

**DIVE BRIEF**

J&J sends blood pressure drug back to Idorsia

The decision is the latest in a series of setbacks for the Actelion spinout and ends a lucrative partnership that began in 2017.

Published Sept. 6, 2023

By Kristin Jensen

[Idorsia Ltd.](#)

Dive Brief:

- Idorsia said Wednesday that Johnson & Johnson plans to return most of the rights to its most closely watched experimental drug, aprocitentan, for patients with resistant hypertension.
- U.S. and European regulators are currently reviewing approval applications for the medication, and the Food and Drug Administration was originally slated to give an answer by Dec. 19. However, the FDA could take up to three more months to review additional materials on how best to ensure the drug is used safely, Idorsia said.
- As part of the deal, Idorsia will pay J&J as much as 306 million Swiss francs, or about \$343 million, to reacquire rights to the drug. The total amount depends on regulatory approvals, potential future licenses and commercial sales. J&J will retain rights to aprocitentan for pulmonary hypertension.

Dive Insight:

J&J's decision to pull back from a medication so close to a potential approval is another in a series of setbacks for Idorsia, whose shares are trading at all-time lows. Earlier this year, Idorsia said a cardiovascular drug failed in a key clinical trial. A few months later, the company announced plans to lay off as many as 500 employees as it cut costs to conserve cash for operations.

Aprocitentan is the company's best hope for a major cash influx. After Idorsia reported positive Phase 3 results in May 2022, analysts at Jefferies predicted it could eventually bring in sales of \$2.5 billion a year in the U.S. and Europe. But even then, concern about potential side effects emerged.

Now, the FDA is asking Idorsia to outline a risk mitigation strategy for aprocitentan. The agency uses such programs for drugs that have notable safety concerns; they are designed to help doctors and patients follow best practices to ensure that a medication's benefits outweigh its risks.

Idorsia was formed through a spinoff after J&J's \$30 billion buyout of Actelion in 2017. A few months later, J&J acquired rights to aprocitentan, offering an initial payment of \$230 million, development funds and potential royalties. Idorsia also got to share revenue from a J&J drug for multiple sclerosis now sold as Ponvory. That agreement will also end with the return of rights to aprocitentan.

Idorsia may now be on the hunt for a new partner. In its statement Wednesday, the Swiss biotech said it's "initiating activities to determine the best approach to maximize the value of aprocitentan."