



## DIVE BRIEF

# PTC to lay off more staff following drug setback in Europe

For the second time this year, PTC is restructuring, this time after the EMA decided against renewing a conditional approval for the company's drug Translarna.

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*An empty laboratory Ozankutsal via Getty Images*

**Dive Brief:**

- PTC Therapeutics on Friday announced its second round of layoffs this year in an attempt to preserve cash following a regulatory setback for its drug Translarna.
- The New Jersey-based company's restructuring expands an initial reprioritization in May that focused the company's resources on higher potential programs. The new cuts affect approximately 25% of staff, primarily those working on early-stage programs and at a gene therapy facility in New Jersey.
- The layoffs follow a decision by European regulators to deny PTC's request to convert Translarna's conditional clearance there to a full approval for types of Duchenne muscular dystrophy. The company said it would request a re-examination of the decision, during which time the drug can remain on the market.

**Dive Insight:**

Over the past year, PTC has replaced its CEO, fired its CFO and rolled out two restructuring plans.

The initial round of layoffs was expected to impact about 8% of its workers, and came after the study failure of an experimental drug called vatiquinone in Friedreich ataxia, an inherited disorder affecting the nerves.

PTC said at the time that it would focus on drugs that could offer a “return on investment.” But now it’s at risk of losing an approved drug.

Cleared for nonsense mutation Duchenne muscular dystrophy, Translarna has had conditional authorization from the European Medicines Agency since 2014. PTC secured a renewal of that approval in 2017, but agreed to conduct another placebo-controlled study of the drug in return.

That trial failed to meet its goal, however, falling short of reaching statistical significance in the primary analysis subgroup. Data from that study informed the EMA’s decision, PTC said.

The company is appealing the decision, and expects to review a new opinion in January 2024.

Translarna earned PTC \$96 million in net product revenue during the second quarter. The drug is licensed in several countries outside of the EU, including Great Britain, Brazil and Russia.

PTC shares fell by about 1.5% Friday to trade around \$22 apiece.