12th January 2015

Sector View

Biotechnology

Good news for AC-170 in allergic conjunctivitis in the USA

	1 M	3 M	6 M	31/12/13
Healthcare	2.1%	5.2%	8.6%	21.2%
DJ Stoxx 600	-0.8%	3.4%	-0.6%	2.9%

*Stoxx Sector Indices

Companies covered			
CELLECTIS			**EUR8,8**
Last Price	EUR22	*Market Cap.*	EUR613m
ERYTECH		**No rating**	**EUR37**
Last Price	EUR27	*Market Cap.*	*EUR183m*
GALAPAGOS		**BUY**	**EUR23**
Last Price	EUR15,87	*Market Cap.*	*EUR481m*
NICOX		**Under review**	**U.R.**
Last Price	EUR1,876	*Market Cap.*	*EUR186m*
TRANSGENE			**EUR12**
Last Price	EUR6,75	*Market Cap.*	*EUR260m*
ZEALAND		**BUY**	**DKK83,5**
Last Price	DKK88	*Market Cap.*	*DKK2,041m*

Nicox, the ophthalmic speciality company, and nitric oxide specialist announced this morning that its pre-NDA meeting with the FDA for AC-170 has turned positive. AC-170 is a treatment under development for allergic conjunctivitis and has been developed by Aciex Therapeutics in the US. This news is positive as the FDA recommended the NDA submission as opposed to asking for additional clinical data - there was still a risk of a need for a second phase III trial. We think it's time to have a look at Nicox's strategy, in particular in the US.

28 January 2015: Breakfast with Michele Garufi, CEO of Nicox.

ANALYSIS

- **AC-170 comes closer to commercialisation**. Ahead of our investors' breakfast-meeting on January 28th with Michele Garufi, Nicox announced this morning that the pre-NDA meeting for AC-170 turned positive, i.e. the FDA is not requiring another phase III trial before the submission of the NDA. Based on efficacy and safety data, the FDA recommended submission of the NDA following this pre-NDA meeting. Note that a second pre-NDA meeting will take place in Q1 this year with regards to the Chemistry, Manufacturing and Controls (CMC) data package. AC-170 is a topical formulation of cetirizine for the treatment of allergic conjunctivitis and has been developed by Aciex Therapeutics in the US prior to its merger with Nicox in October last year. Nicox's CEO expects the **potential for this product at around USD50m**. This news is positive and in line with Nicox's strategy. Brick by brick, Nicox is building up its ophthalmology franchise notably in the US. Let's have a closer look at Nicox's strategy and pipeline.

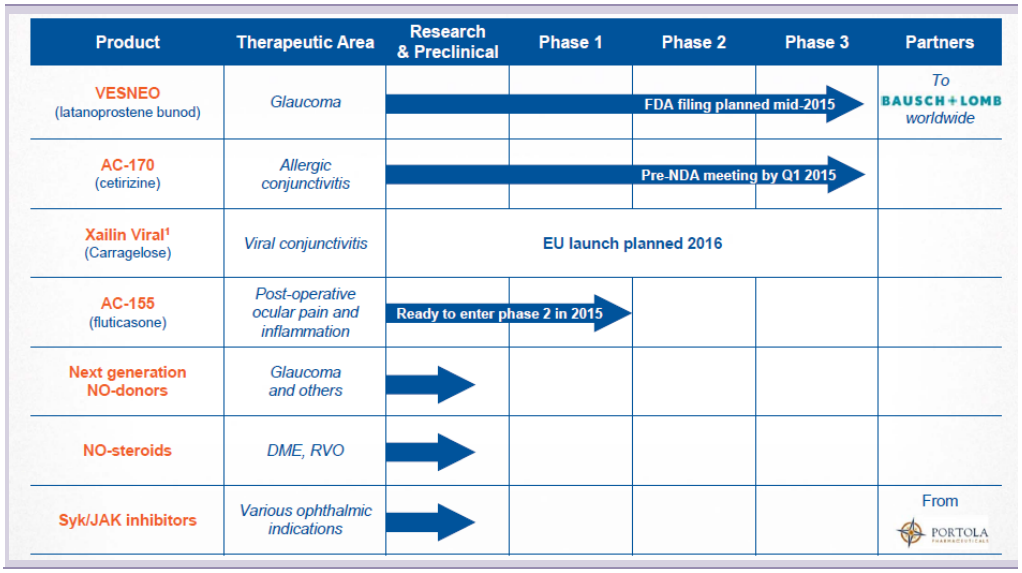
- **Four ophthalmology-acquisitions in a little more than a year**. Nicox has already completed four acquisitions in the ophthalmology space: **Eupharmed** (Italy, December 2013 for EUR3.5m in shares) with 2013 sales of EUR3.9m, **Doliage** (France, September 2014 for EUR5m in shares) with 2013 sales of EUR2.6m, **Carragelose** a product from Marinomed (Austria, September 2014 for EUR5.3m in a 50/50 cash/shares mix) to be marketed in 2016, **Aciex Therapeutics** with its AC-170 for allergic conjunctivitis (USA, H2 2014, for USD65m in shares + potentially USD55m in shares)

- **One potential significant product (Vesneo) and AC-170 could reach the market by mid 2016.** Last September, Vesneo (latanoprostene bunod, former BOL-303259-X and NCX 116) reported positive top-line phase III results for the reduction of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. Vesneo's two phase III trials are being conducted by Nicox's partner Bausch+Lomb/Valeant in the US and Europe (APOLLO and LUNAR clinical studies with a total of 840 patients). If approved, Vesneo, which is a nitric oxide-donating prostaglandin F2-alpha analog, would be the first-ever validation of Nicox's nitric oxide (NO)-donating technology. According to B+L, Vesneo's peak sales could reach USD**1bn WW of which USD500m from the US alone**. B+L is planning to submit an NDA mid-2015 in the US, meaning a potential launch in mid-2016. The second product with possible significant potential, AC-170 for allergic conjunctivitis, comes from the acquisition of Aciex Therapeutics finalised in October 2014. AC-170 has already completed two phase III trials and Nicox will hold another pre-NDA with the FDA in Q1 2015. Pending FDA approval, AC-170 could reach the market around the end of 2016, and according to Nicox's CEO, Michele Garufi, this product could reach around **USD50m in peak sales** which seems reasonable considering that the allergic conjunctivitis market is estimated at over USD800m in the US (IMS) and growing, and that B+L already commercialises Bepreve with sales amounting to approximately USD35m.

- **The US in sight.** In the past (deal with B+L in March 2010), as well as more recently with the exercise of its option to co-promote Vesneo in the US (August 2014) and the acquisition of the US-based Aciex, Nicox seems to have ambitions in the US. Following the deal with Aciex, the shareholding structure has been modified and, now, US-based investors account for more than 20% in the capital with newcomers like Bay City Capital and Health Care Venture. Moreover, in October 2014, Michele Garufi declared in French newspapers it was eyeing the US stock market...

- **Nicox, now a pure-player in ophthalmology drug-development**. With the acquisition of Nicox's US ophthalmic diagnostics division by its partner Valeant in November 2014 in a deal worth USD20m, Nicox is now exclusively focusing on its ophthalmology drug-related pipeline.

Fig. 1: Nicox's pipeline



Source: Company Data..

VALUATION

- Nicox is currently under review.
- At end September 2014, Nicox had EUR32.9m in cash.

NEXT CATALYSTS

- Second pre-NDA meeting with the FDA for AC-170 in Q1 2015.
- 2014 FY sales (EUR4.5m for the first 9 months) – no date specified yet.
- NDA submission for Vesneo in Q2 2015

Click here to download document

Analyst :
Pierre Corby
33(0) 1.70.3657.45
pcorby@bryangarnier.fr

Sector Team :
Eric Le Berrigaud
Hugo Solvet

Bryan Garnier stock rating system

For the purposes of this Report, the Bryan Garnier stock rating system is defined as follows:

Stock rating

BUY — Positive opinion for a stock where we expect a favourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential upside based on valuation), but also takes into account a number of elements including a SWOT analysis, positive momentum, technical aspects and the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

NEUTRAL — Opinion recommending not to trade in a stock short-term, neither as a BUYER or a SELLER, due to a specific set of factors. This view is intended to be temporary. It may reflect different situations, but in particular those where a fair value shows no significant potential or where an upcoming binary event constitutes a high-risk that is difficult to quantify. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

SELL — Negative opinion for a stock where we expect an unfavourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential downside based on valuation), but also takes into account a number of elements including a SWOT analysis, positive momentum, technical aspects and the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

Distribution of stock ratings

BUY ratings 72% NEUTRAL ratings 0% SELL ratings 28%

Research Disclosure Legend

1	Bryan Garnier shareholding in Issuer	Bryan Garnier & Co Limited or another company in its group (together, the "Bryan Garnier Group") has a shareholding that, individually or combined, exceeds 5% of the paid up and issued share capital of a company that is the subject of this Report (the "Issuer").	No
2	Issuer shareholding in Bryan Garnier	The Issuer has a shareholding that exceeds 5% of the paid up and issued share capital of one or more members of the Bryan Garnier Group.	No
3	Financial interest	A member of the Bryan Garnier Group holds one or more financial interests in relation to the Issuer which are significant in relation to this report	No
4	Market maker or liquidity provider	A member of the Bryan Garnier Group is a market maker or liquidity provider in the securities of the Issuer or in any related derivatives.	No
5	Lead/co-lead manager	In the past twelve months, a member of the Bryan Garnier Group has been lead manager or co-lead manager of one or more publicly disclosed offers of securities of the Issuer or in any related derivatives.	No
6	Investment banking agreement	A member of the Bryan Garnier Group is or has in the past twelve months been party to an agreement with the Issuer relating to the provision of investment banking services, or has in that period received payment or been promised payment in respect of such services.	No
7	Research agreement	A member of the Bryan Garnier Group is party to an agreement with the Issuer relating to the production of this Report.	No
8	Analyst receipt or purchase of shares in Issuer	The investment analyst or another person involved in the preparation of this Report has received or purchased shares of the Issuer prior to a public offering of those shares.	No
9	Remuneration of analyst	The remuneration of the investment analyst or other persons involved in the preparation of this Report is tied to investment banking transactions performed by the Bryan Garnier Group.	No
10	Corporate finance client	In the past twelve months a member of the Bryan Garnier Group has been remunerated for providing corporate finance services to the issuer or may expect to receive or intend to seek remuneration for corporate finance services from the Issuer in the next six months.	No
11	Analyst has short position	The investment analyst or another person involved in the preparation of this Report has a short position in the securities or derivatives of the Issuer.	No
12	Analyst has long position	The investment analyst or another person involved in the preparation of this Report has a long position in the securities or derivatives of the Issuer.	No
13	Bryan Garnier executive is an officer	A partner, director, officer, employee or agent of the Bryan Garnier Group, or a member of such person's household, is a partner, director, officer or an employee of, or adviser to, the Issuer or one of its parents or subsidiaries. The name of such person or persons is disclosed above.	No
14	Analyst disclosure	The analyst hereby certifies that neither the views expressed in the research, nor the timing of the publication of the research has been influenced by any knowledge of clients positions and that the views expressed in the report accurately reflect his/her personal views about the investment and issuer to which the report relates and that no part of his/her remuneration was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in the report.	Yes
15	Other disclosures	Other specific disclosures: Report sent to Issuer to verify factual accuracy (with the recommendation/rating, price target/spread and summary of conclusions removed).	No

A copy of the Bryan Garnier & Co Limited conflicts policy in relation to the production of research is available at www.bryangarnier.com

London
Heron Tower
110 Bishopsgate
London EC2N 4AY
Tel: +44 (0) 207 332 2500
Fax: +44 (0) 207 332 2559
Authorised and regulated by the Financial Conduct Authority (FCA)

Paris
26 Avenue des Champs Elysées
75008 Paris
Tel: +33 (0) 1 56 68 75 00
Fax: +33 (0) 1 56 68 75 01
Regulated by the Financial Conduct Authority (FCA) and the Autorité de Contrôle prudential et de resolution (ACPR)

New York
750 Lexington Avenue
New York, NY 10022
Tel: +1 (0) 212 337 7000
Fax: +1 (0) 212 337 7002
FINRA and SIPC member

Geneva
rue de Grenus 7
CP 2113
Genève 1, CH 1211
Tel +4122 731 3263
Fax+4122731 3243
Regulated by the FINMA

New Delhi
The Imperial Hotel
Janpath
New Delhi 110 001
Tel +91 11 4132 6062
+91 98 1111 5119
Fax +91 11 2621 9062