BIOPHARMADIVE

FibroGen's Duchenne drug fails second trial in latest study setback

The biotech has seen its share value collapse in recent months as the medicine, pamrevlumab, missed the mark in three late-stage trials.

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An illustration of necrotic muscle fiber in Duchenne muscular dystrophy. Jose Luis Calvo Martin, Jose Enrique Garcia-Maurino Muzquiz via Getty Images

An experimental medicine from FibroGen has failed a second late-stage trial in Duchenne muscular dystrophy, adding to a string of clinical setbacks that have caused the biotechnology company's shares to collapse in recent months.

FibroGen has been struggling to regain its footing ever since the Food and Drug Administration in 2021 rejected its anemia pill roxadustat, which is approved in Europe and some other countries. FibroGen's rebound plans leaned heavily on the company's only other medicine in advanced testing, pamrevlumab, which is in Phase 3 studies for a variety of different diseases, from Duchenne to idiopathic pulmonary fibrosis and cancer.

Positive readouts in any of those trials could have helped turn FibroGen around. Instead, the company has reported a succession of less-than-ideal results. A trial in Duchenne patients who can no longer walk failed in early June, followed by a setback in the IPF study weeks later. The company then stopped a second IPF trial

and laid off staff, marking the second time it's restructured since 2021.

In July, CEO Enrique Conterno resigned, citing "personal reasons." Chief Commercial Officer Thane Wettig has been serving as FibroGen's head executive in the interim.

The latest study evaluated pamrevlumab in Duchenne patients that can still walk. FibroGen said that the drug missed all of its main and secondary goals, failing to provide a meaningful improvement over placebo in motor function and other tests.

One other Phase 3 study is ongoing for pamrevlumab, in pancreatic cancer. Initial results are expected by the end of the year, according to a federal database.

FibroGen plans to dig through the Duchenne data before determining the next steps for the program. Full results will be presented at an upcoming medical meeting.

"We are committed to sharing all learnings from this trial with the Duchenne community and hope that there are insights that may help future efforts to develop treatments for this devastating disease," Wettig said in a statement.

The company also has a prostate cancer drug in early-stage testing.

FibroGen shares fell by 27% on Wednesday, to less than $1 apiece.