

# **Press Release**

# Nicox Third Quarter 2018 Business Update and Financial Highlights

- NCX 470 Phase 2 clinical study initiated in Q3 2018 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
- Net revenue from VYZULTA<sup>™</sup> sales increased by 66% compared to Q2 2018

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October 17, 2018 – release at 7:30 am CET Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided upcoming milestones and operational highlights, as well as revenue and cash position for Nicox and its subsidiaries (the "Nicox Group") as of September 30, 2018.

# **Key Upcoming Milestones**

- **Q1 2019:** Planned Investigational New Drug (IND) submission to the U.S. Food and Drug Administration (FDA) for NCX 4251 to enable a Phase 2 clinical study<sup>1</sup> in patients with acute exacerbations of blepharitis.
- Q1 2019: Expected delivery of ZERVIATE<sup>™</sup> (cetirizine ophthalmic solution), 0.24% commercial product to partner Eyevance Pharmaceuticals LLC, followed by a commercial launch in the U.S. planned for the spring 2019 allergy season.
- **H2 2019**: Expected top-line data from the NCX 470 Phase 2 clinical study for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

# Third Quarter 2018 and Recent Operational Highlights

- In September 2018, Nicox and Fera Pharmaceuticals amended their 2015 agreement granting Fera exclusive rights to develop and commercialize naproxcinod for the U.S. market. The development of naproxcinod will focus on an undisclosed rare disease for which Fera expects to apply for an Orphan Drug Designation from the FDA. Nicox will be eligible to potentially receive a single \$40 million sales-based milestone if naproxcinod reaches \$1 billion yearly sales (for any indication) in the U.S. Royalties remain at 7% of net sales of naproxcinod in the U.S. Fera remains responsible for all clinical development, manufacturing, regulatory, and commercialization activities.
- In Q3 2018, our lead product candidate NCX 470, a novel second generation nitric oxide (NO)donating prostaglandin analog entered Phase 2 clinical study to evaluate its efficacy and safety compared to latanoprost 0.005% for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension and to select the optimal Phase 3 dose. The study is expected to randomize 420 patients in clinical sites across the U.S. Top-line data are expected in the second half of 2019.



# **Third Quarter 2018 Financial Highlights**

As of September 30, 2018, the Nicox Group had cash and cash equivalents of €25.7 million as compared with €32.7 million at June 30, 2018 and €41.4 million at December 31, 2017. Net revenue<sup>2</sup> for the third quarter of 2018 was \$0.438 million, comprised exclusively of royalties on third quarter 2018 sales of VYZULTA<sup>TM</sup> by global partner Bausch + Lomb, after deduction of royalty payments due by Nicox. This represents an increase of 66% in net revenue<sup>3</sup> received by Nicox compared to the second quarter of 2018. The Nicox Group recorded no revenues for the third quarter of 2017.

Only the figure related to the cash position of the Nicox Group as of December 31, 2017 is audited; all other figures of this press release are non-audited.

#### References

- 1. Subject to successful completion of formulation and preclinical studies currently conducted by Nicox
- 2. Net revenue consists of revenue from collaborations less royalty payments which corresponds to Net profit in the consolidated statements of profit or loss
- 3. Based on revenue in U.S. Dollars

#### 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 on novel and proprietary formulations of well-established molecules that have previously been used in other indications and therapeutic areas as well as future generation stand-alone NO donors in formulation development and testing 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<sup>™</sup> (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 Bausch + Lomb since December 2017 as well as ZERVIATE<sup>™</sup> (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.

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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 4<sup>th</sup> 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.

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