ARENA PHARMACEUTICALS INC
Form 8-K
June 28, 2012

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): June 27, 2012

Arena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-31161**	**23-2908305**
(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

(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))

In this report, Arena Pharmaceuticals, Arena, Company, we, us and our refer to Arena Pharmaceuticals, Inc., unless the context otherwise provides. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.

Item 8.01 Other Events.

On June 27, 2012, we and Eisai Inc., or Eisai, announced that the US Food and Drug Administration, or FDA, approved Arena s internally discovered and developed drug, BELVIQ (lorcaserin hydrochloride). Below is information on the following: (i) certain expected payments and financial terms relating to the previously announced Amended and Restated Marketing and Supply Agreement between Eisai and our wholly owned subsidiary, Arena Pharmaceuticals GmbH; (ii) the FDA approval of BELVIQ; and (iii) the lorcaserin marketing authorization application, or MAA, submission with the European Medicines Agency, or EMA.

Update on Amended and Restated Marketing and Supply Agreement with Eisai

Following the FDA approval of BELVIQ, we will receive the following milestone payments from Eisai under the Amended and Restated Marketing and Supply Agreement:

- $20 million, which is due within 30 days of the FDA approval. This payment was triggered because the FDA-approved prescribing information includes the efficacy and safety data from our BLOOM-DM trial in patients with type 2 diabetes.

- $5 million following the scheduling designation for BELVIQ by the Drug Enforcement Administration of the US Department of Justice, or DEA.

- $60 million following DEA scheduling designation and delivery of launch supply.

Other financial terms, including additional milestones, the purchase prices and purchase price adjustments are described in the current report on Form 8-K we filed with the Securities and Exchange Commission on May 10, 2012. The first purchase price adjustment of $25 million, plus a milestone payment of $30 million, are due if annual net sales reach $250 million.

FDA Approval of BELVIQ

The FDA approved BELVIQ (pronounced BEL-VEEK) as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of 30 kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes). The indication includes the following limitations of use: (i) the safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established, and (ii) the effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

Three double-blind, randomized, placebo-controlled trials demonstrated that BELVIQ along with diet and exercise was more effective than diet and exercise alone at helping patients lose 5% or more of their body weight after one year and managing the weight loss for up to two years.

In clinical trials, the most common adverse reactions for patients without diabetes treated with BELVIQ were headache, dizziness, fatigue, nausea, dry mouth, and constipation. In patients with diabetes, the most common adverse reactions were hypoglycemia, headache, back pain, cough, and fatigue.

The FDA has recommended that BELVIQ be classified by the DEA as a scheduled drug. The DEA will review the FDA s recommendation and determine the final scheduling designation. Once the DEA has provided the final scheduling designation, Eisai will announce when BELVIQ will be available to patients and physicians in the United States.

We will manufacture and supply the finished commercial product from our facility in Switzerland, and Eisai will market and distribute BELVIQ in the United States.

As part of the approval of BELVIQ, we and Eisai committed to conduct post-marketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcomes trial will include echocardiographic assessments.

Important Safety Information

Pregnancy: BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Nursing: BELVIQ should not be taken while breastfeeding.

Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions: BELVIQ and certain medicines for depression, migraine, the common cold, and mood, anxiety, psychotic or thought disorders or other medical problems may affect each other causing serious or life-threatening side effects. Patients should tell their doctor if they are taking medicines to treat any of these conditions such as: triptans, tricyclics, lithium, selective serotonin uptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), or antipsychotics; linezolid, an antibiotic; tramadol; dextromethorphan, an over-the-counter medicine used to treat the common cold or cough; over-the-counter supplements such as tryptophan or St. John s Wort. BELVIQ and these medicines should be discontinued immediately and symptomatic treatment measures should be initiated if patients taking BELVIQ and these other medicines experience any of the following: mental changes such as agitation, hallucinations, confusion, or other changes in mental status; coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes); restlessness; racing or fast heartbeat, high or low blood pressure; sweating or fever; nausea, vomiting, or diarrhea; or muscle rigidity (stiff muscles).

Valvular Heart Disease: Certain weight loss drugs have been associated with problems with the valves in the heart. Patients taking BELVIQ who have trouble breathing,

swelling of the arms, legs, ankles, or feet, dizziness, fatigue, or weakness that will not go away, or fast or irregular heartbeat should call their doctor right away. Before taking BELVIQ, patients should tell their doctor if they have or had heart problems including congestive heart failure, or heart valve problems. Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (such as cabergoline). Patients who develop signs and symptoms of valvular heart disease while taking BELVIQ should be evaluated and discontinuation of BELVIQ should be considered by their doctor.

Changes in Attention or Memory: Problems with thinking, sleepiness, confusion, and fatigue have been reported in patients taking BELVIQ.

Patients taking BELVIQ should not drive a car or operate heavy machinery until they know how BELVIQ affects them.

Mental Problems: Taking BELVIQ at higher than the recommended dose may cause psychiatric problems such as: hallucinations, feeling high or in a very good mood (euphoria), feelings of standing next to yourself or out of your body (disassociation). The recommended dose of 10 mg twice daily should not be exceeded. Patients should be monitored for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. BELVIQ should be discontinued if patients develop suicidal thoughts or behaviors.

Low Blood Sugar (Hypoglycemia): Weight loss can cause low blood sugar in people with type 2 diabetes mellitus who are on medicines to treat it such as metformin, insulin, or sulfonylureas. Blood sugar levels should be monitored for patients who take BELVIQ. Changes to medicines may be needed if low blood sugar develops.

Painful Erections (Priapism): If patients taking BELVIQ experience an erection lasting more than 4 hours, whether it is painful or not, they should stop using BELVIQ and call their doctor or go to the nearest emergency room right away. BELVIQ should be taken with caution by men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with a deformed penis. Patients should tell their doctor if they take medicines used to treat erectile dysfunction.

Slow Heartbeat: BELVIQ may cause a slow heartbeat. Patients taking BELVIQ should tell their doctor if they have a history of a slow heartbeat or heart block.

Decreases in Blood Cell Count: BELVIQ may cause decreases in red or white blood cell count. A doctor may do tests to check a patient s blood cell count during treatment with BELVIQ.

Increase in Prolactin: BELVIQ may increase the amount of a hormone the body makes, called prolactin. Patients taking BELVIQ should tell their doctor if their breasts begin to make milk or have a milky discharge or if their breasts begin to increase in size.

Increased Pressure in the Arteries of the Lung (Pulmonary Hypertension): Certain weight loss drugs have been associated with the rare but life-threatening side effect of increased pressure in the arteries of the lung. It is unknown if BELVIQ increases the risk for this condition.

Most Common Adverse Reactions In Non-Diabetic Patients: Headache, dizziness, fatigue, nausea, dry mouth, and constipation.

Most Common Adverse Reactions in Diabetic Patients: Hypoglycemia, headache, back pain, cough, and fatigue.

Response to BELVIQ should be evaluated at 12 weeks of treatment to determine if therapy should be discontinued.

Lorcaserin MAA submission with the EMA

We previously filed an MAA for lorcaserin with the EMA, which was accepted in March 2012. In accordance with the MAA review process, we have received from our rapporteur and co-rapporteur a draft assessment report which provides an initial review of our application and sets forth proposed questions and requests for additional information. We expect to receive the definitive list of questions in the form of a final 120 day assessment report around the end of July 2012. The final list of questions and requests for additional information in this 120 day assessment report will need to be addressed before lorcaserin can be recommended for approval for commercialization in the European Union. Under the applicable rules, the 120 day assessment report should be responded to within three months, and we expect to respond within such time period.

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 safety, efficacy, mechanism of action, DEA scheduling, commercialization and use of BELVIQ; rights and obligations under the amended and restated marketing and supply agreement with Eisai; future studies of BELVIQ; and the timing and other aspects of the MAA review process. 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, the following: the timing and outcome of DEA, EMA and other regulatory review is uncertain; approval of lorcaserin in the United States or other territories does not assure that our MAA filing will be approved by the EMA; limitations on the indicated uses, restricted distribution methods and other limitations on BELVIQ or, if approved, any of our other drug candidates; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the pace of market acceptance; cash and revenues generated from BELVIQ, including timing and impact of competition; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; unexpected or unfavorable new data; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than we or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; data and other information related to any of our research and development programs may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for regulatory review, approval or continued marketing; our ability to obtain and defend our patents; the timing, success and cost of our research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner expected or at all; having adequate funds; and satisfactory resolution of litigation or other disagreements with others. 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.

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: June 27, 2012

Arena Pharmaceuticals, Inc.

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