## Press Release

# Nicox provides 2018 Outlook and 2017 Estimated Financial Results

- **VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, marketed by partner Bausch + Lomb in the U.S. since December 2017**
- **ZERVIATE™ (cetirizine ophthalmic solution), 0.24%, U.S. launch planned by partner Eyevance Pharmaceuticals for the 2018 fall allergy season**
- **Pipeline candidates moving towards clinical development, with IND submissions to the U.S. FDA planned for NCX 470 in Q3 2018 and NCX 4251 in Q1 2019**
- **Estimated cash position of €41.4 million as of December 31, 2017**

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March 6, 2018 – release at 7:30 am CET
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), international ophthalmology company, today provided an overview of its milestones and activities, and announced its estimated financial and operating results for the year ended December 31, 2017. The Company's Board of Directors will adopt the 2017 consolidated financial statements on March 16, 2018.

*"2017 was a year of outstanding achievements for Nicox, with the U.S. Food and Drug Administration approval of our two lead products, VYZULTA™, the first drug based on our proprietary nitric oxide (NO)-donating research platform, and ZERVIATE™. We are off to a strong start in 2018, with VYZULTA™ already being marketed in the U.S. by our partner Bausch + Lomb, and ZERVIATE™ set to be launched in the U.S. by Eyevance later this year. The future revenue streams from these two products, together with our strong cash balance, leave us well positioned to advance our wholly-owned programs, NCX 470 and NCX 4251, into clinical development,"* **stated Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"We are strengthening the R&D team that will further develop our internal drug candidates with the recent hiring of Tomas Navratil as our Head of Development, and the planned opening of a development office in Research Triangle Park, North Carolina. In 2018 we also expect to make significant advances in our NO-donating research pipeline, targeting IOP reduction, both with our next-generation of stand-alone NO-donors, and with novel therapeutic classes targeting primary outflow. We expect 2018 to be another year of important accomplishments."*

**Commercial Stage Products Updates**

In 2017, both of Nicox's lead assets were approved by the U.S. Food and Drug Administration (FDA).

- **VYZULTA™ marketed in the U.S. by Bausch + Lomb**: Indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, VYZULTA™, the first prostaglandin analog with one of its metabolites being nitric oxide (NO), is the first approved product to utilize Nicox's proprietary NO-donating research platform. Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) launched VYZULTA™ in the U.S. in December 2017.

  Bausch + Lomb holds exclusively licensed worldwide rights to VYZULTA™, which was approved by

the U.S. FDA in November 2017. Nicox received $17.5 million from Bausch + Lomb upon the approval, of which $15 million was paid to Pfizer under a previous agreement signed in 2009. The current lead branded products in this market, Travatan Z (travoprost ophthalmic solution), 0.004% and Lumigan (bimatoprost ophthalmic solution), 0.01% and 0.03%, had sales of $570 million and $687 million, respectively, in 2016[1]. Nicox estimates that the U.S. patents covering VYZULTA™ could be extended from 2025 to 2030.

- **ZERVIATE™ expected to be launched in the U.S. by Eyevance Pharmaceuticals for the 2018 fall allergy season**: Indicated for the treatment of ocular itching associated with allergic conjunctivitis, ZERVIATE™ is the first and only topical ocular formulation of cetirizine. ZERVIATE™ was approved by the U.S. FDA in May 2017.

  In September 2017, Nicox licensed exclusive U.S. commercial rights for ZERVIATE™ to Eyevance Pharmaceuticals, LLC, an ophthalmic specialty pharmaceutical company backed by a specialized investment group and led by a team experienced in the U.S. ophthalmic market. Nicox received a non-refundable upfront payment of $6 million upon signature of this agreement. The annual U.S. market for topical ocular allergy products is approximately $700 million[2]. Eyevance plans to launch ZERVIATE™ in the U.S. for the 2018 fall allergy season.

  Nicox is currently exploring partnerships for ZERVIATE™ outside of the U.S. The product is protected by U.S. patents to 2030 and 2032, and by Japanese patents to 2030.

**Pipeline Updates**

Nicox continues to progress its two pipeline products towards clinical development and is also advancing several innovative, discovery-stage assets.

- **NCX 470 Investigational New Drug (IND) submission for Phase 2 planned in Q3 2018**: NCX 470 is a novel NO-donating bimatoprost prostaglandin analog in development for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension. We believe that NCX 470 has the potential for an IOP-lowering activity greater than VYZULTA™. Nicox is conducting IND-enabling non-clinical studies and, subject to their successful completion, currently plans to submit an IND application to the U.S. FDA in the third quarter of 2018 to support a Phase 2 clinical study.

- **NCX 4251 IND submission for Phase 2 planned in Q1 2019**: NCX 4251 is a novel, patented ophthalmic formulation of fluticasone propionate being developed for the first time as a targeted topical treatment of the eyelid for acute exacerbation of blepharitis. Blepharitis is a common ocular condition in which the edges of the eyelids become red and swollen, and may contain dandruff-like matter. The annual U.S. revenues of steroids, antibiotics and their combinations prescribed for blepharitis total more than $500 million[3]. Nicox is conducting formulation and IND-enabling non-clinical studies and, subject to their successful completion, currently plans to submit an IND application to the U.S. FDA in the first quarter of 2019 to support a Phase 2 clinical study.

- **Next-Generation of Stand-alone NO-donors and Novel NO-Donating Compounds**: Nicox has active research programs targeting NO-donation in the eye and has discovered multiple novel compounds that release NO from pharmacologically active and non-active scaffolds. These novel chemical entities are thought to lower IOP by stimulating the primary fluid outflow mechanism from the anterior segment of the eye. The Company's next-generation of stand-alone NO-donors is designed to optimize NO dosing when administered alone or with current standard-of-care treatments as adjunctive therapy or as fixed-dose combination products to lower IOP in patients with open-angle glaucoma or ocular hypertension. New data on repeated dosing of NCX 667, the lead stand-alone NO-donor, was presented at the Association for Research in Vision and Ophthalmology (ARVO) 2017 Annual Meeting. Multiple candidates currently in the lead optimization stage of development have demonstrated IOP-lowering in various animal models of ocular hypertension. Some of these candidates are currently being investigated for targeted extended release intraocular drug delivery as part of two exploratory strategic collaborations with **pSivida Corp.** and **Re-Vana Therapeutics.** The collaborations will evaluate whether their biodegradable extended release technologies are suitable for use with Nicox's new NO-donating compounds.

**Other 2017 and Early 2018 Highlights**

- In August 2017, 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 €26.3 million, and net proceeds were €24.5 million.

- In September 2017, Nicox and VISUfarma amended certain elements of their agreement relating to the August 2016 transfer of Nicox's European and International commercial operations to VISUfarma. Subsequently, Nicox and VISUfarma agreed that Nicox would no longer be responsible for completing development and regulatory approval for AzaSite (azithromycin ophthalmic solution) 1% in Europe. These changes result in a net income of €4.7 million.

- In October 2017, Nicox entered into two collaborations to explore the potential for extended release formulations of Nicox's next-generation of stand-alone NO-donors for the reduction of IOP, with Re-Vana Therapeutics concerning their EyeLief™ long-acting photo-crosslinked biodegradable drug delivery platform, and with pSivida Corp. concerning their biodegradable extended release drug delivery system.

- In January 2018, Nicox appointed Tomas Navratil, Ph.D. as Vice President, Head of Development, effective January 1, 2018. In this newly-created position, reporting to Michael Bergamini, Ph.D., Executive Vice President, Chief Scientific Officer of Nicox, Dr. Navratil is responsible for leading all of the Company's non-clinical and clinical development activities. Nicox has subsequently decided to open a development office in Research Triangle Park, North Carolina (U.S) and is in the process of recruiting additional development team members to support the IND submissions and the starts of the NCX 470 and NCX 4251 clinical studies.

**2017 Financial Summary**

This press release presents estimated results for the full-year 2017 (unaudited). The audit procedures by the Statutory auditors are underway. The Company's Board of Directors will adopt the 2017 consolidated financial statements on March 16, 2018.

At the end of December 2017, the estimated Net Loss of the Group amounts to €3.6 million compared to €19.0 million at end of December 2016. This estimated Net Loss includes the European commercial business which is treated as Discontinued Operations since their transfer in August 2016.

The Group had estimated cash, cash equivalents and financial instruments of €41.4 million as of December 31, 2017, compared to €28.9 million on December 31, 2016.

- Net revenue for the 12 months to December 2017 was €2.3 million, which is comprised exclusively of the U.S. FDA approval milestone payment from Bausch + Lomb, and royalty revenue following the launch of VYZULTA™ in the second half of December 2017, after deduction of Nicox's milestone and royalty payments to Pfizer under a previous agreement signed in 2009. The non-refundable upfront payment received from Eyevance was not immediately recognizable as revenue accordingly to IFRS accounting principles. The operating expenses for the period were €20.8 million compared to €21.3 million for the 12 months to December 31, 2016.

- The Group recorded a Net Loss from Continued Operations of €8.3 million as of December 2017, compared to a Net Loss of €6.7 million at the same date in 2016. The net loss for 2017 have been significantly reduced due to the non-cash impact of the reduction of deferred tax liability related to Nicox Ophthalmics, Inc. following the new US tax law voted in December 2017 decreasing significantly the federal corporate tax rate. The 2016 loss was significantly decreased by the non-cash impact of the reduction in the value of a potential earn-out payable in shares to Nicox Ophthalmics, Inc. former shareholders.

**Notes:**

1. MS Health Analytics 2016 reported sales and TRx (Total Prescriptions)
2. IMS Health Analytics and TRx (Total Prescriptions), not including OTC products for ocular allergy
3. Internal estimate based on IMS Health Analytics data.

## About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's portfolio includes two ophthalmic products approved for commercialization in the U.S., VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, and ZERVIATE™ (cetirizine ophthalmic solution), 0.24%, licensed in the U.S. to Eyevance Pharmaceuticals. In addition to VYZULTA and ZERVIATE, Nicox has a pipeline of development-stage assets based on the Company's proprietary NO-donating research platform, and product candidates using repurposed molecules, clinically and commercially validated in other indications, with a potential to offer novel treatments for various ocular conditions. Nicox's pipeline also includes a next-generation of stand-alone NO-donors in the research stage and other exploratory novel NO-donating compounds targeting IOP reduction. 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 |
| Invest Securities | Martial Descoutures | Paris, France |
| Gilbert Dupont | Damien Choplain | Paris, France |

*The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.*

## Upcoming financial and business conferences

| | | |
|---|---|---|
| March 12-14 | Cowen 38th Annual Health Care Conference | Boston, USA |
| March 20-21 | Oppenheimer's 28th Annual Healthcare Conference | New York, USA |
| April 8-10 | HC Wainwright Global Biotechnology Conference | Monaco, Principality of Monaco |
| April 16-17 | SmallCap Event | Paris, France |
| May 29 | Conférence Gilbert Dupont 16th Annual Healthcare | Paris, France |
| June 27-28 | European MidCap Event | Paris, France |
| October 1-3 | Conférence Cantor Global Healthcare | New York, USA |

## Contacts


**Nicox**
Gavin Spencer,
EVP, Chief Business Officer
T +33 (0)4 97 24 53 00
communications@nicox.com

**Investor Relations**
Europe
Nicox
Corporate Communications Department
T +33 (0)4 97 24 53 00
communications@nicox.com

United States
Argot Partners
Melissa Forst
T +1 (212) 600-1902
melissa@argotpartners.com

**Media Relations**
United Kingdom
Jonathan Birt
T +44 7860 361 746
jonathan.birt@ymail.com

France
NewCap
Nicolas Merigeau
T +33 (0)1 44 71 94 98
nicox@newcap.eu

United States
Argot Partners
David Rosen
T +1 (212) 600-1902
david.rosen@argotpartners.com

## Disclaimer

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any 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 2016*' filed with the French Autorité des Marchés Financiers (AMF) on March 29, 2017, and in the updated and additional risk factors as of August 14, 2017, which are available on Nicox's website (www.nicox.com).

**Nicox S.A.**
Drakkar 2
Bât D, 2405 route des Dolines
CS 10313, Sophia Antipolis
06560 Valbonne, France
T +33 (0)4 97 24 53 00
F +33 (0)4 97 24 53 99

## CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

| | As of December 31: | |
|---|---|---|
| | **2017 (estimated)** | **2016 (audited)** |
| Collaboration revenue | 15,080 | 16 |
| Pfizer royalties payment* | (12,775) | - |
| **Net revenue** | **2,305** | **16** |
| Research and development expenditures | (9,750) | (12,168) |
| Administrative expenses | (9,869) | (8,617) |
| Other income | 987 | 770 |
| Other expenses | (1,207) | (525) |
| **Operating loss before changes in fair value of contingent consideration** | **(17,534)** | **(20,525)** |
| Fair value adjustment of contingent consideration | (984) | 12,741* |
| **Operating loss** | **(18,518)** | **(7,784)** |
| Finance income | 1,314 | 1,202 |
| Finance expense | (1,908) | (107) |
| **Net financial income, (expenses)** | **(594)** | **1,094** |
| **Loss before tax from continuing operations** | **(19,112)** | **(6,690)** |
| Income tax (expense), income | 10,815** | (52) |
| **Loss after tax from continuing operations** | **(8,297)** | **(6,742)** |
| Loss for the period from discontinued operations (net of tax) | 4,678 | (12,293) |
| **Loss for the period** | **(3,619)** | **(19,035)** |

** includes a milestone and royalties*

*** non-cash impact of the reduction in the value of a potential earn-out payable in shares to Nicox Ophthalmics Inc. former shareholders.*

*** non-cash impact of the reduction of deferred tax liability related to Nicox Ophthlamics Inc. following the new US tax law voted in December 2017*

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

| | As of December 31: | |
|---|---|---|
| | 2017 (estimated) | 2016 (audited) |
| **ASSETS** | | |
| **Non-current assets** | | |
| Goodwill | 24,211 | 27,546 |
| Intangible assets | 68,155 | 77,654 |
| Property, plant and equipment | 158 | 204 |
| Non-Current financial assets | 15,437 | 12,652 |
| **Total non-current assets** | **107,961** | **118,056** |
| | | |
| **Current assets** | | |
| Trade receivables | 44 | 104 |
| Government grants receivables | 948 | 396 |
| Other current assets | 523 | 1,164 |
| Prepayments | 1,381 | 168 |
| Cash and cash equivalents | 41,394 | 28,859 |
| **Total current assets** | **44,290** | **30,692** |
| **TOTAL ASSETS** | **152,252** | **148,748** |
| | | |
| **EQUITY AND LIABILITIES** | | |
| **Shareholders' equity** | | |
| Issued capital | 29,459 | 25,005 |
| Share premium | 510,942 | 483,745 |
| Cumulative translation adjustement | 3,973 | 11,868 |
| Treasury shares | - | (478) |
| Accumulated deficit | (416,159) | (415,591) |
| **Total equity** | **128,215** | **104,549** |
| **Non-current liabilities** | | |
| Non-current financial liabilities | 26 | 30 |
| Non-current financial liabilities related to business combinations | - | 923 |
| Deferred taxes liabilities | 15,631 | 29,409 |
| Provisions | 401 | 456 |
| **Total non-current liabilities** | **16,059** | **30,819** |
| **Current liabilities** | | |
| Current financial liabilities | 24 | 32 |
| Current financial liabilities related to business combinations | - | 5,234 |
| Trade payables | 1,929 | 1,338 |
| Deferred income | 4,184 | 4,275 |
| Provisions | 40 | 40 |
| Other current liabilities | 1,801 | 2,462 |
| **Total current liabilities** | **7,978** | **13,380** |
| **TOTAL LIABILITIES AND EQUITY** | **152,252** | **148,748** |