ACELRX PHARMACEUTICALS INC
Form 8-K
December 19, 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): December 16, 2013

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 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

On December 16, 2013, AcelRx Pharmaceuticals, Inc. (the Company) and Grünenthal GmbH (Grünenthal) entered into a Collaboration and License Agreement (the License Agreement) and related Manufacture and Supply Agreement (the Manufacturing Agreement and together with the License Agreement, the Agreements). The License Agreement grants Grünenthal rights to commercialize Zalviso™ (formerly known as ARX-01) the Company s novel sublingual patient-controlled analgesia (PCA) system (the Product), in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia (the Territory), for human use in pain treatment within or dispensed by hospitals hospices, nursing homes and other medically-supervised settings (the Field). The Company retains rights with respect to the Product in countries outside the Territory, including the U.S., Asia and Latin America. Under the Supply Agreement, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory.

License Agreement

Under the terms of the License Agreement, Grünenthal has the exclusive right to commercialize the Product in the Field in the Territory. The Company retains control of clinical development, while Grünenthal will be responsible for certain development activities pursuant to a development plan to be agreed between the parties. Grünenthal is exclusively responsible for marketing approval applications and other regulatory filings relating to the sufentanil drug cartridge for the Product in the Field in the Territory, while the Company is responsible for the CE Mark and other regulatory filings relating to device portions of the Product.

Grünenthal will have a right of first negotiation with respect to proposed exploitation in the Territory of the Product outside of the Field or the proposed exploitation in the Territory of another pharmaceutical product delivered with a PCA device for transmucosal application. Either party has the right to remove Australia from the Territory for purposes of the Agreements if Grünenthal s marketing approval or commercialization activities do not meet specified timelines set forth in the License Agreement.

The Company will receive an upfront cash payment of $30 million, and is eligible to receive up to $220 million in additional milestone payments contingent upon achieving research and development milestones and specified net sales target milestones. Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range on net sales of Product in the Territory.

Unless earlier terminated, the License Agreement continues in effect until the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments, which supply and trademark fee continues for so long as the Company continues to supply the Product to Grünenthal. The License Agreement is subject to earlier termination in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party, upon the bankruptcy or insolvency of either party, or by Grünenthal for convenience.

Manufacturing Agreement

Under the terms of the Manufacturing Agreement, the Company will manufacture and supply the Product for use in the Field for the Territory exclusively for Grünenthal. Grünenthal shall purchase from AcelRx, during the first five years after the effective date of the Manufacturing Agreement, 100% and thereafter 80% of Grünenthal s and its sublicensees and distributors requirements of Product for use in the Field for the Territory. The Product will be supplied at the Company s fully burdened manufacturing cost (as defined in the Manufacturing Agreement). The Manufacturing Agreement requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and under certain specified conditions permits Grünenthal to use a third party back-up manufacturer to manufacture the Product for Grünenthal s commercial sale in the Territory.

Unless earlier terminated, the Manufacturing Agreement continues in effect until the later of the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments or the end of any transition period for manufacturing obligations due to the expiration or termination of the License Agreement. The Manufacturing Agreement is subject to earlier termination in connection with certain termination events in the License Agreement, in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

On December 16, 2013, the Company issued a press release describing the License Agreement and the Manufacturing Agreement. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K.

The foregoing summary is qualified in its entirety by reference to the License Agreement and the Manufacturing Agreement, both of which will be filed as exhibits to the Company s Annual Report on Form 10-K for the period ending December 31, 2013, portions of which will be subject to a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, for certain portions of the License Agreement and the Manufacturing Agreement. The omitted material will be included in the request for confidential treatment.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release titled AcelRx and Grunenthal Announce Collaboration for EU Commercialization of ZALVISO , dated as of December 16, 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: December 19, 2013

ACELRX PHARMACEUTICALS, INC.

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

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