

## Press Release

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# Nicox First Half 2021 Financial Results and Business Update

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- **H1 2021 net revenue<sup>1</sup> of €1.3 million and cash position of €36.5 million**
- **NCX 470 NDA submission remains on track**

September 27, 2021 – 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 SA and its subsidiaries (the “Nicox Group”) for the six months ending June 30, 2021 and provided an update on recent events as well as progress on key programs.

### First Half 2021 Financial Highlights

Net revenue<sup>1</sup> for the first half of 2021 was €1.3 million (including €1.2 million in royalty revenue) versus €2.4 million (including €1.4 million in royalty revenue) for the first half of 2020. Operating expenses for the first half of 2021 were €13.3 million compared to €10.2 million for the first half of 2020.

- The Nicox Group recorded a net loss of €11.7 million for the six months ended June 30, 2021, compared to a net loss of €14.6 million for the same period in 2020.
- As of June 30, 2021, the Nicox Group had cash and cash equivalents of €36.5 million, as compared with €42.0 million at March 31, 2021 and €47.2 million at December 31, 2020. The Company is financed for at least 12 months, based on the development of NCX 470 alone.
- As of June 30, 2021, the Nicox Group had financial debt of €18.0 million consisting of €16.0 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2 million credit agreement guaranteed by the French State and granted in August 2020 in the context of the COVID-19 pandemic. Details of the bond financing agreement can be found in the [Press Release of January 29, 2021](#).

### Recent Events

- The Mississippi Phase 2b clinical trial of **NCX 4251** ophthalmic suspension 0.1%, evaluated against placebo, while not meeting the pre-defined blepharitis primary endpoint, demonstrated statistically significant results on blepharitis signs and symptoms when measured as change from baseline. NCX 4251 was found to be safe and well-tolerated over 14 days’ treatment, with no serious adverse events (see [Press Release of September 23, 2021](#)).
- **VYZULTA**<sup>®</sup> (latanoprostene bunod ophthalmic solution), 0.024%, recently received regulatory approval in Brazil, Jordan and Singapore. Further approvals and launches of VYZULTA will now be reported by our global partner Bausch + Lomb on a quarterly basis.
- Dr. José Boyer has retired as Interim Head of R&D, although he will continue to advise the Company as a consultant. We would like to thank him for his commitment and contribution to Nicox.
- Fera’s resubmitted application for Orphan Drug Designation (ODD) for **naproxcinod** in sickle-cell disease has been refused by the U.S. Food and Drug Administration (FDA), and Fera is currently seeking to discuss the next steps with the FDA. Fera continues to review other undisclosed therapeutic indications for naproxcinod.

## Key Programs Updates

- **NCX 470:** The New Drug Application submission timing to the U.S. FDA remains in line with our expectations, driven by the end of 2023 date for results from the ongoing Denali Phase 3 clinical trial. In the first Phase 3 clinical trial, Mont Blanc, 494 out of 670 patients (74%) had been randomized as of September 20, and 398 of those patients have completed the 3-month efficacy evaluation. Given recruitment continues to be impacted by COVID-19, we are prudently moving the expectation for Mont Blanc trial top-line results to Q1 2023 (previously Q2 2022). The Phase 3 program, evaluating NCX 470 for lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension, is expected to support NDA submissions in the U.S. and China, and will also provide data for countries accepting the same package for approval.
- **NCX 4251:** Following the results of the Phase 2b Mississippi trial, the Company plans to meet with the U.S. FDA in early 2022 to discuss next steps in the development of this innovative product candidate for blepharitis.
- **ZERVIA<sup>TM</sup> in China:** A Phase 3 clinical trial intended to support an application for regulatory approval in China, conducted and financed by our partner Ocumension, is ongoing.

Only figures at December 31, 2020 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, 2021.

### About Nicox

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Nicox S.A. is an international 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 nitric oxide-donating prostaglandin 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<sup>®</sup> in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIA<sup>®</sup> in allergic conjunctivitis, licensed in multiple geographies, including to Eyeavance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East 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.
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	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.*

### Contacts

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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 2020*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 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>2021</b>	<b>2020</b>
	<i>(in thousands of € except for per share data)</i>	
Revenues from collaborations	2,043	3,271
Royalty payments	(721)	(891)
<b>Net Profit from collaborations</b>	<b>1,322</b>	<b>2,380</b>
Research and development expenditures	(10,000)	(6,533)
Administrative expenses	(3,263)	(3,496)
Other income	466	840
Other expenses	(90)	(174)
<b>Operating loss before amortization of intangible assets</b>	<b>(11,565)</b>	<b>(6,983)</b>
Amortization of intangible assets	(587)	(645)
<b>Operating loss</b>	<b>(12,152)</b>	<b>(7,628)</b>
Finance income	1,451	1,213
Finance expense	(1,036)	(8,166) <sup>(1)</sup>
<b>Net financial income/(expense)</b>	<b>415</b>	<b>(6,953)</b>
<b>Loss before tax</b>	<b>(11,737)</b>	<b>(14,581)</b>
Income tax (expense) / benefit	24	(26)
<b>Net loss for the period</b>	<b>(11,713)</b>	<b>(14,607)</b>

<sup>(1)</sup> Included €6.1 million of expenses without cash impact related to the impairment of VISUfarma assets sold in July 2020.

NICOX SA  
INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	As of June 30, 2021	As of Dec. 31, 2020
	<i>(in thousands of €)</i>	
<b>ASSETS</b>		
<b>Non-current assets</b>		
Goodwill	24,433	23,663
Intangible assets	66,356	64,848
Property, plant and equipment	1,029	1,166
Non-current financial assets	69	68
<b>Total non-current assets</b>	<b>91,887</b>	<b>89,745</b>
<b>Current assets</b>		
Clients	1,283	1,723
Government grants receivables	1,130	736
Other current assets	317	237
Prepayments	2,209	2,630
Cash and cash equivalents	36,528	47,195
<b>Total current assets</b>	<b>41,467</b>	<b>52,521</b>
<b>TOTAL ASSETS</b>	<b>133,354</b>	<b>142,266</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Shareholder's equity</b>		
Issued capital	37,112	37,030
Share premium	528,513	528,595
Cumulative translation adjustment	4,597	2,959
Treasury shares	(873)	(605)
Accumulated deficit	(478,033)	(467,169)
<b>Total Equity</b>	<b>91,316</b>	<b>100,810</b>
<b>Non-current liabilities</b>		
Non-current financial liabilities	16,031	13,429
Deferred tax liabilities	12,255	11,868
Non current provisions	819	754
<b>Total non-current liabilities</b>	<b>29,105</b>	<b>26,051</b>
<b>Current liabilities</b>		
Current financial liabilities	2,917	5,646
Trade payables	3,433	2,422
Deferred income	5,113	5,174
Other current liabilities	1,470	2,163
<b>Total current liabilities</b>	<b>12,933</b>	<b>15,405</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>133,354</b>	<b>142,266</b>