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, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On June 27, 2018, AcelRx Pharmaceuticals, Inc. issued a press release entitled "AcelRx receives European Commission approval for DZUVEO™," a copy of which is attached as Exhibit 99.1 to this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated June 27, 2018

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: July 2, 2018

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

AcelRx receives European Commission approval for DZUVEO™

AcelRx's DZUVEO receives EU approval for management of acute moderate to severe pain in medically monitored settings

REDWOOD CITY, Calif., June 27, 2018 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx or the Company), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, today announced that the European Commission (EC) has approved DZUVEO (under development in the U.S. as DSUVIA™) for the management of acute moderate to severe pain in adults in medically monitored settings.

"The EC approval is an important milestone for AcelRx, and an exciting new opportunity for healthcare providers for managing acute moderate to severe pain in medically monitored settings. The current standard of care in these settings is primarily intravenous opioids," said Vince Angotti, Chief Executive Officer of AcelRx. "DZUVEO is a novel, non-invasive, sublingual tablet that we expect will challenge the current standard of care and provide a new option to healthcare practitioners that does not require the time, expense and effort to start an intravenous line."

DZUVEO represents the second EC approval for an AcelRx developed product, with the first being ZALVISO, which is currently being marketed in Europe by Grünenthal.

AcelRx previously announced the acceptance of the resubmitted New Drug Application for DSUVIA (approved in Europe as DZUVEO) by the U.S. Food and Drug Administration, for which the FDA has assigned a PDUFA (Prescription Drug User Fee Act) date of November 3, 2018.

About DZUVEO (tradename of DSUVIA in the U.S.)
DZUVEO (sufentanil sublingual tablet, 30 microgram), under development as DSUVIA in the U.S., is designed to reduce acute moderate-to-severe pain in medically monitored settings and address dosing errors associated with intravenous (IV) administration via its non-invasive single-dose applicator (SDA). Sufentanil is an opioid analgesic currently marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration while still providing rapid pain relief. The safety and clinical utility of DZUVEO has been established in patients following multiple types of surgery, as well as in patients presenting to the emergency room with moderate to severe pain due to trauma, injury or illness. In the U.S., the U.S. Food and Drug Administration assigned the Company a Prescription Drug User Fee Act (PDUFA) date of November 3, 2018 for a decision on its resubmitted DSUVIA NDA (New Drug Application).

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has two product candidates in the United States, including DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised (or monitored) settings, and Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg) being developed as a non-invasive patient-controlled analgesia (PCA) system for treatment of moderate-to-severe acute pain in medically supervised settings. The Company has received EC approval for Zalviso and DZUVEO for marketing in the Europe.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, the statement related to the size and significance of a potential market for DZUVEO in Europe and the potential that DZUVEO will challenge the standard of care in the management of acute moderate to severe pain. This and similar forward-looking statements are based on AcelRx's current expectations and involve significant risks and uncertainties. AcelRx's actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including without limitation, any delays or the inability to obtain and maintain market acceptancy of DZUVEO in Europe, or any other risks described in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission (SEC) filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 10, 2018. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations, except as required by law.

Investors
Brian Korb, Solebury Trout
646-378-2923
investors@acelrx.com

Raffi Asadorian
Chief Financial Officer, AcelRx
investors@acelrx.com

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