



BioMarin to replace CEO Bienaimé with Genentech veteran

The rare disease drug developer is turning to former Genentech head Alexander Hardy as the launch of its Roctavian gene therapy stumbles.

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Employees of BioMarin Pharmaceutical at a manufacturing facility in Novato, California. Courtesy of BioMarin Pharmaceutical

BioMarin is bringing on a new chief executive as the gene therapy company struggles with an initially disappointing launch for an important new product.

Alexander Hardy, 55, will take over the reins at BioMarin as of Dec. 1, having stepped down from his role as CEO of Roche's Genentech unit on Wednesday. He replaces Jean-Jacques Bienaimé, 70, who led the company for 18 years and will initially stay on as an adviser and board member.

"Serving as CEO of this industry-leading, innovative and impactful company over the past 18 years has been the highlight of my career," said Bienaimé on a call with investors Wednesday evening. "We have built an incredible organization with great potential to be further unlocked by Alexander and the team."

Hardy will be tasked with guiding BioMarin through a pivotal period in its development. After years of ups and downs, the company in June finally won U.S. approval for Roctavian, the first

gene therapy to treat hemophilia A. But complicated negotiations with payers have made it difficult to move patients onto the therapy, which has a list price of \$2.9 million in the U.S. and is also approved in Europe.

On Wednesday, BioMarin said it now expects Roctavian to bring in less than \$10 million in revenue this year, down from a previous estimate of \$50 million to \$150 million. So far, just two commercial patients in Germany have received the therapy, including one on Wednesday.

“No matter which way you cut it, while early, the results on [Roctavian] thus far have been a clear disappointment,” wrote Stifel analyst Paul Matteis in a Nov. 1 note to clients. “It’s hard to not also wonder whether the sluggish launch of Roctavian, and the broader ups/downs for [BioMarin] over recent years, made it logical to move on to a successor sooner versus later.”

Still, BioMarin said sales are ramping up better than expected for its Voxzogo therapy for a condition called achondroplasia that affects bone growth. The company increased its sales estimate for Voxzogo to between \$435 million and \$455 million for the year, up from a range of \$400 million to \$440 million.

Hardy nodded to the issues he faces in BioMarin’s statement announcing his hiring, identifying “the opportunity that lies ahead in unlocking the full value of Voxzogo and Roctavian.” Genentech tapped Hardy as CEO in 2019 and before that he held a number of roles there and at Roche, Genentech’s parent company, including leading patient access services and serving as head of global product strategy.

While lowering its forecast for the year, BioMarin said reimbursement issues for Roctavian are looking up in the U.S. and other parts of the world. The company is in final price negotiations

with Italian officials and has a tentative agreement on Roctavian's price in Germany, where 60 people are eligible for the next steps before treatment.

During his tenure as CEO, Bienaimé oversaw BioMarin's transformation from a single-product company with about 300 employees and \$26 million in revenue to one that expects to pull in "well over" \$2 billion this year. BioMarin's workforce now includes more than 3,000 people in dozens of countries.

Bienaimé will stay on the company's board until its annual meeting for stockholders in 2024, though he will be replaced as chairman by Richard Meier, the company's lead independent director. Bienaimé will serve as an adviser to the company through the end of 2024, BioMarin said.

Shares in BioMarin traded down by nearly 10% at one point Thursday morning, before gaining back some of those losses.