

ACELRX PHARMACEUTICALS INC

Form 8-K

January 25, 2013

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) January 18, 2013

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in charter)

DELAWARE
(State of incorporation)

001-35068
(Commission

File No.)

41-2193603
(IRS Employer

Identification No.)

Edgar Filing: ACELRX PHARMACEUTICALS INC - Form 8-K

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 Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On January 18, 2013, AcelRx Pharmaceuticals, Inc. (the Company) and Patheon Pharmaceuticals Inc. (Patheon) entered into a Manufacturing Services Agreement (the Services Agreement) and a related Amended and Restated Capital Expenditure and Equipment Agreement (the Capital Agreement) relating to the manufacture of Sufentanil NanoTabs (the Product) for use with the Company's Sufentanil NanoTab PCA System, or ARX-01.

Under the terms of the Services Agreement, Patheon has agreed to manufacture, supply, and provide certain validation and stability services with respect to, the Product for sale in the United States, Canada, Mexico and other countries, subject to agreement by the parties to any additional fees for such other countries. The Company has agreed to purchase, subject to Patheon's continued material compliance with the terms of the Services Agreement, all of its Product requirements for the United States, Canada and Mexico from Patheon during the Initial Term of the Services Agreement (as defined below), and at least eighty percent (80%) of its Product requirements for such territories after the Initial Term.

The term of the Services Agreement extends until December 31, 2017 (the Initial Term) and will automatically renew thereafter for periods of two years, unless terminated by either party upon eighteen months' prior written notice; provided, however, that the Services Agreement may not be terminated without cause prior to the end of the Initial Term. In addition to usual and customary termination rights which allow each party to terminate the Services Agreement for material, uncured breaches by the other party, the Company can terminate the Agreement upon thirty days' prior written notice if a governmental or regulatory authority takes any action or raises any objection that prevents the Company from importing, exporting, purchasing or selling the Product. Patheon may terminate the Services Agreement upon six months' prior written notice if the Company assigns any of its rights under the Services Agreement to an assignee that Patheon reasonably determines is a competitor of Patheon. Either party may terminate the Services Agreement immediately upon the bankruptcy or insolvency of the other party.

The Services Agreement contains representations, warranties and indemnity obligations customary for agreements of this type, and establishes certain minimum batch quantities per production cycle and pricing for bulk Product, which pricing may be adjusted annually, as set forth in the Services Agreement.

Under the terms of the Capital Agreement, the Company will be responsible for the cost of certain future modifications to Patheon's Cincinnati facility, the aggregate cost of which is expected to be less than \$3.5 million. If additional equipment and facility modifications are required to meet the Company's Product needs, the Company may be required to contribute to the cost of such additional equipment and facility modifications. The Capital Agreement also requires that the Company make a one-time payment of \$480,000 to Patheon to partially offset taxes incurred and paid by Patheon in connection with facility modifications already completed by Patheon. The Company may seek reimbursement from Patheon for this payment if it receives approval from the U.S. Food and Drug Administration for ARX-01. The Capital Agreement further requires that the Company pay a maximum overhead fee of \$200,000 annually during the term of the Services Agreement, which amount may be reduced to \$0 based on the amount of annual revenues earned by Patheon under the Services Agreement and the Development Agreements (as defined below).

The Capital Agreement supersedes the Capital Expenditure and Equipment Agreement entered into by the Company and Patheon on May 25, 2011. The Company is also party to Master Agreements for Pharmaceutical Development Services, or Development Agreements, with each of Patheon and Patheon Inc. (Canada), dated August 7, 2009 and October 28, 2009, respectively.

The foregoing is a summary of the material terms of the Services Agreement and Capital Agreement, and does not purport to be complete and is qualified in its entirety by reference to the full text of the Services Agreement and Capital Agreement, each of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending March 31, 2013.

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: January 25, 2013

ACELRX PHARMACEUTICALS, INC.

By: /s/ James H. Welch
Name: James H. Welch
Title: Chief Financial Officer