

## Press Release

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# Nicox First Half 2020 Financial Results and Business Update

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- **H1 2020 net revenue<sup>1</sup> of €2.4 million and cash position of €45.4 million including €5 million from the divestment of the VISUfarma shareholding received in July**
- **NCX 470 Mont Blanc Phase 3 clinical trial initiated on schedule and on track for adaptive dose selection in Q4 2020**
- **Dose selection will enable the start of the second part of the Mont Blanc trial and the initiation of the second Phase 3 trial, Denali**
- **Post-first half closing €2 million loan facility guaranteed by the French state secured, bringing non-dilutive financing to date in 2020 to €22 million**

September 10, 2020 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today reported the financial results for Nicox and its subsidiaries (the “Nicox Group”) for the six months ending June 30, 2020 and provided an update on its activities as well as key upcoming milestones.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox, said:** *“We are very pleased with the excellent progress in the Mont Blanc trial recruitment and the preparation for initiation of the Denali trial, together with our Chinese partner Ocumension, in Q4 2020. Additional support for these activities has come from the non-dilutive financing strategy we have implemented since March which includes the expansion of our collaboration with Ocumension, as well as the divestment of our VISUfarma shareholding in July. As one of the few European R&D companies having two products commercialized in the United States, with expansion in many other markets ongoing, we also expect to see recurrent royalty revenue steadily increasing in the years ahead and contributing to the future growth of the company. With this revenue, and the non-dilutive financing, we believe that the company is now financed to complete the NCX 4251 Phase 2b trial planned to start later this year and beyond the top-line results from the Mont Blanc trial.”*

### Key Expected Upcoming Milestones

- **NCX 470 Mont Blanc Phase 3 clinical trial:** The first Phase 3 trial of NCX 470 for lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension has an initial adaptive design portion designed to select the optimal dose of NCX 470 which will then continue into a subsequent head-to-head 3-month safety and efficacy evaluation vs. latanoprost. With the recently announced completion of enrolment of the adaptive cohort, the trial is on track for that selection of optimal NCX 470 dose in the coming weeks. The completion of the adaptive design portion will also enable the start of the second Phase 3 trial, or the Denali trial, before the end of 2020.
- **NCX 470 Denali Phase 3 clinical trial:** The second Phase 3 glaucoma clinical trial, Denali, which is jointly managed and funded equally by Nicox and Ocumension, is currently expected to start in Q4 2020. The Denali trial will include clinical sites in both the U.S. and China, with the majority of the patients being in the U.S. The Denali trial was designed to fulfill the regulatory requirements to support NDA filings in the U.S. and China.
- **NCX 4251 Phase 2b clinical trial:** This Phase 2b trial, Mississippi, will include both blepharitis and dry eye endpoints with the option of declaring either the blepharitis or dry eye endpoints as the primary efficacy outcome of the trial. The trial is planned to be initiated before the end of 2020.

- **ZERVIA<sup>TM</sup> China:** A Phase 3 clinical trial intended to support an application for regulatory approval in China, to be conducted and financed by our partner Ocumension, is currently expected to start by the end of 2020.
- **Nitric oxide (NO)-donating phosphodiesterase-5 (PDE5) inhibitors** for IOP lowering: IND-track candidate expected to be announced by the end of 2020.

We continue to closely watch the spread of COVID-19 and its impact. We do not currently anticipate delays to our clinical timelines but we are monitoring the situation and will provide updates if there is an impact on our development projects and timelines.

### **Nicox Secures €2 Million in a Non-Dilutive Loan Facility Guaranteed by the French State**

In the third quarter 2020 we entered into a €2 million credit agreement, granted by Société Générale and LCL and guaranteed by the French State, in the context of the COVID-19 pandemic. This non-dilutive financing contributes to strengthening the Company's cash position. This loan is not secured against any of the Company's assets. Up to 90% of the loan is guaranteed by the French State. It has an initial maturity of 12 months with the option for Nicox to take a 1 to 5-year repayment period after that.

### **Strengthening Development Management**

We appointed Sushanta Mallick, Ph.D., to a position of Vice President of External Development, effective August 1, 2020. In this position, Dr. Mallick will be the development lead for our key collaborations and will also oversee a subset of clinical development activities. He brings over 25 years of ophthalmology development experience including senior roles with Alcon, QLT, Aerie and Shire, and will report to Tomas Navratil, Ph.D., EVP & Head of R&D of the Nicox Group and General Manager of Nicox Ophthalmics, Inc.

### **First Half 2020 Financial Highlights**

Net revenue<sup>1</sup> for the first half of 2020 was €2.4 million (including €1.0 million in milestone revenue) versus €5.6 million (including €4.7 million in upfront and milestone revenue) for the first half of 2019. Operating expenses for the first half of 2020 were €10.2 million compared to €11.4 million for the first half of 2019.

- The Nicox Group recorded a net loss of €14.6 million for the six months ended June 30, 2020, compared to a net loss of €0.8 million for the same period in 2019. This difference is mainly explained by the fact that, pursuant to accounting principles, €14 million of the €15 million upfront received from Ocumension in H1 2020 are not taken into consideration as they are recorded as deferred revenues (included in "contract liabilities" in the statement of financial position) and further by a non-cash value adjustment of €6.9 million on VISUfarma assets successfully divested in July to strengthen Nicox's cash position. Moreover, the net loss in the first half of 2019 was reduced thanks as well to the recognition of a non-cash income of €3.8 million for deferred tax assets recognized by our U.S. subsidiary.
- As of June 30, 2020, the Nicox Group had cash and cash equivalents of €40.4 million, adjusted on a pro forma basis to €45.4 million including the €5 million received in July from the sale of our shareholding in VISUfarma, as compared with €45.2 million at March 31, 2020 and €28.1 million at December 31, 2019.
- As of June 30, 2020, the Nicox Group had financial debt of €17.7 million in the form of a bond financing agreement with Kreos Capital signed in January 2019. Full details of the bond financing agreement can be found in the Press Release of January 25, 2019 - [http://www.nicox.com/assets/files/EN- Kreos-PR\\_201901.pdf](http://www.nicox.com/assets/files/EN- Kreos-PR_201901.pdf).

Only figures at December 31, 2019 are audited, all other figures of this press release are non-audited.

#### **Notes**

1. Net revenue consists of revenue from collaborations less royalty payments which we refer to as net profit from collaborations in the condensed consolidated statements of profit or loss for the six-month period ended June 30, 2020.

## About Nicox

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Nicox S.A. is an ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470, a novel, second-generation nitric oxide-donating bimatoprost analog, for lowering intraocular pressure in patients with glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch & Lomb, and ZERVIATE™ in allergic conjunctivitis, licensed in multiple geographies, including to Eyevence Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and Southeast Asian markets.

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](http://www.nicox.com).

## Analyst coverage

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Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.



*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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## Forward-Looking Statements

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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 3<sup>rd</sup> chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2019' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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**NICOX SA**  
**INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

	<b>6 Months period ending June 30,</b>	
	<b>2020</b>	<b>2019</b>
	<i>(in thousands of €)</i>	
Revenues from collaborations	3,271	6,214
Royalty payments	(891)	(624)
<b>Net Profit from collaborations</b>	<b>2,380</b>	<b>5,590<sup>(1)</sup></b>
Research and development expenditures	(6,533)	(7,539)
Administrative expenses	(3,496)	(3,720)
Other income	840	489
Other expenses	(174)	(97)
<b>Operating loss before amortization of intangible assets</b>	<b>(6,983)</b>	<b>(5,277)</b>
Amortization of intangible assets	(645)	(17)
<b>Operating loss</b>	<b>(7,628)</b>	<b>(5,294)</b>
Finance income	1,213	1,458
Finance expense	(8,166) <sup>(2)</sup>	(714)
<b>Net financial income/(expense)</b>	<b>(6,953)</b>	<b>744</b>
<b>Loss before tax</b>	<b>(14,581)</b>	<b>(4,550)</b>
Income tax (expense) / benefit	(26)	3,799 <sup>(3)</sup>
<b>Net loss for the period</b>	<b>(14,607)</b>	<b>(751)</b>

<sup>(1)</sup> Includes €4.7 million of non-recurrent revenue received from our partners Ocumension and Eyevance

<sup>(2)</sup> Includes €6.9 million of expenses without cash impact related to the impairment of VISUfarma assets sold in July 2020

<sup>(3)</sup> Non-cash income tax for deferred tax assets recognized by our U.S subsidiary

**NICOX SA**  
**INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

	As of June 30, 2020	As of Dec. 31, 2019
	<i>(in thousands of €)</i>	
<b>ASSETS</b>		
<b>Non-current assets</b>		
Goodwill	25,930	25,847
Intangible assets	71,708	72,120
Property, plant and equipment	1,453	1,670
Non-current financial assets	70	11,023
<b>Total non-current assets</b>	<b>99,161</b>	<b>110,660</b>
<b>Current assets</b>		
Current financial assets available for sale	5,000 <sup>(1)</sup>	-
Trade receivables	1,357	1,069
Government grants receivables	1,286	864
Other current assets	248	1,297
Prepayments	1,647	814
Cash and cash equivalents	40,392	28,102
<b>Total current assets</b>	<b>49,930</b>	<b>32,146</b>
<b>TOTAL ASSETS</b>	<b>149,091</b>	<b>142,806</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Shareholder's equity</b>		
Issued capital	33,491	33,231
Share premium	518,180	518,441
Cumulative translation adjustment	8,044	7,811
Accumulated deficit	(464,159)	(450,186)
<b>Total Equity</b>	<b>95,556</b>	<b>109,297</b>
<b>Non-current liabilities</b>		
Non-current financial liabilities	14,687	10,168
Deferred tax liabilities	13,006	12,964
Non-current provisions	576	549
Contract liabilities	8,500 <sup>(2)</sup>	-
<b>Total non-current liabilities</b>	<b>36,769</b>	<b>23,681</b>
<b>Current liabilities</b>		
Current financial liabilities	4,373	2,481
Trade payables	4,847	4,996
Contract liabilities	5,500 <sup>(2)</sup>	-
Other current liabilities	2,046	2,351
<b>Total current liabilities</b>	<b>16,766</b>	<b>9,828</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>149,091</b>	<b>142,806</b>

<sup>(1)</sup> VISUfarma's assets divested in July 2020

<sup>(2)</sup> Includes an amount of €14 million over a payment of €15 million received from Ocumension Therapeutics following the execution in March 2020 of the amendment to the licensing agreement for NCX 470 in China