



Nicox first half 2016 business and financial update

- Latanoprostene bunod licensee Bausch + Lomb receives Complete Response Letter from U.S. FDA pertaining to B+L manufacturing facility; no efficacy or safety concerns or additional clinical trials regarding the compound identified for approval
- AC-170 NDA under FDA Priority Review approval process
- Cash position of €34.1 million¹: Nicox sufficiently financed through completion of clinical proof-of-concept trials for pipeline assets NCX 4251 and NCX 470 by end of 2018
- Refocusing on R&D-only allows significant reduction in operating costs going forward

September 22, 2016

Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today announced its financial results for the six months ended June 30, 2016, and provided an update on its activities.

“Following the recently completed transaction with GHO Capital involving our European and International commercial assets, we are now well positioned to refocus our resources on our promising R&D pipeline as we await FDA approval decisions for latanoprostene bunod and AC-170” commented Michele Garufi, Chairman and Chief Executive Officer of Nicox. “This transaction allows us to reduce our infrastructure costs by €6 million (approximately 66%) and, together with the recent financing of €18 million, to accelerate the development of our proprietary pipeline assets, including obtaining clinical proof-of-concept data for NCX 4251 and NCX 470 by the end of 2018.”

Operational highlights for the six months to June 30, 2016 and post-reporting period

- In August 2016, Nicox completed the transfer of its European and International commercial operations to a new pan-European ophthalmic specialty pharmaceutical company led by GHO Capital. The transaction was valued at up to €26 million and the Company received a €9 million upfront cash payment upon closing of the transaction and a minority stake in the new company.
- In July 2016, Nicox completed a financing through a reserved capital increase of ordinary shares of the Company with a specific category of investors. Gross proceeds from the financing were €18 million.
- On July 21, 2016, latanoprostene bunod licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) announced its receipt of a Complete Response Letter

(CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for the use of latanoprostene bunod for the treatment of glaucoma. The CRL cited concerns pertaining to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Florida. The FDA's letter did not identify any efficacy or safety concerns with respect to the latanoprostene bunod NDA or additional clinical trials needed for the approval of the NDA. Bausch + Lomb is currently working with the FDA to resolve and address the CGMP concerns. Latanoprostene bunod has the potential to generate significant revenue for Nicox through milestones (up to \$132.5 million net, mainly on commercial sales targets) and royalties (potential net tiered royalties on sales from 6% to 11%).

- In June, Nicox announced that the U.S. FDA had accepted the Company's NDA for AC-170, a novel, proprietary eye drop formulation of cetirizine, targeting the treatment of ocular itching associated with allergic conjunctivitis. The FDA also granted Priority Review and assigned a Prescription Drug User Fee (PDUFA) goal date of October 18, 2016 (contingent upon the information and data provided by Nicox during the review period). Approval of the AC-170 NDA prior to December 1st, 2016 will trigger a milestone payment of \$35 million in Nicox shares to former Acix shareholders or \$10 million in Nicox shares if approval of the NDA is received after this date. Nicox is currently in partnering discussions in the United States for this program.

Other Updates

- Philippe Masquida, EVP, Managing Director European & International Operations, will be leaving the company at the end of September 2016, following the successful completion of the transfer of the European and International commercial operations. Nicox sincerely thanks Philippe for his years of service and his significant contributions to the commercial business.

First-half financial summary²

The Group's revenues have been retreated following reclassification of the European commercial business as Discontinued Operations. For information, the European and International product sales of the operations transferred to VISUfarma BV, the new Group led by GHO Capital, were €7.1 million over the first half of 2016, an increase of 50% compared to the same period in 2015.

Excluding Discontinued Operations the operating expenses for the period were €12.0 million compared to €8.8 million for the six months to June 2015. The increase in operating expenses over the period is mainly explained by costs related to the submission of the AC-170 NDA.

Excluding the Discontinued Operations, the Group recorded a net loss of €12.3 million as of June 2016, compared to a net loss of €10.1 million³ at the same date in 2015.

The Group had cash, cash equivalents and financial instruments of €12.3 million as of June 30, 2016, compared to €29 million on December 31, 2015; however, considering the financing in July of this year of €18 million gross and the €8.9 million cash payment following the transfer of the European commercial operations to VISUfarma BV, our unaudited cash, cash equivalents and financial instruments at August 31, 2016 are estimated at €34.1 million.

The half-yearly financial report will be available in French by the end of September 2016 on Nicox's website www.nicox.com in the section Investor Information > Regulated information > Financial Information.

The procedures relating to the limited review of the interim financial statements have been carried out. The limited review report will be issued after the finalisation of the procedures required for the publication of the first half financial report.

¹ Unaudited cash, cash equivalents and financial instruments at August 31, 2016.

² Revenues, costs, assets and liabilities for the European commercial operations are treated as “Discontinued Operations” in accordance with IFRS 5

³ The net loss for H1 2015 has been adjusted to remove the European commercial operations.

About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an international R&D company focused on the ophthalmic market. For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
Invest Securities	Martial Descoutures	Paris, France
Gilbert Dupont	Damien Choplain	Paris, France
Stifel	Max Hermann	London, UK



Upcoming financial and business conferences

October 5-6	Large & Midcap Event	Paris, France
November 15-16	Stifel 2016 Healthcare Conference	New York, US
November 18-19	Actionnaria	Paris, France
November 21-23	Deutsches Eigenkapitalforum	Frankfurt, Germany
December 13	Guggenheim Securities 4th Annual Boston Healthcare Conference	Boston, US

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CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – JUNE 30, 2016

	As of June 30,	
	2016 ²	2015 restated ^{3,4}
	<i>(in thousands of € except for per share data)</i>	
Revenues	9	80
Cost of sales	-	(2)
Gross margin	9	77
Selling expenses	(97)	(1,154)
General and administrative expenses	(4,376)	(4,731)
Research and development expenses	(6,544)	(2,288)
Other operating income	284	448
Other operating expense	(981)	(616)
Total operations loss before fair value changes of contingent consideration and impairment of intangible assets	(11,706)	(8,264)
Fair value changes of contingent considerations	(995)	(2,576)
Impairment of intangible assets	-	-
Operating loss	(12,702)	(10,840)
Finance income	54	986
Finance costs	(241)	(487)
Net finance revenues	(186)	509
Loss before tax	(12,888)	(10,331)
Income tax	(18)	(10)
Loss from continuing operations	(12,906)	(10,341)
Loss from discontinued operations	(11,307)	(5,431)
Net loss of the year	(24,213)	(15,772)
Attributable to owners of the Compagny	(24,213)	(15,772)
Total comprehensive income (loss) for the period, net of tax (€/share)	(1,06)	(0,72)
Basic/diluted earnings per share from continuing operations (€/share)	(0,56)	(0,47)
Basic/diluted earnings per share from discontinued operations (€/share)	(0,49)	(0,25)

² Revenues, costs, assets and liabilities for the European commercial operations are treated as “Discontinued operations” in accordance with IFRS 5

³ The net loss for H1 2015 has been adjusted to remove the European commercial operations.

⁴ For a greater clarity of the Group performance, the presentation of the consolidated statement of comprehensive income has been modified. Lines, gross margin, fair value of changes of contingent considerations and impairment of intangible assets have been created.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 30, 2016

	As of June 30th, 2016	As of December 31st, 2015
	<i>(in thousands of €)</i>	
ASSETS		
Non-current assets		
Goodwill	26,154	32,245
Intangible assets	73,688	92,141
Property, plant and equipment ^a	262	866
Other investments, including derivatives	184	253
Total non-current assets	100,288	125,505
Current assets		
Inventories	-	948
Trade receivables	42	3,027
Subsidies receivables	813	727
Other receivables	975	3,013
Prepayments	778	526
Other current assets, including derivatives	-	532
Cash and cash equivalents	12,342	29,070
Assets held for sales	24,524	-
	24,524	-
Total current assets	39,475	37,843
TOTAL ASSETS	139,763	163,348
EQUITY AND LIABILITIES		
Equity attributable to equity holders of the parent		
Share capital	22,899	22,870
Premium related to share capital	469,089	469,119
Currency translation adjustment	8,688	10,049
Treasury shares	(355)	(458)
Consolidates reserves	(397,471)	(372,310)
Net income/(loss)	(24,213)	(27,939)
Total Equity	78,622	101,331
Non-current liabilities		
Non-current financial debts	39	1,567
Non-current liabilities related to business combination	1,401	2,066
Deferred tax liabilities	27,923	30,759
Non-current provisions	448	617
Total non-current liabilities	29,811	35,009
Current liabilities		
Current financial debts	40	308
Current liabilities related to business combination	18,481	16,832
Trade payables	1,916	5,364
Deferred income/revenue	2	2
Other current liabilities	(2,513)	4,502
Liabilities directly associated with the assets held for sales	8,378	-
Total current liabilities	31,329	27,008
TOTAL EQUITY AND LIABILITIES	139,763	163,348

² Revenues, costs, assets and liabilities for the European commercial operations are treated as “Discontinued operations” in accordance with IFRS 5