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Hepatitis C Pill Rockets Gilead Into Big Leagues

Biotech's Promising Treatment Continues Its Historic Drug Launch

By [Jonathan D. Rockoff](#) [Follow](#)

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Chief Operating Officer John Milligan noted Sovaldi's high levels of use. ILLUSTRATION: BLOOMBERG NEWS

For decades, a liver disease that would slowly kill the infected person didn't even have a name, let alone an effective medicine.

Now, a new pill promising to cure most cases of the disease, eventually called hepatitis C, is believed to be the biggest new drug launch ever, catapulting maker Gilead Sciences Inc. into the ranks of the top-selling pharmaceutical companies.

The pill, Sovaldi, notched \$3.5 billion in second-quarter sales, Gilead said Wednesday. As a result of its lucrative move into hepatitis C treatment, the Foster City, Calif., company roughly doubled its revenue guidance for the year's net product sales to \$21 billion to \$23 billion.

Such sales would put Gilead, once best known for its drugs treating HIV/AIDS, on par with the total revenues of biotechnology trailblazer Amgen Inc. and insulin pioneer Eli Lilly & Co.



Gilead Sciences reported strong sales of its hepatitis C treatment, Sovaldi, above. ILLUSTRATION: AP

As it enters the industry big leagues, Gilead is facing more public scrutiny. Sovaldi's list price, about \$1,000 a day for a 12-week course of treatment, has drawn criticism from politicians and insurance officials who say the health-care system can't afford such expensive treatments.

Gilead counters with the pill's effectiveness: Studies show it cures about 9 out of 10 patients, helping them avoid more costly care such as liver transplants. The company said in a conference call with analysts and investors that 9,000 patients have been cured by Sovaldi since it went on sale.

Gilead said 47 state Medicaid agencies are covering the cost of Sovaldi, albeit after authorizing its use for each patient, while the remaining three states are deciding whether to reimburse the drug. Gilead said it is preparing to talk with senators who have questioned the pricing.

The company has previously faced criticism from patients and insurers regarding its pricing of HIV/AIDS treatments.

Commercial challenges also loom for Gilead. AbbVie Inc., Bristol-Myers Squibb Co. and Merck & Co. are among the companies working on new drugs to compete with Gilead's. A rival could gain advantage, analysts say, if it could develop treatment that works in less time than the 12 weeks with Sovaldi currently.

And companies including Merck, AbbVie and Roche Holding AG are battling Gilead over valuable patent rights tied to Sovaldi, aiming to get a piece of that pie.

Analysts estimate Sovaldi will surpass \$10 billion in sales this year, making it one of the world's biggest sellers.

Early use of the pill, which the U.S. Food and Drug Administration approved last December, is outpacing the trajectory of the drug previously said to have the fastest launch ever, an older hepatitis C treatment called Incivek from Vertex Pharmaceuticals Inc.

Sales could go even higher if Gilead wins approval for another hepatitis C pill, which it aims to combine with Sovaldi in the first all-oral treatment, an easier-to-take regimen sought by patients. The company said it saw signs that many patients were waiting for the new regimen to go on sale.

FDA review of the second pill, ledipasvir, is "moving ahead nicely," said Norbert Bischofberger, Gilead's research-and-development chief. The deadline for approval is Oct. 10.

Gilead's chief operating officer, John Milligan, said he hoped insurers "will be preparing" for a potential ledipasvir approval. He attributed some of the insurer criticism of Sovaldi's price to high levels of use that the plans didn't expect.

Another Gilead executive, Paul Carter, suggested the company may not price ledipasvir as high as Sovaldi, saying the "majority of value" in its combination

with Sovaldi would be in Sovaldi. Yet other executives said it was too early to speculate about pricing.

Gilead didn't include in its guidance sales of a new blood-cancer drug, which the FDA approved Wednesday. Analysts estimate the pill, Zydelig, will have about \$1 billion in sales in 2017. It marks Gilead's first medicine for cancer, another disease it's targeting.

In Gilead laboratories, "we've never had so many things going forward as we do today, and we've never felt more confident" about their prospects, Dr. Milligan said. Given its pipeline, he added, Gilead doesn't feel a "strong need" to do deals to bring in new compounds.

Gilead shares, up 53% over the past year through Wednesday's close, rose 36 cents to \$90.70 in after-hours trading.

Overall for the second quarter, Gilead reported a profit of \$3.66 billion, or \$2.20 a share, up from \$722.6 million, or 46 cents a share, a year earlier. Excluding items, adjusted per-share earnings rose to \$2.36 from 50 cents. Excluding items, adjusted per-share earnings rose to \$2.36 from 50 cents. Revenue more than doubled to \$6.53 billion from \$2.77 billion.

—Tess Stynes contributed to this article

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