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Momenta Is Exiting Biosimilars; Is That A Bellwether For Biosimilar Sentiment?

by Jessica Merrill

CEO Craig Wheeler talked to *Scrip* about the challenging biosimilar market dynamics and the company's decision to end most biosimilar drug development. The path to value creation in biosimilars is not clear, he said.

[*Momenta Pharmaceuticals Inc.*](#) is exiting the biosimilar drug development space to redirect resources to novel pipeline drugs for immune-mediated diseases, in a move that could add fuel to growing concerns about a lackluster biosimilar market.

The decision, announced Oct. 1, comes after a lengthy strategic review process that started in January as the company sought and failed to find a buyer for its biosimilar business. Ultimately, the company determined it would terminate development of all but two late-stage programs, a biosimilar version of [*AbbVie Inc.*](#)'s mega-blockbuster *Humira* (adalimumab) and a biosimilar of [*Regeneron Pharmaceuticals Inc.*](#)'s *Eylea* (aflibercept) in development in collaboration with [*Mylan NV*](#). The company expects to end development of five other biosimilar programs in development with Mylan, including a biosimilar of [*Bristol-Myers Squibb Co.*](#)'s *Orencia* (abatacept).

The decision by Momenta, an early entrant in the complex generic space and later biosimilars, could add fuel to the debate about the commercial opportunity for biosimilars. Some other biosimilar manufacturers, and even FDA Commissioner Scott Gottlieb, have raised concerns about the commercial hurdles for biosimilars in the US that could stifle investment in biosimilar drug development (*see sidebar*). The number of biosimilar development programs in

Enthusiasm For US Biosimilars Wanes For Some, But Not Others

By Jessica Merrill

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Three years after the first biosimilar launched in the US, the market has failed to deliver notable return on investments. Some players

FDA's Biosimilar Biological Product Development Program dipped in the last months of 2017. ([Also see "Biosimilars: Is Small Dip In Development Indicative Of Sustained Downward Trend?"](#) - Pink Sheet, 11 Sep, 2018.)

Momenta CEO Craig Wheeler talked to *Scrip* about the company's decision. He put some of the blame for Momenta fizzling out in biosimilars on the challenging dynamics in the category and some on company-specific issues, most notably the delayed launch of *Glatopa* 40 mg, a generic *Copaxone* (glatiramer) formulation, with partner [Sandoz International GMBH](#). A manufacturing issue at [Pfizer Inc.](#), the third-party manufacturer for the product, set the FDA approval of the drug back, ultimately allowing Mylan to get to market first with a 40 mg generic.

"We never had the chance to be the first generic in the marketplace," Wheeler said. "It took a tremendous amount of revenue out from underneath us."

Momenta ended up generating less revenues from its share of *Glatopa* 20 mg and 40 mg combined in the second quarter, just \$11.8m, versus \$19.1m in the year-ago period when only *Glatopa* 20 mg was available, because of the launch of Mylan's 40 mg product.

Novel Drug Investment Beat Out Biosimilars

"At the same time, the biosimilar business had become more challenging, mostly because of the patent delays that we were seeing in launching products," Wheeler added. For example, the company had originally forecast that a biosimilar version of Humira might launch in the US in 2017 and later readjusted the timeline to 2019. Now, after AbbVie has settled several patent infringement suits with biosimilar developers, it appears a launch of biosimilar Humira will be delayed until 2023.

Momenta was looking to move several novel autoimmune disease drugs forward and needed to prioritize its investments. The novel drugs beat out the biosimilars (*see sidebar*).

"We chose to reduce biosimilars as opposed to novel drugs, because the path to value creation on the novel drug side is clear," he said. "On the biosimilar side, with the continuing patent delays, nobody was ever sure

like Mylan are going public with frustrations over market barriers, while others, like Amgen, say they are encouraged by steady progress. Teva, however, is limiting its investment in biosimilars.

[Read the full article here](#)

Momenta Refocuses On Three Novel Autoimmune Drugs In Transition To More Traditional Biotech

By [Jessica Merrill](#)

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when we were going to get to market, how many competitors were going to be in the market, and if there would be any real significant margin once we launched them."

Momenta launched a comprehensive process to sell the business, but ran up against a wall, because of the competitive dynamics. While there was a lot of interest, Wheeler said, most of the players in the space had portfolios that overlapped with the Momenta portfolio.

"What we did find was that there were not a lot of new companies looking to enter the biosimilar business," Wheeler said. "It kind of tells you that people are aware this is a competitive business, and the players that are going to succeed here are the larger generics players."

The company is in discussions with Mylan about next steps for the programs, which it has the right to exit under the 2016 collaboration agreement. The partners have not publicly disclosed the other programs in development. The two partnered in 2016, with Mylan paying \$45m upfront to Momenta and agreeing to pay \$200m in milestone fees; each company agreed to share equally in costs and profits. Mylan is responsible for commercializing the products under the deal.

But, Wheeler speculated, "they are exactly the kind of company that should be playing in [biosimilars]. They can play with a broad portfolio. They have the international footprint to take advantage of it."

While Mylan is committed to biosimilars with a deep pipeline of drugs in development, CEO Heather Bresch is one of the leaders who has expressed concern about the lack of commercial incentives in the market for biosimilars. The company also is in the midst of exploring strategic alternatives. (*Also see "Mylan To Explore Strategic Options, Claiming Investors Have Failed To Appreciate The Value"* - Scrip, 8 Aug, 2018.) Mylan declined to comment on the news from Momenta.

Momenta is now turning its attention to three clinical-stage programs for autoimmune diseases, and announced a restructuring that will eliminate 50% of the workforce or 110 employees, largely in biosimilar drug development (*see sidebar*).

Momenta will invest in three novel drugs and end development of all but two late-stage biosimilars under a new business strategy. The company is reducing its workforce by 50%, or about 110 employees.

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