Jazz Pharmaceuticals Receives FDA Complete Response Letter Regarding JZP-6 for Treatment of Fibromyalgia

October 11, 2010

-- Company to host conference call on Monday, October 11 at 8:30 AM ET --

PALO ALTO, Calif., Oct 11, 2010 /PRNewswire via COMTEX/ --

Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that the U.S. Food and Drug Administration (FDA) has sent the company a complete response letter (CRL) regarding the company's New Drug Application (NDA) for JZP-6 (sodium oxybate) for the treatment of fibromyalgia. The CRL states that the FDA cannot approve the NDA in its present form. In the letter, the FDA discusses a number of topics, including the need for additional clinical studies, the appropriate patient population, methods for ensuring safe use, and the proposed REMS, concentration and trade name for the product.

"We have requested a meeting with FDA in order to discuss and clarify the contents of the CRL and will then evaluate our next steps for JZP-6," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We continue to believe there is a significant unmet medical need among fibromyalgia patients that could be met by JZP-6 if it were approved by FDA."

Conference Call Information

Jazz Pharmaceuticals will host an investor conference call and live audio webcast today (October 11) at 8:30 AM Eastern Time/ 5:30 AM Pacific Time to discuss this release and respond to investor questions. The live webcast may be accessed from the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary.

Investors may participate in the conference call by dialing 866-700-6067 in the U.S., or 617-213-8834 outside the U.S., and entering passcode 43104766.

An archived version of the webcast will be available for at least one week on the investors section of the Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals (Nasdaq: JAZZ) is a specialty pharmaceutical company that identifies, develops and commercializes innovative treatments for important, underserved markets in neurology and psychiatry. For further information see www.jazzpharmaceuticals.com.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including but not limited to statements related to Jazz Pharmaceuticals' JZP-6 (sodium oxybate) product candidate, including statements related to Jazz Pharmaceuticals' plans to meet with the FDA, the outcome of any such meeting and all future regulatory matters, including its future approval and the future development of JZP-6. These forward-looking statements are based on the company's current expectations and inherently involve significant risks and uncertainties. Jazz Pharmaceuticals' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the uncertain and time-consuming regulatory approval process for JZP6, risks related to potential further development of JZP-6, and other risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals' Securities and Exchange Commission filings and reports, including in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on August, 11, 2010. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

SOURCE Jazz Pharmaceuticals, Inc.