BIOPHARMADIVE

Biogen says growth is coming, but won't specify when

CEO Chris Viehbacher said the company has "the elements to think about a return to topline growth." Yet, that goal hinges on the successful launch of multiple new products.

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Permission granted by Biogen

For the first time in more than three years, Biogen is reporting an annual increase in quarterly revenue.

In earnings released Wednesday, the Cambridge, Massachusetts-based drugmaker said it recorded $2.53 billion in revenue between July and September, up 1% from the same three-month period a year prior.

Whether the growth increases, or even continues, depends on how well the company's newer products perform. In the meantime, Biogen expects its revenue in 2023 to be lower than last year's total — although not by as much as previously thought.

"We've got the elements to think about a return to topline growth," said Chris Viehbacher, Biogen's CEO, on a Wednesday morning call with reporters. "Over time, we believe the new business will offset the decline in the mature business."

Of those new products, arguably the most closely watched is Leqembi, an Alzheimer's disease treatment that recently received

full approval from the Food and Drug Administration. With that approval in hand, and the removal of other commercial barriers, Biogen and its partner Eisai predict use and sales of Leqembi to dramatically increase in the coming months.

Eisai, which led the development of Leqembi, said this week that around 800 patients in the U.S. were on the drug by the end of October, and the goal is to grow that total to 10,000 by March. That aim is "on the more optimistic side," wrote RBC Capital Markets analyst Brian Abrahams in a note to clients. Yet Abrahams and his still predict an "upward inflection" for Leqembi, ultimately resulting in peak annual sales north of $10 billion.

"This was always going to be a gradual launch," Viehbacher said. "Obviously, sales will be expected to ramp at some point. But it has always been a difficult product to forecast because there's just no real good analogs here."

The FDA granted conditional approval to an intravenous version of Leqembi in January, followed by a first-of-its-kind full clearance in July. But challenges from insurers and the broader healthcare system have hindered the drug's sales, which, according to Eisai, reached $2.7 million across the second and third quarters. Highlighting this, Viehbacher noted how the Cleveland Clinic, "one of the most respected medical centers in the world," just administered its first infusion of Leqembi early this month.

"I think we're seeing all of the green shoots of growth," he said. "But it is complex, and we're seeing varied response in terms of even medical centers."

Eisai and Biogen are currently testing an under-the-skin injection of Leqembi that the companies as well as analysts believe will lift sales and become a potentially more convenient option for patients. Clinical trial results presented in October appear to

support this newer form. Eisai intends to submit an approval application to the FDA by the end of March, meaning subcutaneous Leqembi could be cleared and on the market by early 2025.

Elsewhere, Biogen is in the early stages of launching three products. One, Qalsody, was approved in April for a small segment of ALS patients who have specific genetic mutations. Another, Zurzuvae, is a new postpartum depression drug that Biogen secured rights to through a multibillion-dollar collaboration agreement with Sage Therapeutics.

With only a few hundred patients eligible for Qalsody, Viehbacher said the drug is "not going to by any means move the needle commercially." Sales expectations for Zurzuvae have diminished, too, since the FDA decided against approving it in major depressive disorder, a far more common condition than postpartum depression.

Still, Viehbacher believes both drugs are symbolic of Biogen's mission.

"On the one hand, we have to balance risk and have to become a lot more conscious about how we allocate our capital," he said. "But so many people in our industry say Biogen is really a special company, and I think it is because we do go after these harder-to-solve medical problems. We don't necessarily think about how big it's going to be from a revenue point of view first."

Historically known for its work in neuroscience, Biogen has on multiple occassions tried to diversify. Under a revamped executive team and board of directors, the company says it's now diving deeper into research areas like immunology and rare diseases. To that end, Biogen in September completed the $7 billion acquisition of Reata Pharmaceuticals, which gave it a new-to-market

treatment for an uncommon neuromuscular condition known as Friedreich's ataxia.

That drug, called Skyclarys, is off to a strong start, according to RBC's Abrahams. Third quarter revenue reached $43 million, or double the consensus estimates on Wall Street. With Skyclarys, "we have an opportunity to bolster that rare disease portfolio," Viehbacher said.

In September, Biogen appointed a new research head in Jane Grogan, who had served as chief scientific officer at the cell and gene therapy developer Graphite Bio. The role tasks Grogan with deciding what drugs and technologies Biogen should invest its research and development dollars.

Viehbacher, who helmed Sanofi during its acquisition of Genzyme, has said he's open to using deals to spur growth at Biogen. "Clearly, we need to improve the productivity of our research, and that would be both internal and external. We are looking at doing an awful lot more collaborations."

Not all deals are of interest, though. "Our focus is no longer on doing anything of significance in [mergers and acquisitions], at least for the time being," he said. "It would be more around licensing and collaborations … to bolster the early-stage pipeline."

Shares of Biogen were down more than 4% early Wednesday afternoon, to trade just north of $234 apiece.

Editor's Note: This story has been updated to include information on Biogen's stock price.