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): August 10, 2020

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))

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 2.02 Results of Operations and Financial Condition

On August 10, 2020, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended June 30, 2020 (the "Release"). A copy of the Release is furnished herewith as Exhibit 99.1.

The information contained in this Item 2.02 and in Exhibit 99.1 shall be deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated August 10, 2020

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: August 10, 2020

ACELRX PHARMACEUTICALS, INC.

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

Exhibit 99.1

AcelRx Pharmaceuticals Reports Second Quarter 2020 Financial Results

U.S. Army Milestone C approval and exclusive distribution agreement with Zimmer Biomet for dental surgery highlight second quarter and recent achievements

REDWOOD CITY, Calif., August 10, 2020 – 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 reported its second quarter 2020 financial results.

“Despite the challenges with COVID in the second quarter, we made meaningful progress towards generating long-term shareholder value and expanding the DSUVIA launch through advancements with the Department of Defense and our exclusive agreement with Zimmer Biomet for dental surgeries,” said Vince Angotti, Chief Executive Officer of AcelRx. “We expect these two revenue streams, both of which require minimal AcelRx commercial investment, to be the main drivers of our near-term revenue growth. Hospital and ambulatory surgery centers remain the core focus of our commercial team, and we expect recent hospital system wins to positively impact revenues in the mid to long term. We continue to execute on our strategy while focusing on prudent cash management.”

Second Quarter and Recent Highlights

- DSUVIA achieved Milestone C approval from the Department of Defense, a decision that approves DSUVIA for use in all U.S. Army sets, kits and outfits (SKOs). AcelRx expects that initial stocking orders beginning later this year for U.S. Army SKOs alone will approximate $30 million over the next three years, dependent on troop deployment schedules.

- The DoD issued a Notice of Intent, converting to a Request for Proposal (RFP), for the purchase of up to 12,200 boxes or 122,000 DSUVIA units, expected to be ordered in the third quarter of 2020, which is separate from expected purchases for SKOs.

- In July, AcelRx entered into a distribution agreement with Zimmer Biomet to market DSUVIA® (sufentanil sublingual tablet), 30 mcg, within the dental and oral surgery markets in the United States exclusively through Zimmer Biomet's Dental division, expanding U.S. availability of DSUVIA. It is estimated that the applicable market in dental surgeries is over 7 million annual procedures.

- In July, AcelRx completed a $10 million common stock offering priced at the market with two leading life science investors.

Financial Information

- As previously announced:
  - Cash, cash equivalents and short-term investments balance of $43.7 million as of June 30, 2020;
  - Second quarter 2020 net revenues were $2.9 million, of which approximately $2.6 million relates to the recognition of revenue related to the Company's Zalviso® agreement with Grünenthal that was previously deferred;
  - Combined R&D and SG&A expenses for the second quarter of 2020 totaled $8.4 million compared to $12.5 million for the second quarter of 2019. Excluding stock-based compensation expense, these amounts were $7.3 million for the second quarter of 2020 compared to $11.2 million for the second quarter of 2019. R&D and SG&A expenses for the first half of 2020 totaled $23.1 million compared to $23.8 million in the first half of 2019. Excluding stock-based compensation expense, these figures were $20.9 million for the first half of 2020 compared to $21.5 million for the first half of 2019. The decrease in combined R&D and SG&A expenses in the second quarter of 2020 was primarily due to a reduction of $1.9 million in DSUVIA-related commercialization expenses, a $1.7 million reduction in personnel costs, and a net benefit of $0.5 million from the receipt of a breakup fee from Tetraphase, net of expenses incurred related to the transaction in the quarter. See the "Reconciliation of Non-GAAP Financial Measures" table below for a reconciliation of the non-GAAP operating expenses described above to their related GAAP measures.
- For the second quarter of 2020, net loss was $6.6 million, or $0.08 per basic and diluted share, compared to $12.4 million, or $0.16 per basic and diluted share, for the second quarter of 2019. Net loss for the first half of 2020 was $22.5 million, or $0.28 basic and diluted net loss per share, compared to $26.1 million, or $0.33 basic and diluted net loss per share, for the prior year period.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, August 10, 2020 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is accessible by visiting the Investors page of AcelRx's website at www.acelrx.com and clicking on the webcast link. The webcast will be accompanied by a slide presentation. Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor page of AcelRx's website at www.acelrx.com.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO™ in Europe, approved by the FDA in November 2018, 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 in June 2018 and AcelRx is currently in discussions with potential European marketing partners.

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. AcelRx 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.

Non-GAAP Financial Measures
To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), AcelRx uses certain non-GAAP financial measures in this press release, in particular, excluding stock-based compensation expense from its operating expenses. AcelRx believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, AcelRx believes that these non-GAAP financial measures, when considered together with AcelRx's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare AcelRx's results from period to period and to its forward-looking guidance. In addition, these types of non-GAAP financial measures are regularly used by investors and analysts to model and track AcelRx's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate AcelRx's business and to make operating decisions. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with AcelRx's consolidated financial statements prepared in accordance with GAAP. The non-GAAP financial measures in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to near-term revenue drivers, the expected impact of recent hospital system wins on revenue and the timing of such impact, the timing and size of military orders and the ongoing effects of the COVID-19 pandemic and its anticipated impacts on AcelRx's business. 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 financial trends, 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 the risk that the military and hospital systems delay, or fail to place, orders, that AcelRx may not experience the expected benefits from the Zimmer Biomet commercial opportunity or that the impacts AcelRx is experiencing from the ongoing COVID-19 pandemic may be prolonged or exacerbated. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described in AcelRx'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. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx 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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Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30		Six Months Ended June 30	
	2020	2019	2020	2019
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 303	$ 768	$ 577	$ 894
Contract and other collaboration	2,621	173	2,733	312
Total revenue	2,924	941	3,310	1,206
Operating costs and expenses:				
Cost of goods sold (1)	1,370	1,810	2,881	3,040
Research and development (1)	813	1,163	2,225	2,540
Selling, general and administrative (1)	7,575	11,329	20,886	21,305
Total operating costs and expenses	9,758	14,302	25,992	26,885
Loss from operations	(6,834)	(13,361)	(22,682)	(25,679)
Other income (expense):				
Interest expense	(872)	(500)	(1,727)	(876)
Interest income and other income (expense), net	270	456	205	1,083
Non-cash interest income (expense) on liability related to sale of future royalties	834	996	1,677	(611)
Total other income (expense)	232	952	155	(404)
Provision for income taxes	(4)	(3)	(4)	(3)
Net loss	$ (6,606)	$ (12,412)	$ (22,531)	$ (26,086)
Basic and diluted net loss per common share	$ (0.08)	$ (0.16)	$ (0.28)	$ (0.33)
Shares used in computing basic and diluted net loss per common share	80,662	78,902	80,360	78,846

(1) Includes the following non-cash, stock-based compensation expense:

Cost of goods sold	$ 27	$ 68	$ 73	$ 129
Research and development	184	233	384	457
Selling, general and administrative	879	1,045	1,779	1,867
Total	$ 1,090	$ 1,346	$ 2,236	$ 2,453

	June 30, 2020	December 31, 2019
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 43,686	$ 66,137
Total assets	67,400	91,356
Total liabilities	127,532	132,774
Total stockholders' (deficit) equity	(60,132)	(41,418)

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less associated stock-based compensation expense)

	Three Months Ended June 30		Six Months Ended June 30	
	2020	**2019**	**2019**	**2018**
Operating expenses (GAAP):				
Research and development	$ 813	$ 1,163	$ 2,225	$ 2,540
Selling, general and administrative	7,575	11,329	20,886	21,305
Total operating expenses	8,388	12,492	23,111	23,845
Less associated stock-based compensation expense	1,063	1,278	2,163	2,324
Operating expenses (non-GAAP)	$ 7,325	$ 11,214	$ 20,948	$ 21,521