

ARENA PHARMACEUTICALS INC

Form 8-K

July 25, 2006

**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 25, 2006**

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-31161

23-2908305

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(State or other jurisdiction
of incorporation)

(Commission File Number)

(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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In this report, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceuticals, Inc. and/or our wholly owned subsidiary, BRL Screening, Inc., unless the context otherwise provides.

Item 2.02. Results of Operations and Financial Condition.

On July 25, 2006, we issued a press release reporting our financial results for the second quarter and six months ended June 30, 2006. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01. Other Events.

Clinical Update on Lorcaserin Program

We announced today an outline of our plans for the Phase 3 lorcaserin program. We expect to enroll a total of approximately 6,000 patients in three pivotal trials. About half of these patients will enter a two-year trial evaluating the 20 mg dose (10 mg dosed twice daily) versus placebo. In this trial, all patients will receive echocardiograms at baseline and follow-up echocardiograms at 6, 12, 18 and 24 months after starting the trial. Echocardiograms will be reviewed by an independent Data Safety Monitoring Board (DSMB) at 6 and 12 months. The DSMB will only review echocardiographic data, and will make a judgment as to whether it is safe to proceed with the trial. Assuming a positive six month safety assessment from the DSMB in this first pivotal trial, two additional one-year pivotal trials, enrolling approximately 1,500 patients each, will be initiated. In these additional pivotal trials we plan to evaluate the 20 mg and 10 mg doses versus placebo, with one of the trials evaluating patients with diabetes. Diet and exercise will be part of each of the pivotal trials in accordance with FDA guidelines. In addition to the above planned pivotal trial program, several other small studies, such as drug interaction and abuse potential studies, will be conducted.

We also announced today results from a Thorough Electrocardiogram Study of lorcaserin in 244 healthy male and female volunteers. This study was conducted in accordance with ICH and FDA guidance to evaluate cardiovascular safety, including effects on QT interval, using electrocardiogram, or ECG, readings. The QT interval on an ECG can measure drug-induced prolongation of cardiac muscle repolarization, an adverse cardiac event that can be caused by some drugs. This single-site, double-blind, randomized, placebo- and positive-controlled study evaluated the ECG effects of orally administered lorcaserin in doses of 15 mg once daily and supra-therapeutic 40 mg once daily over 7 consecutive days. A moxifloxacin group was used as a positive control. Top-line results demonstrated that treatment with lorcaserin showed no signal of any ECG effects at projected peak blood levels 2 ½ times higher than anticipated in the pivotal trials. The spectrum of adverse events appears comparable to previous trials with lorcaserin, although, as expected, these events were observed with greater frequency at the supra-therapeutic 40 mg dose than in previous trials using therapeutic doses.

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 that are not historical facts about the timing, design and other planned aspects of the expected clinical trials of lorcaserin, the safety assessment of lorcaserin, and other statements about our ability to develop lorcaserin. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, our planned clinical trials

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may not proceed at the time or in the manner we expect or at all, the results of preclinical studies or clinical trials may not be predictive of future results, the timing, success and cost of our research and development, our ability to partner lorcasearin, APD125 or other of our compounds or programs, our ability to obtain additional financing, our ability to obtain and defend our patents, and the timing and receipt of payments and fees, if any, from our collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements are disclosed in our filings with the Securities and Exchange Commission. These forward-looking statements represent our judgment as of the time of the filing of this Form 8-K. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release issued July 25, 2006, reporting financial results for the second quarter and six months ended June 30, 2006.
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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 25, 2006

Arena Pharmaceuticals, Inc.,
a Delaware corporation

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

Exhibit No.	Description
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99.1 Press release issued July 25, 2006, reporting financial results for the second quarter and six months ended June 30, 2006.

