

Nicox

Mont Blanc top-line data timelines pushed forward

Nicox has completed screening for additional patients for its Mont Blanc Phase III study of lead candidate NCX-470 for the treatment of open-angle glaucoma and ocular hypertension. Given that the primary efficacy endpoint measurements conclude at three months following a patient's first NCX-470 dosing, the company now expects to report top line efficacy data in November 2022, earlier than its previous guidance of Q123. The Mont Blanc data release is potentially a key catalyst for the company, given NCX-470's opportunity as a best-in-class single-agent glaucoma therapy.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	14.4	(10.2)	(0.30)	0.0	N/A	N/A
12/21	8.6	(15.5)	(0.32)	0.0	N/A	N/A
12/22e	5.3	(18.7)	(0.43)	0.0	N/A	N/A
12/23e	7.0	(19.8)	(0.44)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

We anticipate that positive [Mont Blanc](#) top line study data, demonstrating superior intraocular pressure (IOP) lowering efficacy to latanoprost, would materially de-risk future NCX-470 development and likely drive a re-rating on the stock. In the 433-patient US multicentre 28-day [Dolomites Phase II trial](#) the highest tested NCX-470 concentration (0.065%) demonstrated statistical superiority in IOP lowering to the latanoprost arm at day 28, delivering [up to 1.4mmHg of additional lowering of IOP](#) at this time point ($p < 0.025$). The Phase III NCX-470 trials are testing a higher 0.1% drug concentration, which may provide further IOP reduction.

While Nicox's [updated timeline](#) for a November 2022 Mont Blanc readout is an encouraging development, we are not revising our existing H226 launch timing estimate for the product, as outlined in [our recent Outlook report](#). Commercial approval of the product will also require data from the second Phase III study, [Denali](#). The company continues to expect to report Denali top line data after 2023, but has not yet provided formal updated guidance. However, the company expects to announce a new date for availability of the results once it obtains a more firm estimate of the overall timelines of this trial.

Clinical study timing update

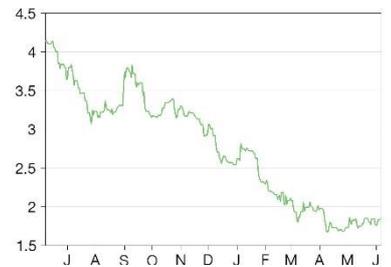
Pharma and biotech

7 June 2022

Price €1.75
Market cap €76m

Estimated net cash (€m) at 31 March 2022	14.6
Shares in issue	43.2m
Free float	86%
Code	COX
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



Business description

France-based Nicox develops therapeutics for the treatment of ocular conditions. Its lead candidate NCX-470 is in Phase III studies for the treatment of glaucoma, and it is advancing NCX-421 for dry eye disease. Nicox also receives licence revenue for its FDA-approved drugs Vyzulta and Zerviate.

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