



## Nicox first half 2015 highlights

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- **Product pipeline on track for near-term major progress**
    - **VESNEO™ NDA submitted by Valeant**
    - **Three further regulatory submissions planned by Nicox within the next 12 months**
  - **Accelerating development of additional NO-donating ophthalmology programs**
  - **Revenues from existing products €4.6 million in H1 2015, up 114% from H1 2014**
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August 28, 2015

Sophia Antipolis, France

**Nicox S.A.** (Euronext Paris: FR0000074130, COX), the international ophthalmic company, today announced its financial results for the six months ended June 30, 2015, and provided an update on its activities.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said: *"The submission of the NDA for VESNEO™ to the FDA by our partner Valeant is a pivotal milestone for Nicox and provides validation for our high-value NO-donating pipeline. VESNEO™ is the first ophthalmic product to emerge from our proprietary platform, and its progress is a great achievement for both companies. Together with our product pipeline, the growing European commercial platform and the new nitric oxide-donating development programs, Nicox is building a leading presence in the global ophthalmology drug market, which is expected to grow considerably in the next few years."*

### **Business update for the six months to June 30 2015 and post-reporting period**

#### **VESNEO™ NDA submission confirmed by Valeant**

Nicox's licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant group) submitted a New Drug Application (NDA) recently to the US Food and Drug Administration (FDA) for VESNEO™ (latanoprostene bunod ophthalmic solution 0.024%), an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma or ocular hypertension.

VESNEO™ is a nitric oxide (NO)-donating prostaglandin F2-alpha analog discovered using Nicox's proprietary R&D platform, which is designed to engineer NO-donating compounds for therapeutic use. Valeant has previously estimated that peak sales of VESNEO™ may exceed \$500 million in the US and \$1 billion worldwide should the product be approved. The partnership with Valeant could therefore generate significant revenues for Nicox through a mix of milestones (up to \$132.5 million net<sup>1</sup> mainly on commercial

sales targets) and royalties (potential net<sup>2</sup> tiered royalties on sales from 6% to 11%) if launched. Following the divestment of Nicox's US commercial operations, Nicox has informed Valeant that it wishes not to co-promote VESNEO™ in the United States.

Results from studies investigating the mechanism of action of VESNEO™ were published in June 2015 by Cavet *et al.* in *Investigative Ophthalmology & Visual Science*. In addition, clinical data were presented at major glaucoma conferences: the 25<sup>th</sup> American Glaucoma Society Annual Meeting (Feb 26 - Mar 1, Coronado), the Glaucoma 360 conference (Feb 5-7, San Francisco) and the World Glaucoma Congress 2015 (June 6-9, Hong Kong).

### **Ophthalmology pipeline continuing to progress beyond VESNEO™**

- **AC-170** – Two positive pre-NDA meetings were held with the FDA regarding AC-170, a novel formulation of cetirizine developed for the treatment of ocular itching associated with allergic conjunctivitis. The purpose of the first meeting was to discuss the clinical package for AC-170, and based on the available efficacy and safety data, the FDA recommended submission of an NDA. The second pre-NDA meeting was focused on the Chemistry, Manufacturing and Controls (CMC) data package. The NDA submission remains on track, with the objective to obtain FDA approval by the end of 2016.
- **NCX 4251** – Nicox's nanocrystalline fluticasone propionate (formerly known as AC-155) for the treatment of blepharitis, is expected to go directly into phase 2 clinical trials following toxicity studies and IND filing, pending IND approval by the FDA.
- **NCX 470 and the NO-donor pipeline** – Nicox has decided to advance several additional programs from its proprietary nitric oxide (NO)-donating platform. These include two programs targeting glaucoma: NCX 470 which will be moved toward clinical-stage trials 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.
- **AzaSite® and BromSite™** – Nicox plans to file European Marketing Authorization Applications (MAAs) for both AzaSite® (azithromycin ophthalmic solution for bacterial conjunctivitis) and BromSite™ (bromfenac ophthalmic solution for pain and inflammation after cataract surgery) by the end of H1 2016. Nicox signed an exclusive license agreement with InSite Vision in February 2015 for AzaSite® and BromSite™ in Europe, Middle East and Africa.

### *Other Updates*

- The development of OHT (RPS-OH), a diagnostic test for ocular herpes in-licensed from Rapid Pathogen Screening, Inc. (RPS®), has been discontinued. AAT (RPS-AP), a diagnostic test for the combined detection of adenoviral and allergic conjunctivitis also in-licensed from RPS®, remains in clinical development.
- Outside the Nicox's ophthalmology core business field, a decision has been taken by Nicox's undisclosed financial partner not to advance naproxinod and other undisclosed compounds in Duchenne muscular dystrophy (DMD).

### **First-half financial summary**

The Group's revenues in the first half of 2015 totaled €4.6 million compared to €2.1 million a year before<sup>3</sup> and consisted exclusively of European and International product sales. The growth in sales was helped by the acquisition of Doliage and the launch of new products in the Xailin™ range.

The Group recorded a net loss of €15.8 million as of June 2015, compared to a net loss of €16.0 million at the same date in 2014. The Group's net loss remains stable following the divestment of Nicox Inc. at the end of 2014.

The Group had cash, cash equivalents and financial instruments of €39.5 million as of June 30, 2015, compared to €31.9 million on December 31, 2014. Nicox completed a financing in March 2015 with the participation of major institutional investors specialized in life sciences, mainly from the US, which brought gross proceeds of €27 million.

The positive sales momentum seen in the first half is expected to continue in the second half of the year. This is expected to be offset by growing R&D costs, reflecting continued investment in the near-term product pipeline, including the planned submission of regulatory applications for several products over the next 12 months.

**Michele Garufi** added: *“Our Research and Development costs, which we expect will increase in the second half of the year, are fueling significant progress in our late-stage development and regulatory activities. We expect three regulatory filings in the next 12 months in addition to VESNEO™, with the potential for two FDA approvals in 2016. Along with the significant commercial potential of VESNEO™, these investments would create additional substantial value for the Company.”*

**The half-yearly financial report will be available in French by the end of September 2015 on Nicox’s website [www.nicox.com](http://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.*

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## Notes

1. Potential net milestones from Valeant to Nicox following payments due to Pfizer as part of 2009 agreement
  2. Potential net royalties from Valeant to Nicox following payments due to Pfizer as part of 2009 agreement
  3. Revenues as of June 30, 2014 have been restated following the divestment of Nicox Inc.
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## 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 VESNEO™ 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 recently submitted to the FDA by the Company’s licensee Valeant. Our pipeline also features: AC-170, a pre-NDA candidate for the treatment of ocular itching associated with allergic conjunctivitis; AzaSite®, a pre-MAA candidate in Europe for bacterial conjunctivitis; and BromSite™, a pre-MAA candidate in Europe for pain and inflammation after cataract surgery. The Group operates directly in six countries, including the United States. It has proprietary commercial operations in Europe’s five largest markets complemented by an expanding international network of distributors.

Nicox is headquartered in France and has more than 130 staff worldwide. It 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](http://www.nicox.com).

## Upcoming 2015 events

### Financial and business conferences

Sept. 11	Goldman Sachs Symposium	London, UK
Sept.16-18	Kepler Cheuvreux Autumn Conference	Paris, France
Oct.14	Portzamparc Forum Healthcare Conference	Paris, France
Nov.5	Société Générale Healthcare Forum	Paris, France
Nov. 12-13	Bryan Garnier Healthcare Conference	Paris, France
Nov.20-21	Actionaria 2015	Paris, France
Nov.24	Natixis MidCap Conference	Paris, France

### Scientific conferences

Sept. 23-26	SOE – Congreso Sociada Espanola de Oftalmologia (Booth 139 & 131)	Sevilla, Spain
Oct. 7-10	EVER 2015 – European Association for Vision and Eye Research	Nice, France
Nov. 14-17	AAO – American Academy of Ophthalmology	Las Vegas, US

**Analyst coverage**

Bryan, Garnier & Co	Hugo Solvet	Paris, France
Stifel	Max Herrmann	London, UK
Invest Securities	Martial Descoutures	Paris, France
Kepler Cheuvreux	Alexandra Ralli	Paris, France



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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 4<sup>th</sup> 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](http://www.nicox.com)).

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## NON AUDITED INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – JUNE 2015

	As of June 30,	
	2015	2014 restated <sup>1</sup>
<i>(in thousands of € except for per share data)</i>		
Revenues	4,567	2,136
Cost of sales	(2,540)	(1,695)
Selling expenses	(7,398)	(5,575)
Administrative expenses	(5,692)	(4,026)
Research and development expenses	(2,288)	(1,798)
Other income	515	700
Other expense	(1,698)	(210)
<b>Operating loss from continued operations</b>	<b>(14,534)</b>	<b>(10,468)</b>
Finance income	1,029	160
Finance expense	(2,256)	(716)
Share of Profit (loss) of associates	-	-
<b>Loss from continued operations before income tax</b>	<b>(15,761)</b>	<b>(11,024)</b>
Income tax expense	(11)	(110)
<b>Net loss before discontinued operations</b>	<b>(15,772)</b>	<b>(11,134)</b>
<b>Discontinued operations</b>	<b>-</b>	<b>(4,830)</b>
<b>Group net loss for the period<sup>2</sup></b>	<b>(15,772)</b>	<b>(15,964)</b>
Exchange differences on translation of foreign operations	6,237	(102)
Actuarial (losses)/gains from defined benefit plans	10	(29)
Gains on treasury shares	4	-
<b>Other comprehensive income (loss) for the period, net of tax</b>	<b>6,251</b>	<b>(131)</b>
<b>Total comprehensive income (loss) for the period, net of tax</b>	<b>(9,521)</b>	<b>(16,095)</b>
Attributable to:		
- Equity holders of the parent	(9,521)	(16,095)
- Non-controlling interests	-	-
<b>Basic and diluted loss per share attributable to equity holders of the parent</b>	<b>(0.14)</b>	<b>(0.21)</b>

<sup>1</sup> Following Nicox Inc. divestment

<sup>2</sup> Including non-cash IFRS adjustments amounting to €3.2 million as of June 30, 2015, compared to zero as of June 30, 2014.

## NON AUDITED INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION – JUNE 2015

	As of June 30, 2015	As of Dec. 31, 2014 Restated <sup>3</sup>
<i>(in thousands of €)</i>		
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant & equipment	999	902
Goodwill	40,110	37,354
Intangible assets	89,419	80,202
Financial assets	232	95
Deferred income tax assets	0	0
<b>Total non-current assets</b>	<b>130,760</b>	<b>118,553</b>
<b>Current assets</b>		
Inventories	1,388	1,504
Trade receivables	2,038	1,675
Government subsidies receivable	886	1,238
Current assets	2,051	2,098
Current financial assets	6,178	9,253
Prepaid expenses	645	367
Cash and cash equivalents	33,350	22,619
<b>Total current assets</b>	<b>46,536</b>	<b>38,755</b>
<b>TOTAL ASSETS</b>	<b>177,296</b>	<b>157,308</b>
<b>EQUITY AND LIABILITIES</b>		
Common shares	22,848	19,848
Other reserves	96,376	83,700
Non-controlling interests	-	-
<b>Total Equity</b>	<b>119,224</b>	<b>103,548</b>
<b>Non-current liabilities</b>		
Other contingencies and liabilities	602	548
Other financial liabilities <sup>4</sup>	19,503	15,860
Deferred income tax liabilities <sup>5</sup>	29,904	27,783
Finance lease	272	323
Other liabilities	215	152
<b>Total non-current liabilities</b>	<b>50,496</b>	<b>44,666</b>
<b>Current liabilities</b>		
Other contingencies and liabilities	55	-
Finance lease	219	213
Financial liabilities	147	608
Trade payables	3,167	3,635
Social security and other taxes	3,747	4,297
Other contingencies and liabilities	241	339
<b>Total current liabilities</b>	<b>7,576</b>	<b>9,093</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>177,296</b>	<b>157,308</b>

<sup>3</sup> In accordance with IFRS 3 (Business Combinations), Nicox made adjustments during the Acix and Doliage purchase price allocation periods to some of the provisional amounts recognized in 2014.

<sup>4</sup> Including earn-out related to Nicox Ophthalmics, Inc. (ex-Aciex); NCX 4240, AzaSite and BromSite acquisitions or in-licensing

<sup>5</sup> Mainly related to Nicox Ophthalmics, Inc. (ex-Aciex) assets