Nicox: 2015 Financial Results and Business Update

- **Latanoprostene bunod New Drug Application (NDA) under review by the U.S. Food & Drug Administration (FDA) with a PDUFA (Prescription Drug User Fee Act) date of July 21, 2016**
- **AC-170 NDA to be submitted early Q2, 2016**
- **2015 revenues €10 million, a 67% increase vs. 2014**

April 15, 2016

Sophia Antipolis, France.

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic company, today announced its financial and operating results for the year ended December 31, 2015, as approved by the Board of Directors on April 14, 2016, and provided an overview of its activities.

"During 2015, we saw strong growth in our sales revenue, integration of our acquisitions and continued progress in our development programs," commented **Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"We are on the brink of submitting our first ophthalmology NDA for AC-170 in allergic conjunctivitis, and are awaiting the completion of the FDA's review of latanoprostene bunod, partnered with Bausch + Lomb, in glaucoma. Together with our expectations for our European commercial business, we expect 2016 to be a year of significant development and transformation for our company."*

2015 operational highlights

- **Latanoprostene bunod NDA filed with U.S. FDA by Nicox's licensee Bausch + Lomb.** In July 2015, Bausch + Lomb (a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.) filed an NDA with the U.S. FDA seeking approval for latanoprostene bunod ophthalmic solution 0.024% as an intraocular pressure lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma or ocular hypertension. The FDA accepted this NDA for review in September 2015 and set an action date of July 21, 2016 to finalize its review, as per the Prescription Drug User Fee Act (PDUFA).
- **Final preparation of AC-170 NDA submission.** Following two pre-NDA meetings with the FDA regarding AC-170, a novel, proprietary, cetirizine eye drop formulation developed for the treatment of ocular itching associated with allergic conjunctivitis, Nicox's NDA for AC-170 is in final preparation. The Company expects to submit its NDA for AC-170 to the U.S. FDA early Q2, 2016. The Company is

planning to seek Priority Review for AC-170, which, if obtained, could result in an FDA decision by the end of 2016 based on PDUFA performance goals.

- **Corporate and pipeline update**
  - **NCX 4251:** Nicox's nanocrystalline fluticasone propionate being developed for the treatment of blepharitis is now in formulation studies, with the goal of entering directly into Phase 2.
  - **New NO-donors:** Nicox is advancing several nitric oxide (NO)-donating candidates including two glaucoma programs, NCX 470, a novel NO-donating bimatoprost, which is now advancing through pre-IND (Investigational New Drug) development prior to entering first-in-man clinical studies and next-generation stand-alone NO-donors which are currently in the lead optimization phase. Promising preclinical results were presented at the ARVO 2015 Annual Meeting, one of the key scientific events in the ophthalmology calendar.
  - **European operations:** Nicox is currently evaluating a number of strategic options for its European commercial business for which discussions remain ongoing. Nicox's European pipeline (AzaSite®, BromSite™ and NCX 4240 for which the date of dossier submission has not been decided yet) could potentially be included in these strategic discussions.
- **Other 2015 and Post Reporting Period Events**
  - In February 2015, Nicox in-licensed the Europe, Middle East and Africa rights to AzaSite®, BromSite™ and AzaSite Xtra™ from InSite Vision Inc.
  - In March 2015, Nicox completed a financing with the participation of major institutional investors specialized in life sciences, mainly from the U.S., which brought gross proceeds of €27 million.
  - In November 2015, Nicox out-licensed U.S. development and commercialization rights for naproxcinod, an NO-donating anti-inflammatory drug-candidate, to Fera Pharmaceuticals.
  - In December 2015, Nicox completed a 5-for-1 reverse split of its common stock, reducing the number of outstanding common shares to approximately 22.9 million.
  - In January 2016, Nicox Ophthalmics, Inc. granted Ora Inc., the world's leading ophthalmic clinical research and product development firm, exclusive worldwide rights for the development and commercialization of the OTC asset AC-120, an innovative drug-candidate for morning eyelid swelling ("puffy eyes").

2015 Financial Summary

In accordance with IFRS5, 2014 revenues and expenses set out below do not include Nicox Inc., which was divested to Valeant in November 2014.

- Nicox's revenues totaled €10 million in 2015, compared to €6.0 million in 2014, and were composed exclusively of European and International product sales. The growth in sales was helped by the acquisition of Doliage in France and the launch of new products in the Xailin™ range.
- Selling, Administrative and Research and Development costs amounted to €31.7 million in 2015, compared to €28.6 million in 2014, mostly due to an increase in research and development costs. The Group generated an operating loss of €28.9 million in 2015, compared to €21.6 million in 2014.
- On December 31, 2015, the Group's cash, cash equivalents and financial instruments were €29.6 million, compared to €32.0 million on December 31, 2014.

Key upcoming milestones

- Q2, 2016: submission of AC-170 NDA to FDA
- July 21, 2016: PDUFA date for latanoprostene bunod NDA

Half-year 2016 financial results will be published on September 22, 2016.

About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an international commercial-stage company focused on the ophthalmic market. With a heritage of innovative R&D, business development and marketing expertise, Nicox is building a diversified portfolio of ophthalmic products that can help people enhance their sight.

Nicox's advanced pipeline features latanoprostene bunod for the lowering of intra-ocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension, and for which a New Drug Application (NDA) was submitted to the FDA by the Company's licensee Valeant. The Company's pipeline also features AC-170, a pre-NDA candidate for the treatment of ocular itching associated with allergic conjunctivitis, as well as two pre-MAA candidates in Europe: AzaSite® for bacterial conjunctivitis and BromSite™ for pain and inflammation after cataract surgery. Beyond these late-stage candidates, Nicox is developing a pipeline of next generation ophthalmology-focused candidates which utilize its proprietary nitric oxide (NO)-donating research platform. The Group has operations in Europe and the United States.

Nicox is listed on Euronext Paris (Category B: Mid Caps) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes. For more information on Nicox, its commercial 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

Upcoming 2016 events

Financial and business conferences

May 10	Gilbert Dupont Forum Santé	Paris, France
May 17	SFAF Bio Day	Paris, France
May 19	European Mid Small Cap Forum	London, UK
June 6-9	BIO 2016	San Francisco, US

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This press release contains certain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these 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 2014*' filed with the French *Autorité des Marchés Financiers* (AMF) on April 10, 2015, which is available on Nicox's website (www.nicox.com).

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – DECEMBER 31, 2015

	As of December 31,	
	2015	**2014 restated**[1]
	(in thousands of € except for per share data)	
Revenues	9,963	5,982
Cost of sales	(5,306)	(3,291)
Gross margin	**4,657**	**2,691**
Selling expenses	(13,631)	(13,524)
General and administrative expenses	(11,723)	(10,636)
Research and development expenses	(6,303)	(4,432)
Other operating income	1,825	1,337
Other operating expense	(807)	(646)
Total operations loss before fair value changes of contingent consideration and impairment of intangible assets	**(25,981)**	**(25,210)**
Fair value changes of contingent considerations	(2,920)	4,522
Impairment of intangible assets	-	(879)
Operating loss	**(28,900)**	**(21,567)**
Finance income	1,545	535
Finance costs	(550)	(857)
Net finance revenues	**996**	**(322)**
Loss before tax	**(27,905)**	**(21,889)**
Income tax	(34)	(97)
Loss from continuing operations	**(27,939)**	**(21,986)**
Loss from discontinued operations	-	(1,172)
Net loss of the year	**(27,939)**	**(23,158)**
Attributable to owners of the Compagny	(27,939)	(23,158)
Total comprehensive income (loss) for the period, net of tax (€/share)	**(1,25)**	**(1,43)**
Basic/diluted earnings per share from continuing operations (€/share)	(1,25)	(1,36)
Basic/diluted earnings per share from discontinued operations (€/share)	-	(0,07)

(1) Following adjustments on previous years, the net loss 2014 has been increased by € 266 000. 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 – DECEMBER 31, 2015

	As of December 31,	
	2015	2014 Restated[1]
	(in thousands of €)	
ASSETS		
Non-current assets		
Goodwill	32,245	29,490
Intangible assets	92,141	80,799
Property, plant and equipmenta	866	902
Other investments, including derivatives	253	95
Total non-current assets	**125,505**	**111,285**
Current assets		
Inventories	948	1,504
Trade receivables	3,027	1,605
Subsidies receivables	727	1,238
Other receivables	3,013	2,168
Prepayments	526	367
Other current assets, including derivatives	532	9,253
Cash and cash equivalents	29,070	22,619
Total current assets	**37,843**	**38,755**
TOTAL ASSETS	**163,348**	**150,041**
EQUITY AND LIABILITIES		
Equity attributable to equity holders of the parent		
Share capital	22,870	19,848
Premium related to share capital	469,119	447,211
Currency translation adjustment	10,049	2,683
Tresury shares	(458)	-
Consolidates reserves	(372,310)	(350,303)
Net income/(loss)	(27,939)	(23,158)
Total Equity	**101,331**	**96,281**
Non-current liabilities		
Non-current financial debts	1,567	1,315
Non-current liabilites related to business combination	2,066	14,683
Deferred tax liabilites	30,759	27,783
Non-current provisions	617	548
Total non-current liabilities	**35,009**	**44,329**
Current liabilities		
Current financial debts	308	540
Current liabilites related to business combination	16,832	619
Trade payables	5,364	3,635
Deferred income/revenue	2	-
Other current liabilities	4,502	4,636
Total current liabilities	**27,008**	**9,430**
TOTAL EQUITY AND LIABILITIES	**163,348**	**150,041**

(1) Restated following the purchase price allocation of Nicox Ophthalmics (previously Aciex) and Laboratoires Nicox (previously Laboratoires Doliage) and the retroactive adjustment of the prices of acquisition of the companies Nicox Farma S.r.l (previously Eupharmed), Nicox Ophthalmics Inc et Laboratoires Nicox.