

# Nicox first half 2014 financial results

- Revenues for the first six months totalled €2.6 million, reflecting the first full contribution of Eupharmed and of Nicox's recently launched ophthalmic products
- National US launches of diagnostic tests Sjö™ and RetnaGene™
- Launch of European and ROW operations with AdenoPlus<sup>®</sup> and Xailin™
- Top-line phase 3 results for latanoprostene bunod expected by year-end
- Proposed acquisition of Aciex Therapeutics, Inc., significant step forward in Nicox's strategy of creating an international ophthalmic company built around therapeutics and diagnostics

August 28, 2014.

Sophia Antipolis, France.

**Nicox S.A.** (NYSE Euronext Paris: COX), the international ophthalmic company, today announced its financial results for the six months ended June 30, 2014, and provided an update on its activities.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said: "We continued to deliver our strategy of building an international ophthalmic company in the first half of the year, with revenues starting to grow as we roll out new products through our commercial infrastructure in the US and Europe and we expect sales to continue their positive momentum in the second half of the year. Our efforts to build a strong therapeutic portfolio alongside our diagnostic franchise will be significantly boosted by the proposed acquisition of Aciex Therapeutics, which will bring a diverse pipeline of ophthalmic therapeutic technologies and product candidates, including AC-170 in phase 3 for allergic conjunctivitis. In particular, we look forward to the top-line efficacy phase 3 results for latanoprostene bunod, the most advanced and promising compound in development for treatment of increased IOP and glaucoma, from our partner Bausch + Lomb (Valeant) later this year."

## Review of the first six months of 2014 and post-reporting period

Proposed acquisition of Aciex Therapeutics, Inc.

In July 2014, Nicox signed an agreement to acquire all of the outstanding equity of Aciex Therapeutics, Inc., a private, US-based, ophthalmic development pharmaceutical company with a strong near-term pipeline of

therapeutics addressing major segments of the ophthalmic market, including allergy and inflammation. The acquisition will significantly broaden and strengthen Nicox's therapeutic development pipeline, which would include two phase 3 candidates (latanoprostene bunod, currently being developed by Nicox's partner Bausch + Lomb, and Aciex's AC-170 for allergic conjunctivitis). In addition, the proposed acquisition brings other therapeutic candidates which could enter clinical studies within 12 to 18 months and a collaborative research agreement on preclinical Syk/JAK inhibitors.

The transaction includes a \$65 million upfront payment in newly issued Nicox shares, plus contingent value rights giving rights to shares, for a potential additional value of up to \$55 million. The upfront payment will give Aciex's shareholders 21.5% of the enlarged group, a fixed ratio which is not subject to variations in the Nicox share price or the euro/dollar exchange rate. The completion of the acquisition remains subject to the approval of Nicox's shareholders, with an Extraordinary General Meeting (EGM) to be convened to vote on the transaction.

## Latanoprostene bunod

Latanoprostene bunod is a nitric oxide (NO)-donating prostaglandin F2-alpha analog currently in phase 3 clinical development with Bausch + Lomb (B+L), a division of Valeant Pharmaceuticals International, Inc., for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension. Top-line phase 3 data are expected during the second half of 2014.

Clinical and preclinical results obtained with latanoprostene bunod were presented by B+L at the Association for Research in Vision and Ophthalmology (ARVO) 2014 Annual meeting in Florida, including results from two clinical studies (CONSTELLATION and KRONUS) as well as some preclinical results on the effect of latanoprostene bunod on primary human trabecular meshwork cell contractility and underlying signaling pathways.<sup>1</sup>

Under the licensing agreement signed in 2010, Nicox had an option to co-promote latanoprostene bunod products in the US. Nicox notified B+L on August 6, 2014, of its decision to exercise this option. Nicox and B+L will negotiate a co-promotion agreement which will be signed at a later stage.

## Commercial operations launched in Europe and ROW

In the first half of 2014, Nicox launched Xailin™, a new range of tear lubricants for relief of dry eye symptoms (classed as medical devices), and AdenoPlus®, an *in vitro* diagnostic medical device that aids in the identification of adenovirus to assist in the differential diagnosis of acute conjunctivitis, in Europe. Nicox has established specialist sales teams in the five major European markets (Italy, UK, Germany, Spain and France). In addition, partnerships have been established with third parties for the distribution of Nicox's products in Switzerland, Turkey, Benelux, South Africa and Poland. Revenues from European and rest of world operations totaled €2.1 million in the first half of 2014.

In May 2014, Nicox's Italian subsidiary Eupharmed entered into an exclusive agreement with Santen SAS, enabling Eupharmed to continue to distribute Cationorm<sup>®</sup>, an innovative treatment for dry eye symptoms, in Italy. As agreed at the time of the Eupharmed acquisition in December 2013, Nicox made an additional earn-out payment to Fin Posillipo SPA, Eupharmed's former shareholder, in the form of 821,996 newly issued Nicox shares.

## **US** commercial operations

In June 2014, Nicox's subsidiary Nicox Inc. launched expanded access to the RetnaGene<sup>™</sup> portfolio of tests to assess the risk for advanced age-related macular degeneration (AMD). Nicox has rights to promote the RetnaGene<sup>™</sup> portfolio to eye care practitioners in North America as per an agreement signed in January 2014 with Sequenom Laboratories, an affiliate of Sequenom, Inc. At the end of June 2014, Sjö<sup>™</sup>, an advanced diagnostic panel for the early detection of Sjögren's syndrome, was also rolled-out throughout the US, following its launch in selected US markets in November 2013. In July 2014, Nicox acquired the rights to market Sjö<sup>™</sup> to all healthcare practitioners in North America. Nicox Inc. strengthened its field force to support these launches. Revenues from the Group's US operations totaled €0.5 million in the first half of 2014.

In July 2014, Nicox and Rapid Pathogen Screening (RPS<sup>®</sup>) agreed to restructure the terms of their partnership in North America. RPS<sup>®</sup> has assumed responsibility for marketing AdenoPlus<sup>®</sup> to eye care professionals in North America, as well as two other diagnostic products currently in development, and will pay Nicox royalties on sales. Nicox retains rights to commercialize AdenoPlus<sup>®</sup> and the previously licensed development products in all markets outside North America.

## Naproxcinod repositioned in Duchenne muscular dystrophy (DMD)

In February 2014, Nicox granted an undisclosed financial partner the right to enter into a period of exclusive evaluation to assess the potential development of naproxcinod, a CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory candidate, and of next generation NO-donors outside the ophthalmology area. The evaluation is entirely funded by the partner and is focused initially on DMD. Promising preclinical results obtained with naproxcinod in models of muscular dystrophy were published in Human Molecular Genetics in early 2014.<sup>2</sup>

#### Management team

In August 2014, Nicox appointed Michael Bergamini, Ph.D., as Chief Scientific Officer (CSO) and Executive Vice President. Dr. Bergamini brings over 30 years of experience in the eye care industry and has played key roles in the discovery, translation, development, registration, and US and international launch of a number of pharmaceuticals, as well as several medical device products. From 2009 to 2014, Dr Bergamini served as the Director of the Office of Clinical Trials, as an Executive-in-Residence, and as a Senior Research Analyst at the University of North Texas Health Science Center, where he has been an Adjunct Professor of Pharmacology & Neuroscience since the late 1990s. From 1997 to 2009, he held several senior positions with Alcon Research Ltd., the world's leader in eye care, including Vice President, Pharmaceutical Development and Glaucoma Development. He previously worked for Laboratorios Cusí, SOLA/Barnes-Hind, the Liposome Company, Inc., and Allergan Pharmaceuticals, Inc.

#### **Board of Directors**

Nicox's Board has decided to co-opt Adrienne Graves, former CEO of Santen Inc., the US subsidiary of Santen, and Luzi von Bidder, former Chairman of Acino Holding AG and former Chairman and CEO of Novartis Ophthalmics AG, as members of the Board, to replace Vaughn Kailian and Vicente Anido. Vaughn Kailian has informed Nicox of his decision to step down from the Board of Directors with effect from August

11, 2014, for personal reasons which make it difficult for him to continue his commitment to Nicox. Vicente Anido has decided to step down from Nicox's Board due to his increasing responsibilities at Aerie Pharmaceuticals, Inc., with effect from August 6, 2014. The co-options of Dr. Graves and of Mr von Bidder will be submitted to Nicox's shareholders for approval at the General Meeting to be convened in the Fall notably to vote on the proposed acquisition of Aciex. Nicox's Board of Directors also intends to propose to such General Meeting the appointment of Les Kaplan, Executive Chairman of Aciex Therapeutics, Inc. and former Executive Vice President and President, Research and Development of Allergan, Inc., as member of the Board, subject to the prior approval by Nicox's shareholders of the acquisition of Aciex Therapeutics, Inc.

#### Presence at major international congresses

Nicox participated in several key international congresses in the ophthalmic field, including; the Hawaiian Eye meeting (US), the Società Italiana Trapianto di Cornea (SITRAC) National Congress (Italy), the International Ocular Inflammation Society Congress (IOIS) (Spain), the South Eastern Congress of Optometry International (SECO) (US), the Journées Réflexions Ophtalmologiques (JRO) (France), the 2014 ASCRS (American Society of Cataract and Refractive Surgery) • ASOA (American Society of Ophthalmic Administrators) Symposium & Congress (US), the Société Française d'Ophtalmologie (SFO) Congress (France) and the Optometry's Meeting® (117<sup>th</sup> Annual AOA Congress & 44<sup>th</sup> Annual AOSA Conference) (US).

#### Additional disclosure

The Company is currently pursuing negotiations which could lead to potential additional acquisitions of national European ophthalmic companies in the near- to medium-term. These acquisitions would be stock-based transactions, using the authorization granted by the Company's shareholders at the general meeting held on July 27, 2012, representing approximately €10 million if all transactions are completed. No final agreements have been entered into and there is no certainty that the Company will complete these contemplated acquisitions.

#### Review of the consolidated financial results as of June 30, 2014

Nicox's revenues totalled €2.6 million for the six months ending June 30, 2014. This compares to €0.2 million for the same period in 2013. Revenues significantly increased in 2014 driven by the acquisition in December 2013 of Eupharmed Srl, an established Italian pharmaceutical company specialized in ophthalmology, and the launch of new products by Nicox's sales force in the US and the five major European markets (France, Italy, Germany, Spain and UK).

Selling, administrative, research and development costs were €16.7 million in the first half of 2014 (H1 2013: €9.3 million), with 64% of these costs related to selling expenses, reflecting the significant financial investments made in North America and Europe to transform Nicox into a commercial ophthalmic company.

As a result, Nicox recorded a net loss of €15.9 million for the six months ending June 30, 2014, compared to a net loss of €9.2 million in the first half of 2013.

As of June 30, 2014, the Group had cash, cash equivalents and financial instruments of €41.4 million,

compared to €58.5 million on December 31, 2013.

## Consolidated statement of comprehensive income

#### Revenues

Nicox's revenues totalled €2.6 million for the six months ending June 30, 2014, compared to €0.2 million for the same period of 2013. Almost all of the revenues in the first half derived from product sales, 82% of which were in Europe following the acquisition of Eupharmed in December 2013, the launch of the Xailin<sup>™</sup> range in March 2014 and the promotion of AdenoPlus<sup>®</sup>; some 18% of total revenues were realized in the US, driven by the launch of Sjö<sup>™</sup> in November 2013. Nicox also recognized €0.05 million of revenues from an R&D collaboration. In the first half 2013 revenues amounted to €0.2 million, mainly from the US.

#### Cost of sales

Cost of sales amounted to €1.7 million during the first six months of 2014 compared to €0.2 million for the same period in 2013. This corresponds mainly to the cost of goods sold in relation to the sales of the Eupharmed product portfolio, Xailin<sup>™</sup> and AdenoPlus<sup>®</sup> as well as manufacturing and supply chain expenses.

## Selling, administrative and research and development costs

Selling, administrative, research and development costs were €16.7 million in the first half of 2014 compared to €9.3 million in the first half of 2013. In the first half of 2014, 64% of these costs were related to selling expenses, 25% to administrative expenses (including Corporate Development expenses) and 11% to research and development expenses. This compares to 40% related to selling expenses, 40% to administrative expenses, and 20% to research and development expenses in the first half of 2013. The significant increase in selling expenses in the first half of 2014 compared to the first half of 2013 reflects the substantial commercial investments made in Europe and North America to transform Nicox into a commercial ophthalmic company.

For the six months ending June 30, 2014, selling expenses were €10.8 million, compared to €3.7 million in the first half of 2013. Selling expenses comprise marketing and commercial costs. The company invested heavily in strengthening its commercial organizations and presence in the US and Europe, as well as in marketing and promoting all its new products. These activities followed the signature of agreements with RPS<sup>®</sup> in June 2012 for AdenoPlus<sup>®</sup> launched in 2012; with Immco in June 2013 for Sjö<sup>TM</sup>, launched in November 2013; and with Sequenom for RetnaGene<sup>TM</sup>, launched in June 2014. In March 2014, Nicox launched the Xailin<sup>TM</sup> range, and initiated a new promotion campaign for AdenoPlus<sup>®</sup> in Europe. As of June 30, 2014, the Group employed 136 people in Marketing and Commercial functions, compared to 16 at the same date in 2013. By the end of the first half of 2014, Nicox was generating recurring revenues in more than 10 countries, both through its own sales force and its distribution network.

During the period, administrative expenses amounted to €4.1 million, compared to €3.6 million in the first half of 2013, and include personnel-related costs in support functions, the remuneration of corporate officers, as well as communication and business development expenses. Administrative expenses for the first six months of 2014 grew 13% over the same period in 2013, to support the substantial growth of commercial activities in Europe and the US. The Group employed 21 people in its administrative departments compared

to 16 at the same date in 2013.

Research and development expenses were stable and totaled €1.8 million for the first six months ended June 30, 2014, compared to €1.9 million in the first semester of 2013. In the first six months of 2014, Research and Development expenses were essentially related to development activities for two innovative diagnostic tests for ocular use, following the agreement with RPS<sup>®</sup> in 2012, and to research activities in ophthalmological domains from our R&D center in Italy. The Group employed 14 people in R&D as of June 30, 2014, compared to 12 people at the end of June 2013.

#### Other income

Other income amounted to €0.7 million on June 30, 2014, compared to €0.3 million in the first six months of 2013. In the first half of 2014, other income included €0.3 million of operational subsidies from the research tax credit in France compared to 0.2 million at the same date in 2013.

#### Other expense

Other expense amounted to €0.2 million in the first six months of 2014 and is mainly linked to unrealized losses on foreign currency transactions.

#### **Operating loss**

The Group generated an operating loss of €15.3 million in the first six months of 2014, compared to a net loss of €9.3 million during the same period in 2013. The significant increase in the net loss for the first half of 2014 is consistent with the financial investments made for commercial activities in North America to launch Sjö<sup>™</sup> and RetnaGene<sup>™</sup> and in Europe to launch the Xailin<sup>™</sup> range and to market AdenoPlus<sup>®</sup>.

#### Other results

In the first semester of 2014, the Group recorded a net financial loss of €0.6 million linked to financial depreciation compared to a net financial profit €0.04 million at the same date in 2013.

## Total net loss for the period

Nicox recorded a net loss of €15.9 million for the six months ending June 30, 2014, compared to a net loss of €9.2 million in the first half of 2013.

## Consolidated statement of financial position

Intangible assets totaled €2.3 million as of June 30, 2014, and are mainly related to the net value of the license fee paid to RPS<sup>®</sup> for the worldwide licensing agreement signed in June 2012, as well as the value of regulatory dossiers purchased from Eupharmed and Customer Relationship Management (CRM) software.

Goodwill amounted to €5.4 million as of June 30, 2014 and is exclusively linked to the acquisition of Eupharmed SrI in December 2013.

The indebtedness incurred by Nicox is mainly short-term operating debt. On June 30, 2014, the Group's current liabilities totaled €7.0 million, including €0.2 million of finance lease, €3.8 million of payables,

€1.4 million of accrued compensation for employees, €1.4 million of payable taxes, €0.2 million of other contingencies and liabilities.

As of June 30 2014 the Group's cash, cash equivalents and financial instruments were €41.4 million, compared to €58.7 million on December 31, 2013.

#### References

- 1. The abstracts are available on the ARVO 2014 Online Planner (http://www.arvo.org/ARVO\_2014\_Mobile\_App/).
- 2. Uaesoontrachoon K, Quinn JL, Tatem KS, Van der Meulen JH, Yu Q, Phadke A, Miller BK, Gordish-Dressman H, Ongini E, Miglietta D, Nagaraju K. Long-term treatment with naproxcinod significantly improves skeletal and cardiac disease phenotype in the mdx mouse model of dystrophy. *Hum Mol Genet*. 2014, 23(12):3239-49.

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#### **About Nicox**

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an emerging international company focused on the ophthalmic market. With a heritage of innovative R&D, business development and commercial expertise, the Nicox team is building a diversified portfolio of therapies and diagnostic tools that can help people to enhance their sight. The Company's commercial portfolio and near-term pipeline already include several innovative diagnostic tests intended for eye care professionals, as well as a range of eye care products. Nicox's key proprietary asset in ophthalmology is latanoprostene bunod, a novel compound based on Nicox's proprietary nitric oxide (NO)-donating R&D platform, currently in Phase 3 clinical development in collaboration with Bausch + Lomb for the potential treatment of glaucoma and ocular hypertension. Further NO-donors are under development, notably through partners.

Nicox is headquartered in France, with research capabilities in Italy, a growing commercial infrastructure in North America and in the major European markets and an expanding international presence through partners. Nicox S.A. is listed on Euronext Paris (Compartment B: Mid Caps). For more information on Nicox or its products please visit <a href="https://www.nicox.com">www.nicox.com</a>.

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the 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 2013 » filed with the French Autorité des Marchés Financiers (AMF) on April 2, 2014 and available on Nicox's website (www.nicox.com) and on the AMF's website (www.amf-france.org).

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## INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – JUNE 2014

	For the period of six months ended June 30	
	2 014	2013
	(in thousands of €except for per share data)	
Revenues	2,595	183
Cost of sales	(1,686)	(223)
Selling expenses	(10,750)	3,701
Administrative expenses	(4,173)	(3,611)
Research and development expenses	(1,803)	(1,945)
Other income	700	265
Other expense	(210)	(219)
Operating loss	(15,327)	(9,251)
Finance income	160	128
Finance expense	(724)	(87)
Loss before income tax	(15,891)	(9,210)
Income tax expense	(35)	14
Net loss	(15,926)	(9,196)
Exchange differences on translation of foreign operations	(102)	(31)
Other comprehensive income (loss) for the period,	,	, ,
net of tax	(102)	(31)
Total comprehensive income (loss) for the period, net of tax	(16,028)	(9,227)
Attributable to:		
- Equity holders of the parent	(16,028)	(9,227)
- Non-controlling interests	-	-
Basic and diluted loss per share attributable to equity holders of the parent	(0.22)	(0.13)

## INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS OF JUNE 30, 2014

	As of Jun. 30 2014	As of Dec. 31 2013
(in thousands of €)		
ASSETS		
Non-current assets		
Property, plant & equipment	1,105	614
Goodwill	5,406	5,406
Intangible assets	2,255	2,373
Financial assets	249	824
Deferred income tax assets	-	89
Total non-current assets	9,015	9,306
Current assets		
Inventories	984	1,111
Trade receivables	1,430	294
Government subsidies receivable	825	500
Other current assets	1,166	739
Financial assets	6,148	6,111
Prepaid expenses	434	205
Cash and cash equivalents	35,275	52,363
Total current assets	46,262	61,323
TOTAL ASSETS	55,277	70,629
EQUITY AND LIABILITIES		
Equity		
Common shares	15,027	14,863
Other reserves	32,400	46,519
Non-controlling interests	-	-
Total Equity	47,427	61,382
Non-current liabilities		
Other contingencies and liabilities	434	421
Deferred income tax liabilities	-	-
Finance lease	408	104
Total non-current liabilities	842	525
Current liabilities		
	98	60
Other contingencies and liabilities	98 207	60 47
Other contingencies and liabilities Finance lease		
Other contingencies and liabilities Finance lease Current financial liabilities	207	47
Other contingencies and liabilities Finance lease Current financial liabilities Trade payables	207	47 2,014
Other contingencies and liabilities Finance lease	207 - 3,837	47 2,014 2,896
Other contingencies and liabilities Finance lease Current financial liabilities Trade payables Social security and other taxes	207 - 3,837 2,696	47 2,014 2,896 3,450