

Perseverance pays off for Foamix



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If at first you don't succeed, do a bigger study. Foamix has finally shown a statistically significant benefit with its acne foam, FMX-101, in a third – and substantially upsized – phase III trial. But the numerical benefit, while slightly better than that seen in the two previous pivotal failures, is not much wider than in previous trials. Foamix plans to file a new drug application on the latest data, which might be enough for approval, but there is still the question of how big the market for FMX-101 is – a similar-looking topical prescription acne product, Aczone, recently acquired by Almirall from Allergan, made \$174m in 2017. Another question is whether Israel-based Foamix, which had just \$56m in cash at the end of June, would be able to launch FMX-101 alone – something it [previously told Vantage](#) that it planned to do, at least in the US. Still, with the group's stock rising 54% in premarket trading this morning, back to levels seen before the project flunked the smaller phase III studies, a fundraising looks imminent.

Foamix's phase III trials of FMX-101

	Trial 04 (NCT02815267)	Trial 05 (NCT02815280)	FX2017-22 (NCT03271021)
Co-primary endpoints	n=450	n=450	n=1,507
Placebo-adjusted change in no. inflammatory lesions	2.99 (p=0.0071)	2.74 (p=0.0058)	3.53 (p<0.0001)
Placebo-adjusted IGA success (percentage points)	3.32 (p=0.2178)	6.78 (p=0.0423)	11.17 (p<0.0001)

All data at 12 weeks; Source: Company press releases.