

Urogen N.A. Announces Phase 2 Results for U101 in Chronic Pelvic Pain

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BURLINGAME, Calif.--(BUSINESS WIRE)--Urogen N.A., Inc. reported that U101 did not meet the primary endpoint in a Phase 2 clinical study in Chronic Pelvic Pain of bladder origin. However, the Company believes the trial provided the information necessary to proceed with development of the product.

The primary endpoint was improvement in pain and urgency at the end of the study as monitored by the PORIS questionnaire (Patient Overall Rating of Improvement of Symptoms), a validated measurement tool used in clinical trials of chronic pelvic pain. The study, a placebo-controlled, double-blind, three week trial involving 90 patients with chronic pelvic pain, showed that U101 was well-tolerated, with an adverse event profile comparable to that of placebo.

In the trial, there was a statistically significant improvement in the primary endpoint at the highest enrolling site ($p= 0.013$) as well as improvements in several other clinically relevant endpoints compared to placebo. At that clinical site, U101 showed a 70% response rate with active drug versus a 16% response rate in patients on placebo. The response after just one week of therapy appeared to be sustained for at least three days.

An analysis of all subjects in the trial showed a significant improvement in urinary urgency at visit 1 on a ten point analog urgency scale for patients on active drug versus placebo ($p=0.006$). Furthermore, there was a trend toward improvement in pain in all subjects at visit 1 (PORIS question 1-pain) but this did not achieve statistical significance. Analysis of the pain component of the primary endpoint was hampered because a substantial number of patients entered into the trial had minimal or transient pain.

Urogen believes the overall results of the trial may have been compromised by issues of patient selection. The Company believes it understands the reasons for differences between the Phase IIa and Phase IIb clinical trial results and that incorporation of appropriate protocol changes will allow it to achieve positive results in subsequent trials.

Urogen management will be holding a conference call at 2:00PM/EST (11:00AM/PST) on October 31, 2006. Interested parties may dial in to the call at 866-314-4865 (International 617-213-8050) and use the following participant passcode: 27974471. The live webcast can be accessed at www.urogen.com.

This press release includes forward-looking statements. These statements may be identified by the use of forward-looking terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," or "will," or the negative thereof or other variations thereon or comparable terminology. In particular, forward-looking statements include, without limitation, statements related to the implications of clinical results and prospects for future clinical testing. As with any new pharmaceutical product, there are significant risks in development, regulatory approval and commercialization of Urogen's products. There are no guarantees that future clinical studies will confirm the preliminary results discussed in this press release or that U101 or any other Urogen product or products will receive regulatory approval for any medical condition. Further, even if Urogen were to receive regulatory approval for a product, there can be no assurance that such a product would prove to be commercially successful.

Urogen has previously announced the signing of a merger agreement with Valentis, Inc. (NASDAQ:VLTS). Valentis is expected to file with the Securities and Exchange Commission, or

the Commission, a Registration Statement on Form S-4, which will include a joint proxy statement/prospectus of Valentis and Urogen and other relevant materials in connection with the proposed transaction. The joint proxy statement/prospectus will be mailed to the stockholders of Valentis and Urogen. Investors and security holders of Valentis and Urogen are urged to read the joint proxy statement/prospectus and the other relevant materials when they become available because they will contain important information about Valentis, Urogen and the proposed merger. The joint proxy statement/prospectus and other relevant materials (when they become available), and any other documents filed by Valentis or Urogen with the Commission, may be obtained free of charge at the Commission's web site at www.sec.gov. Investors and security holders are urged to read the joint proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

With respect to the proposed merger additional risks include: the future financial condition of Valentis (either before or after the merger), the continued qualification of the common stock of Valentis for listing on the Nasdaq Capital Market (either before or after the merger), risks associated with the discontinuance of the existing Valentis operations, risks associated with unsatisfactory results from the clinical trials of Urogen products, the successful integration of Valentis and Urogen, costs and potential litigation associated with the merger, industry-wide changes and other causes, the risk that the transaction may not be completed, the failure of either party to meet the closing conditions set forth in the merger agreement or that the closing of the transaction may be delayed due to failure to obtain required approvals. These and other important factors to be discussed in the joint proxy statement/prospectus may cause the actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these risks and uncertainties, you are cautioned not to place undue reliance on any forward-looking statements. Urogen does not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments. Urogen and its respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Valentis and Urogen in favor of the proposed merger. Information about the directors and executive officers of Urogen and their respective interests in the proposed merger will be available in the joint proxy statement/prospectus. Investors should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. This press release does not constitute an offer of any securities for sale or the solicitation of any proxy.

Urogen N.A., Inc. is a specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products for urological disorders. Urogen has five programs in development that are either in or positioned to enter Phase 2 clinical trials. The pipeline includes U101, for the treatment of Chronic Pelvic Pain (CPP); U102, targeting symptoms of CPP secondary to pelvic irradiation; U103, targeting dyspareunia; U301, targeting acute urethral discomfort; and U302, targeting urethritis.

SOURCE: Urogen N.A., Inc.

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