PHARMA

Microbiome therapeutics could be the next big thing in pharma

The microbiome-based therapeutic market is expected to be worth \$1.6 billion by 2026.

By: Maia Anderson June 24, 2023 3 min read



The <u>microbiome</u> has been the hot keyword in recent years as scientists have started <u>piecing together</u> how it contributes to our overall health.

Probiotic supplements have <u>boomed in popularity</u> with consumers who are trying to improve their <u>gut health</u>, and now skin microbiome products are starting to <u>pop up</u> in beauty aisles.

But microbiome therapeutics, or prescription drugs targeting the microbiome, are still in the very nascent stages of research and development, and big pharmaceutical companies have been hesitant to get into the space (outside of a handful of exploratory partnerships). That could change soon, as the microbiome-based therapeutic market is expected to be worth \$1.6 billion by 2026, according to data analytics and consulting firm <u>GlobalData</u>. Plus, two drugs targeting the gut microbiome have received FDA approval in the past year, which Stefan Lutzmayer, a thought leadership consultant at life sciences research and analytics firm Iqvia, said has led to "some excitement" in the industry.

"Going forward, we expect to see more products gain market authorization and this first breakthrough to mark the start of a new era of microbiome therapeutics," Lutzmayer and his colleagues wrote in a March 2023 <u>research report</u> on microbiome therapeutics.

The state of the microbiome industry

Historically, big pharma companies have been hesitant to invest much money into the microbiome space because that industry segment "tends to be more risk averse," Lutzmayer told Healthcare Brew.

"Outside of the infectious disease space, there hasn't been any randomized controlled clinical trials that really show efficacy for the microbiome as a treatment modality," he said.

Instead of acquiring small microbiome-focused pharma companies, large pharmaceutical companies have invested in research and development platforms, he said. That way, big pharma will be ready to enter the field once more clinical data is collected.

In 2018, Genentech <u>partnered</u> with biotech company Microbiotica to develop inflammatory bowel disease (IBD) drugs, and in 2019, Merck <u>teamed up</u> with biotech business 4D Pharma to develop vaccines based on the microbiome. In 2020, Gilead <u>collaborated</u> with microbiome company Second Genome to develop IBD drugs, and in March 2023, J&J began <u>working with</u> biotech company Holobiome to develop prebiotics and probiotics for infant and maternal immune health.

"Large pharmaceutical companies tend to invest in the microbiome field depending on the strategic fit with their existing portfolio or to broaden their pipeline," Lutzmayer and his colleagues wrote in the Iqvia report.

Today, most of the research in microbiome therapeutics focuses on infectious diseases, gastrointestinal diseases, dermatology, and oncology, according to GlobalData. The pharma companies with the most microbiome-based products are Vedanta Biosciences, Mikrobiomik, Kaleido Biosciences, 4D Pharma, Seres Therapeutics, and Galenus Therapeutics.

New Jersey-based Ferring Pharmaceuticals was the first drugmaker to get a microbiome therapeutic FDA-approved in November 2022 with its drug Rebyota, which treats recurrent Clostridioides difficile, or C. diff, infection.

Seres Therapeutics, based in Massachusetts, received the second FDA approval in April 2023 for its microbiome drug SER-109, which also treats recurrent C. diff infection.

Iqvia researchers, in their report, project that "the next five years will see more approvals of microbiome therapeutics to treat recurrent C. diff infection. Moreover, our microbiome understanding and regulation will continue to evolve."

Accessed at: <u>https://www.healthcare-brew.com/stories/2023/06/24/microbiome-therapeutics-could-be-the-next-big-thing-in-pharma</u>

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