

Press Release

Nicox Announces 2019 Financial Results and 2020 Key Milestones

- **Increase of net royalties by 105%**
- **Cash position of €28.1 million as of December 31, 2019**

March 6, 2020 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the financial and operating results for Nicox and its subsidiaries (the “Nicox Group”) for the year ended December 31, 2019, as approved by the Board of Directors on March 5, 2020, and provided upcoming 2020 key milestones.

2019 Financial Summary

Net revenue¹ for the full year 2019 was €6.9 million (€2.1 million in net royalties, €4.8 million in upfront and milestone payments), compared to €4.0 million (€1 million in net royalties and €3 million in an upfront payment) for the full year 2018.

Operating expenses for the period 2019 decreased to €25.5 million from €26.5 million for the 12 months to December 31, 2018. Research and development expenses increased by €1.4 million reflecting the investments in the successful clinical trials for NCX 470 and NCX 4251 while administrative and other expenses decreased by €2.4 million.

Net loss of the Nicox Group for the full year 2019 was €18.9 million against €18.4 million in the full year 2018.

As of December 31, 2019, the Nicox Group had cash and cash equivalents of €28.1 million as compared with €22.1 million at December 31, 2018. The December 31, 2019 cash position does not include the last tranche of loan under the bond financing agreement with Kreos Capital which was drawn down in December 2019 but received on January 2, 2020, adding approximately €7.7 million to the year-end cash position of the Group.

As of December 31, 2019, the Nicox Group had a financial debt of €11.1 million in the form of a bond financing agreement with Kreos Capital signed in January 2019 adjusted to approximately €18.8 million by including the last tranche of loan drawn down in December 2019.

Events after the Reporting Period

- Nicox successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) (see [Press Release of March 5, 2020](#)). The Mont Blanc trial, the first Phase 3 clinical trial of NCX 470, is expected to start by the end of Q2 2020, with top-line results expected in Q3 2021. The Mont Blanc trial will be initiated with 0.065% and 0.1% doses of NCX 470, with one dose being selected during the trial through an adaptive design.
- Nicox received approval from the U.S. Patent and Trademark Office of a formulation patent for NCX 470, extending the U.S. patent coverage to 2039 (see [Press Release of February 3, 2020](#)). Nicox has also received approval of this patent in Japan.

- Nicox presented NCX 470 Dolomites Phase 2 results at the Glaucoma 360 New Horizons Forum (February 7, 2020) and at the American Glaucoma Society (AGS) Annual Meeting (February 27 – March 1, 2020). NCX 4251 Danube Phase 2 results were also presented at AGS.
- Nicox's research activities are being concentrated on nitric oxide (NO)-donating phosphodiesterase-5 (PDE5) inhibitors program for glaucoma for which we expect to be able to announce an Investigational New Drug (IND)-track candidate in 2020 and therefore we are terminating our research collaboration with Cycleron Therapeutics, Inc.
- We strengthened our Clinical Development function by appointing Kristie Veasey to the position of Director Clinical Operations, effective March 2, 2020. Reporting to Dr. José Boyer, Vice President of Clinical Development, Ms. Veasey will be responsible for leading clinical operations for some of our upcoming clinical trials. She brings over 19 years of experience in clinical research and development in both the Pharmaceutical Industry and Clinical Research Organizations, with the majority of her professional experience in the therapeutic area of ophthalmology including at Lexitas Pharma Services, Clearside Biomedical and Inspire Pharmaceuticals, Inc.

Key Expected Upcoming Milestones

- **NCX 470 Phase 3 clinical trial preparation:** Phase 3 clinical trial ('Mont Blanc') is expected to be initiated by the end of Q2 2020.
- **NCX 4251:** Meeting with the U.S. FDA is scheduled in Q1 2020 to discuss the next steps of the clinical development plan.
- **ZERVIAE™ U.S. launch:** Commercial launch of ZERVIAE™ (cetirizine ophthalmic solution), 0.24% in the U.S. is planned by Nicox's partner Eyevance Pharmaceuticals in H1 2020.
- Presentations on Nicox's ophthalmology research and development programs at key U.S. scientific conferences including the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and the American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting.

Note

1. 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 Cycleron). 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 ZERVIAE™ (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

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

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 4th 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 (www.nicox.com).

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CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	As of December 31:	
	2019	2018 ⁽¹⁾
Revenue from collaborations	8,260	4,717
Royalty payments	(1,405)	(690)
Net profit	6,855	4,027
Research and development expenditures	(17,747)	(16,331)
Administrative expenses	(7,666)	(9,506)
Other income	970	1,786
Other expenses	(85)	(644)
Operating loss before amortization of intangible assets	(17,673)	(20,668)
Amortization of intangible assets	(659)	-
Operating loss	(18,332)	(20,668)
Finance income	2,565	2,461
Finance expense (2)	(7,013)	(71)
Net financial income, (expense)	(4,446)	2,390
Loss before tax	(22,778)	(18,278)
Income tax (expense) / benefit	3,856	(113)
Loss after tax	(18,922)	(18,391)
Loss for the period	(18,922)	(18,391)

- (1) Financial statements as at December 31, 2018 were not restated with adjustments led by the effects of IFRS16 first-time adoption
- (2) Finance expenses in 2019 included a non-cash item of €(6.1) million reflecting the credit risk adjustment of the loan notes with VISUfarma B.V.
- (3) Income tax (expense) / benefit in 2019 included a non-cash item of €3.7 million for the first recognition of deferred tax assets related to ZERVIAE

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of December 31:	
	2019	2018 ⁽¹⁾
ASSETS		
Non-current assets		
Goodwill	25,847	25,359
Intangible assets	72,120	71,397
Property, plant and equipment	1,670	269
Non-Current financial assets ⁽²⁾	11,023	15,473
Total non-current assets	110,660	112,498
Current assets		
Trade receivables	1,069	616
Government grants receivables	864	1,247
Other current assets	1,297	691
Prepayments	814	1,479
Cash and cash equivalents	28,102	22,059
Total current assets	32,146	26,092
TOTAL ASSETS	142,806	138,590
EQUITY AND LIABILITIES		
Shareholders' equity		
Issued capital	33,231	29,719
Share premium	518,441	510,683
Cumulative translation adjustment	7,811	6,697
Accumulated deficit	(450,186)	(433,445)
Total equity	109,297	113,653
Non-current liabilities		
Non-current financial liabilities	10,168	54
Deferred taxes liabilities	12,964	16,373
Provisions	549	441
Total non-current liabilities	23,681	16,868
Current liabilities		
Current financial liabilities ⁽³⁾	2,481	31
Trade payables	4,996	4,281
Deferred income	-	1,256
Provisions	-	76
Other current liabilities	2,351	2,425
Total current liabilities	9,828	8,069
TOTAL LIABILITIES AND EQUITY	142,806	138,590

(1) Financial statements as at December 31, 2018 were not restated with adjustments led by the effects of IFRS16 first-time adoption

(2) Non current financial assets in 2019 included a non-cash item of €(6.1) million reflecting the credit risk adjustment of the loan notes with VISUfarma B.V.

(3) Deferred taxes liabilities were decreased in 2019 by €3.7 million due to the first recognition of deferred tax assets related to ZERVATE