, as we worked with regulators in the United States and Europe on the marketing applications for naproxcinod. We will collaborate closely with both regulatory authorities in the coming months. We will also focus on securing potential licensing agreements for naproxcinod in Europe and the rest of the world, ensuring the continued success of our existing partnerships and prioritizing our research programs. We will continue to manage our cash resources in the most cost-effective manner to ensure the future growth of the Company whilst also pursuing appropriate in-licensing and M&A opportunities."*

Key events of the first six months of 2010:

- NicOx and Bausch + Lomb signed a Worldwide Licensing Agreement for the glaucoma candidate NCX 116
- The European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for naproxcinod
- Joint Advisory Committee of the U.S. Food and Drug Administration (FDA) voted that they did not have sufficient evidence to support the approval of naproxcinod for the relief of the signs and symptoms of osteoarthritis
- Additional clinical data for naproxcinod and preclinical results for NCX 434 and NCX 1236, two of the Company's nitric oxide (NO)-donating New Molecular Entities, were presented at scientific and medical conferences
- NicOx and TOPIGEN Pharmaceuticals Inc. mutually terminated their collaboration for TPI 1020 as a result of the acquisition of TOPIGEN

Post reporting period:

- On July 22, 2010, NicOx announced the receipt of a Complete Response Letter from the U.S. Food and Drug Administration (FDA), stating that it could not approve the New Drug Application (NDA) for naproxcinod. NicOx plans on discussing the Complete Response Letter and potential next steps with the FDA, as early as possible.

Eric Castaldi, Chief Financial Officer of NicOx, declared: *"NicOx has a strong cash position, with no long-term debt and cash and cash equivalents totaling €128.4 million at the end of June 2010. We will continue to ensure careful conservation of our funds."*

Financial summary for the first half of 2010:

Revenues for the first half of 2010 were €7.4 million, compared to €1.1 million during the same period in 2009. These revenues correspond to the initial license payment received from Bausch + Lomb in the first quarter of the year, as per the agreement signed in March 2010.

For the first six months of 2010, operating expenses were €36.4 million, compared to €32.7 million for the same period in 2009. These expenses correspond principally to personnel costs related to the regulatory processes for naproxcinod both in the United States and in Europe, investments in naproxcinod's supply chain and costs related to the anticipated cancellation of certain manufacturing and pre-commercial activities following the decision of the FDA.

NicOx recorded a total net loss for the period of €27.5 million for the first six months of 2010, compared to a corresponding net loss of €27.2 million for the same period in 2009. On June 30, 2010, NicOx had cash and cash equivalents of €128.4 million, compared to €148.3 million on December 31, 2009.

Review of the first six months of 2010:

Signature of a Worldwide Licensing Agreement with Bausch + Lomb

In March 2010, NicOx and Bausch + Lomb signed a Worldwide Licensing Agreement granting Bausch + Lomb exclusive rights to develop and commercialize NCX 116, an NO-donating prostaglandin F2-alpha analog for the potential treatment of glaucoma and ocular hypertension. Both companies have already held an initial meeting to agree on the next steps for the development of NCX 116. Under the terms of this agreement, NicOx received an initial license payment of \$10 million and stands to receive potential milestones totaling \$169.5 million, as well as tiered double-digit royalties on the sales of NCX 116.

Regulatory status of naproxcinod in the United States

A Joint Advisory Committee of the FDA, including the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, voted by 16 to 1 with 1 abstention on May 12, 2010 that they did not have sufficient evidence at that time to support the approval of naproxcinod for the relief of the signs and symptoms of osteoarthritis.

On July 22, 2010, NicOx announced the receipt of a Complete Response Letter from the U.S. Food and Drug Administration (FDA) related to the New Drug Application (NDA) for naproxcinod. The FDA informed NicOx that its review of the NDA was complete and that it did not approve the naproxcinod application. The FDA recommended conducting one or more long-term controlled studies to assess the cardiovascular and gastrointestinal safety of naproxcinod. Additional studies to demonstrate a clinically meaningful therapeutic benefit attributable to the nitric oxide donation were also recommended. No clinical efficacy studies were requested. NicOx plans to discuss the Complete Response Letter and potential next steps as early as possible with the FDA.

Regulatory status of naproxcinod in Europe

In January 2010, the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for naproxcinod, which was submitted through the centralized procedure in December 2009. NicOx is seeking approval for an indication for the relief of the signs and symptoms of primary osteoarthritis. The Medicinal Products for Human Use (CHMP) opinion is expected by mid-2011, the exact timing depending on the interactions needed with the health authorities in the last phase of the review process.

Presentation of scientific results for naproxcinod

Detailed results from the 301 study were published in the May issue of *Osteoarthritis and Cartilage*. Additional clinical data for naproxcinod were presented in May at the *American Society of Hypertension Annual Scientific Meeting and Exposition* in New York and in June at the *European Meeting on Hypertension* in Oslo and the *Annual European Congress of Rheumatology* in Rome.

Presentation of promising preclinical results in international conferences

Preclinical results obtained with two of NicOx's NO-donating New Molecular Entities (NMEs) were presented in congresses in the first half of 2010. In May, preclinical findings obtained with NCX 1236, a lead compound for the potential treatment of Neuropathic Pain, were presented at the International Congress on *Neuropathic Pain* in Athens. Preclinical results for NCX 434, a potential preclinical candidate in Diabetic Macular Edema (DME), were presented in May at the *Ocular Diseases & Drug Discovery conference* in Boston and in June at the *Retina International World Congress* in Stresa.

Review of the consolidated financial results for the six months ended June 30, 2010 and 2009:

Revenues

NicOx's revenues totaled €7.4 million for the six months ended June 30, 2010 compared to €1.1 million for the six months ended June 30, 2009.

This significant increase results from the recognition as revenues during the first quarter of 2010 of €7.4 million corresponding to the initial license payment received from Bausch + Lomb following the signature of a licensing agreement in March 2010 that granted Bausch + Lomb exclusive worldwide rights to develop and commercialize NCX 116. This amount has been immediately recognized in revenues because the Company will not have continuing involvement in the future development of the compound which is subject of this collaboration agreement. No revenues have been recorded in the second quarter of 2010.

Operating expenses

For the six months ended June 30, 2010, operating expenses totaled €36.4 million, compared to €32.7 million for the six months ended June 30, 2009, of which, 74% was attributable to research and development expenses and 26% attributable to selling and administrative expenses in the first semester of 2010, compared to 77% and 23% respectively in the first semester of 2009.

NicOx S.A.,

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Research and development expenses were €26.9 million during the first semester of 2010, compared to €25.1 million during the first semester of 2009 (including €0.1 million allocated to cost of sales in 2009 corresponding to the expenses incurred by NicOx in performing research activities under the contract signed with Pfizer). In the first semester of 2010, research and development expenses correspond principally to personnel expenses related to the activities performed in relation with the naproxinod New Drug Application and Marketing Authorization Application submitted respectively in the US and in Europe and to investment expenses in dedicated manufacturing facilities of its active ingredient supplier DSM in order to increase the naproxinod supply chain capacity and flexibility. Following the decision in July 2010 of the FDA not to approve the marketing application for naproxinod in the US, indemnities in an amount of €6.9 million have been booked as research and development expenses in the accounts as of June 30, 2010, to be paid to suppliers involved in the manufacturing of naproxinod for the anticipated cancellation of purchase orders. The Company employed 79 people in research and development on June 30, 2010, compared to 93 people at the same date in 2009.

General and administrative expenses were €3.2 million in the first semesters of 2010 and 2009 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 and corporate development expenses totaled €6.2 million during the first six months ended June 30, 2010 compared to €4.4 million during the same period in 2009 and correspond to market research and analysis activities for naproxinod, as well as the business development and communication activities of the Company. The Company employed 48 people in its selling, general and administrative departments on June 30, 2010, compared to 39 people on June 30, 2009.

Other income

Other income totaled €1.6 million during the first semester of 2010 compared to €3.1 million in the first semester of 2009. Other income corresponds mainly to the operational subsidies from the research tax credits in France and in Italy.

Operating result

The operating loss amounted to €27.4 million in the six months ended June 30, 2010, compared to €28.5 million in the same period in 2009.

Other results

Net financial income totaled €0.1 million during the first semester of 2010, compared to €1.3 million during the first semester of 2009, and represents mainly the returns on the financial investments of the Company's cash, cash equivalents.

The income tax expense incurred by NicOx during the first six months of 2010 relates to tax from its US and Italian subsidiaries and totaled €0.3 million, compared to €0.1 million during the same period in 2009.

Total net loss of the period

The total net loss for the period was €27.5 million on June 30, 2010, compared to €27.2 million on June 30, 2009. Notwithstanding the strong increase of the revenues recognized in the first six months of 2010 following the initial license payment received from Bausch + Lomb, the total net loss on June 30, 2010 remains at the same level as last year due to the impact of the anticipated cancellation of manufacturing and pre-commercial activities related to naproxinod following the decision of the FDA not to approve the application of the product in the United States.

Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On June 30, 2010, the Company's current liabilities totaled €16.6 million, including €12.0 million in accounts payable to suppliers and external collaborators (including €5.9 million with respect to the cancellation of orders of naproxinod active drug substance), €2.5 million in accrued compensation for employees, €1.9 million in other contingencies and liabilities (corresponding to the costs related to the anticipated cancellation of certain manufacturing and pre-commercial activities following the decision of the FDA) and €0.2 million for other liabilities.

The Company's cash and cash equivalents were €128.4 million on June 30, 2010, compared to €148.3 million on December 31, 2009, and €76.8 million on June 30, 2009. 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 will continue to pursue the European regulatory process for naproxinod and follow-up with the FDA after the Complete Response Letter. NicOx will actively seek to enter into partnerships for naproxinod. The Company's cash position is strong and NicOx is taking all necessary steps to preserve it.

Risks factors which are likely to have a material effect on NicOx's business are presented in the 4th chapter of the « Document de référence, rapport financier annuel et rapport de gestion 2009 » filed with the French Autorité des Marchés Financiers (AMF) on March 5, 2010 and available on NicOx's website (www.nicox.com) and on the AMF's website (www.amf-france.org).

The Company notably draws the investors' attention to the following risk factors:

- *Risques liés à la dépendance de la Société à l'égard du naproxinod* (Risks related to the Company's dependence on the success of its lead product naproxinod)
- *Risques commerciaux et développements cliniques* (Clinical developments and commercial risk)
- *Risques liés aux contraintes réglementaires et à la lenteur des procédures d'approbation* (Risks linked to regulatory constraints and slow approval procedures)
- *Manque de capacités dans les domaines de la vente et du marketing* (Lack of sales and marketing capabilities)
- *Incertitude relative aux prix des médicaments et aux régimes de remboursement, ainsi qu'en matière de réforme des régimes d'assurance maladie* (Uncertainty on drug pricing and reimbursement policies and on the reforms of the health insurance systems)

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 naproxinod, an NME and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate developed for the relief of the signs and symptoms of osteoarthritis (OA). In July 2010, the U.S. Food and Drug Administration (FDA) provided a Complete Response Letter to the New Drug Application (NDA) for naproxinod stating that it does not approve the naproxinod application. The naproxinod Marketing Authorization Application (MAA) submitted by NicOx in December 2009 is currently under review by the European Medicines Agency (EMA).

In addition to naproxinod, 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 hypertension, cardiometabolic diseases, eye diseases and dermatological diseases.

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 Référence 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, 2010

| | For the period ended June 30, | |
|--|---|-----------------|
| | 2010 | 2009 |
| | (in thousands of € except for per share data) | |
| Revenues | 7,423 | 1,119 |
| Cost of sales..... | - | (75) |
| Research and development expenses..... | (26,924) | (25,031) |
| Administrative expenses..... | (3,214) | (3,234) |
| Selling expenses..... | (6,241) | (4,403) |
| Other income..... | 1,600 | 3,130 |
| Operating loss | (27,356) | (28,494) |
| Finance income..... | 183 | 1 388 |
| Finance expense..... | (70) | (54) |
| Loss before income tax | (27,243) | (27,160) |
| Income tax expense..... | (257) | (77) |
| Net loss of the period | (27,500) | (27,237) |
| Exchange differences on translation of foreign operations..... | (38) | (1) |
| Other comprehensive income (loss) for the period, net of tax | (38) | (1) |
| Total comprehensive income (loss) for the period, net of tax | (27,538) | (27,238) |
| Attributable to: | | |
| - Equity holders of the parent | (27,538) | (27,238) |
| - Non-controlling interests | - | - |
| Basic and diluted loss per share attributable to equity holders of the parent | (0.38) | (0.57) |

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 30, 2010

| | June 30, 2010 | December 31, 2009 |
|---|----------------------------|--------------------------|
| | (in thousands of €) | |
| ASSETS | | |
| Non-current assets | | |
| Property, plant & equipment | 2,782 | 2,772 |
| Intangible assets | 794 | 797 |
| Government subsidies receivable | 936 | 477 |
| Other financial assets | 267 | 238 |
| Deferred income tax assets | - | 156 |
| Total non-current assets | 4,779 | 4,440 |
| Current assets | | |
| Government subsidies receivable | 3,263 | 2,597 |
| Other current assets | 988 | 1,329 |
| Prepaid expenses | 1,213 | 784 |
| Cash and cash equivalents | 128,448 | 148,275 |
| Total current assets | 133,912 | 152,985 |
| TOTAL ASSETS | 138,691 | 157,425 |
| EQUITY AND LIABILITIES | | |
| Common shares..... | 14,505 | 14,434 |
| Other reserves | 103,046 | 128,444 |
| Non-controlling interests | - | - |
| Total Equity | 117,551 | 142,878 |
| Non-current liabilities | | |
| Other contingencies and liabilities | 4,369 | 4,069 |
| Deferred income tax liabilities | 98 | 91 |
| Finance lease..... | 44 | 6 |
| Total non-current liabilities..... | 4,511 | 4,166 |
| Current liabilities | | |
| Other contingencies and liabilities | 1,890 | - |
| Finance lease | 18 | 7 |
| Trade payables | 12,034 | 6,136 |
| Current income tax payable | - | 19 |
| Social security and other taxes | 2,504 | 3,909 |
| Other liabilities..... | 183 | 310 |
| Total current liabilities..... | 16,629 | 10,381 |
| TOTAL EQUITY AND LIABILITIES | 138,691 | 157,425 |