



## Questcor Updates Status of Supplemental New Drug Application

UNION CITY, Calif., Sept 08, 2010 /PRNewswire via COMTEX News Network/ -- Questcor Pharmaceuticals, Inc. (Nasdaq: QCOR) today announced that the U.S. Food and Drug Administration (FDA) has informed Questcor that the FDA will require additional time beyond the current action date of September 11, 2010 to complete its review of Questcor's supplemental new drug application (sNDA) for H.P. Acthar(R) Gel (repository corticotropin injection) in the treatment of infantile spasms (IS). In conjunction with the FDA's review of this sNDA, Questcor and the FDA have been updating and modernizing the product label for Acthar, which has not been modified since 1978, when multiple sclerosis was added to the label. This step of the review process is now complete. Questcor has been notified that the FDA needs some additional time to finalize the wording on the label, review the proposed medication guide, and define post-approval commitments, if any, for the IS indication.

"We are pleased to be nearing the finish line and look forward to the FDA finalizing its review of our sNDA," said Don M. Bailey, President and Chief Executive Officer of Questcor. "Our business strategy and plans for Acthar remain intact, based on the direction that the FDA appears to be taking not only with our sNDA but also with the additional updates to the Acthar label. We expect to continue executing our plans for the multiple sclerosis and nephrotic syndrome markets, including the significant expansion of our sales force."

"To date, third quarter 2010 prescription and sales levels are encouraging. Despite the significant organizational focus on the effort to double our sales force, MS new paid prescriptions reached a monthly record in August. In the first two months of the third quarter, these prescriptions have increased modestly compared to the first two months of the second quarter of 2010. At the current quarterly run rate, vial shipments by Questcor in the third quarter of 2010 would exceed the record just set in the second quarter. Of note, so far, with a majority of state Medicaid bills for the second quarter of 2010 (the first full quarter in which all Medicaid managed care organizations were participating in the Medicaid rebate program) received, our sales reserve provision appears adequate," Mr. Bailey concluded.

Investors are cautioned that the statements above are based on interim information; however, the FDA may or may not approve Acthar for the treatment of IS, may or may not require additional significant changes to the label, and may or may not impose other requirements on Questcor. Also, interim sales and Medicaid usage results in the third quarter of 2010 are not necessarily indicative of full quarter results. While Questcor believes that its Medicaid rebate provision is sufficient, this provision ultimately might prove to be inadequate. Please refer to the cautionary statements later in this press release and a full description of the risks of investing in Questcor in its filings with the Securities and Exchange Commission.

### Conference Call

Questcor has scheduled a conference call on Thursday, September 9, 2010 at 9:00 a.m. Eastern Time, 6:00 a.m. Pacific Time to discuss the recent developments as well as provide insight on the third quarter sales performance to date. The conference call will be simultaneously web cast under "Events & Presentations" on the Investor Relations section of the Questcor web site at [www.questcor.com](http://www.questcor.com). The conference call will be archived for future review until October 9, 2010.

#### Conference call details:

Date:	Thursday, September 9, 2010
Time:	9:00 a.m. ET / 6:00 a.m. PT
Dial-in (U.S.):	877-941-8632
Dial-in (International):	480-629-9820
Web cast:	<a href="http://ir.questcor.com/">http://ir.questcor.com/</a>

To access an audio replay of the call:

Access number (U.S.):	800-406-7325
Access number (International):	303-590-3030
Replay Passcode #:	4362089

### About H.P. Acthar Gel(R)

H.P. Acthar Gel(R) is a natural adrenocorticotrophic hormone (ACTH) designed to provide a prolonged release after

intramuscular or subcutaneous injection. Acthar is currently approved in the U.S. for the treatment of acute exacerbations of multiple sclerosis, nephrotic syndrome, and several other diseases and disorders. The FDA is in the final stages of reviewing the sNDA application for the use of Acthar in the treatment of patients with infantile spasms. For more information, please visit [www.acthar.com](http://www.acthar.com).

### **About Questcor**

Questcor Pharmaceuticals, Inc. is a biopharmaceutical company with products that help patients with serious, difficult-to-treat medical conditions. Questcor markets H.P. Acthar(R) Gel (repository corticotropin injection), which is approved for the treatment of certain disorders with an inflammatory component, including the treatment of exacerbations associated with multiple sclerosis and to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythamatosus. In addition, Questcor plans to market Acthar for the treatment of patients with infantile spasms, a rare form of refractory childhood epilepsy, in the event Questcor's sNDA receives FDA approval. Acthar is not indicated for, but is used in treating opsoclonus myoclonus syndrome, a rare autoimmune-related childhood neurological disorder. The Company also markets Doral(R) (quazepam), which is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. For more information, please visit [www.questcor.com](http://www.questcor.com).

Note: Except for the historical information contained herein, this press release contains forward-looking statements that have been made pursuant to the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "if," "should," "would," "forecasts," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Factors that could cause or contribute to such differences include, but are not limited to, the following:

- Questcor's ability to continue to successfully implement its Acthar-centric business strategy, including its expansion in the MS marketplace and other therapeutic areas;
- FDA approval of and the market introduction of competitive products and our inability to market Acthar in IS prior to approval of IS as a labeled indication;
- The uncertainty of receiving approval of IS as a labeled indication and risks associated with potential label modifications and other actions required by the FDA either prior to or following any such approval;
- Questcor's ability to operate within an industry that is highly regulated at both the Federal and state level;
- Regulatory changes or other policy actions by governmental authorities and other third parties as recently adopted U.S. healthcare reform legislation is implemented;
- Questcor's ability to accurately forecast the demand for its products;
- Questcor's ability to receive high reimbursement levels from third party payers;
- Questcor's ability to estimate the quantity of Acthar used by government entities and Medicaid-eligible patients;
- That the actual amount of rebates and chargebacks related to the use of Acthar by government entities, including the Department of Defense Tricare network, and Medicaid-eligible patients may differ materially from Questcor's estimates;
- Questcor's expenses and other capital needs for upcoming periods;
- The inventories carried by Questcor's distributors, specialty pharmacies and hospitals;
- Volatility in Questcor's monthly and quarterly Acthar shipments and end-user demand;
- The complex nature of Questcor's manufacturing process and the potential for supply disruptions or other business disruptions;
- Questcor's ability to attract and retain key management personnel;
- Research and development risks, including risks associated with Questcor's sNDA for IS and its preliminary work in the area of nephrotic syndrome;
- Uncertainties regarding Questcor's intellectual property;
- The impact to Questcor's business caused by economic conditions;
- Questcor's limited pipeline for new products and its ability to identify product acquisition candidates and consummate transactions on terms acceptable to the Company; and
- Other risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2009 and other documents filed with the Securities and Exchange Commission.

The risk factors and other information contained in these documents should be considered in evaluating Questcor's prospects and future financial performance.

Questcor undertakes no obligation to publicly release the result of any revisions to these forward-looking statements, which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

For more information, please visit [www.questcor.com](http://www.questcor.com) or [www.acthar.com](http://www.acthar.com).

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