

# **Press Release**

# Nicox first half 2017 business and financial update

- ZERVIATE<sup>TM</sup> (cetirizine ophthalmic solution), 0.24% New Drug Application (NDA) approved
- Investigational New Drug (IND) submissions for NCX 470 for IOP lowering and NCX 4251 for blepharitis planned for H1 2018
- Bausch + Lomb responded to VYZULTA<sup>™</sup> (latanoprostene bunod ophthalmic solution), 0.024% Complete Response Letter (CRL) received from U.S. Food and Drug Administration (FDA)
- Gross proceeds from financing of €26.25 million

September 8, 2017 – release at 7:30 am CET Sophia Antipolis, France

**Nicox S.A.** (Euronext Paris: FR0013018124, COX), the international ophthalmic company, today announced its financial results for the six months ended June 30, 2017, and provided an update on its activities.

"The first half of 2017 was marked by significant developments across our core programs" commented Michele Garufi, Chairman and Chief Executive Officer of Nicox. "The recent FDA approval of the ZERVIATE™ NDA brings us one step closer to our objective of securing a commercialisation partner for this innovative ophthalmic product for the U.S. market. For VYZULTA™, our partner Bausch + Lomb has resolved the FDA's concerns surrounding their Tampa manufacturing plant and rapidly submitted a response to the CRL received in August."

Michele Garufi concluded, "Subsequent to the close of the second quarter, we strengthened our balance sheet through a reserved capital increase of ordinary shares, the gross proceeds of which were €26.25 million. These funds allow us to advance our novel, patented pipeline candidates NCX 470 and NCX 4251 and to submit INDs for Phase 2 clinical studies during the first semester 2018."

# **Second Quarter 2017 and Recent Developments**

- In August 2017, Nicox completed a financing through a reserved capital increase of ordinary shares
  of the Company with a specific category of investors. Gross proceeds from the financing were
  €26.25 million.
- On August 7, 2017, Nicox's licensee Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) announced that it had received a CRL from the FDA concerning the NDA for VYZULTA<sup>TM</sup> (latanoprostene bunod ophthalmic solution), 0.024% for intraocular pressure lowering in patients with open angle glaucoma or ocular hypertension. The CRL from the FDA referred to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Florida. Bausch + Lomb has informed Nicox that it submitted its response to the FDA on August 17, 2017. The NDA had been resubmitted to the FDA by Bausch + Lomb in February 2016 following receipt of a previous CRL. Neither CRL issued to Bausch + Lomb mentioned any efficacy or safety issues with respect to the NDA for VYZULTA, nor any additional clinical trials for the approval of the NDA.
- On May 31, 2017, Nicox announced that the FDA had approved the NDA for ZERVIATE™ (cetirizine ophthalmic solution 0.24%; formerly AC-170), the first topical ocular formulation of this well-known antihistamine, for the treatment of ocular itching associated with allergic conjunctivitis. Nicox is currently seeking a licensing partner for commercialization in the United States.



# Other Updates

• Nicox and VISUfarma have amended certain elements of our agreement relating to the August 2016 transfer of Nicox's European and International commercial operations to VISUfarma. Under the terms of the amended agreement, VISUfarma and Nicox have agreed to amend the terms and conditions related to the €5 million potential milestone payments, which would have been made in a combination of ordinary shares and interest-bearing loan notes. As a result, Nicox will receive an additional €1.65 million in deal consideration in a combination of ordinary shares and interest-bearing loan notes, making the total consideration for the assets equal to an aggregate of €22.65 million, increased from the €21 million initially. Nicox is now eligible to receive a milestone payment of up to €3.35 million in a combination of ordinary shares and interest-bearing loan notes if certain business objectives are achieved by VISUfarma. Nicox and VISUfarma also agreed that Nicox will no longer be responsible for completing development and regulatory approval for NCX 4240 in Europe. No payments are due by either party, now or subsequently, as a result of this change. Nicox retains rights to develop NCX 4240 in the United States and Japan. And finally, Nicox will make a one-time cash payment of €479,000 to VISUfarma.

# **H1 2017 Financial Summary**

Following reclassification in 2016 of the European commercial business as Discontinued Operations, the operating profit and loss account items described below include only the Continuing Operations.

The operating expenses for the six month period ended June 30, 2017 were €10.2 million compared to €12.0 million for same period ended June 30, 2016. The decrease in operating expenses in 2017 is mainly due to the significant R&D expenses recorded during the first six months in 2016 due to the filing of an NDA for ZERVIATE<sup>TM</sup> with the FDA as well as expenses for additional studies undertaken to address potential questions of the FDA as part of their review of this application.

The Group recorded a net loss from continuing operations of €12.2 million as of June 30, 2017, compared to a net loss of €12.9 million for the same period in 2016.

The Group had cash, cash equivalents of €20.4 million as of June 30, 2017, compared to €28.9 million on December 31, 2016. Following the closing of the €26.25 million financing announced on August 15, 2017, the Group's cash, cash equivalents as of August 31, 2017 are estimated to be €44,07 million (non-audited figures).

#### **About Nicox**

Nicox S.A. is an international ophthalmic company developing innovative solutions to help maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel drug candidates that target multiple ophthalmic conditions, including glaucoma. Nicox currently has one product at the review stage with the U.S. Food and Drug Administration (FDA), VYZULTA<sup>TM</sup> (latanoprostene bunod ophthalmic solution) 0.024%, licensed worldwide to Bausch + Lomb, and one product with an approved New Drug Application (NDA), ZERVIATE<sup>TM</sup> (cetirizine ophthalmic solution) 0.24%. In addition our promising drug-candidate pipeline includes clinical stage assets based both on our proprietary NO-donating research platform and on the repurposing of existing molecules as well as a next-generation of stand-alone nitric-oxide donors and exploratory novel NO-donating compounds with the potential to offer novel approaches to treat a range of ophthalmic conditions. 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
Invest Securities
Gilbert Dupont

Hugo Solvet
Martial Descoutures
Damien Choplain

Paris, France
Paris, France
Paris, France





update the information contained in analyst reports.

# Upcoming financial and business conferences

September 25-27 November 23-24

Cantor Fitzgerald's 3rd Annual Healthcare Conference

New York, US Paris, France

# **Contacts**

#### Nicox

Gavin Spencer, **Executive Vice President Corporate Development** T +33 (0)4 97 24 53 00 communications@nicox.com

#### **Investor Relations**

Europe

Nicox Corporate Development Department T +33 (0)4 97 24 53 00 communications@nicox.com

# **United States**

**Argot Partners** Melissa Forst T +1 (212) 600-1902 melissa@argotpartners.com

# **Media Relations**

**United Kingdom** Jonathan Birt T +44 7860 361 746 jonathan.birt@ymail.com

#### France

NewCap Nicolas Merigeau T +33 (0)1 44 71 94 98 nicox@newcap.eu

# **United States**

**Argot Partners** Eliza Schleifstein T +1 (917) 763-8106 eliza@argotpartners.com

#### Disclaimer

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 2016 filed with the French Autorité des Marchés Financiers (AMF) on March 29, 2017, and in the updated and additional risk factors as of August 14, 2017, which are available on Nicox's website (www.nicox.com).

# Nicox S.A.

Drakkar 2 Bât D, 2405 route des Dolines CS 10313, Sophia Antipolis 06560 Valbonne, France T+33 (0)4 97 24 53 00 F +33 (0)4 97 24 53 99



# INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

6 Months period ending June 30,		
2017	2016	
(in thousands of € except for per share data)		

Revenues	-	9
Selling expenses	-	(97)
General and administrative expenses	(5,078)	(4,376)
Research and development expenses	(5,091)	(6,544)
Other operating income	344	284
Other operating expense	(75)	(981)
Total operating income (loss) before fair value changes of contingent consideration ,and impairment of intangible asserts	(9,900)	(11,706)
Fair value changes of contingent considerations	(1,688)	(995)
Total operating income (loss)	(11,588)	(12,702)
Finance income	604	54
Finance costs <sup>1</sup>	(1,164)	(241)
Net finance revenues	(560)	(186)
Loss before tax	(12,148)	(12,888)
Income tax	(20)	(18)
Loss from continuing operations	(12,168)	(12,906)
Loss from discontinued operations <sup>2</sup>	-	(11,307)
Net loss for the year	(12,168)	(24,213)
Attributable to owners of the Company	(12,168)	(24,213)
Total comprehensive income (loss) for the period, net of tax	(0,48)	(1,06)
Basic/diluted earnings per share from continuing operations (€/share)	(0,48)	(0,56)
Basic/diluted earnings per share from discontinued operations (€/share)	-	(0,49)

 $<sup>^{1}</sup>$  Increase compared to H1 2016 is due mainly to an unrealized loss on the debt in dollars Nicox Ophthalmics, Inc. has with Nicox S.A.

<sup>&</sup>lt;sup>2</sup> Following Nicox European commercial operations divestment



# INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	As of June 30, 2017	As of Dec. 31 2016
	(in thousands of €)	
ASSETS		
Non-current assets		
Goodwill	25,444	27,546
Intangible assets	71,646	77,654
Property, plant and equipment	183	204
Non-current financial assets	13,102	12,652
Total non-current assets	110,375	118,056
Current assets		
Trade receivables	69	104
Government grants receivables	687	396
Other current assets	581	1,164
Prepayments	919	168
Cash and cash equivalents	20,443	28,859
Total current assets	22,699	30,692
TOTAL A005T0	400.074	440.740
TOTAL ASSETS	133,074	148,748
EQUITY AND LIABILITIES		
Equity attributable to equity holders of the parent		
Issued capital	25,670	25,005
Share premium	490,222	483,745
Accumulated deficit	(425 828)	(415,591)
Treasury shares	-	(478)
Currency translation adjustements	7,263	11,868
Total Equity	97,327	104,549
Non-current liabilities		
Non-current financial liabilities	17	30
Non-current financial liabilities related to business combination	704	923
Deferred taxes liabilities	27,164	29,409
Provisions	441	456
Total non-current liabilities	28,326	30,819
Current liabilities		
Current financial liabilities	36	32
Current financial liabilities related to business combination	-	5,234
Trade payables	2,063	1,338
Deferred income	3,615	4,275
Provisions	40	40
Other current liabilities	1,667	2,462
Total current liabilities	7,421	13,380
TOTAL LIABILITIES AND EQUITY	133,074	148,748