



NicOx first half 2012 financial results

July 27, 2012. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (NYSE Euronext Paris: COX) today reports financial results for the six months ended June 30, 2012, and provided an update on its activities.

Key highlights for the first half of 2012

- Worldwide in-licensing agreement with RPS[®] for innovative diagnostic tests in the ocular field, including AdenoPlus[™]
- Management team strengthened with the appointments of Jerry St. Peter in the United States and Philippe Masquida in Europe
- Positive phase 2b results observed with glaucoma candidate BOL-303259-X; Bausch + Lomb to move compound into phase 3 development program
- 11.8% investment in Altacor, a privately-held ophthalmology company based in the United Kingdom

*"During the first six months of 2012, NicOx made significant progress in delivering its strategy of becoming an international, late-stage development and commercial ophthalmology player," said **Michele Garufi, Chairman and CEO of NicOx**. "We achieved the first step through the acquisition of worldwide rights to a promising portfolio of ocular diagnostic products from RPS[®]. We expect to launch AdenoPlus[™], our first commercially available product, by the end of 2012 under the leadership of Jerry St. Peter in the US and Philippe Masquida in Europe. Discussions are advancing to further expand our product portfolio in the US and in Europe through further acquisitions and in-licensing."*

Eric Castaldi, Chief Financial Officer of NicOx, added: *"We are investing in creating small, specialist sales teams in the US and Europe to commercialise the recently in-licensed AdenoPlus[™] diagnostic test. As of June 30, 2012, the Company had cash and cash equivalents of more than €88 million, putting us in a good position to continue to invest in targeted commercial and late-stage opportunities in ophthalmology."*

Financial summary

Revenues were €7.5 million in the first half of 2012, compared to zero for the corresponding period of 2011. This reflects a one-off \$10 million milestone payment (corresponding to €7.5 million) received from Bausch + Lomb in April 2012, following its decision to continue the development of BOL-303259-X.

Research and development costs and administrative and selling costs were €8.1 million in the first half of 2012, compared to €8.8 million in the first half of 2011.

NicOx recorded a total net loss of €0.4 million in the first half of 2012, compared to a net loss of €7.8 million for the same period in 2011. On June 30, 2012, the Group had cash and cash equivalents totaling €88.5 million, compared to €93.1 million on December 31, 2011.

Review of the first six months of 2012

Worldwide licensing agreement with RPS[®] for ocular diagnostics

NicOx and Rapid Pathogen Screening, Inc (RPS[®]) entered into a licensing agreement in June 2012, with effect from July 2012, granting NicOx worldwide rights to unique point-of-care tests in the ocular field. AdenoPlus[™], an easy-to-use diagnostic test for the in-office detection of adenoviral conjunctivitis, is already authorized for marketing in the US and in Europe. The Company expects to launch AdenoPlus[™] in the US and in key European markets by the end of 2012.

The worldwide licensing agreement also covers two additional diagnostic tests currently in development as well as an exclusive worldwide option to negotiate an agreement for an additional promising product, based on RPS[®] meeting certain milestones which include on-going external discussions.

Under the agreement, NicOx paid RPS® a total of \$4 million in license and option fees. The financial terms also include single-digit royalties and potential additional milestone payments of up to \$2 million. NicOx will also pay half of the development costs for the two development-stage products, subject to an agreed budget.

Bausch + Lomb to move into phase 3 following positive phase 2b results

The phase 2b study conducted by Bausch + Lomb with BOL-303259-X (NCX 116) in patients with open-angle glaucoma or ocular hypertension met its primary endpoint and showed promising results on a number of secondary endpoints. Bausch + Lomb will initiate a global phase 3 development program for BOL-303259-X and paid a \$10 million milestone payment to NicOx (€7.5 million) in April 2012. BOL-303259-X is a novel nitric oxide-donating prostaglandin F2 alpha analog licensed by NicOx to Bausch + Lomb in March 2010.

Building the Group's commercial organization

In the first half of 2012, the Company appointed Jerry St. Peter as Executive Vice President and General Manager of NicOx Inc., the U.S. subsidiary of NicOx, and Philippe Masquida as Executive Vice President, Managing Director of European Operations. Both Jerry St. Peter and Philippe Masquida have extensive senior-level international experience, notably in the ophthalmology field.

Following the in-licensing of AdenoPlus™, which is already authorized for marketing in the US and in Europe, NicOx is building up its commercial organization in the US and in Europe. The commercial teams will manage the commercialization of AdenoPlus™ and other ophthalmology products, both diagnostic and therapeutic, that the Company plans to acquire or in-license in the future.

Investment in Altacor

In March 2012, NicOx acquired 11.8% of the shares of Altacor, a privately-held ophthalmology company based in the United Kingdom. Altacor markets Clinitas™, a range of five products for dry eye, in the UK and Ireland. On May 31, 2012, NicOx's Board of directors decided not to exercise an option to acquire the remaining 88.2% of equity of Altacor. NicOx retains its 11.8% stake and will continue to support Altacor through the presence of Gavin Spencer, Executive Vice President, Corporate Development of NicOx as a member of Altacor's Board of Directors.

Meeting with the FDA on April 3, 2012

NicOx met with the US Food and Drug Administration (FDA) on April 3, 2012, to discuss the proposed use of naproxinod 375 mg twice daily (*bid*) for the treatment of signs and symptoms of osteoarthritis (OA) of the knee, under a proposed new NDA (New Drug Application) that would require additional clinical data prior to any such NDA submission.

Having assessed the requirements for further clinical data discussed with the FDA and its impact on the overall development program of naproxinod, NicOx has initiated the process of seeking a partner to fund and manage any further development and potential commercialization of naproxinod.

NicOx had previously submitted an NDA for naproxinod 375 mg *bid* and 750 mg *bid* for the treatment of signs and symptoms of OA not limited to the knee. NicOx received a Complete Response Letter in July 2010 stating that the FDA did not approve that naproxinod NDA. NicOx initiated a Formal Dispute Resolution process in July 2011 regarding that decision involving the previously submitted NDA. These were not the topic of the April 3, 2012 meeting.

Subject to NicOx finding a potential partner to pursue the development of naproxinod 375 mg *bid* in knee OA, if the Company moves forward with this new NDA, the Company anticipates that the Formal Dispute Resolution process initiated in July 2011 under the previously submitted NDA would be closed.

Nitric oxide (NO)-donating R&D pipeline

In line with the strategic decision to become a late-stage development and commercial specialty ophthalmology company, the Board decided to review and rationalize the Company's R&D pipeline and to discontinue any programs deemed non-core in view of the Company expansion in the ophthalmic space. As a result the Company will no longer pursue the development of NCX 6560, a new molecular entity for cardiovascular indications, or research programs targeting neuropathic pain (including NCX 1236) and pulmonary arterial hypertension (including NCX 226).

The Company is evaluating various options to pursue the development of NO-donating compounds targeting eye conditions, including NCX 434 and NCX 422. The Company may choose to develop these programs in-house or with a partner.

Review of the consolidated financial results for the six months ended June 30, 2012 and 2011

The interim consolidated financial statements for the six months ended June 30, 2012 and 2011 have been prepared in accordance with applicable IFRS principles and a limited review has been performed by the auditors.

On March 21, 2012, NicOx acquired 11.8% of the shares of Altacor, a privately-held ophthalmology company based in the United Kingdom, and, further, entered into an exclusive option agreement to acquire the remaining shares of Altacor

in shares and/or warrants, cash or a combination of cash and shares. Under IAS 27, the Group was deemed to have the power to control Altacor as it had, until May 31, 2012, the option to acquire the remainder of Altacor's shares in cash. Therefore, on March 31, 2012 Altacor's transaction was considered a business combination in accordance with the above mentioned accountancy rules. In this context, NicOx has accounted for the combination of NicOx and Altacor using the purchase method of accounting in accordance with IFRS 3, 'Business Combinations'.

On May 31, 2012 NicOx decided not to exercise the option to acquire the remaining 88.2 % of equity of Altacor. Therefore, on June 30, 2012 NicOx is deemed to have lost the power to control Altacor and in consequence has reversed all the assets and liabilities of Altacor as of May 31, 2012.

Nevertheless, under IFRS principles the Group is deemed to exercise a significant influence over Altacor as a result of its participation in the share capital and Board of Directors of Altacor. Consequently, the presented consolidated half-year financial statements for the six months to June 30, 2012 include Altacor for the period from May 31 to June 30, 2012, on the basis of the equity method.

Consolidated statement of comprehensive income

Revenues

For the six month ended June 30, 2012, NicOx revenues totaled €7.5 million compared to zero revenue in the first semester of 2011.

The revenues recognized on June 30, 2012 correspond to the milestone payment of \$10 million invoiced to Bausch + Lomb in March 2012, following their decision to continue the development of BOL-303259-X (NCX 116). This amount has been immediately recognized in revenues because the Company will not have continuing involvement in the future development of this compound which is the subject of the collaboration agreement signed in 2010 with Bausch + Lomb.

Research and development costs, administrative and selling costs

For the first half of 2012, research and development costs, administrative and selling costs decreased to €8.1 million compared to €8.8 million for the first semester of 2011. In 2010 and in 2011, NicOx implemented two consecutive restructurings of its entities and activities. As part of the restructuring in 2010, the US offices of NicOx were closed in August 2010, the headcount of the French and Italian entities of the Group were significantly reduced and activities were redefined in order to protect the Company's cash and cash equivalents and refocus the Group's key strategic priorities. In the last quarter of 2011, the Group has implemented an additional reduction of its workforce by approximately one third in order to align its structure with the corporate strategy of becoming an international, late-stage development and commercial ophthalmology Group. On June 30, 2012, 43% of these expenses concerned research and development expenses and 57% administrative and selling expenses, compared to 60% and 40%, respectively, on June 30, 2011.

During the first semester of 2012, research and development expenses were €3.2 million, compared to €5.2 million during the same period in 2011. In the first six months of 2012, research and development expenses primarily related to activities at the research center and ongoing regulatory activities for naproxinod. On June 30, 2012, the Group employed 19 people in research and development, compared to 40 people at the same date in 2011.

Administrative expenses were €1.9 million in the first six months of 2012 compared to €2.6 million during the same period in 2011 and include personnel expenses in administrative and financial functions, as well as the remuneration of corporate officers. Selling expenses totaled €3.0 million on June 30, 2012, compared to €1.0 million in the first semester of 2011, and correspond for the first six months of 2012 principally to communication and business development activities (including notably €0.7 million of costs incurred over the period in relation with the acquisition of the 11.8% of Altacor). The Group employed 18 people in its selling and administrative departments on June 30, 2012, compared to 16 people on June 30, 2011.

Other income

During the first six months of 2012, other income was €0.6 million compared to €0.5 million in the first semester of 2011. In 2012, other income corresponds for €0.2 million to the operational subsidies from the research tax credit in France and for €0.4 million to an unrealized foreign exchange gain.

Other expense

Other expense, which refers exclusively to restructuring costs, amounted to €0.6 million on June 30, 2012, compared to an income of €0.1 million on June 30, 2011. On June 30, 2012, the Group has accrued an amount of €0.9 million with respect to an undertaking vis-à-vis employees of the Italian subsidiary in the event of a potential further restructuring.

Operating loss

For the first six months of 2012 the Group generated an operating loss of €0.5 million, compared to an operating loss of €8.2 million during the same period in 2011.

Other results

In the first six months of 2012, net financial income totaled €0.1 million (including the share of Altacor's results), compared to €0.4 million during the first six months of 2011, 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 semester of 2012 relates to tax from its Italian subsidiary and totaled €0.04 million, compared to €0.08 million on June 30, 2011.

Total net loss for the period

On June 30, 2012, NicOx recorded a net loss of €0.4 million compared to €7.8 million on June 30, 2011. This significant decrease of the net loss in the first six months of 2012 is explained by the strong increase of the revenues recognized over the period as indicated above.

Consolidated statement of financial position

The indebtedness incurred by NicOx is mainly short-term operating debt. On June 30, 2012, the Group's current liabilities totaled €5.2 million, including €1.8 million in accounts payable to suppliers and external collaborators, €1.6 million in other contingencies and liabilities with respect to the restructuring cost accrued, €1.0 million in taxes payable and €0.8 million in accrued compensation for employees.

On June 30, 2012, the Group's cash and cash equivalents were €88.5 million, compared to €93.1 million on December 31, 2011.

About NicOx

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is creating an international, late-stage development and commercial ophthalmology group based around therapeutics, diagnostics and devices.

NicOx has in-licensed innovative ocular diagnostics from RPS®, including AdenoPlus™, a test for the detection of adenoviral conjunctivitis already authorized for marketing in the United States and Europe. The Company has a partnership with Bausch + Lomb for the development of BOL-303259-X, a novel glaucoma candidate based on NicOx's proprietary nitric oxide-donating R&D platform.

Further nitric oxide-donating compounds are under development in non-ophthalmology indications notably through partners, including Merck (known as MSD outside the United States and Canada) and Ferrer.

NicOx S.A. is headquartered in France and is listed on Euronext Paris (Compartment C: Small 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.

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 2011* » filed with the French Autorité des Marchés Financiers (AMF) on February 29, 2012 and available on NicOx's website (www.nicox.com) and on the AMF's website (www.amf-france.org).

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INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – JUNE 30, 2012

	For the period of six months ended, June 30,	
	2012	2011
	(in thousands of € except for per share data)	
Revenues.....	7,552	-
Research and development expenses.....	(3,173)	(5,250)
Administrative expenses.....	(1,932)	(2,562)
Selling expenses.....	(2,956)	(976)
Other income.....	627	532
Other expense.....	(570)	102
Operating loss	(452)	(8,154)
Finance income	321	471
Finance expense.....	(85)	(39)
Share of Profit (loss) of associates.....	(95)	-
Loss before income tax	(311)	(7,722)
Income tax expense.....	(42)	(83)
Net loss.....	(353)	(7,805)
Exchange differences on translation of foreign operations.....	(21)	47
Other comprehensive income (loss) for the period, net of tax	(21)	47
Total comprehensive income (loss) for the period, net of tax	(374)	(7,758)
Attributable to:		
- Equity holders of the parent	374	7,758
- Non-controlling interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent.....	0.00	(0.11)

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 30, 2012

	As of June 30, 2012	As of December 31, 2011
	(in thousands of €)	
ASSETS		
Non-current assets		
Property, plant & equipment	611	843
Intangible assets	99	117
Investments in associates and joint ventures	2,317	-
Other financial assets	273	263
Deferred income tax assets	56	65
Total non-current assets	3,356	1,288
Current assets		
Government subsidies receivable... ..	1,087	866
Other current assets	795	367
Prepaid expenses	334	172
Cash and cash equivalents	88,509	93,136
Total current assets	90,725	94,541
TOTAL ASSETS	94,081	95,829
EQUITY AND LIABILITIES		
Common shares	14,578	14,563
Other reserves	69,58	69,761
Non-controlling interests	-	-
Total Equity	84,136	84,324
Non-current liabilities		
Other contingencies and liabilities	4,671	4,592
Deferred income tax liabilities	1	3
Finance lease	46	58
Total non-current liabilities	4,718	4,653
Current liabilities		
Other contingencies and liabilities	1,55	3,59
Finance lease	24	24
Trade payables	1,793	1,185
Social security and other taxes	1,782	1,89
Other liabilities	78	163
Total current liabilities	5,227	6,852
TOTAL EQUITY AND LIABILITIES	94,081	95,829