MedicalXpress

Cempra shares plummet ahead of FDA meeting on antibiotic

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Shares of drugmaker Cempra Inc. plunged Wednesday after federal regulators raised concerns about potential liver toxicity risks with its closely watched experimental antibiotic.

Wall Street analysts said the company's drug could still reach the market but with major restrictions or a requirement for a large, follow-up safety study. That could present "significant additional financing risk" for the small North Carolina company, according to Janney analyst Debjit Chattopadhyay.

"Cempra will need additional capital during 2017, by our estimates," states Chattopadhyay, who holds a neutral rating on the company.

Shares of Cempra—which currently has no drugs on the market—fell more than 60 percent to close at $7.30.

Cempra is among a handful of drugmakers working to develop new antibiotics as many bacterial strains have grown resistant to decades-old drugs like penicillin.

The company has asked the Food and Drug Administration to approve its drug solithromycin for a common form of pneumonia that causes more than 1 million infections and roughly 7,000 U.S. deaths per year, according to Cempra.

The FDA posted its review of the drug online Wednesday ahead of a

public advisory panel later this week, saying the drug appears to work as well as an older antibiotic. But FDA staffers focused most of their attention on elevated liver enzymes reported in a small number of patients. Those chemical measures can predict more serious liver damage, a major risk with virtually all new prescription drugs. Drugs are principally metabolized by the liver.

The agency's review notes that Cempra's drug is similar to Ketek, another antibiotic that was linked to cases of severe liver damage and deaths in 2007.

While overall adverse events were similar between Cempra and an older antibiotic, FDA reviewers concluded that the elevated liver enzymes "comprise a genuine liver injury signal." Additionally, the company's study of roughly 900 patients was not large enough to predict rates of liver injury in a larger population, regulators state.

One path to market would require the company to conduct a 12,000-patient before the FDA considered approving the drug, according to an FDA reviewer specializing in liver toxicology. Another approach would involve placing a number of warnings and restrictions on the drug, including banning its use for more than 7 days.

On Friday an outside panel of experts will vote on whether to recommend approval for the drug and under what conditions. The FDA is not required to follow the panel's advice, though it often does.

While approval is still a possibility, Jeffries analyst Eun Yang states that the "lack of clear timeline for approval and uncertain market potential may continue to weigh on shares." Yang holds a buy on the company's shares.

The federal government has awarded a series of contracts to encourage

development of antibiotics that can be stockpiled for use against a national outbreak or bioterrorism attack. In March, Cempra received $25 million in continuing funding from the government's Biomedical Advanced Research and Development Authority to study its drug in pediatric patients.