

# **Press Release**

# Nicox: Second Quarter 2019 Business Update and Financial Highlights

- Enrollment completed in the NCX 470 Phase 2 clinical trial in patients with glaucoma and ocular hypertension with results expected in early Q4 of this year
- Q2 2019 net revenue, including licensing payments, of €5.2 million

July 17, 2019– release at 7:30 am CET Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided Q2 2019 operational highlights, revenue and cash position for Nicox and its subsidiaries (the "Nicox Group"), as well as key upcoming milestones.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said, "Completion of enrollment in the NCX 470 glaucoma trial was a major step in delivering on the strategy for Nicox and keeps us on track for reporting the results of this study in early Q4, along with those of the NCX 4251 blepharitis trial later in the quarter. In preparation for the next steps with these two programs, we are strengthening the development function and have hired Dr. José Boyer into the new position of Vice President of Clinical Development. Our strategic business development activities continue to be fruitful with the recent NCX 4251 licensing deal in China consolidating our partnership there with Ocumension and we are expanding our global licensing efforts outside the US and Europe in order to optimize the value of our portfolio."

## **Key Upcoming Milestones**

- NCX 470 Phase 2 results: Following completion of enrollment, top-line data from the first efficacy Phase 2 clinical trial for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension expected in early Q4 of this year.
- NCX 4251 Phase 2 results: Trial in patients with acute exacerbations of blepharitis continuing on track for top-line data expected in Q4 of this year.
- **ZERVIATE partnering outside of the U.S.**: Multiple discussions ongoing for potential new licensing agreements in significant markets.
- **ZERVIATE U.S. launch:** Commercial launch of ZERVIATE (cetirizine ophthalmic solution), 0.24% in the U.S. is expected by our partner Eyevance Pharmaceuticals in H1 2020

### Second Quarter 2019 and Recent Operational Highlights

- The total number of prescriptions for VYZULTA in the U.S. in the second quarter of 2019 increased by 17% compared to Q1 2019<sup>1</sup> and by 161% compared to the second quarter 2018<sup>1</sup>.
- Earlier this week we announced that we had completed enrollment of patients in our multicenter, United States (U.S.) Phase 2 clinical study evaluating NCX 470, a novel second generation NOdonating bimatoprost analog, being tested in patients with glaucoma or ocular hypertension for its ability to lower IOP. This study is a head-to-head comparison of once-daily administration of three different doses of NCX 470 versus latanoprost, which is the most widely prescribed first-line



therapy for glaucoma and ocular hypertension. Top-line data of the study is expected early in Q4 of this year.

- In July 2019 we received a \$3 million milestone payment from partner Eyevance Pharmaceuticals, triggered by the completion of the regulatory and manufacturing activities under Nicox's responsibility necessary for the final manufacturing milestone payment in preparation for the launch of ZERVIATE in the U.S. From now on all manufacturing and regulatory responsibilities, together with decisions on launch timing, lie with Eyevance. Eyevance has informed Nicox that the launch of ZERVIATE in the U.S. is currently projected in H1 2020.
- In July 2019 we entered into an exclusive license agreement with Ocumension Therapeutics for the development and commercialization of our product candidate, NCX 4251, currently in a Phase 2 trial in the U.S. in patients with acute exacerbations of blepharitis, for a territory comprising mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, Nicox received an upfront payment of €2 million and may potentially receive development and sales milestones of up €10 million together with tiered royalties of between 5% and 10% on sales of NCX 4251.
- VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, has now been made available in Canada by our partner Bausch + Lomb, following approval there in December 2018.
- We have amended our bond financing agreement with Kreos Capital signed in January 2019. We have already drawn down €8 million under the agreement. The original agreement allowed for Nicox to draw down a second tranche of €7 million on August 1<sup>st</sup>, 2019, and a third tranche of €5 million on November 1<sup>st</sup>, 2019. Under the amendment, Nicox may draw down either €7 million or €12 million on November 1<sup>st</sup>, 2019, subject to notice to Kreos by October 10<sup>th</sup>, 2019. Full details of the bond financing agreement can be found in the Press Release of January 25, 2019 <a href="http://www.nicox.com/assets/files/EN-\_Kreos-PR\_201901.pdf">http://www.nicox.com/assets/files/EN-\_Kreos-PR\_201901.pdf</a>

#### **Strengthening Management in Clinical Development**

We appointed José L. Boyer, Ph.D., to the newly-created position of Vice President of Clinical Development, effective June 10, 2019. In this position, Dr. Boyer will be responsible for leading our clinical development activities, and will report to Tomas Navratil, Ph.D., Executive Vice President, Head of Development of Nicox. Dr. Boyer has more than 30 years of experience in academic research and drug development in the pharmaceutical industry including senior leadership roles in ophthalmology development at Parion Biosciences and Inspire Pharmaceuticals.

#### Second Quarter 2019 Financial Highlights

As of June 30, 2019, the Nicox Group had cash and cash equivalents of €17.3 million as compared with €23.5 million at March 31, 2019 and €22.1 million at end December 31, 2018. These cash and cash equivalents do not include the €2 million upfront payment from Ocumension nor the \$3 million milestone payment from Eyevance received in July. Net revenue<sup>2</sup> for the second quarter of 2019 was €5.2 million versus €0.2 million in the second quarter of 2018.

Only figures at 31 December 2018 are audited. All figures of this press release are non-audited.

#### Notes

- 1. Bloomberg data, comparing the period of the weeks ending 5 April 2019 to 28 June 2019 with the periods of the weeks ending 4 January 2019 to 29 March 2019 and 6 April 2018 to 29 June 2018
- 2. Net revenue consists of revenue from collaborations less royalty payments which corresponds to Net profit in the consolidated statements of profit or loss

#### 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 has three programs



in development including NCX 470, a novel, second-generation NO-donating bimatoprost analog, for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with Cyclerion). 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 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, LLC.

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

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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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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 2018*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2019 which are available on Nicox's website (<u>www.nicox.com</u>).

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