ARENA PHARMACEUTICALS INC
Form 8-K
November 04, 2010

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): **October 29, 2010**

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.

Item 1.02 Termination of a Material Definitive Agreement.

Following the completion of a Phase 1 clinical trial program for APD597 (which is also referred to as JNJ-38431055) under its collaboration with us, Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, decided not to advance APD597 and notified us on October 29, 2010 that, effective December 28, 2010, it is terminating our collaborative agreement, dated December 20, 2004. APD597 is a GPR119 agonist intended for the treatment of type 2 diabetes.

Upon termination of the collaborative agreement, all rights under the licenses we granted to Ortho-McNeil-Janssen under the agreement will terminate and revert to us, including rights relating to APD597. Ortho-McNeil-Janssen will also be required to deliver and assign to us rights and information relating to regulatory filings, including the Investigational New Drug Application, or IND, relating to APD597, as well as certain other technology that may be useful to the development of GPR119 agonists that were subject to the collaboration. In addition, Ortho-McNeil-Janssen will cease reimbursing us for the cost of prosecuting our GPR119 patent portfolio.

Item 8.01 Other Events.

On November 4, 2010, we announced data from a Phase 1 clinical trial program of APD597 under our collaboration with Ortho-McNeil-Janssen. The Phase 1 program evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of APD597, and included single and multi-ascending studies in healthy volunteers and in subjects with type 2 diabetes. APD597 was well tolerated and showed dose-proportional pharmacokinetics with a half-life of six to seven hours in solution and approximately 13 hours in suspension in healthy volunteers. The Phase 1 program also provided evidence for incretin stimulation (GLP-1, GIP and PYY) and reductions in post-meal glucose increases with APD597 treatment in both overweight and obese non-diabetic volunteers and in subjects with type 2 diabetes. In general, reductions in post-meal glucose increases were greater with APD597 in combination with sitagliptin, a DPP-4 inhibitor, compared to sitagliptin alone.

We own internally discovered, oral GPR119 agonists, including next generation compounds that we discovered after the research portion of our collaboration with Ortho-McNeil-Janssen ended in October 2007, and a portfolio of patent applications and, in some cases, granted patents directed to a range of materials and methods that are related to the discovery and development of GPR119 receptor agonists. We believe that approximately half of the top 20 pharmaceutical companies in the world have either acknowledged having an internal or collaborative GPR119 program or published medicinal chemistry patents directed to GPR119 agonists. The technologies covered by our patents and patent applications include materials and methods that may be used to identify and determine the activity of molecules that modulate the GPR119 receptor, methods that measure the incretin response to GPR119 agonists and pharmaceutical compositions containing GPR119 agonists along with DPP-4 inhibitors.

We believe GPR119 represents a novel pharmaceutical mechanism for discovering oral small molecule agonists for the treatment of diabetes. GPR119 is expressed in beta cells, which are located in the pancreas and responsible for producing insulin in response to increases in blood

glucose. Stimulation of GPR119 has been shown to promote insulin release by beta cells in response to elevated blood glucose levels. In addition, GPR119 is expressed in cells other than pancreatic beta cells, such as endocrine cells in the gastrointestinal tract. In preclinical studies and clinical trials, GPR119 has been shown to stimulate the release of GLP-1, GIP and PYY, incretins that play important roles in insulin regulation and metabolism.

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 termination of the Ortho-McNeil-Janssen collaboration and related expectations and future activities; the therapeutic indication and use, safety, efficacy, tolerability, mechanism of action and potential of APD597 alone and in combination; the potential of GPR119; and our GPR119 patent portfolio and program. 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 risk that APD597 or GPR119 agonists as a class may not realize their potential or ever receive marketing approval; the risk that regulatory authorities may not find data and other information related to our clinical trials and other studies sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; our response to the complete response letter for the lorcaserin NDA may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request additional information prior to approval; unexpected new data; risks related to commercializing new products; 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 we or others expect or at all; our ability to obtain adequate funds; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from our collaborators; and satisfactory resolution of pending and any future 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 4, 2010

Arena Pharmaceuticals, Inc.

By: /s/ Steven W. Spector
Steven W. Spector

Senior Vice President, General Counsel and

Secretary