

Press Release

Nicox Provides First Half 2022 Business Update and Financial Results

- **Topline results from first pivotal Phase 3 glaucoma clinical trial on NCX 470, Mont Blanc, due in November 2022**
- **Net revenue €1.4 million for H1 2022; cash of €31.6 million on June 30, 2022**

September 16, 2022 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today provided business and financial results for Nicox SA and its subsidiaries (the “Nicox Group”) for the first half of 2022.

“I joined Nicox because I saw the potential for NCX 470 to be the first true successor to the first prostaglandin analog approved for the lowering of intraocular pressure, Xalatan, which I launched while at Pharmacia. Substantial progress has been made this year with completion of enrolment in the pivotal Phase 3 Mont Blanc trial for our lead asset, NCX 470, targeting glaucoma, and we are just weeks away from the results of the first of the two Phase 3 trials. These data, due in November, could provide the cornerstone for building the future of the company,” said **Andreas Segerros, Chief Executive Officer of Nicox**. *“NCX 470 has already demonstrated a statistically significant improvement over the standard of care for intraocular pressure lowering, latanoprost, in a robust Phase 2 clinical trial. We have also demonstrated beneficial effects in an in vivo model of damage to the optic nerve head and retina. We believe the ongoing Phase 3 program will demonstrate the potential for NCX 470 as a best-in-class glaucoma treatment, addressing a major need in this nearly \$6 billion worldwide market, and we are excited to see these results.”*

Andreas Segerros continued, *“In my first few months here I have discovered a very strong ophthalmology-focussed R&D team, which we have since rounded out with excellent new hires, supported by an experienced, competent, corporate, finance and legal organisation. I am delighted to have joined Nicox at such an important time in the company’s history. After reviewing the portfolio, I believe we are well positioned to build upon the strength of the NCX 470 program by potentially advancing our novel nitric oxide-donating phosphodiesterase-5 inhibitor, NCX 1728, and through the opportunistic addition of other programs to the development pipeline.”*

“The NCX 470 data presented to date has the potential to significantly impact the glaucoma treatment paradigm.” said **Dr Robert Weinreb, Distinguished Professor and Chair of Ophthalmology at the University of California, San Diego, and member of Nicox’s Glaucoma Clinical Advisory Board**.

First Half 2022 Business Update

- Andreas Segerros joined Nicox as Chief Executive Officer on June 1, 2022. He brings significant pharma and venture capital expertise, including in ophthalmology, specifically as Global Head of Ophthalmology at Pharmacia, where he launched XALATAN® (latanoprost), making it the industry’s first billion-dollar ophthalmic drug.
- With the appointment of Andreas Segerros as Chief Executive Officer, the role was separated from that of Chairman. Jean-Francois Labbé, Board member and Chairman of the Audit Committee, was appointed as Chairman of the Board of Directors of Nicox SA, effective July 28, 2022.

- **NCX 470**, Nicox's lead clinical product candidate, is a novel, potentially best-in-class, nitric oxide (NO)-donating prostaglandin analog eye drop currently in a Phase 3 program for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Topline results from the first Phase 3 clinical trial, Mont Blanc, are due in November. Positive results of the Dolomites Phase 2 clinical trial on NCX 470 were [reported](#) in October 2019.
- Patient enrollment is continuing in both the United States (U.S.) and China in the ongoing Denali Phase 3 clinical trial of **NCX 470** in patients with open-angle glaucoma or ocular hypertension. The Denali trial is being jointly conducted and equally financed with our Chinese partner, Ocumension Therapeutics. Based on the current recruitment rates, the Company expects topline results after 2024. The timeline has been impacted by COVID-19, specifically the lockdown in China, and longer-term effects on the wider glaucoma clinical trial environment.
- **NCX 4251** is a novel, patented, ophthalmic suspension of fluticasone propionate nanocrystals for dry eye disease. The Company is currently looking for partnerships outside of China to advance development of this program. NCX 4251 is exclusively licensed to Ocumension Therapeutics in the Chinese market.
- **VYZULTA**[®] (latanoprostene bunod ophthalmic solution), 0.024%, is now approved in 18 markets, including approval in Lebanon in the second quarter of 2022. Following a launch in Thailand in the second quarter of 2022, it is now commercialized in 8 territories, and a launch in Brazil is expected in the fourth quarter of this year. VYZULTA is indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension.

First Half 2022 Financial Results

As of June 30, 2022, the Nicox Group had cash and cash equivalents of €31.6 million, as compared with €35.1 million at March 31, 2022 and €42.0 million at December 31, 2021. The Company estimates that it is financed into Q4 2023, based on the development of NCX 470 alone, and assuming the extension¹ of the interest only period of the existing Kreos debt.

As of June 30, 2022, the Nicox Group had financial debt of €20.6 million consisting of €18.6 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 and a €2.0 million credit agreement guaranteed by the French State in August 2020 in the context of the COVID-19 pandemic.

Net revenue² for the first half of 2022 was €1.4 million (including €1.3 million in royalty revenue) versus €1.3 million (including €1.2 million in royalty revenue) for the first half of 2021.

Operating expenses for the first half of 2022 were €12.7 million compared to €13.4 million for the first half of 2021.

The Nicox Group recorded a net loss of €17.0 million for the six months ended June 30, 2022, compared to a net loss of €11.7 million for the same period in 2021. The H1 2022 net loss includes €11.1 million of non-recurring, non-cash items due to the decision to seek a partner to pursue the development of NCX 4251 in the U.S.

Only the figure related to the cash position of the Nicox Group as of December 31, 2021 is audited; all other figures in this press release are non-audited.

About Nicox

Nicox SA 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 open-angle glaucoma or ocular hypertension. The company is also conducting research on NCX

¹ Nicox has the option to extend the interest-only period of the existing Kreos debt by 6 months if the Mont Blanc trial on NCX 470 meets its primary endpoint of non-inferiority to latanoprost

² Net revenue consists of revenue from collaborations less royalty payments which corresponds to Net profit in the consolidated statements of profit or loss

1728, a nitric oxide-donating phosphodiesterase 5 inhibitor, in intraocular pressure lowering and retinal conditions. NCX 4251, a novel, patented, ophthalmic suspension fluticasone propionate nanocrystals for topical ocular application for dry eye disease, is being developed by Ocumension Therapeutics in China under an exclusive license agreement and is available for partnering elsewhere. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC (a wholly-owned subsidiary of Santen Pharmaceutical Co., Ltd.), in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of 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.

Analyst coverage

Bryan, Garnier & Co	Dylan Van Haaften	Paris, France
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Arsene Guekam	Paris, France

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Forward-Looking Statements

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 3rd chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2021' filed with the French Autorité des Marchés Financiers (AMF) on April 29, 2022 which is available on Nicox's website (www.nicox.com)

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NICOX SA
INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	6 Months period ending June 30,	
	2022	2021
	<i>(in thousands of € except for per share data)</i>	
Revenues from collaborations	2,322	2,043
Royalty payments	(892)	(721)
Net Profit from collaborations	1,430	1,322
Research and development expenditures	(7,778)	(10,000)
Administrative expenses	(3,724)	(3,263)
Other income	371	466
Other expenses	(1,190)	(90)
Operating loss before amortization of intangible assets	(10,891)	(11,565)
Amortization of intangible assets	-	(587)
Impairment of intangible assets ⁽¹⁾	(10,472)	-
Operating loss	(21,363)	(12,152)
Finance income	3,915	1,451
Finance expense	(1,237)	(1,036)
Net financial income/(expense)	2,678	415
Loss before tax	(18,685)	(11,737)
Income tax (expense) / benefit	1,679	24
Net loss for the period	(17,006)	(11,713)

⁽¹⁾ Non-cash adjustment on NCX4251 estimated fair value due to the Group decision to seek for a partner to pursue the development in USA.

NICOX SA
INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	As of June 30, 2022	As of Dec. 31, 2021
	<i>(in thousands of €)</i>	
ASSETS		
Non-current assets		
Goodwill	27,954	25,637
Intangible assets	32,550	39,974
Property, plant and equipment	916	1,023
Non-current financial assets	158	237
Total non-current assets	61,578	66,871
Current assets		
Clients	1,992	1,086
Government grants receivables	1,056	1,452
Other current assets	205	377
Prepayments	2,766	2,853
Cash and cash equivalents	31,644	41,970
Total current assets	37,663	47,738
	99,241	114,609
TOTAL ASSETS		
EQUITY AND LIABILITIES		
Shareholder's equity		
Issued capital	536,115	536,200
Share premium	7,688	5,953
Cumulative translation adjustment	(893)	(847)
Treasury shares	(525,431)	(508,892)
Accumulated deficit	60,702	75,552
Total Equity		
Non-current liabilities		
Non-current financial liabilities	7,538	9,236
Deferred tax liabilities	578	661
Non current provisions	28,846	31,057
Total non-current liabilities		
Current liabilities		
Current financial liabilities	4,097	3,649
Trade payables	1,947	1,970
Deferred income	2,886	2,035
Other current liabilities	9,693	8,000
Total current liabilities		
	99,241	114,609
TOTAL LIABILITIES AND EQUITY		