## Press Release

# Nicox First Half 2018 Financial Results and Business Update

- **NCX 470 Phase 2 clinical study initiated in Q3 2018**
- **NCX 4251 on track for U.S. IND filing in Q1 2019 to enable first-in-human Phase 2 clinical study**

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

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmic company, today reported the financial results for the Nicox Group for the six months ending June 30, 2018 and provided an update on its activities.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, *said: "Nicox is entering a new and exciting phase with the initiation of the Phase 2 study for our lead product candidate NCX 470 for IOP reduction in patients with open-angle glaucoma or ocular hypertension, and by strengthening our U.S. presence in our new site in Research Triangle Park in North Carolina. We have assembled the right team to achieve our important near term clinical and corporate milestones and continue delivering on all objectives in line with our growth strategy."*

### Key Upcoming Milestones

- **Q1 2019:** Planned Investigational New Drug (IND) submission to the United States (U.S). Food and Drug Administration (FDA) for NCX 4251 to enable a Phase 2 clinical study in patients with acute exacerbations of blepharitis.
- **Q1 2019:** Expected delivery of ZERVIATE™ (cetirizine ophthalmic solution), 0.24% commercial product to Eyevance Pharmaceuticals LLC, followed by a launch for the spring 2019 allergy season in the U.S.
- **H2 2019**: Expected top-line data from the NCX 470 Phase 2 study for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

### Product and Product Candidates Updates

- A Phase 2 study was initiated in Q3 2018 for Nicox's product candidate **NCX 470, a novel second generation nitric oxide (NO)-donating prostaglandin analog**. This multicenter, double-masked, 28-day, parallel group, dose response study aims to evaluate the efficacy and safety of NCX 470 compared to latanoprost 0.005% in adult patients with elevated IOP due to open-angle glaucoma or ocular hypertension. The study is expected to randomize 420 patients in clinical sites across the U.S. The primary endpoint of the study is the mean reduction in diurnal IOP after 4 weeks of treatment, while the overall objective is to identify the appropriate dose of NCX 470 to be advanced into Phase 3 studies. This Phase 2 study was initiated following the submission of an IND application in June 2018, ahead of the previously disclosed target date of the third quarter of 2018. Nicox expects to report top-line data from this Phase 2 study in the second half of 2019.

- Preclinical and formulation development of Nicox's product candidate **NCX 4251, a novel, patented ophthalmic suspension of fluticasone propionate nanocrystals**, is continuing on track for the Q1 2019 IND submission to the U.S FDA to enable a Phase 2 study to evaluate the safety and efficacy of NCX 4251 compared to its vehicle in patients with acute exacerbations of blepharitis. An additional and positive pre-IND meeting was held with the U.S. FDA in June 2018, which addressed specific questions on development, including the potential primary endpoints. Based on FDA feedback, we are finalizing the design of the first-in-human Phase 2 study.

- Two molecules from our **future generation stand-alone NO-donors** that target IOP reduction**, NCX 667 and NCX 1660**, are currently in formulation development and testing with the Re-Vana EyeLief™ technology under the research collaboration agreement signed in October 2017. Depending on the release profile of these molecules with this technology in preclinical animal models of ocular pharmacokinetics, they may be advanced into further development and/or we may decide to test other molecules in the same technology.

- Our **research activities** continue both in our research collaboration agreement with Ironwood, announced in June 2018, which is focused on combining Ironwood's expertise in soluble guanylate cyclase with our proprietary NO-donating research platform, and in our internal programs combining NO with other undisclosed pharmacological mechanisms of action. We expect to be able to announce a preclinical candidate from one of these programs in the next 18 months.

- **VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%** is now a revenue generating asset for Nicox, following the U.S. launch in December 2017 by partner Bausch + Lomb. In March 2018, the Company announced an amendment to the global licensing agreement under which royalties paid to Nicox on worldwide net sales of VYZULTA will increase by 1% over the original royalty on net sales above $300 million per year. In addition, the potential milestone payments payable to Nicox by Bausch + Lomb have been increased by $20 million.

- We expect to ship commercial product and trade samples for **ZERVIATE™ (cetirizine ophthalmic solution), 0.24%** to our partner Eyevance by Q1 2019, which will allow Eyevance to launch ZERVIATE™ in the United States in time for the 2019 spring allergy season. The shipment of product triggers a $1 million milestone payment to Nicox by Eyevance, with up to $3 million of potential future milestones payments related to certain regulatory acceptance provisions and certain near term manufacturing objectives.

## H1 2018 Financial Summary

Net revenue[1] for the first half of 2018 was €0.3 million, comprised exclusively of royalties on H1 2018 sales of VYZULTA™ by global partner Bausch + Lomb, after deduction of royalty payments due by Nicox. The Nicox Group recorded no revenues for the first half of 2017.

The operating expenses for the first half of 2018 were consistent with the same period last year (€10.0 million for the first six months of 2018 compared to €10.2 million for the first six months of 2017).

The Nicox Group recorded a net loss of €7.6 million for the six months ended June 30, 2018, compared to a net loss of €12.2 million for the same period in 2017.

As of June 30, 2018, the Nicox Group had cash and cash equivalents of €32.7 million as compared with €36.3 million at March 31, 2018 and €41.4 million at December 31, 2017.

**Reference**

1. Net revenue consists of revenue from collaborations less royalty payments which corresponds to Net profit from collaborations in the condensed consolidated statements of profit or loss for the six-month periods ended June 30, 2018.

The diligences related to the half-year review were performed by the auditors. The review report will be issued once procedures will be finalized over the half-year financial report.

## About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio includes three programs in development based on our proprietary NO-donating research platform and reformulated molecules that have previously been used in other indications and therapeutic areas as well as future generation stand-alone NO donors in the preclinical research stage and other exploratory novel NO-donating compounds targeting ophthalmic conditions including glaucoma and ocular hypertension. In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by partner since December 2017 as well as ZERVIATE™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevance Pharmaceuticals. 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 | Jamina El-Bougrini | 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.*

## Contacts


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

Investors & media
United States
LifeSci Advisors, LLC
Monique Kosse
T +1 212-915-3820
M +1 646-258-5791
monique@lifesciadvisors.com

Investors & media
Europe
LifeSci Advisors, LLC
Hans Herklots
T +41 79 598 7149
hherklots@lifesciadvisors.com

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

Media
Italy
Argon Healthcare International
Pietro Pierangeli
pietro.pierangeli@argonhealthcare.com
Chiara Tettamanti
chiara.tettamanti@argonhealthcare.com
T +39 02 4951.8300

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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 2017*' filed with the French Autorité des Marchés Financiers (AMF) on March 19, 2018, which is 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

## INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| | 6 Months period ending June 30, | |
|---|---|---|
| | 2018 | 2017 |
| | *(in thousands of € except for per share data)* | |
| Revenues from collaborations | 503 | - |
| Royalty payments | (203) | - |
| **Net Profit from collaborations** | **300** | - |
| | | |
| Research and development expenses | (5,816) | (5,091) |
| Administrative expenses | (4,108) | (5,078) |
| Other income | 986 | 344 |
| Other expenses | (100) | (75) |
| **Operating loss before changes in fair value of contingent consideration** | **(8,738)** | **(9,900)** |
| | | |
| Fair value adjustment of contingent consideration | - | **(1,688)** |
| **Operating loss** | **(8,738)** | **(11,588)** |
| | | |
| Finance income | 1,254 | 604 |
| Finance expense | (70) | (1,164) |
| **Net financial income/(expense)** | **1,184** | **(560)** |
| | | |
| **Loss before tax** | **(7,554)** | **(12,148)** |
| | | |
| Income tax (expense) / benefit | (96) | (20) |
| | | |
| **Net loss for the period** | **(7,650)** | **(12,168)** |

## INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| | As of June 30, 2018 | As of Dec. 31, 2017 restated* |
|---|---|---|
| | *(in thousands of €)* | |
| **ASSETS** | | |
| **Non-current assets** | | |
| Goodwill | 24,907 | 24,211 |
| Intangible assets | 70,120 | 68,155 |
| Property, plant and equipment | 166 | 158 |
| Non-current financial assets* | 14,661 | 13,990 |
| **Total non-current assets** | **109,854** | **106,514** |
| **Current assets** | | |
| Trade receivables | 744 | 44 |
| Government grants receivables | 893 | 948 |
| Other current assets | 342 | 523 |
| Prepayments | 2,486 | 1,381 |
| Cash and cash equivalents | 32,687 | 41,394 |
| **Total current assets** | **37,152** | **44,290** |
| **TOTAL ASSETS** | **147,006** | **150,804** |
| **EQUITY AND LIABILITIES** | | |
| **Sharholder's equity** | | |
| Issued capital | 29,589 | 29,459 |
| Share premium | 510,812 | 510,942 |
| Cumulative translation adjustement | 5,683 | 3,973 |
| Treasury shares | - | - |
| Accumulated deficit* | (423,842) | (417,607) |
| **Total Equity** | **122,242** | **126,767** |
| **Non-current liabilities** | | |
| Non-current financial liabilities | 52 | 26 |
| Deferred tax liabilities | 16,081 | 15,631 |
| Provisions | 427 | 401 |
| **Total non-current liabilities** | **16,560** | **16,059** |
| **Current liabilities** | | |
| Current financial liabilities | 32 | 24 |
| Trade payables | 3,107 | 1,929 |
| Deferred income | 3,306 | 4,184 |
| Provisions | 46 | 40 |
| Other current liabilities | 1,713 | 1,801 |
| **Total current liabilities** | **8,204** | **7,978** |
| **TOTAL LIABILITIES AND EQUITY** | **147,006** | **150,804** |

***** *The Group retrospectively applied IFRS 9 on January 1, 2018 and consequently assessed an expected credit loss for the notes receivable issued by VISUfarma. Accordingly, the Group decreased the value of the notes receivable by €1.4 million and restated the lines "Non-current financial assets" and "Accumulated deficit" as of December 31, 2017 in the consolidated statements of financial position.*