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

INDEX TO EXHIBITS

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99.1	Press Release titled “AcelRx and Grunenthal Announce Collaboration for EU Commercialization of ZALVISO™,” dated as of December 16, 2013.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx and Grünenthal Announce Collaboration for EU Commercialization of ZALVISO™

- FDA establishes the PDUFA action date of July 27, 2014 for Zalviso -

- Conference Call Scheduled Monday, December 16th 2013 for 8:30 a.m. Eastern Time –

Redwood City, California and Aachen, Germany – December 16, 2013 - AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) and Grünenthal GmbH announced today that they have entered into a commercial collaboration, covering the territory of the European Union, certain other European countries and Australia for ZALVISO™ (previously known as ARX-01) for potential use in pain treatment within or dispensed by a hospital, hospice, nursing home or other medically supervised setting. ZALVISO, a drug-device combination product utilizing the opioid agonist sufentanil formulated in a proprietary sublingual tablet formulation and delivered through a pre-programmed, non-invasive proprietary delivery device is AcelRx's lead program. AcelRx retains all rights in remaining countries, including the U.S. and Asia.

Under the terms of the agreement, AcelRx will receive an upfront cash payment of $30 million. AcelRx is eligible to receive approximately $220 million in additional milestone payments, based upon successful regulatory and product development efforts and net sales target achievements. Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales of ZALVISO in the Grünenthal territory.

"As an established leader in providing pain management solutions to patients throughout Europe, Grünenthal is an excellent partner for AcelRx and for ZALVISO," said Richard King, President and CEO. "Grünenthal's commercial track record across Europe demonstrates their ability to achieve commercial success in this large market, and will, following regulatory approval, enable patients in Europe suffering with moderate-to-severe pain in a medically supervised setting to receive the benefits of our innovative, patient-centric product ZALVISO."

"We are extremely pleased to enter into this collaboration with AcelRx and its proven concept of a patient-controlled analgesia system to address a significant unmet medical need, thereby allowing hospitals to avoid the challenges of intravenous line-related infections, as well as freeing hospital personnel from the need to program intravenous infusion pump systems. With ZALVISO Grünenthal is building on its presence in the hospital market, an area that provides us with significant growth opportunities in the mid- and long-term," said Prof. Eric-Paul Pâques, Grünenthal's Chief Executive Officer.

Grünenthal will be responsible for all commercial activities for ZALVISO, including obtaining and maintaining pharmaceutical product regulatory approval in the Grünenthal territory. AcelRx will be responsible for maintaining device regulatory approval in the Grünenthal territory and manufacturing and supply of ZALVISO to Grünenthal for commercial sales and clinical trials.

ZALVISO PDUFA Date

In addition, AcelRx announced today that the U.S. Food and Drug Administration (FDA) has established a Prescription Drug User Fee Act (PDUFA) action date of July 27, 2014, for AcelRx's New Drug Application (NDA) for Zalviso. AcelRx announced on December 2, 2013 that FDA accepted for filing the Zalviso NDA.

Conference Call at 8:30 a.m. Eastern time on Monday, December 16, 2013

AcelRx will conduct a conference call and webcast today, December 16, 2013 at 8:30 a.m. Eastern time (5:30 a.m. Pacific time) to discuss the Grünenthal partnership. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (877) 870-4263 for domestic callers, (855) 669-9657 for Canadian callers, or (412) 317-0790 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors section of the company's website at www.acelrx.com and selecting the webcast link for Grünenthal collaboration conference call. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at www.acelrx.com

About ZALVISO

ZALVISO is an investigational pre-programmed, non-invasive, handheld system that allows hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil microtablets to manage their pain. ZALVISO is designed to address the limitations of IV PCA by offering:

- A high therapeutic index opioid - ZALVISO uses the high therapeutic index, highly lipophilic opioid sufentanil, enabling delivery via a non-intravenous route, and also supporting fast onset of effect.
- A non-invasive route of delivery - The sublingual route of delivery used by ZALVISO eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections in IV PCA treated patients. In addition, because ZALVISO patients do not require direct connection to an IV PCA infusion pump through IV tubing, ZALVISO allows for ease of patient mobility.

- A simple, pre-programmed PCA solution – ZALVISO is a pre-programmed PCA system designed to eliminate the risk of programming errors.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. AcelRx's lead product candidate, ZALVISO, is designed to solve the problems associated with post-operative intravenous patient-controlled analgesia which has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the complexity of infusion pumps. AcelRx has announced positive results from each of the three Phase 3 clinical trials for ZALVISO and has submitted an NDA to the FDA seeking its approval. AcelRx has also announced positive top-line results for a Phase 2 trial for ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from the U.S. Army Medical Research and Materiel Command. The company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

About Grünenthal

The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. Building on its unique position in pain treatment, its objective is to become the most patient-centric company and thus to be a leader in therapy innovation. Grünenthal is one of the last five remaining research-oriented pharmaceutical companies with headquarters in Germany which sustainably invests in research and development. Research and development costs amounted to about 26 percent of revenues in 2012. Grünenthal's research and development strategy concentrates on selected fields of therapy and state-of-the-art technologies. We are intensely focused on discovering new ways to treat pain better and more effectively, with fewer side-effects than current therapies. Altogether, the Grünenthal Group has affiliates in 26 countries worldwide. Grünenthal products are sold in more than 155 countries. Today, approx. 4,400 employees are working for the Grünenthal Group worldwide. In 2012, Grünenthal achieved revenues of USD 1,251 mn. More information: www.grunenthal.com.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to potential approval of the NDA for Zalviso in the U.S. and the timing thereof, the potential of approval of the MAA for Zalviso in the EU and the timing thereof, the ability to successfully manufacture Zalviso to meet the requirements of Grünenthal and the therapeutic and commercial potential of Zalviso in the Grünenthal territory. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and

uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: AcelRx's ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of AcelRx's product candidates, including Zalviso, in the United States, Europe, Australia and other countries; the ability to attract additional funding partners or collaborators with development, regulatory and commercialization expertise; the ability to obtain sufficient financing to commercialize Zalviso; the market potential for AcelRx's other product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 5, 2013. 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

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