

Daiichi torches Esperion's Nexletol milestone promises



[Madeleine Armstrong](#)



Despite assurances by Esperion, Daiichi is refusing to pay up after the Clear Outcomes disappointment.

"We know that we will be receiving milestones of \$300m and \$140m." So said Esperion's chief executive officer, Sheldon Koenig, during a conference call earlier this month to discuss data from the Clear Outcomes study of Nexletol.

However, this statement now looks optimistic at best, in light of an [SEC filing](#) revealing that Esperion's partner in Europe, Daiichi Sankyo, does not believe that the data justify paying any milestone at all. With cash running low and a big debt payment looming there are now real doubts about Esperion's future. The group's stock plunged 67% in early trade.

20% reduction

The disagreement might be a matter of interpretation. The milestone is tied to the level of risk reduction seen in Clear Outcomes, with a decrease of 20% or more triggering the biggest windfall. On the primary endpoint, Mace-4, there was [a mere 13% reduction](#) - hence Daiichi's refusal to pay out, according to the SEC filing.

Mace-4 is a composite of cardiovascular death, non-fatal myocardial infarction or stroke, and coronary revascularisation. The harder Mace-3 - which excludes coronary revascularisation - is more important in Europe, and was a secondary endpoint in Clear Outcomes. However, the reduction here was only slightly more impressive, at 15%.

These data might have convinced some doctors, but investors were [much less enthusiastic](#).

Upcoming milestones Esperion could receive

Amount	Partner	Contingent upon
\$200m	Daiichi Sankyo	CV relative risk reduction of 15-20% in EU label
Above plus \$100m	Daiichi Sankyo	CV relative risk reduction of $\geq 20\%$ in EU label
\$140m	Otsuka	\$20m on 1st JNDA submission; \$70m on 1st NHI price listing in Otsuka territory; \$50m upon inclusion of CV risk reduction in US label (dependent on RRR)

Daiichi Sankyo partnership covers Europe (Jan 2019 deal) & other territories (Apr 2021 expansion); Otsuka partnership covers Japan (Apr 2020 deal). Source: SEC filings.

Esperion contended that the original agreement referred only to “cardiovascular risk reduction” rather than the primary endpoint specifically. The group highlighted a 23% decrease in the risk of myocardial infarction – which, importantly, crosses that 20% threshold.

This dispute looks set to be heading to the courts, and success will depend on the exact wording of the contract, which was redacted when Esperion filed it with the SEC.

Even if Esperion is correct a protracted legal battle would be bad for the company, which only has enough money to get it to the end of this year. It also has \$265m convertible loan that falls due in 2025.

The group additionally hopes for \$140m in milestones from its partner in Japan, Otsuka. Part of this [depends on the magnitude of cardiovascular risk reduction on Nexletol's US label](#), but the amount at stake here is much smaller, at just \$50m.

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