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): July 14, 2021

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.)

25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
(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))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ACRX	The Nasdaq Global Market

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 1.01 Entry Into a Material Definitive Agreement.

Out-License Agreement (DZUVEO®)

On July 14, 2021, AcelRx Pharmaceuticals, Inc. (the "Company") entered into a License and Commercialization Agreement (the "DZUVEO Agreement") with Laboratoire Aguettant, a corporation organized and existing under the laws of France ("Aguettant"), pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican Republic, Monaco, Switzerland and the United Kingdom (the "Territory") for the management of acute moderate to severe pain in adults in medically monitored settings. The Company will supply Aguettant with primary packaged product and Aguettant will then complete secondary packaging of the finished product.

The DZUVEO Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the launch of DZUVEO (or December 31, 2022 if the launch occurs between January 1, 2022 and April 30, 2022). The term will automatically renew for successive five marketing year periods, unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

The Company is entitled to receive up to €47 million in a combination of up-front and sales-based milestone payments. Aguettant will purchase product from the Company at an agreed price ("DZUVEO Purchase Price"), subject to adjustment. Aguettant will also make revenue share payments that, combined with the DZUVEO Purchase Price, range from 35% to 45% of net sales in the Territory.

Beginning in the third marketing year, the parties will establish binding annual minimums for purchase orders to be submitted by Aguettant.

Aguettant has the right to grant sublicenses to its affiliates or, with the prior approval of the Company, third parties, subject to certain limitations.

The DZUVEO Agreement also provides Aguettant with a right of first negotiation for eighteen (18) months before the Company can enter into a collaboration regarding ZALVISO® in Europe.

In-License Agreement

On July 14, 2021, the Company entered into a License and Commercialization Agreement (the "PFS Agreement") with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to U.S. Food and Drug Administration approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine prefilled syringe containing 10 ml of a solution of 50 micrograms/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S.

The PFS Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the first launch of a product (or December 31 of the same calendar year if the first launch of a product occurs between January 1 and April 30 of a calendar year). The term will automatically renew for successive five marketing year periods, unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

Aguettant is entitled to receive up to $24 million in sales-based milestone payments. The Company will purchase each product from Aguettant at an agreed price ("PFS Purchase Price"), subject to adjustment. The Company will also make revenue share payments that, combined with the PFS Purchase Price, will range from 40% to 45% of net sales in the United States.

The Company and Aguettant will agree on minimum sales obligations twelve (12) months prior to the launch of each product.

The Company has the right to grant sublicenses to its affiliates or, with the prior approval of Aguettant, third parties, subject to certain limitations.

The foregoing summary of the DZUVEO Agreement and the PFS Agreement does not purport to be complete and is qualified in its entirety by reference to the DZUVEO Agreement and the PFS Agreement, copies of which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

On July 14, 2021, the Company issued a press release announcing the execution of the DZUVEO Agreement and the PFS Agreement, a copy of which is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 14, 2021

ACELRX PHARMACEUTICALS, INC.
By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

AcelRx Enters into Licensing Agreement for DZUVEO® in Europe and In-licensing Agreement for Two Products in the U.S.

AcelRx to receive up to approximately $55 million in combined up-front and sales-based milestone payments for DZUVEO licensing agreement

AcelRx obtains the rights to file NDAs and commercialize two innovative pre-filled syringe product candidates for the U.S.

HAYWARD, Calif., July 14, 2021 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced agreements with Laboratoire Aguettant (Aguettant) providing Aguettant with a license to commercialize DZUVEO in Europe, and providing AcelRx with two innovative pre-filled syringe product candidates for the U.S.

Under the DZUVEO licensing agreement, Aguettant will have the right to commercialize DZUVEO in Europe. AcelRx is entitled to receive up to approximately $55 million in a combination of up-front and sales-based milestone payments at various annual sales levels from Aguettant, along with revenue share payments ranging from 35% to 45% of net sales. AcelRx will manufacture and supply DZUVEO to Aguettant at an agreed supply price.

Under the terms of a separate licensing agreement, AcelRx obtained the rights to file NDAs, and subject to U.S. Food and Drug Administration approval, commercialize in the United States two of Aguettant's innovative, EU-approved, pre-filled syringe products – ready-to-use ephedrine and phenylephrine. Aguettant has the right to receive up to $24 million in sales-based milestone payments, at various annual sales levels up to $60 million, along with revenue share payments of 40 to 45% of the net sales of the two pre-filled syringe products, if approved in the U.S. by the Food and Drug Administration.

"We are excited to enter into a European collaboration for DZUVEO with Aguettant, a well-known, innovative European pharmaceutical company focused on the acute care space across 70 countries," said Vince Angotti, Chief Executive Officer at AcelRx. "This collaboration provides a strategic fit for DZUVEO given Aguettant's existing product portfolio. Having the ability to commercialize two product candidates in the United States with a track record of success in Europe aligns with our strategy of building a complementary product portfolio to DSUVIA while limiting the cost of development," continued Angotti.

“DZUVEO complements our existing product portfolio and we’re delighted about this strategic opportunity to partner with AcelRx,” said Eric Rougemond, Chief Executive Officer at Laboratoire Aguettant. “Our worldwide presence in the acute care space makes us an ideal European partner for DZUVEO. Partnering with AcelRx to commercialize two of our key acute care products in the U.S. further reinforces our mutual commitment to this strategic partnership.”

The Fulford Group and Karana Biotech provided strategic and transactional advisory services to AcelRx.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only 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. The European Commission approved DZUVEO for marketing in Europe for the management of acute moderate to severe pain in adults in medically monitored settings.

This release is intended for investors only. For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

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 one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

About Laboratoire Aguettant
Aguettant is an independent pharmaceutical company dedicated to the development, manufacturing and distribution of innovative injectable medicines. Aguettant specializes in acute care settings, mainly anaesthesia, critical care and emergency, with a constant focus on redefining drug delivery standards to reduce risk for users and patients. Founded in Lyon, France in 1903, Laboratoire Aguettant has a strong foundation in Europe and is present in 70 countries globally through its affiliates and partners' network. For more information about the company, visit its website: www.aguettant-corporate.com

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the commercial opportunity of AcelRx's agreements with Aguettant, the submission of new drug applications, the potential approval of product candidates by the U.S. Food and Drug Administration, and the ability to successfully manufacture DZUVEO to meet the requirements of Aguettant. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of strategy, plans or intentions may also include forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including, without limitation, risks related to delays in, or AcelRx's inability to obtain, regulatory approval for product candidates, the ability to obtain sufficient financing to commercialize product candidates, and the market potential for product candidates. In addition, such risks and uncertainties may include, but are not limited to, those described in the Company's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. The Company's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, the Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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