

10th October 2016

Healthcare

Nicox

Price EUR8.33

AC-170 got a CRL... We see the glass as half full

Fair Value EUR14 (+68%)

CORPORATE

Bloomberg	COX FP
Reuters	NCOX.LN
12-month High / Low (EUR)	13.4 / 6.0
Market Cap (EURm)	208
Avg. 6m daily volume (000)	281.3

ANALYSIS

- Nicox announces this morning that it has received a Complete Response Letter (CRL) from the FDA regarding the potential approval of AC-170 (eye drop formulation of cetirizine developed for the treatment of ocular itching associated with allergic conjunctivitis). Importantly, the regulator stated reason for the CRL pertains solely to a Good Manufacturing Practice (GMP) inspection at a third party facility producing the active pharmaceutical ingredient and supplying it to the manufacturer of the finished product.
- This is obviously unfortunate, but we see two good news behind this decision: 1/ the letter just mentioned manufacturing issues and the regulator did not request any additional clinical or non-clinical data to strengthen the NDA; 2/ because of this delay in the approval, the potential related milestone payment to Acix shareholders is more likely to be USD10m (vs USD35m should a green light be granted before December 1st 2016)... Thus reducing the associated dilution to 5% rather than 17% on the basis of the current share price.

VALUATION

- We stick to our FV of EUR14 knowing that AC-170 stands for roughly EUR2.5 per share.

NEXT CATALYSTS

- Q4 16/Q1 16: Potential update on latanoprostene bunod's CRL.

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Distribution of stock ratings

BUY ratings 72%

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