



## Nicox to acquire Aciex Therapeutics, Inc.

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- Significant step forward in Nicox's strategy of creating an international ophthalmic company built around therapeutics and diagnostics
- Aciex brings a near-term pipeline of ophthalmic therapeutic product candidates, including lead program AC-170 in phase 3 for allergic conjunctivitis
- Transaction, subject to the approval of Nicox's shareholders, includes a \$65 million upfront payment in newly issued Nicox shares, plus contingent value rights giving right to shares, for a potential additional value of up to \$55 million
- Conference calls to be held today at 2 pm CET / 1 pm BST / 8 am EDT in French and 3 pm CET / 2 pm BST / 9 am EDT in English

July 2, 2014.

Sophia Antipolis, France.

**Nicox S.A.** (NYSE Euronext Paris: COX) today announced it has 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 completion of the acquisition remains subject to the approval of Nicox's shareholders and other customary conditions.

Aciex's therapeutic pipeline includes:

- AC-170 for allergic conjunctivitis, which has completed two phase 3 trials and for which Nicox plans to seek a pre-NDA meeting before the submission of a New Drug Application (NDA);

- AC-155, in development for post-operative inflammation and pain, which is expected to enter phase 2 studies in 2015;
- A collaborative research agreement with Portola Pharmaceuticals, Inc. for small molecule dual Syk/JAK inhibitors for potential topical ophthalmic treatments;
- A portfolio of clinical and pre-clinical product candidates targeting areas including ocular allergy, dry eye and other inflammatory eye conditions, and
- A proprietary manufacturing process that can be used to repurpose existing drugs by producing novel, patentable nanocrystalline forms.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said: *“This proposed acquisition is another significant step forward in Nicox’s strategy of creating an international ophthalmic company built around therapeutics and diagnostics with its own commercial infrastructure in the United States and in the major European markets. The combination with Acix would enable Nicox to expand its therapeutic pipeline to target major segments of the ophthalmic sector, including the \$816 million US allergic conjunctivitis market<sup>1</sup>. Together with the expansion of our diagnostics franchise, this acquisition further enhances our ability to create a unique company with a transatlantic commercial presence as well as a diversified proprietary product portfolio.”*

**Les Kaplan, Ph.D, Executive Chairman of Acix, and Thomas Cavanagh, President of Acix**, added: *“We are excited about the opportunity to combine our robust pipeline derived from our collaboration with Ora, Inc., with the financial and commercial strengths of Nicox. With a portfolio of programs now either in or approaching the clinic, we believe that this transaction will accelerate their development and commercialization. We look forward to working with the Nicox team to ensure the success of the expanded business.”*

Under the proposed acquisition, Nicox will acquire all outstanding shares of Acix on a cash-free debt-free basis through a reverse triangular merger, governed by US laws and regulations. Acix shareholders will receive an upfront payment of \$65 million entirely in the form of 20,627,024 newly issued Nicox shares, plus contingent value rights (CVRs) giving right to Nicox shares based on the potential US FDA approval(s) of AC-170 and of two additional undisclosed products within a pre-determined period. These CVRs are defined as follows: \$35 million for the US approval of AC 170 on or before the earlier of 18 months after the date of filing of an NDA with the FDA or December 1, 2016; or \$10 million if the approval is granted after this date, but on or before the earlier of 30 months after the date of filing of an NDA with the FDA or December 1, 2017; and \$10 million each for the following two US product approvals by July 1, 2021. These could potentially bring the total consideration to a maximum of \$120 million. In general, and subject to certain negotiated exceptions, the Nicox shares issued to Acix stockholders will be subject to lock-up restrictions.<sup>2</sup>

MTS Securities, LLC, an affiliate of MTS Health Partners L.P., is serving as the exclusive financial advisor to Nicox in this transaction. Mintz Levin Cohn Ferris Glovsky and Popeo, P.C. is serving as US legal counsel to Nicox and Clifford Chance Europe LLP is serving as French legal counsel to Nicox. Aquilo Partners, L.P. acted as the exclusive financial advisor to Acix in this transaction, and WilmerHale is serving as the legal advisor to Acix.

Nicox's shareholders will be invited to vote on this proposed transaction at a dedicated Extraordinary General Meeting (EGM) which is expected to be held in the Fall. A report containing additional information will be made available to the shareholders prior to the EGM

### **Additional Therapeutic R&D Pipeline Background**

The acquisition of Acix will complement Nicox's leading position in the therapeutic application of nitric oxide (NO)-donating compounds for ophthalmic use. Nicox's lead asset, latanoprostene bunod, is currently in phase 3 trials for the reduction of intraocular pressure in glaucoma and ocular hypertension conducted by its licensing partner Bausch + Lomb. Nicox is also selecting the lead compounds from its internal research portfolio for the next-generation of NO-donors for the treatment of elevated intraocular pressure (IOP).

The combined therapeutic pipeline of Nicox and Acix will include:

- **AC-170** – a novel formulation of cetirizine (a leading antihistamine marketed under brand names including Zyrtec<sup>®</sup>), being developed for topical application in the eye for the first time for the treatment of allergic conjunctivitis. Two phase 3 safety and efficacy studies have demonstrated statistically significant results for AC-170 over vehicle control for the primary endpoint of ocular itching. Treatment emergent adverse events were similar in severity and frequency in the active and placebo groups. Nicox plans to seek a pre-NDA meeting by Q1 2015.
- **Latanoprostene bunod** – an NO-donating prostaglandin F<sub>2</sub>-alpha analog in phase 3 clinical development for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension. Latanoprostene bunod is based on Nicox's proprietary NO-donating research platform and was licensed to Bausch + Lomb in March 2010. Top-line phase 3 results are expected in Q4 2014.
- **AC-155** – a novel nanocrystalline form of fluticasone (a leading corticosteroid marketed under brand names including Flonase<sup>®</sup> and Flovent<sup>®</sup>), also being developed for topical application in the eye for the first time. It uses Acix's proprietary manufacturing process and is being developed for post-operative inflammation and pain. Fluticasone's approximately ten-fold greater affinity than dexamethasone for the glucocorticoid receptor might allow reducing its dosing frequency. AC-155 is expected, pending FDA agreement, to move directly into a phase 2 clinical trial in 2015, following toxicity studies and IND filing.
- Acix has a collaborative research agreement with Portola Pharmaceuticals, Inc., signed in 2013, that provides Acix with exclusive rights to jointly develop Portola's preclinical small molecule dual Spleen Tyrosine Kinase (Syk) and Janus Kinase (JAK) inhibitors for topical ophthalmic indications. These are targeted at ophthalmic diseases including ocular allergy, dry eye and other inflammatory eye conditions, for which there is a promising potential for Syk and JAK inhibition.
- Acix's extensive pipeline includes a number of additional clinical and pre-clinical programs that principally target ocular allergy, ocular inflammation and blepharitis and which offer opportunities for both in-house development and external collaborations. The pipeline has been developed through a close partnership with Ora, Inc., a leading ophthalmic Contract Research Organization (CRO) and development company. Nicox will continue to work closely with Ora following completion of the acquisition.

- Acix has a proprietary manufacturing process, applicable to certain classes of molecules, which can be used to produce novel, patentable nanocrystalline forms of existing drugs in a number of therapeutic fields, including ophthalmology.

### **Nicox's Commercial Presence**

The Nicox Group is present in the US and in Europe. The acquisition of Acix follows the recent expansion of Nicox's commercial presence for its ophthalmic diagnostics franchise in the US to support its recently launched products, including Sjö™ for the early detection of Sjögren's syndrome in patients with dry eye symptoms, and RetnaGene™ for comprehensive risk assessment for advanced age-related macular degeneration (AMD). The US team also promotes AdenoPlus®, launched in late 2012, a point-of-care test to aid in the differential diagnosis of acute conjunctivitis. Two other diagnostic tests, one targeting both adenoviral and allergic conjunctivitis and the other targeting ocular herpes, are in development.

In Europe, Nicox markets Xailin™, a proprietary brand of tear lubricants for relief of dry eye symptoms, and AdenoPlus®. An additional range of products is also marketed in Italy through the Group's subsidiary Eupharmed, acquired at the end of 2013. Nicox has established its own commercial sales forces in the US and in Europe's five largest markets (France, Germany, Italy, Spain, and the UK). In addition, Nicox has already established partnerships with third parties for the marketing and sale of its products in several additional territories including Switzerland, Turkey, Benelux, South Africa and Poland, and Nicox is working on securing distribution agreements in other key international markets, including Japan.

### **Conference Call Information**

Nicox will hold conference calls today, July 2, 2014:

- In French at 2 pm CET / 1 pm BST / 8 am EDT: +33 (0)1 70 91 86 60; conference ID 2606085
- In English at 3 pm CET / 2 pm BST / 9 am EDT: +44 (0)20 3427 1905 or +1 646 254 33 66; conference ID 1126205

The presentation will be available on Nicox's website: [www.nicox.com](http://www.nicox.com).

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### **About Acix**

Acix Therapeutics, Inc., located in Boston, MA, is a venture-backed ophthalmic pharmaceutical company focused on developing first-in-class products to treat ocular diseases. Existing investors in Acix include Akorn, Inc., Bay City Capital, HealthCare Ventures, New Enterprise Associates and Ora Investment Group. Acix's product pipeline, which includes both clinical stage and pre-IND assets, is designed to fill significant unmet therapeutic needs and allow the Company to build a sustainable ophthalmic franchise. Acix was founded in 2007 with technology licensed from Afferent Therapeutics LLC, a spin-out from Ora, Inc. For more information about Acix, visit [www.acixrx.com](http://www.acixrx.com).

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## References

- 1 IMS SMART Solution Data – MATTY April 2014.
- 2 Shareholders will be free to sell 25% of their shares after 90 days from the closing, 25% after 120 days, 25% after 150 days and shall be able to sell all of their shares after 180 days from the closing. Shares received under the CVRs can be traded immediately after they are issued.



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

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](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).



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