



# Nicox and Sequenom announce the launch of expanded access to RetnaGene™ test portfolio in the U.S.

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Sophia Antipolis, France and San Diego, Calif.

**Nicox S.A.** (NYSE Euronext Paris: COX), the international ophthalmic company, and **Sequenom, Inc.** (NASDAQ:SQNM), a life sciences company providing innovative genetic analysis solutions, today announced that Nicox's subsidiary, Nicox Inc. is launching expanded access to Sequenom Laboratories' RetnaGene™ portfolio of laboratory-developed genetic tests in the United States (U.S.). The RetnaGene portfolio includes **RetnaGene AMD** and **RetnaGene LR**, specialized genetic tests, which assess an individual's risk for advanced age-related macular degeneration (AMD).

"Expanding access to the RetnaGene portfolio of tests is an important milestone in the progress of the Nicox Ophthalmic Diagnostics franchise in the U.S.," commented Jerry St. Peter, Executive Vice President and General Manager of Nicox Inc. "AMD is a leading cause of blindness in the U.S. and is estimated to affect over 15 million Americans, including 10 to 15% suffering from an advanced form of the disease. The RetnaGene tests allow for improved patient management, by examining the most relevant genetic markers for a more accurate prediction of advanced AMD risk. Both the RetnaGene tests and our groundbreaking test for the early detection of Sjögren's syndrome, Sjö™, will be supported by our rapidly expanding specialist sales force."

# RetnaGene™ – A portfolio of laboratory-developed tests that advances AMD risk assessment

AMD is the most common cause of visual impairment and the leading cause of blindness in the elderly population in the developed world. The RetnaGene portfolio includes two laboratory-developed genetic tests performed exclusively by Sequenom Laboratories that evaluate an individual's risk of advanced AMD. The RetnaGene AMD test assesses the risk for wet AMD (also called choroidal neovascularization, CNV) within

two, five and ten years in patients aged 55 and older with early or intermediate dry AMD. The RetnaGene™ LR test assesses the lifetime risk of advanced AMD (wet or dry) in patients who have not been diagnosed with AMD, aged 55 and older and/or with a family history of AMD. The RetnaGene tests evaluate genotype and other known risk factors, giving a more complete assessment of a patient's individual risk for developing advanced AMD than with current phenotype-based standards.

"Currently there is much debate in the medical community surrounding the best way to incorporate genetic testing for AMD into clinical practice. Expanded access to the RetnaGene tests will provide broader use and education to clinicians about this important technology," said Quan Dong Nguyen, MD, MSc, who holds the McGaw Memorial Endowed Chair in Ophthalmology and is the Inaugural Director of the Truhlsen Eye Institute, University of Nebraska Medical Center.

In January 2014, Sequenom Laboratories granted Nicox Inc. exclusive promotion and marketing rights for its RetnaGene tests. Nicox Inc. has significantly strengthened its field force to support the expanded access of the RetnaGene portfolio, which is now available to its customers in the U.S.

"We believe the new offering of the RetnaGene tests by Nicox will help to fuel the momentum in the field while also developing enhanced opportunities for clinical trials and research to continue to investigate the utility of genetic testing services for AMD," said **Diana Do, MD**, Associate Professor of Ophthalmology and Director of the Carl Camras Center for Innovative Clinical Research in Ophthalmology at the Truhlsen Eye Institute, University of Nebraska Medical Center.

Both RetnaGene tests offer a quick and simple method for collecting DNA specimens with an easy-to-use inoffice buccal swab. The RetnaGene tests were developed, validated and are performed exclusively by
Sequenom Laboratories and are available through contract with Nicox. U.S. eye care practitioners can obtain
more information and order specimen collection materials for the RetnaGene test by calling
+1.855.MY.NICOX (+1.855.696.4269). Additional information can be found on Nicox's new website
specifically intended for a U.S. audience: www.mynicox.com. The Nicox Inc. team will be available at the
Optometry's Meeting® (117th Annual AOA Congress & 44th Annual AOSA Conference) being held from
June 25 to 29, 2014 in Philadelphia, Pennsylvania, to discuss its ophthalmic diagnostics offering, including
RetnaGene™ and Sjö™ (booth number: 1630).

"We are pleased with the timely progress of our partnership with Nicox and we are confident in Nicox's ability to successfully expand access to the RetnaGene portfolio of tests in the ophthalmic arena in the U.S.," stated William Welch, Chief Executive Officer of Sequenom, Inc.

# About AMD, a leading cause of blindness in the U.S.

AMD is an insidious, progressive eye disorder that starts with relatively harmless tiny yellow deposits on the retina (the light sensitive tissue in the eye) and increases in prevalence and severity with age. It is estimated that AMD currently affects approximately 15 million people in the United States and is a leading cause of vision loss in Americans aged 60 and over. Advanced AMD represents 10 to 15 percent of all AMD cases and is estimated to affect at least 1.75 million patients in the U.S.<sup>2</sup>

Geographic atrophy is considered the advanced stage of the dry form of AMD. Another advanced form of AMD is neovascular or 'wet AMD', which causes profound loss of central vision and is the leading source of

legal blindness in people over age 50 in the developed world. Wet AMD is caused by abnormal growth of fragile and leaky blood vessels, known as choroidal neovascularization (CNV) in the macula (a small area where vision is keenest at the center of the retina) in response to chronic inflammatory stress.

Genetics are highly influential in the development of AMD, with up to 71 percent of heritability for advanced AMD.<sup>3</sup> The advanced "wet" form of the disease accounts for approximately 90 percent of severe vision loss associated with the disease.<sup>4,5</sup> Conversion to wet AMD can be sudden, with vision loss being rapid and severe. A missed conversion can lead to delayed therapeutic intervention and the potential for irreversible central vision loss. On the contrary, an early risk assessment may enable patients to benefit from a personalized patient management plan with the goal of preserving vision.

## Exclusive agreement between Nicox Inc. and Sequenom Laboratories for RetnaGene

Under the terms of the agreement signed in January 2014, Sequenom's affiliate Sequenom Laboratories granted Nicox Inc. exclusive rights to promote the RetnaGene AMD and RetnaGene LR laboratory-developed tests to eye care practitioners in North America (United States, Canada, Puerto Rico and Mexico) and co-exclusive rights towards specialized retina physicians. Sequenom Laboratories provides the sample collection materials and performs the testing exclusively in its CLIA-certified laboratory at an agreed price to Nicox. Further, Sequenom Laboratories contributes existing commercial and clinical expertise, and marketing intelligence to expedite increased market demand and uptake within the general ophthalmology and optometry segments. Nicox is responsible for all marketing and promotional activities, and is directly promoting the RetnaGene tests to eye care practitioners.

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#### References

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- 3. Seddon JM, Cote J, Page WF, et al. The US twin study of age-related macular degeneration: relative roles of genetic and environmental influences. *Arch Ophthalmol.* 2005; 123(3):321-327.
- 4. Jager RD, Mieler WF, Miller JW. Age-related macular degeneration. N Engl J Med. 2008;358(24):2606-2617.
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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>.

#### **About Sequenom**

Sequenom, Inc. (NASDAQ: SQNM) is a life sciences company committed to improving healthcare through revolutionary genomic and genetic analysis solutions. Sequenom develops innovative technology, products and diagnostic tests that target and serve molecular diagnostic markets. Website: www.sequenom.com.

#### **About Sequenom Laboratories**

Sequenom Laboratories, a CAP accredited and CLIA-certified molecular diagnostics laboratory, has developed a broad range of laboratory-developed tests, with a focus on prenatal and ophthalmological diseases and conditions. Branded under the names SensiGene®, MaterniT21<sup>TM</sup> PLUS, HerediT<sup>TM</sup>, NextView<sup>TM</sup> and RetnaGene<sup>TM</sup>, these molecular genetic laboratory-developed tests, performed exclusively by Sequenom Laboratories, provide early patient management information for obstetricians, geneticists, maternal fetal medicine specialists and ophthalmologists. Sequenom Laboratories is changing the landscape in genetic disorder diagnostics using proprietary cutting edge technologies.

Sequenom®, MaterniT21 $^{\text{TM}}$  PLUS, SensiGene®, HerediT $^{\text{TM}}$ , NextView $^{\text{TM}}$ , and RetnaGene $^{\text{TM}}$  are trademarks of Sequenom, Inc. All other trademarks and service marks are the property of their respective owners.

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#### Forward-looking statements

#### Nicox

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).

#### Sequenom

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Sequenom's, Nicox's, and healthcare provider expectations related to expanded access to the RetnaGene portfolio of tests and the impact, effects, and benefits of such tests on Sequenom, Nicox, healthcare providers, and patients, Sequenom's and Nicox's expectations regarding future performance under the agreement between Sequenom and Nicox and the expected or potential benefits and impact of the agreement on Sequenom, Nicox, healthcare providers and patients, Sequenom's commitment to improving healthcare through revolutionary genomic and genetic analysis solutions, and Sequenom Laboratories's changing the landscape in genetic disorder diagnostics, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with market demand for and acceptance and use of technology and tests such as the RetnaGene portfolio of tests, reliance upon the collaborative efforts of other parties such as Nicox, healthcare providers and others, Sequenom or other parties obtaining or maintaining regulatory approvals that impact Sequenom's business, government regulation particularly with respect to diagnostic products and laboratory developed tests, publication processes, the performance of designed product enhancements, Sequenom's ability to develop and commercialize technologies and products, particularly new technologies such as laboratory developed tests, Sequenom's financial position, the timing and amount of reimbursement that Sequenom Laboratories receives from payors for its laboratory developed tests, Sequenom's ability to manage its existing cash resources or raise additional cash resources, competition, intellectual property protection and intellectual property rights of others, litigation involving Sequenom, and other risks detailed from time to time in Sequenom's most recently filed reports on Form 8-K, its most recently filed Quarterly Report on Form 10-Q and its Annual Report on Form 10-K/A and 10-K for the year ended December 31, 2013, and other documents subsequently filed with or furnished to the Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and Sequenom undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

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