

Press Release

Nicox: Business Update and 2016 Financial Results

- **Two potential U.S. product approvals for Vyzulta™¹ (latanoprostene bunod ophthalmic solution) 0.024% and ZERVIAE™² (cetirizine ophthalmic solution) 0.24% expected in 2017**
- **Strong pipeline including two products poised to enter in Phase 2 clinical trials**
- **Significant reduction in future fixed costs**
- **Cash position of €28.9 million as of December 31, 2016**

March 31, 2017
Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today announced its financial and operating results for the year ended December 31, 2016, as approved by the Board of Directors on March 29, 2017, and provided an overview of its milestones and activities.

"The transfer of commercial operations has allowed Nicox to refocus resources on its global therapeutic R&D pipeline. The recent resubmissions of the Vyzulta™ and ZERVIAE NDAs give Nicox the potential for two product approvals in 2017, both of which are expected to be sources of significant recurrent revenue for the company," said Michele Garufi, Chairman and Chief Executive Officer of Nicox. "In addition, the advancement of the pre-IND activities for both NCX 4251 and NCX 470 means we now also have two products poised to enter proof-of-concept clinical trials in the next 12 months, whilst our research team is continuing to work on novel programs utilizing our nitric oxide-donating technology. 2017 should be a transformational year for the company, and we are well positioned to continue to grow as a major R&D player in the ophthalmic space."

Key upcoming milestones

- August 24, 2017: Potential U.S. FDA approval of Vyzulta™ NDA
- H2 2017: Expected launch of Vyzulta™ in the United States by Bausch + Lomb, subject to FDA approval
- Q3 2017: Potential U.S. FDA approval of ZERVIAE NDA
- Q4 2017: Start of Phase 2 clinical study for NCX 4251
- Q1 2018: Start of Phase 2 clinical study for NCX 470

Review of the main 2016 and post-reporting operational events

- Pipeline update
 - **Latanoprostene bunod (Vyzulta™): An investigational nitric oxide (NO) donating prostaglandin.** Nicox's licensee, Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.), resubmitted the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) on February 24 2017, seeking approval for latanoprostene bunod ophthalmic solution, 0.024% as an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open-angle glaucoma (OAG) or

ocular hypertension (OHT). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 24, 2017. The NDA was resubmitted in response to a Complete Response Letter (CRL) received³ by Valeant from the FDA in July 2016. Bausch + Lomb expects, subject to FDA approval, to launch Vyzulta in the United States in H2 2017.

- **ZERVIAE (formerly AC-170), a novel, proprietary, cetirizine eye drop formulation** for the treatment of ocular itching associated with allergic conjunctivitis. The NDA was resubmitted to the FDA on March 8, 2017 by Nicox. The FDA is expected to acknowledge its receipt of the resubmission within 30 days, state the classification, and provide the due date for action, with a maximum review period of 6 months if the resubmission is a Class 2 resubmission. The NDA was resubmitted in response to a CRL received⁴ by Nicox from the FDA in October 2016. Nicox plans to enter into a licensing agreement for commercialization of ZERVIAE in the United States. Approval of the ZERVIAE NDA on or before 1st December 2017 would trigger a milestone payment in Nicox shares equivalent to \$6.8 million⁵
- **NCX 4251, a novel ophthalmic suspension of fluticasone propionate nanocrystals** being developed for the first time as a topical treatment for acute exacerbation of blepharitis. Subject to IND filing and acceptance, Nicox plans to initiate a Phase 2 clinical trial during the fourth quarter of 2017 and expects the trial to take approximately 1 year to complete.
- **NCX 470, a novel nitric oxide (NO) donating bimatoprost analog** being developed for IOP lowering in patients with OAG or OHT. Subject to IND filing and acceptance, Nicox expects to start a Phase 2 clinical study in early 2018 and to complete the study in approximately 1 year.
- **New NO-donors:** Nicox is continuing research on novel NO-donors, including next-generation stand-alone NO-donors which are currently in the lead optimization phase. Promising preclinical results on these were presented at the AOPT 2017 meeting in Florence, Italy.
- Other 2016 Events
 - In January 2016, Nicox out-licensed over-the-counter (OTC) asset AC-120 to Ora, Inc. AC-120 is an eye drop that targets morning eyelid swelling (also known as 'puffy eyes'), a common complaint of aging individuals, particularly women, and a condition with a range of different causes
 - In July 2016, Nicox announced it had entered into an agreement to transfer its commercial operations to a new pan-European ophthalmic specialty pharmaceutical company led by GHO Capital. This transaction subsequently closed in August 2016.
 - 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.

2016 Financial Summary⁶

Following reclassification of the European commercial business as Discontinued Operations, the operating profit and loss account items described below include only the Continuing Operations.

- The operating expenses for the period were €21.3 million compared to €17.6 million for the 12 months to December 31, 2015. The increase in operating expenses over the period is mainly explained by costs related to the submission of the AC-170 NDA and completion of a Phase 3b safety trial, as well as the preclinical development of NCX 470 and NCX 4251.
- The Group recorded a net loss from Continued Operations of €6.7 million as of December 2016, compared to a net loss of €19.8 million⁷ at the same date in 2015. The significant decrease in the loss for the year 2016 is mainly due to the non-cash impact of the reduction in the value of a potential earn-out payable in shares to Nicox Ophthalmics Inc. former shareholders.

At the end of December 2016, the net loss of the Group amounts to €19.0 million compared to €27.9 million at

end of December 2015.

The Group had cash, cash equivalents and financial instruments of €28.9 million as of December 31, 2016, compared to €29.7 million on December 31, 2015.

Notes:

1. Vyzulta is the provisionally approved tradename for latanoprostene bunod ophthalmic solution, 0.024%.
2. ZERVIA TE is the provisionally approved tradename for AC-170, cetirizine ophthalmic solution, 0.24%.
3. In July 2016, Valeant received a Complete Response Letter (CRL) from the FDA regarding the company's original NDA for latanoprostene bunod. The concerns raised by the FDA pertained 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 latanoprostene bunod or additional clinical trials needed for its NDA approval.
4. In October 2016, Nicox announced the receipt of a CRL from the FDA in response to the ZERVIA TE NDA. The FDA's stated reason for the CRL pertained solely to a CGMP inspection at a third party facility producing the active pharmaceutical ingredient (API), cetirizine, and supplying it to the manufacturer of the finished product. The production site has since received an establishment inspection report (EIR). An EIR is issued by the FDA when the FDA considers that an inspection is "closed" under 21 CFR 20.64(d)(3). The safety and efficacy data submitted by Nicox in the ZERVIA TE NDA have not resulted in the FDA requesting any further clinical or non-clinical testing for the approval of the ZERVIA TE NDA. Furthermore, the CRL did not include any concerns related to the finished product manufacturing facility.
5. The payment of \$10 million in Nicox shares to ex-Aciex shareholders will be reduced by \$3.2 million related to the costs incurred by Nicox in running the additional clinical safety study on ZERVIA TE. (see Document E 14-060 dated of September 30, 2014 available on Nicox' website). ZERVIA TE was developed by Aciex Therapeutics, Inc., which became a wholly-owned subsidiary of Nicox in October 2014 and was subsequently renamed Nicox Ophthalmics, Inc
6. Revenues, costs, assets and liabilities for the European commercial operations are treated as "Discontinued Operations" in accordance with IFRS 5
7. The net loss for 2015 has been adjusted to remove the European commercial operations.

About Nicox

Nicox is an international ophthalmic R&D company utilizing innovative science to maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel therapies that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products at the pre-approval stage with the U.S. Food and Drug Administration (FDA) and a promising pipeline including next-generation stand-alone nitric-oxide donors, with the potential to treat a range of ophthalmic indications. Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
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Gilbert Dupont	Damien Choplain	Paris, France
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Upcoming financial and business conferences

April 4-5	Needham's 16 th Annual Healthcare Conference	New York, US
April 18-19	Small Cap Event	Paris, France
May 3-4	Deutsche Bank 42 nd Annual Health Care Conference	Boston, US
May 22-23	BioEquity Europe	Paris, France
May 30	Gilbert Dupont 15 th Annual Healthcare Conference	Paris, France
June 19-22	2017 BIO International Convention	San Diego, US

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CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – DECEMBER 31, 2016

	As of December 31,	
	2016	2015 restated ¹
	<i>(in thousands of € except for per share data)</i>	
Revenues	16	67
Gross Margin	16	67
Selling expenses	-	(1,194)
General and administrative expenses	(8,617)	(9,674)
Research and development expenses	(12,168)	(6,159)
Other operating income	770	994
Other operating expense	(525)	(543)
Total operating income (loss) before fair value changes of contingent consideration ,and impairment of intangible assets	(20,525)	(16,509)
Fair value changes of contingent considerations	12,741	(4,215)
Impairment of intangible assets	-	-
Total operating income (loss)	(7,784)	(20,723)
Finance income	1,202	1,514
Finance costs	(107)	(543)
Net finance revenues	(1,094)	972
Loss before tax	(6,690)	(19,752)
Income tax	(52)	-
Loss from continuing operations	(6,742)	(19,752)
Loss from discontinued operations	(12,293)	(8,187)
Net loss of the year	(19,035)	(27,939)
Attributable to owners of the Company	(19,035)	(27,939)
Total comprehensive income (loss) for the period, net of tax	(0,80)	(1,25)
Basic/diluted earnings per share from continuing operations (€/share)	(0,28)	(0,88)
Basic/diluted earnings per share from discontinued operations (€/share)	(0,51)	(0,37)

¹ Following Nicox European commercial operations divestment

CONSOLIDATED STATEMENT OF FINANCIAL POSITION – DECEMBER 31, 2016

	As of December 31,	
	2016	2015
<i>(in thousands of €)</i>		
ASSETS		
Non-current assets		
Goodwill	27,546	32,245
Intangible assets	77,654	92,141
Property, plant and equipmenta	204	866
Other investments, including derivatives	12,652	253
Total non-current assets	118,056	125,505
Current assets		
Inventories	-	948
Trade receivables	104	3,027
Subsidies receivables	396	727
Other receivables	1,164	3,013
Other current assets, including derivatives	-	532
Prepayments	168	526
Cash and cash equivalents	28,859	29,070
Total current assets	30,692	37,843
TOTAL ASSETS	148,748	163,348
EQUITY AND LIABILITIES		
Equity attributable to equity holders of the parent		
Share capital	25,005	22,870
Premium related to share capital	483,745	469,119
Currency translation adjustment	11,868	10,049
Tresury shares	(478)	(458)
Consolidates reserves	(396,555)	(372,310)
Net income/(loss)	(19,035)	(27,939)
Total Equity	104,549	101,331
Non-current liabilities		
Non-current financial debts	30	1,567
Non-current liabilities related to business combination	923	2,066
Deferred tax liabilities	29,409	30,759
Non-current provisions	456	617
Total non-current liabilities	30,819	35,009
Current liabilities		
Current financial debts	32	308
Current liabilities related to business combination	5,234	16,832
Trade payables	1,338	5,364
Deferred income/revenue	4,275	2
Provisions	40	-
Other current liabilities	2,462	4,502
Total current liabilities	13,380	27,008
TOTAL EQUITY AND LIABILITIES	148,748	163,348