



July 17, 2012

## **Somaxon Pharmaceuticals Announces Settlement of Silenor Patent Litigation With Mylan and PAR**

SAN DIEGO, July 17, 2012 (GLOBE NEWSWIRE) -- Somaxon Pharmaceuticals, Inc. (Nasdaq:SOMX), a specialty pharmaceutical company, today announced that it has entered into separate settlement arrangements with Mylan Inc. and its subsidiary, Mylan Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. and its subsidiary Par Pharmaceutical, Inc. to resolve pending patent litigation involving Silenor® 3 mg and 6 mg tablets.

The settlement agreement with Mylan grants Mylan the exclusive right to begin selling an authorized generic version of Silenor (i.e., a generic version sold under Somaxon's New Drug Application) on January 1, 2020, or earlier under certain circumstances. Mylan's right to sell such an authorized generic product could extend for a period of as long as 360 days, and after such period Mylan will have the non-exclusive right to sell a generic version of Silenor under its Abbreviated New Drug Application. In connection with the settlement agreement, the parties also entered into a supply agreement under which Mylan has agreed to supply the company with commercial quantities of Silenor 3 mg and 6 mg tablets.

The settlement agreement with Par grants Par the right to begin selling a generic version of Silenor 180 days after the earlier of the date that a third party's generic version of Silenor is first sold in the United States under a license from Somaxon or a final court decision that the asserted patents are not infringed, invalid or unenforceable, or earlier under certain circumstances.

Each of the settlement agreements will become effective upon the entry by the U.S. District Court for the District of Delaware of an order dismissing the litigation with respect to Mylan or Par, as applicable.

"These settlement agreements reflect our continued confidence in the strength of our Silenor patents and allow us to more confidently devote resources to building the Silenor brand," said Richard W. Pascoe, Somaxon's President and Chief Executive Officer. "We will continue to defend Silenor's intellectual property against the remaining generic challengers with the goal of protecting its market exclusivity while allowing us to minimize further uncertainty and the cost of litigation. We believe that with the evolving clarity on Silenor's exclusivity and revenue, we are well positioned to continue to work with our advisor, Stifel Nicolaus Weisel, to evaluate strategic alternatives with the objective of fully leveraging Silenor for the benefit of our stockholders."

### **Financial Guidance**

Somaxon estimates net product sales for Silenor for the second quarter ended June 30, 2012 to be approximately \$2.8 to \$2.9 million.

Actual financial results for the second quarter of 2012 could vary based upon many factors, including but not limited to changes in actual Silenor sales and actual levels of sales discounts and allowances.

### **About Somaxon Pharmaceuticals, Inc.**

Headquartered in San Diego, CA, Somaxon Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded products and product candidates to treat important medical conditions where there is an unmet medical need and/or high level of patient dissatisfaction, currently in the central nervous system therapeutic area. Somaxon's product Silenor, available by prescription in the United States, is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.

For more information, please visit the company's web site at [www.somaxon.com](http://www.somaxon.com).

The Somaxon Pharmaceuticals logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=13679>

### **Safe Harbor Statement**

*Somaxon cautions readers that statements included in this press release that are not a description of historical facts are forward-looking statements. For example, statements regarding the settlement of litigation with Mylan and Par and the review and approval of the settlement agreements by the U.S. Department of Justice and/or the U.S. Federal Trade Commission, as*

*well as entry by the U.S. District Court for the District of Delaware of an order dismissing the litigation with respect to such parties, the process of seeking strategic alternatives and the ability to derive stockholder value from one or more related transactions and Somaxon's other activities and plans are forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Somaxon that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Somaxon's business, including, without limitation, Somaxon's ability to successfully market and sell Silenor; the market potential for insomnia treatments, and Somaxon's ability to compete within that market; risks related to the settlement agreements with Mylan and Par, including any legal or regulatory challenges to the settlement agreements by the U.S. Department of Justice and/or the U.S. Federal Trade Commission, and the outcome of any such challenges; Somaxon's ability, together with its strategic advisor Stifel Nicolaus Weisel, to successfully enter into one or more transactions to enhance stockholder value; Somaxon's ability to raise sufficient capital to fund its operations, and the impact of any such financing activity on the level of its stock price; the impact of any inability to raise sufficient capital to fund ongoing operations, including patent infringement litigation; the scope, validity and duration of patent protection and other intellectual property rights for Silenor; whether the approved label for Silenor is sufficiently consistent with such patent protection to provide exclusivity for Silenor; Somaxon's ability to successfully enforce its intellectual property rights and defend its patents, including any developments relating to the submission of abbreviated new drug applications for generic versions of Silenor 3 mg and 6 mg and related patent litigation; the possible introduction of generic competition for Silenor; the potential to enter into an agreement with any third party relating to over-the-counter rights for Silenor; Somaxon's ability, together with any partner, to receive FDA approval for an over-the-counter version of Silenor; changes in healthcare reform measures and reimbursement policies; the ability of Somaxon to ensure adequate and continued supply of Silenor to successfully meet anticipated market demand; Somaxon's ability to operate its business without infringing the intellectual property rights of others; Somaxon's reliance on its licensees, Paladin Labs and CJ CheilJedang, for critical aspects of the commercial sales process for Silenor outside of the United States; the performance of Paladin and CJ CheilJedang and their adherence to the terms of their contracts with Somaxon; inadequate therapeutic efficacy or unexpected adverse side effects relating to Silenor that could adversely impact commercial success, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of Silenor; the timing and results of post-approval regulatory requirements for Silenor, and the FDA's agreement with Somaxon's interpretation of such results; and other risks detailed in Somaxon's prior press releases as well as in its periodic filings with the SEC.*

*Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and Somaxon undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934.*

CONTACT: Tran Nguyen / CFO

Somaxon Pharmaceuticals, Inc.

(858) 876-6500

Rob Whetstone/Matt Sheldon

PondelWilkinson, Inc.

(310) 279-5963



Source: Somaxon Pharmaceuticals, Inc.

News Provided by Acquire Media