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): March 12, 2023

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 Blvd., 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.

Asset Purchase Agreement

On March 12, 2023, AcelRx Pharmaceuticals, Inc., or AcelRx, entered into an Asset Purchase Agreement, or the Purchase Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or the Buyer, pursuant to which Buyer agreed to acquire certain assets and assume certain liabilities of AcelRx relating to its sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. The Product expressly excludes the pharmaceutical product referred to as Zalviso (sufentanil sublingual tablets, each 15 mcg), any other multi-dose administration system containing sufentanil sublingual tablets (whether as the sole active ingredient or in combination with other active ingredients), and any single-dose formulation of sufentanil for use outside of a medically supervised setting. Subject to consummation of the transactions contemplated by the Purchase Agreement, or the Closing, AcelRx will be entitled to receive (a) up to $116.5 million in sales-based milestones, (b) quarterly payments in an amount equal to 15% of net sales based on sales of Product to all customers, other than sales to the United States Department of Defense, or DoD, under the Marketing Agreement (as defined below), pursuant to which the Buyer will pay AcelRx 75% of Product net sales to the DoD, and sales by or on behalf of Laboratoire Aguettant, or Aguettant, and (c) 20% of any consideration, excluding royalty payments based on sales of Product and subject to customary exclusions, received by Buyer or its affiliates in connection with a grant to any third party of a license related to Product or by Buyer or its affiliates or equityholders in connection with a sale or transfer to any third party of ownership interest in any assets acquired by Buyer under the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties, and covenants by each party. Buyer agreed not to, after the Closing, practice, license or otherwise exploit any of the intellectual property rights acquired by it under the Purchase Agreement to manufacture, develop or commercialize any product (other than Product) that is or has been commercialized by AcelRx or its affiliate as of the date of the Purchase Agreement, or any product that is competitive with any such product. In addition, after the Closing, Buyer will use commercially reasonable efforts to maintain regulatory approvals for and commercialize Product in the United States. If the Buyer (together with other relevant parties, taken as a whole) fails to commercialize, sell and distribute Product within the six-month period beginning on July 1, 2023, then all rights granted to Buyer pursuant to the Purchase Agreement will, upon AcelRx's written notice, revert back to AcelRx. The Purchase Agreement also contains indemnification rights for each of AcelRx and Buyer for breaches of representations, warranties, and covenants, as well as certain other matters, subject to certain specified limitations.

The Closing is subject to customary conditions (including, the accuracy of representations and warranties, performance of covenants, and no occurrence of a material adverse effect) and the execution of the Amended DZUVEO Agreement (as defined below) and the Amended and Restated Supply Agreement (as defined below) between AcelRx and Aguettant, as well as certain ancillary agreements between AcelRx and Buyer. Such ancillary agreements include (a) an intellectual property agreement, pursuant to which Buyer will grant fully-paid, royalty-free and perpetual licenses to AcelRx under certain specified intellectual property rights acquired by Buyer under the Purchase Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso, (b) a transition services agreement, pursuant to which, during the period specified therein, AcelRx will be paid to provide certain services (including, manufacturing technology transfer, supply chain, regulatory, and medical affairs services) to Buyer, and distribute, on behalf of Buyer, certain inventory of Product transferred to Buyer under the Purchase Agreement, and (c) a marketing agreement, or the Marketing Agreement, pursuant to which AcelRx will have the exclusive right to market and offer Product for sale to DoD and Buyer will pay to AcelRx 75% of net sales of Product sold to DoD, subject to adjustment in certain circumstances.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

Amendments to Certain Agreements Between AcelRx and Aguettant

AcelRx and Aguettant are parties to (a) the License and Commercialization Agreement, dated July 14, 2021, pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in certain European countries for the management of acute moderate to severe pain in adults in medically monitored settings, or the DZUVEO Agreement, and (b) the supply agreement, dated December 6, 2021, with respect to the manufacture and supply of DZUVEO in form of bulk product by AcelRx to Aguettant, or the Supply Agreement. Pursuant to the Purchase Agreement, as a condition of the Closing, AcelRx and Aguettant will enter into an amendment to the DZUVEO Agreement, or the Amended DZUVEO Agreement, and an amendment and restatement to the Supply Agreement, or the Amended and Restated Supply Agreement, in each case, in a form reasonably acceptable to Buyer.

Pursuant to the Amended DZUVEO Agreement, upon execution thereof, (a) Aguettant's obligations to make sales-based milestone payments and to achieve certain levels of minimum sales will terminate, (b) before Aguettant has established a semi-automated packaging line for Product, AcelRx will manufacture and supply DZUVEO in the form of bulk products (*i.e.*, products that are pre-packaged in labeled pouches and packed in bright stock cartons for shipment) to Aguettant or its affiliates or sublicensees, and Aguettant will be responsible for manufacturing finished products from bulk products, and (c) after Aguettant has established such semi-automated packaging line, AcelRx will cause DZUVEO to be manufactured and supplied in the form of bulk tablets (*i.e.*, products in tablet forms supplied in bulk (not packaged) quantities) to Aguettant or its affiliates or sublicensees, and Aguettant will be responsible for manufacturing finished products from bulk tablets. The Amended and Restated Supply Agreement will govern the manufacture and supply of DZUVEO in the form of bulk products or bulk tablets, and contain customary terms, including those with respect to manufacturing requirements, forecast, delivery, and post-delivery inspection.

Pursuant to the Purchase Agreement, AcelRx will assign the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement to Buyer at the Closing.

In addition, AcelRx and Aguettant are parties to the License and Commercialization Agreement, dated July 14, 2021, pursuant to which AcelRx obtained exclusive rights to develop and commercialize certain ephedrine pre-filled syringe and certain phenylephrine prefilled syringe in the United States, or the PFS Agreement. In connection with AcelRx's and Aguettant's agreement to enter into the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement, the parties will enter into an amendment to the PFS Agreement, or the Amended PFS Agreement, pursuant to which, effective on the later of the Closing and April 1, 2023, (a) Aguettant will pay AcelRx a complementary payment in the amount of EUR 1,500,000, and (b) AcelRx's obligation to make a certain specified sales-milestone payment will terminate.

The foregoing summary of the Amended DZUVEO Agreement, the Amended and Restated Supply Agreement, and the Amended PFS Agreement does not purport to be complete and is qualified in its entirety by reference to the respective agreements, copies of which the Company intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

Item 1.02. Termination of a Material Definitive Agreement.

Termination Agreement and Mutual Release Between AcelRx and Catalent

On March 12, 2023, AcelRx and Catalent Pharma Solutions, LCC, or Catalent, entered into a termination agreement and mutual release, or the Termination Agreement, to terminate the Site Readiness Agreement with an effective date of August 15, 2019 and as amended on September 24, 2020, the SRA Agreement, and the commercial supply agreement with an effective date of March 31, 2021, the CSA Agreement. Pursuant to the Termination Agreement, as of the date on which AcelRx has removed and transported certain equipment from Catalent's site, the SRA Agreement and the CSA Agreement will terminate except with respect to certain specified provisions of such agreements.

The foregoing description of the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Termination Agreement, which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

Item 9.01. Financial Statements and Exhibits.

(b) Pro Forma Financial Information.

The Company intends to file a Current Report on Form 8-K to include the pro forma financial information required as a result of the disposition described in Item 1.01 of this Current Report on Form 8-K within four business days of the Closing.

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: March 16, 2023

ACELRX PHARMACEUTICALS, INC.

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