



NicOx announces financial results for the first three quarters of 2010 and provides update on business restructuring

November 3, 2010. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (Euronext Paris: COX) today reported financial results for the nine months ended September 30, 2010 and announced further details of a restructuring of its activities, which is expected to lead to a significant reduction in cash burn for 2011.

Michele Garufi, CEO of NicOx, declared: *"In the last three months we have continued working on the registration process for naproxinod in Europe and discussing with potential commercial partners in this market. We are also pleased with the progress made on the development projects with our partners Merck, Ferrer and Bausch + Lomb and at the same time we continue to pursue synergistic M&A opportunities that will support our growth strategy. Moreover, following receipt of the FDA's Complete Response Letter for naproxinod in July, we are implementing a number of measures to contain our costs and carefully target our activities. We very much regret that the necessary change of focus will affect a number of our employees and I would like to personally thank all of them for their hard work and the significant milestones they have contributed to over the past few years."*

1- Third quarter and first nine months of 2010

Financial summary of the first nine months of 2010

Revenues were €7.4 million for the nine months ended September 30, 2010, 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 2010, as per the agreement signed in March.

For the first nine months of 2010, operating expenses were €41.4 million, compared to €45.7 million for the corresponding period of 2009. These expenses correspond principally to personnel costs related to the regulatory processes for naproxinod both in the United States and in Europe, investments in naproxinod's supply chain and costs related to the anticipated cancellation of certain manufacturing and pre-commercial activities following the decision of the FDA not to approve naproxinod.

For the nine months ended September 30, 2010, the total net loss amounted to €37.8 million compared to €39.9 million for the first nine months of 2009. On September 30, 2010, the Company's cash and cash equivalents totaled €115.9 million, compared to €148.3 million on December 31, 2009.

Eric Castaldi, CFO of NicOx, said: *"NicOx had cash and cash equivalents equaling €115.9 million as of the end of September 2010. Our ongoing efforts to maintain our cash position are expected to result in a significant reduction in the Company's cash burn in 2011, which is expected to be around one third of the anticipated 2010 figure. The 2011 estimated cash burn is solely based on the Company's currently anticipated operating expenses."*

Expansion of the agreement with Merck

In September, NicOx agreed with its partner Merck, known as MSD outside the United States and Canada, to expand the scope of their worldwide license agreement. This decision follows the discovery of a new approach to nitric oxide donation during the course of the joint research program.

2- Post reporting period events

Update on restructuring of NicOx's activities

Following the receipt of the FDA's Complete Response Letter in July 2010, NicOx decided to focus on conserving its cash and to refocus its key strategic priorities. These include actively seeking appropriate M&A opportunities and new alliances on existing programs; continuing to complete the European registration process; preparing naproxinod for its potential commercialization in Europe and seeking potential marketing partners in Europe and the rest of the world; and targeting internal research resources on the most promising programs.

In order to achieve these strategic objectives, NicOx has put in place a restructuring plan which included the closure of its U.S. headquarters in Warren, NJ, announced on August 4, 2010. In addition, the Company has also decided to reduce its workforce in Sophia Antipolis, France, by approximately 50% and NicOx's Italian subsidiary based in Bresso is currently considering a potential restructuring of the research center.

Review of the consolidated financial results for the nine months ended September 30, 2010 and 2009:

Revenues

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

This significant increase in revenues results from the recognition, 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 license 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 subject of this collaboration agreement. No revenues have been recorded in the third quarter of 2010.

Operating expenses

For the nine months ended September 30, 2010, operating expenses totaled €41.4 million, compared to €45.7 million for the nine months ended September 30, 2009. In 2010, 74.4% of the operating expenses were attributable to research and development compared to 72.6% for the same period of 2009, and 25.6% was attributable to selling and administrative expenses, compared to 27.4% for the same period of 2009.

Research and development expenses were €30.8 million in the nine months ended September 30, 2010, compared to €33.2 million during the nine months ended September 30, 2009. In the first nine months of 2010, research and development expenses corresponded principally to (i) personnel expenses related to the naproxinod New Drug Application and Marketing Authorization Application submitted respectively in the US and in Europe; and (ii) investment expenses in dedicated facilities of DSM for the manufacture of the active ingredient of naproxinod to increase the 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 relating to the cancellation of purchase orders placed with suppliers involved in the manufacturing of naproxinod have been booked as research and development expenses in the accounts as of September 30, 2010. The Company employed 73 people in research and development on September 30, 2010, compared to 92 people on September 30, 2009.

General and administrative expenses were €3.9 million on September 30, 2010, compared to €5.1 million on September 30, 2009 and include personnel expenses in administrative and financial functions, as well as the remuneration and expenses of corporate officers, including stock options, free shares and warrant attributions. Selling and corporate development expenses totaled €6.7 million during the first nine months ended September 30, 2010, compared to €7.4 million during the same period in 2009 and correspond to market research and analysis activities performed in the first half of 2010 for naproxinod, as well as the business development and communication activities of the Company. The Company employed 30 people in its selling, general and administrative departments on September 30, 2010, compared to 42 people at the same date in 2009. The decrease of selling and corporate development expenses and of the headcount is directly linked to the closure of the US operations of NicOx following the decision of the FDA not to approve naproxinod.

Other income

Other income totaled €2.0 million during the nine months ended September 30, 2010 compared to €3.2 million in the same period in 2009. Other income corresponds mainly to the operational subsidies from the research tax credits in France and in Italy.

Other expense

Other expense, which concerns restructuring costs, was €5.8 million during the first nine months ended September 30, 2010. Other expense includes an accrual in an amount of €4.7 million corresponding to an estimated cost for a contemplated restructuring plan for NicOx SA's headquarters and Italian subsidiary based on assumptions which may change; the cancellation of expenses in an amount of €1.4 million further to the cancellation of rights on stock options and free shares as a consequence of the restructuring plan; and €2.5 million corresponding to the cost of the closure of the offices of NicOx Inc. in the US.

Operating result

The operating loss amounted to €37.7 million in the nine months ended September 30, 2010, compared to €41.3 million in the same period in 2009.

Other results

Net financial income totaled €0.2 million during the first nine months of 2010, compared to €1.5 million during the first nine months of 2009, and mainly represents the returns on the financial investments of the Company's cash and cash equivalents.

The income tax expense incurred by NicOx during the first nine 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 €37.8 million on September 30, 2010, compared to €39.9 million on September 30, 2009. Notwithstanding the payment of indemnities linked to the cancellation of certain manufacturing activities for naproxinod, the cost of the closure of the US offices and the amounts accrued for the contemplated restructuring of the French and Italian entities, the decrease in net loss for the first nine months of 2010 as compared with 2009 is explained by a significant increase in the revenues recognized during the period following the initial license payment received from Bausch + Lomb. In other respects, further to the decision of the FDA not to approve naproxinod, NicOx has decided not to commit to certain expected expenses linked to the preparation of the anticipated launch of naproxinod in the United States.

Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On September 30, 2010, the Company's current liabilities totaled €14.7 million, including €5.1 million in other contingencies (including €4.7 million with respect to the restructuring cost accrued), €5.5 million in accounts payable to suppliers and external collaborators, €2.3 million in accrued compensation for employees, €1.6 million in taxes payable and €0.2 million for other liabilities.

The Company's cash and cash equivalents were €115.9 million on September 30, 2010, compared to €148.3 million on December 31, 2009, and €66.8 million on September 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 to follow-up on the rejection by the FDA. NicOx will actively seek to enter into partnerships for naproxinod in Europe and in the rest of the world. The Company has cash and cash equivalents equaling €115.9 million as of the end of September 2010 and 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 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 (known as MSD outside the United States and Canada) and Bausch + Lomb, for the treatment of select cardiovascular indications, 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 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 – SEPTEMBER 30, 2010

	For the period of 9 months ended September 30,	
	2010	2009
	(in thousands of € except for per share data)	
Revenues	7,423	1,119
Cost of sales.....	-	(75)
Research and development expenses.....	(30,754)	(33,079)
Administrative expenses.....	(3,940)	(5,127)
Selling expenses.....	(6,665)	(7,431)
Other income.....	2,020	3,244
Other expense.....	(5,824)	-
Operating loss	(37,740)	(41,349)
Finance income.....	313	1,606
Finance expense.....	(86)	(93)
Loss before income tax	37,513	39,836
Income tax expense.....	(327)	(108)
Net loss of the period	(37,840)	(39,944)
Exchange differences on translation of foreign operations.....	15	(3)
Other comprehensive income (loss) for the period, net of tax	-	(3)
Total comprehensive income (loss) for the period, net of tax	(37,825)	(39,947)
Attributable to:		
- Equity holders of the parent	(37,825)	(39,947)
- Non-controlling interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent	(0.51)	(0.84)

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – SEPTEMBER 30, 2010

	September 30, 2010	December 31, 2009
	(in thousands of €)	
ASSETS		
Non-current assets		
Property, plant & equipment	2,326	2,772
Intangible assets	427	797
Government subsidies receivable	-	477
Other financial assets	246	238
Deferred income tax assets	41	156
Total non-current assets	3,040	4,440
Current assets		
Government subsidies receivable	1,660	2,597
Other current assets	2,500	1,329
Prepaid expenses	616	784
Cash and cash equivalents	115,935	148,275
Total current assets	120,711	152,985
TOTAL ASSETS	123,751	157,425
EQUITY AND LIABILITIES		
Common shares.....	14,508	14,434
Other reserves	90,130	128,444
Non-controlling interests	-	-
Total Equity	104,638	142,878
Non-current liabilities		
Other contingencies and liabilities	4,180	4,069
Deferred income tax liabilities	95	91
Finance lease.....	90	6
Total non-current liabilities.....	4,365	4,166
Current liabilities		
Other contingencies and liabilities	5,119	-
Finance lease	32	7
Trade payables	5,457	6,136
Current income tax payable	-	19
Social security and other taxes	3,867	3,909
Other liabilities.....	273	310
Total current liabilities.....	14,748	10,381
TOTAL EQUITY AND LIABILITIES	123,751	157,425