

ARENA PHARMACEUTICALS INC

Form 8-K

July 09, 2008

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): **July 9, 2008**

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its 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

(Registrant's telephone number, including area code)

N/A

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 8-K

(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))
-

In this report, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceuticals, Inc. and its wholly owned subsidiaries, unless the context otherwise provides.

Item 8.01 Other Events.

On July 9, 2008, we announced positive results from a multiple-ascending dose Phase 1b clinical trial of APD791 to evaluate the compound's safety, pharmacokinetics and pharmacodynamics. APD791 is Arena's internally discovered oral drug candidate intended for the treatment of arterial thrombosis and other related conditions.

The Phase 1b trial was a randomized, double-blind, placebo-controlled, multiple-ascending dose trial in 50 healthy adult male and female volunteers. Daily doses ranged from 15 mg to 240 mg and were generally well tolerated. The most frequently reported adverse event was headache, which was more common in the placebo group than in any APD791 dose group. None of the adverse events occurred in a dose-related fashion with the exception of epistaxis (nose bleed), which occurred in two volunteers in the 240 mg group, a dose outside the anticipated therapeutic range.

In addition to evaluating APD791's safety and tolerability profile, the trial evaluated the pharmacokinetics and pharmacodynamics of multiple oral doses of APD791 over a period of one week. APD791 was rapidly absorbed and exposures were related to dose. Dose-dependent inhibition of serotonin-mediated amplification of platelet aggregation was demonstrated starting at the 15 mg dose and will permit the identification of exposure ranges that produce minimal, moderate and near-complete inhibition of serotonin-mediated platelet aggregation. These results further support APD791's novel mechanism of action and preclinical and Phase 1a clinical trial data.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the therapeutic range of APD791 and the exposures which may produce minimal, moderate or near-complete inhibition of serotonin-mediated amplification of platelet aggregation; the tolerability, side effects and efficacy of APD791; the role of serotonin in thrombosis and in increasing cardiovascular risk; how APD791 is believed to work and its intended use and therapeutic potential. 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, Arena's planned clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, the results of preclinical studies or clinical trials may not be predictive of future results, Arena's ability to partner 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 this release. 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: July 9, 2008

Arena Pharmaceuticals, Inc.

By: /s/ Steven W. Spector
Steven W. Spector
Senior Vice President, General Counsel and
Secretary