

ARENA PHARMACEUTICALS INC

Form 8-K

November 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): November 27, 2012

**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.)

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**6154 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.

**Item 1.01 Entry into a Material Definitive Agreement.**

On November 27, 2012, we entered into a Co-Development and License Agreement, or Agreement, with Ildong Pharmaceutical Co., Ltd., or Ildong, for temanogrel, our internally discovered inverse agonist of the serotonin 2A receptor. Under the Agreement, we granted Ildong exclusive rights to commercialize temanogrel in South Korea for myocardial infarction, acute coronary syndrome, stroke, peripheral artery disease, and other cardiovascular diseases, subject to further development and regulatory approval of temanogrel. Initially, Ildong will be responsible for funding and conducting, under the direction of a joint steering committee, the next two planned clinical trials in this program: an additional Phase 1 trial in healthy volunteers and a Phase 2a proof-of-concept trial in patients.

We will maintain ownership of temanogrel outside of South Korea, and have the rights to use data generated by Ildong for the development and potential commercialization of temanogrel outside of South Korea by us or other Arena licensees. In addition, Ildong has agreed to pay us a \$2 million development milestone if the planned additional Phase 1 and Phase 2a clinical trials conducted by Ildong support continued development and we or another Arena licensee initiates a Phase 2b clinical trial of temanogrel. We are also eligible to receive a royalty on net sales of temanogrel in South Korea, while Ildong is eligible to receive a share of future payments received by us related to licensing transactions and sales of temanogrel in other territories.

Unless terminated earlier or extended, the Agreement will continue in effect until the later of the expiration of all issued patents relating to temanogrel in South Korea and 10 years after the first commercial sale of temanogrel in South Korea. Either party has the right to terminate the Agreement early in certain circumstances, including if the other party is in material breach and for certain commercialization or intellectual property concerns.

Ildong will indemnify us for certain losses resulting from third-party claims, including for (a) Ildong's negligence, willful misconduct or violation of law, (b) Ildong's breach of the Agreement, (c) certain uses or misuses of temanogrel (including any product liability claim and other claims relating to sales or development of temanogrel in South Korea), and (d) certain governmental investigations of Ildong. We will indemnify Ildong for certain losses resulting from third-party claims, including for (a) our negligence, willful misconduct or violation of law, and (b) our breach of the Agreement.

**About Thrombosis**

Thrombosis is the formation of a clot, or thrombus, inside a blood vessel. Thrombus formation that occurs in the blood vessels of the heart or brain can lead to serious thrombotic diseases including myocardial infarction, acute coronary syndrome and stroke. One of the initial events in thrombus formation is the activation of platelets, which then aggregate and adhere to one another as they release certain factors, including high concentrations of serotonin. Serotonin promotes further platelet aggregation and also causes constriction, or narrowing, of the blood vessels.

Elevated serotonin levels have been associated with increased cardiovascular risk. The prothrombotic effects of serotonin on platelets and blood vessels are mediated by the serotonin 2A receptor, and inverse agonists of the serotonin 2A receptor have the potential to inhibit this activity.

#### **About Temanogrel**

Temanogrel is an inverse agonist of the serotonin 2A receptor intended for the treatment of thrombotic diseases, and has completed single- and multiple-ascending dose Phase 1 trials in healthy volunteers. Temanogrel has the potential to prevent serotonin-mediated platelet aggregation and reverse serotonin-mediated vasoconstriction. This dual mechanism of temanogrel may be therapeutically useful for the treatment or prevention of thrombotic diseases.

#### **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 development, therapeutic indication and use, safety, efficacy, mechanism of action, regulatory approval and commercialization of temanogrel; the potential of temanogrel and other inverse agonists of the serotonin 2A receptor; rights, obligations, expectations and future activities related to the Agreement, including funding, the development and commercialization of temanogrel and milestone and other payments, and the significance of the Agreement; and our use of data generated under the Agreement, ownership of temanogrel and establishment of other licensing agreements relating to temanogrel. 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: risks related to the implementation and continuation of the Agreement and the development of temanogrel; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the pace of market acceptance; cash and revenues generated from BELVIQ, including the impact of competition; the timing and outcome of regulatory review is uncertain; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative arrangements; the timing and receipt of payments and fees, if any, from collaborators; the entry into or modification or termination of collaborative arrangements; 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 us 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 may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for further research and development, regulatory review or approval or continued marketing; our ability to obtain and defend 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: November 28, 2012

Arena Pharmaceuticals, Inc.

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