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Gilead's $11 Billion Gambit

Hefty Premium Paid for Tiny Pharmasset Reflects Potential of Hepatitis C Market

By Ron Winslow And Peter Loftus

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Gilead Sciences Inc.'s agreement to pay nearly $11 billion to acquire tiny Pharmasset Inc. is a dramatic illustration of the market potential—and public-health challenges—involved in the battle against the hepatitis C virus.

Pharmasset, a Princeton, N.J., company with just over 80 employees and no commercial products, is developing a compound that Gilead and analysts say is on track to be part of the first all-oral regimen for treating hepatitis C. Experts say that gives it a distinct advantage over current treatments in the potentially huge U.S. and global markets for such drugs.

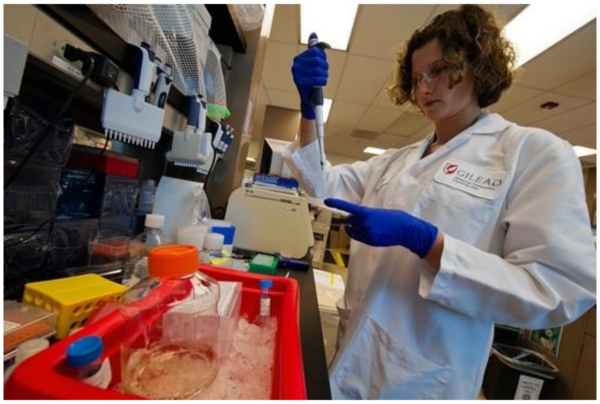
Gilead, which has a blockbuster franchise for medicines that treat HIV, the virus that causes AIDS, is betting that Monday's $137-a-share deal will help it become similarly dominant in hepatitis C. Market-research firm Decision Resources estimates the global hepatitis C market will hit $16 billion in 2015, up from just $1.7 billion in 2010.

The purchase price represents a nearly 89% premium to Pharmasset's closing price Friday, putting it in the rarified ranks of Bristol-Myers Squibb Co.'s $2.1 billion purchase of Medarex and its novel cancer drug in 2009, which carried a 90.5% premium.

In 4 p.m. trading Monday on the Nasdaq Stock Market, Pharmasset shares were up 85% at $134.14.

An estimated four million Americans have hepatitis C, but only about a million of them have been diagnosed. Most victims go untreated rather than endure weekly injections of interferon and twice-daily ribavirin pills—a combination with harsh side effects—for as long as a year. Only about 50% of those treated are cured of the potentially fatal blood-borne virus.

Globally, some 170 million people are thought to have hepatitis C, which can be transmitted sexually, as well as by shared needles and at tattoo parlors. It can cause cirrhosis of the liver, and is the chief reason in the U.S. for liver transplants.



A scientist, shown in August, at Gilead Sciences' Foster City, Calif., lab ILLUSTRATION: BLOOMBERG NEWS

Merck & Co., as well as Johnson & Johnson and its partner Vertex Pharmaceuticals Inc., launched new hepatitis C treatments earlier this year that shorten the treatment time and have improved cure rates. But current versions of the treatments are still taken on top of interferon and ribavirin.

Pharmasset's molecule, PSI-7977, is one of a class of medicines called nucleotide analogs, or "nukes" for short, that small studies in certain patients have shown yield high rates of cure in just 12 weeks, with fewer side effects. They also pose a high barrier to viral resistance.

"Having a program where you don't have to take interferon...would be a big deal and would be a paradigm shift in the treatment of hepatitis C," said Stacey Rizza, an infectious-disease specialist at the Mayo Clinic in Rochester, Minn.

Indeed, several drug companies are trying to develop new, and potentially lucrative, treatments that improve cure rates further and are easier for patients to tolerate. But on the strength of data reported as recently as early this month, "Pharmasset is on the forefront of the interferon-free treatment wave," said Adam Cutler, an analyst at Credit Suisse.

Pharmasset recently announced the start of late-stage, or Phase III, studies of the drug, which could lead to marketing approval by 2014, if all goes well. The company declined to comment on the acquisition deal and didn't participate in a conference call Gilead held with analysts Monday.

While Pharmasset's stock price soared in response to the news, Gilead's was down 9% Monday at $36.26 in 4 p.m. Nasdaq trading, in response to its acknowledgment that the deal would be drag on profits through 2014. Several analysts also commented that the price it paid for Pharmasset's portfolio was steep.

But John Milligan, Gilead's president and chief operating officer, said the company took care in evaluating Pharmasset. "It's a very unusual situation where a compound in Phase II going on to Phase III has the kind of data" PSI 7977 has, Dr. Milligan said. There were also other bidders, he said, but he indicated he didn't know for certain who they were.

"It was a competitive process, so there were a number of factors that drove up the price," he added.

The deal helped lift shares of another small drug developer, Inhibitex Inc., which is testing an experimental hepatitis C drug. Inhibitex shares rose 19% to $10.61 on expectations that it could be acquired.

By contrast with HIV/AIDS therapies, which patients have to take for life just to keep the virus at bay, hepatitis C requires a relatively short course of treatment to achieve a cure. But because people can carry the virus for decades without symptoms, persuading them to stay on six months to a year of treatments—especially given such side effects as flu-like symptoms and anemia—is a challenge.

Credit Suisse's Mr. Cutler said the market opportunity for new medicine was reflected in the swift adoption of Incivek, approved earlier this year and marketed in the U.S. by Vertex. Even though it is given with interferon, it recorded sales of about $420 million in its first full quarter on the market.

Doctors and public health officials hope that as better drugs become available, more people will be diagnosed and agree to treatment for hepatitis C to help avoid the long-term consequences of infections.

Scott D. Holmberg, chief of the epidemiology and surveillance branch for viral hepatitis at the U.S. Centers for Disease Control and Prevention, reported at a major liver conference this month that the number of people who die with hepatitis C in the U.S. now exceeds the number of those who die of HIV/AIDS.

"The public-health implications of hepatitis C are big," Dr. Holmberg said. "We need to test and treat more people."

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