ACELRX PHARMACEUTICALS INC
Form 8-K
March 23, 2015

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): March 22, 2015

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

351 Galveston Drive

Redwood City, CA 94063

(Address of principal executive offices and zip code)

Registrant’s telephone number, including area code: **(650) 216-3500**

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 (see General Instruction A.2. below):

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))

Item 8.01. Other Events.

On March 22, 2015, Grünenthal GmbH (Grünenthal) confirmed that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had received the submitted responses to the Day 120 List of Questions with respect to the Marketing Authorization Application for ZALVISO™ for the management of moderate-to-severe acute pain in adult patients in a medically-supervised environment and that the review of the response has been initiated. AcelRx and Grünenthal expect to receive the EMA Day 180 List of Outstanding Issues during the second quarter of 2015. The evaluation by the CHMP takes up to 210 active days plus 'clock stops', at the end of which the CHMP will adopt an opinion on whether ZALVISO™ should be marketed or not. This opinion is subsequently transmitted to the European Commission, which has the ultimate authority for granting marketing authorizations in the European Union (EU). AcelRx Pharmaceuticals, Inc. and Grünenthal entered into license and supply agreements for ZALVISO™ in the EU, Australia and certain other countries in December 2013.

Signatures

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: March 23, 2015	ACELRX PHARMACEUTICALS, INC.	
	By:	/s/ Timothy E. Morris Timothy E. Morris Chief Financial Officer