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This information is correct as of the date given above. For further details and updates on any points below, please consult the Company's Press Releases and financial documentation.

Questions & Answers on the NCX 470 U.S. New Drug Application (NDA) Submission

NCX 470 has reached an important regulatory step in the United States. Kowa, Nicox's partner for the United States, has submitted the New Drug Application to the FDA. This does not mean the product is approved, but it starts the FDA review process. Below we answer common questions from shareholders in simple terms, including what an NDA is, what the FDA reviews, the usual timing of the review process, who will sell NCX 470 in each territory, and how Nicox may receive future milestone and royalty income if the product is approved and sold.

1. What regulatory milestone has been achieved for NCX 470?

Kowa, Nicox's U.S. partner for NCX 470, submitted the New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA on June 30, 2026. This was an important regulatory step because an NDA is the formal application asking the FDA to review and approve a new medicine for sale and marketing in the United States. The NDA includes information on clinical studies, the drug's formulation, how the drug behaves in the body, and how it is manufactured, processed and packaged.

2. How long does the U.S. NDA review process usually take?

The FDA set the PDUFA (Prescription Drug User Fee Act) review response date by 30 April 2027. A PDUFA date is the target date by which the U.S. FDA aims to complete its review and issue a decision on an NDA. NCX 470 could therefore potentially be approved in Q2 2027.

3. Did the FDA already review the NCX 470 package before submission?

Nicox announced in February 2026 that it had received positive written feedback from the FDA following the NCX 470 pre-NDA meeting. The FDA confirmed that the current data package and proposed content and format of the NDA were generally acceptable for submission.

4. **When could NCX 470 be launched in the United States?**

A U.S. launch would only happen if the FDA approves NCX 470. U.S. approval in Q2 2027 could then lead to product launch, expected in H2 2027, and the start of recurrent revenue. The exact launch timing would be managed by Kowa and would depend on FDA approval, labeling, manufacturing readiness, and commercial preparations.

5. **Who will commercialize NCX 470 in the United States?**

Kowa has the exclusive rights to develop and commercialize NCX 470 in the United States under the July 2025 agreement with Nicox.

6. **Why is the United States market important?**

The United States is the largest market for glaucoma medicines. U.S. approval could facilitate submissions in other countries that accept reference to U.S. FDA approval.

7. **Who will commercialize NCX 470 outside the United States?**

Ocumension Therapeutics has the rights to develop and commercialize NCX 470 for China, Korea and Southeast Asia. Kowa has rights to develop and commercialize NCX 470 in the United States and all other territories.

8. **What financial return does Nicox receive on sales of NCX 470?**

Nicox may receive milestone payments, which are associated with an event such as product approval or reaching a certain sales level, and may also receive royalties, which are a percentage of the sales by the partner (Kowa or Ocumension, depending on the territory concerned). NCX 470 royalties on sales start at between 6% and 8% (depending on the region), which could reach double-digits and up to 20% in the United States. Nicox could also receive a maximum of €136 million in future milestone payments. Nicox has already received €39.5 million in licensing payments for NCX 470. Furthermore, Ocumension paid 50% of the Denali clinical trial costs.

9. **Who pays for regulatory and commercialization costs for NCX 470?**

Kowa and Ocumension bear the regulatory and commercialization costs for NCX 470 in their respective territories.

10. **What data support the NCX 470 NDA?**

The NDA is supported by the Phase 3 program for NCX 470, the Mont Blanc and Denali Phase 3 studies.

11. **What is the status of NCX 470 in Japan?**

Kowa is responsible for the Japan Phase 3 program for NCX 470, which was initiated in summer 2025. Japan is a market where Kowa has strong glaucoma expertise, and the two ongoing clinical trials are the only ones expected to be necessary to submit for approval of NCX 470 in Japan.

12. What is the status of NCX 470 in China?

Ocumension Therapeutics is Nicox's exclusive licensee for China. Nicox announced on June 18, 2026 that Ocumension had received positive pre-submission regulatory feedback from the Chinese Center for Drug Evaluation and considered the feedback sufficient to proceed with submitting the dossier for marketing approval in China. The Chinese NDA submission was announced on August 10, 2026.

13. What are the plans for NCX 470 in Europe?

Kowa is evaluating the potential of NCX 470 in Europe. No submission for European approval has been made, and the timing or pathway in Europe should not be assumed unless and until Nicox or Kowa make a specific announcement.