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Gilead's Dan O'Day is pharma's most charming executive — but with his deals falling apart, charm may not be enough



By Matthew Herper² ³March 9, 2022



Gilead CEO Dan O'Day Emilie Pickering for STAT

The <u>news Gilead Sciences dropped Monday</u>⁵ was so disappointing it irked even the nicest guy in biotech.

Brad Loncar, an investor based in Kansas City whose cancerfocused exchange-traded fund holds Gilead shares, is a Ted Lasso-like font of cheeriness amid bio-Twitter's angry froth. Yet even he was upset about the way Gilead and its CEO, Dan O'Day, released information about a key study of its breast cancer drug, Trodelvy — without any specific data. In 2020, Gilead had paid \$21 billion⁶ for the drug and its maker, Immunomedics.

"I like him personally and respect his career experience, but how does Dan O'Day keep his job as \$GILD CEO with this deal record?" Loncar tweeted⁷. "And probably half the board too."

O'Day doesn't sound like a CEO who intends to go anywhere soon. In an interview with STAT on Tuesday, he defended deals struck under his tenure, particularly the acquisition of Immunomedics, which he said provides a new foundation for Gilead's oncology business.

"I just think we're at the beginning now of Gilead's next chapter, and it's going to be playing out over the course of the next several years, with lots of opportunity," O'Day said. "I just want to say that I'm really proud of what the team has done."

The three major deals Gilead has made since O'Day became CEO in 2019 have been, at best, tarnished. A \$5 billion tie-up with Galapagos, a Belgian biotech, basically <u>unraveled a year ago</u>¹⁰ when the development of the lead drug in the partnership, for lung fibrosis, was stopped because the medicine's benefits didn't outweigh its risks. Earlier this year the studies of a cancer drug developed by biotech Forty Seven, which Gilead bought for \$5 billion in March 2020, were <u>put on clinical hold.</u>¹¹

Investors were waiting for results on Trodelvy. The drug was

meant to slow the progression of breast cancer that tested positive for hormone receptors, but negative for HER2. (Tests for receptors help doctors determine which drugs a breast tumor will respond to, and how high-risk it is.)

Monday morning Gilead said that the study had met its primary endpoint — meaning the result was statistically significant.

But the data were withheld. As if to add insult to injury, Gilead took the unusual step of also including a "frequently asked questions" document 12 when it issued its press release. The first question: Was the result "clinically meaningful"? The answer seemed to have been written by a 1990s-era Bill Clinton.

"There is a broad range of views on what is 'clinically meaningful' in this population," the FAQ said. "We are evaluating the data and will explore potential pathways with regulatory authorities to bring Trodelvy to this group of patients."

Gilead's stock, already down 20% for the year, fell another 3%.

O'Day emphasized that providing only top-line data is the standard for the biotechnology industry, with full results reserved for a medical conference. But O'Day said Gilead provided the FAQ to help investors make sense of the release.

"There's been a tremendous focus on this study in the investing community," O'Day said. "Our desire was to provide some additional qualitative information beyond the press release."

For many, it was still a bitter pill.

Loncar is trying to be charitable about Gilead's recent track record. Hindsight, he notes, is 20/20.

"When all of these deals were announced it's not like everybody came out and warned against them," Loncar said. "But at some point when you spend that many billions of dollars and each one of them has problems, at some point personal responsibility comes into play."

"I think [O'Day] was a good hire by Gilead," Loncar continued. "But it's like in the NFL. If you hire a coach with a great record and he loses every game of the season, you have to question the type of due diligence and the type of decisions they made."

O'Day himself has a bit of a Ted Lasso-like arc: the outsider picked to run a losing team. An American, he worked for years as the second-in-command at the Swiss pharma giant Roche, which was the leading maker of cancer drugs. Meanwhile, Gilead had struggled for years to make inroads into oncology.

At Roche, O'Day planned deals like the buyouts of InterMune, maker of a successful lung drug, and Flatiron Health, the tech company. What also distinguished him in a cutthroat business was an air of warmth, a fast smile, a soft and welcoming voice. If Frank Capra had ever wanted to cast a good guy CEO, he would have cast somebody like O'Day.

But charisma and charm only go so far. O'Day has made some good calls as Gilead's CEO – first among them the decision to ramp up production of the Covid drug remdesivir before it was clear it would be needed, or that it worked. There, he could have

leaned in even harder, conducting more studies that compared the drug to placebo and clearly established its benefit.

Now, though, the analysts who follow Gilead for investment banks are restless. Umer Raffat at Evercore said in a note to investors that there were rumors other bidders for Immunomedics had offered much less than \$21 billion. After the deal was announced, Raffat wrote, Immunomedics released data showing that Trodelvy was less effective when patients had already been treated with certain common breast cancer drugs. That, he wrote, made investors question whether Gilead did its due diligence. It doesn't help, either, that while Gilead sounds worried about Trodelvy, AstraZeneca and its partner Daiichi Sankyo seem over the moon about a competing breast cancer drug, Enhertu.

Salim Syed, an analyst at Mizuho Securities, wrote to his investors that the drug might only slow tumor growth by 1.6 months to 2 months. "Approvable or not, commercial viability [is] at risk," wrote Baird analyst Brian Skorney, arguing that Trodelvy might not be clearly better than generic (and inexpensive) chemotherapy.

O'Day pushed back against long-term concerns about Trodelvy's value. He said that he is "very comfortable" with the \$21 billion Gilead spent to acquire the medicine. The medicine is an antibody-drug conjugate that targets TROP2, a protein that is present on many types of cancers. This, he said, makes Trodelvy "a pipeline in a product," meaning that in the future it could prove effective in many indications, not just the ones that were initially being studied by Immunomedics.

He argued that momentum is building around Gilead's oncology assets, and that the company will deliver over the long term. Moreover, he said, the drugs Gilead has already acquired are helping it draw talent.

"We've gotten some of the best of the best in the industry because of this portfolio," O'Day said. "People that have left other large oncology companies to come work for this portfolio because they see the promise in these mechanisms alone and in combination working together."

Maybe it matters on the edges that O'Day's mission of pushing an HIV drugmaker into cancer is the pharma version of mission impossible. Building inroads into cancer drugs can take years of investment — as it did for Pfizer, which declared its entry again and again before the breast cancer drug Ibrance became a big seller. As often as not, it seems to happen by luck, as when Merck bought Schering-Plough for its stable of heart drugs and ended up with Keytruda, the most successful cancer medicine of the past decade, pretty much by accident.

But it's not just that Gilead hasn't been a great investment over O'Day's tenure. Shares are sitting pretty much where they were in 2013.

O'Day took the job. Now the pressure will mount.

Loncar said he hopes Gilead doesn't take the wrong lesson from the blowback, or that it pulls back from the possibility of smart buys. Its recent deals were done at the biotech bubble's peak. Now, valuations are low, Loncar said, and perhaps it is time for Gilead to find other things to buy.

The alternative may be for Gilead to end up on the receiving end of a deal. That's what happens to biotechs when they get too big. It happened to Genentech. To Celgene. To Alexion. Why not Gilead?

O'Day said that over time investors will come to understand Gilead's potential, and he insists that the company is further along than he would have expected when he took the job.

"I'm as inspired as I've ever been in my career," he said.

About the Author



Matthew Herper²

Senior Writer, Medicine, Editorial Director of Events

Matthew covers medical innovation — both its promise and its perils.

matthew.herper@statnews.com_15
@matthewherper_3
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