

ARENA PHARMACEUTICALS INC

Form 8-K

December 30, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**Current Report**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **December 29, 2005**

**Arena Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-31161**  
(Commission File Number)

**23-2908305**  
(I.R.S. Employer  
Identification No.)

**6166 Nancy Ridge Drive, San Diego, California 92121**

(Address of Principal Executive Offices) (Zip Code)

**(858) 453-7200**

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(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events.**

**APD125**

On December 29, 2005, Arena Pharmaceuticals, Inc. announced that it was granted patent number 1558582, entitled **Diaryl and Arylheteroaryl Urea Derivatives as Modulators of the 5-HT<sub>2A</sub> Serotonin Receptor Useful for the Prophylaxis and Treatment of Disorders Related Thereto**, by the European Patent Office. The patent relates to a class of inverse agonists to the 5-HT<sub>2A</sub> serotonin receptor, which is thought to be involved in the regulation of sleep architecture and sleep maintenance. These inverse agonists may be useful in pharmaceutical compositions for the treatment of insomnia. APD125, discovered by Arena, is an orally available 5-HT<sub>2A</sub> receptor modulator covered under the patent. Arena intends to validate the patent in 31 European jurisdictions, including Germany, France, Italy, the United Kingdom and Spain.

Arena also announced that an ongoing evaluation of the Phase 1 APD125 data has provided additional statistically significant signals (p is less than or equal to 0.05) indicative of improved sleep maintenance. Among the new data are statistically significant increases in stage 3 and stage 4 sleep, reductions in stage 1 sleep, reductions in the number of awakenings, and an increase in delta power during slow wave sleep. The ongoing evaluation also continues to support the encouraging preliminary safety and tolerability profile of APD125.

Arena intends to begin dosing chronic insomniacs in a Phase 2 clinical trial of APD125 in early 2006 under an investigational new drug, or IND, application being reviewed by the FDA. Arena expects results from the Phase 2 clinical trial around the middle of 2006.

**APD791**

On December 29, 2005, Arena announced that it is advancing APD791 into preclinical development from its cardiovascular research program, and expects to initiate clinical development in approximately one year. APD791 is an orally available, selective inverse agonist of the 5-HT<sub>2A</sub> serotonin receptor. By selectively inhibiting the activation of 5-HT<sub>2A</sub> serotonin receptors found on platelets and vascular smooth muscle, Arena believes that APD791 may reduce the risk of arterial thrombosis and conditions such as acute coronary syndrome, heart attack and stroke. Thrombosis is the formation of a clot, or thrombus, inside a blood vessel that restricts the flow of blood.

**Forward-Looking Statements**

Certain statements in this Form 8-K are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the possible usefulness of APD125 and other modulators of the 5-HT<sub>2A</sub> serotonin receptor in pharmaceutical compositions for the treatment of insomnia, whether or where Arena intends to validate the patent, the timing of the expected Phase 2 clinical trial of APD125, the anticipated timing of results from the Phase 2 clinical trial of APD125, the tolerability and efficacy of APD125, the potential of the APD125 program, the initiation of clinical development of APD791, and expectations related to APD791, including whether or how APD791 may be



effective. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the FDA may not allow the Phase 2 clinical trial of APD125 to proceed at the time Arena expects or at all, the results of preclinical studies or clinical trials may not be predictive of future results, the full results of the Phase 1 clinical trial of APD125 may vary from the top-line results, any unfavorable results of APD791 preclinical studies, Arena's ability to partner APD356, APD125 or other of its compounds or programs, the timing, success and cost of Arena's research, out-licensing endeavors and clinical trials, Arena's ability to obtain additional financing, Arena's ability to obtain and defend its patents, and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of the filing of this Form 8-K. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 29, 2005

Arena Pharmaceuticals, Inc.,  
a Delaware corporation

By: /s/ Jack Lief  
Jack Lief  
President and Chief Executive Officer