



# pSivida and Nicox Enter Strategic Collaboration Agreement to Develop Sustained Release Drug to Lower Intraocular Pressure in Patients with Glaucoma

*Focus will be on Combining pSivida's Bioerodible Sustained Release Delivery Technology with Nicox's New Nitric Oxide Donating Compounds*

**Watertown, MA and Sophia Antipolis, France – October 10, 2017** - pSivida Corp, (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug products and technologies, and Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic company, today announced their entry into a collaboration agreement to explore the potential of combining pSivida's bioerodible sustained release drug delivery system with Nicox's nitric oxide (NO)-donating compounds, to develop a sustained release drug to lower intraocular pressure (IOP) in patients with glaucoma or ocular hypertension.

pSivida and Nicox will collaborate on the selection of NO-donating product candidates from Nicox's research portfolio to combine with pSivida's sustained release drug technology. pSivida will be responsible for initial development activities of ocular insert formulations, for which it will receive undisclosed sums by Nicox. The companies may then elect to proceed with further development, including more detailed non-clinical studies to generate pre-clinical data, and the evaluation of further compounds under the collaboration. Nicox would make additional payments for any incremental development activities for each implant formulation product candidate selected by Nicox to progress in development. New intellectual property from the collaboration relating to the drug-device combination will be jointly owned. Nicox and pSivida will negotiate a separate license agreement for any product candidate that the two companies wish to further develop and potentially commercialize as a result of this collaboration. Expected payments from Nicox associated with this agreement are not considered material to Nicox's financial statements at this time.

**Michael Bergamini, Executive Vice President and Chief Scientific Officer, stated** *"We have strong pre-clinical data demonstrating the IOP lowering effect of our novel stand-alone NO donors, such as our lead NCX 667, and believe that their profile makes them product candidates for potential sustained release delivery. The bioerodible technology in development by pSivida, combined with their proven success in developing sustained delivery devices for the eye, puts them at the forefront of this exciting area."*

*"Nicox's NO-donating research platform has been validated in both pre-clinical and human studies for the reduction of IOP."* **commented Nancy Lurker, President & CEO of pSivida,** *"Combining this novel approach to IOP lowering with our bioerodible, sustained delivery device could offer a unique therapy alternative or adjunct to existing therapies to lower IOP in order to help prevent the development and progression of glaucoma."*

**About glaucoma**

Glaucoma is a group of ocular diseases in which the optic nerve is injured, leading to peripheral and, ultimately, central visual loss. Glaucoma can eventually lead to blindness if not treated. Glaucoma is frequently linked to abnormally high intraocular pressure (IOP), due to blockage or malfunction of the eye's aqueous humor drainage system. Current medications are targeted at reducing IOP to slow the progression of the disease. Numerous eye drops are available to either decrease the amount of fluid produced in the eye or improve its flow out of the eye. A significant portion of patients with open-angle glaucoma require more than one medication to lower their IOP within target levels, highlighting the need for more effective treatments.

### About Nicox's next generation of stand-alone NO-donors

Nicox's research team has engineered a novel chemistry for a next generation of stand-alone NO-donating molecules with the potential to optimize NO dosing to be used alone or in combination with existing standard-of-care drugs, either as topical eye drops or in sustained intraocular drug-delivery devices. The preclinical results obtained after repeat dosing in rabbit models of glaucoma demonstrate rapid and sustained IOP-lowering compared to vehicle following repeated dosing one hour apart over the course of four hours with no signs of tachyphylaxis or ocular discomfort<sup>1</sup>. Furthermore, NO-donors result in low tolerance liability as they were found to repeatedly lower IOP on assessed days in these models following twice daily administration over seven days. Similar tolerance liability results were found in non-human primates.

#### Notes:

1. Repeated dosing of NCX 667, a new nitric oxide (NO) donor, retains IOP-lowering activity in animal models of glaucoma, E. Bastia, F. Impagnatiello, E. Ongini, J. Serle, M. Bergamini. Presented at ARVO 2017

### About Nicox

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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™ (latanoprostene bunod ophthalmic solution) 0.024%, licensed worldwide to Bausch + Lomb, and one product with an approved NDA, ZERVIA™ (cetirizine ophthalmic solution) 0.24%, licensed in the U.S. to EyeVance. 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](http://www.nicox.com).

### About pSivida

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pSivida Corp. ([www.psivida.com](http://www.psivida.com)), headquartered in Watertown, MA, is a leader in the development of sustained release drug products for treating eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold directly in the U.S. and three EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Durasert™ micro-insert for posterior segment uveitis, is being independently developed. Two pivotal Phase 3 studies with Durasert achieved their primary efficacy endpoint of prevention of recurrence of uveitis at six months of follow-up with statistical significance, and the Company plans to file an NDA by late December 2017/early January 2018. pSivida's pre-clinical development program is focused on using its core platform technology Durasert™ to deliver drugs to treat wet age-related macular degeneration, glaucoma, osteoarthritis and other diseases. To learn more about pSivida, please visit [www.psivida.com](http://www.psivida.com) and connect on Twitter, LinkedIn, Facebook and Google+.

### Nicox Disclaimer

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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](http://www.nicox.com)).

## **pSivida Disclaimer**

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**SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995:** Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements include uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema ("DME"), which depends on Alimera's ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the successful development and, if approved, commercialization of Durasert (under the ILUVIEN trademark) for posterior segment uveitis in Europe, the Middle East and Africa ("EMEA") by Alimera; the number of clinical trials and data required for the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis marketing approval applications in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; our ability to successfully commercialize Durasert three-year uveitis, if approved; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; potential declines in Retisert® royalties; efficacy and our future development of an implant to treat severe osteoarthritis; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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