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): November 5, 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 November 5, 2020, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 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 November 5, 2020
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: November 5, 2020

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

AcelRx Pharmaceuticals Reports Third Quarter 2020 Financial Results

Third quarter product sales of $1.3M, up significantly compared to $0.3M in the second quarter

The Zimmer Biomet collaboration, addition of DSUVIA® to the U.S. Department of Defense Joint Deployment Formulary and the U.S. Army contract highlight third quarter achievements and growth opportunities

REDWOOD CITY, Calif., November 5, 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 third quarter 2020 financial results.

“The third quarter represented one of our most active and successful quarters since DSUVIA’s approval,” said Vince Angotti, Chief Executive Officer of AcelRx. “We’ve made significant progress on our revenue growth strategy, highlighted by our oral and dental surgery collaboration with Zimmer Biomet, the addition of DSUVIA to the Department of Defense Joint Deployment Formulary and our new U.S. Army contract. With the recent publication of data supporting DSUVIA’s strong value proposition, we have gained momentum in DSUVIA’s use within existing hospital and ambulatory surgery center customers, and the rate of scheduled formulary reviews. Progress within the Department of Defense continues and we expect the initial ordering of DSUVIA for deployed troops in the fourth quarter.”

Third Quarter Highlights

- In July, AcelRx entered into a distribution agreement with Zimmer Biomet to market DSUVIA 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.

- In August, AcelRx announced the publication of a study entitled "Reduced Opioid Use and Reduced Time in the Postanesthesia Care Unit Following Preoperative Administration of Sublingual Sufentanil in an Ambulatory Surgery Setting," by Christian Tvetenstrand, MD and Michael Wolff, MD, in the Journal of Clinical Anesthesia and Pain Management. Highlights of the publication included a greater than 50% overall reduction in opioids administered perioperatively and a 34% reduction in PACU time in the DSUVIA-treated patients compared to historical controls.

- In August, AcelRx announced an investigator-initiated study with Cleveland Clinic that will assess the effects of DSUVIA on post-operative recovery from orthopedic surgery.

- In September, AcelRx announced that the U.S. military's access to DSUVIA had been expanded with the addition of DSUVIA to the Department of Defense Joint Deployment Formulary (JDF).

- In September, the U.S. Army awarded AcelRx with an initial contract of up to $3.6 million over four years for the purchase of DSUVIA to support a DoD study to aid the development of clinical practice guidelines.

Financial Information

- Cash, cash equivalents and short-term investments balance was $43.0 million as of September 30, 2020.

- Net revenues for the third quarter 2020 were $1.4 million, of which approximately $1.3 million relates to product sales (compared to $0.3 million in product sales for the second quarter of 2020).

- Combined R&D and SG&A expenses for the third quarter of 2020 totaled $8.6 million, a significant reduction compared to $12.0 million for the third quarter of 2019. Excluding stock-based compensation expense, these amounts were $7.5 million for the third quarter of 2020 compared to $10.7 million for the third quarter of 2019. The decrease in combined R&D and SG&A expenses in the third quarter of 2020 was primarily due to a reduction of $1.8 million in personnel costs and a $1.1 million reduction in DSUVIA-related commercialization expenses.

- Net loss for the third quarter of 2020 was $8.9 million, or $0.10 per basic and diluted share, compared to $12.7 million, or $0.16 per basic and diluted share, for the third quarter of 2019.

Webcast and Conference Call Information

As previously announced, AcelRx will host a live webcast Thursday, November 5, 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. 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

Forward-Looking and Cautionary Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the timing and size of military orders, the market for DSUVIA in dental and oral surgeries, the expected commencement of an investigator-initiated study and the scope of the study. 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 and the uncertainties inherent in the initiation, execution and completion of investigator-initiated studies. 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.

Limitations of the published study referenced above include that it was an open-label study, the retrospective nature of the control group, and the focus on only general surgery patients.

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Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	**2019**	**2020**	**2019**
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 1,287	$ 559	$ 1,864	$ 1,453
Contract and other collaboration	81	49	2,814	361
Total revenue	1,368	608	4,678	1,814
Operating costs and expenses:				
Cost of goods sold (1)	1,851	2,148	4,732	5,188
Research and development (1)	956	1,058	3,181	3,598
Selling, general and administrative (1)	7,598	10,936	28,484	32,241
Total operating costs and expenses	10,405	14,142	36,397	41,027
Loss from operations	(9,037)	(13,534)	(31,719)	(39,213)
Other income (expense):				
Interest expense	(824)	(828)	(2,551)	(1,704)
Interest income and other income (expense), net	106	645	311	1,728
Non-cash interest income (expense) on liability related to sale of future royalties	825	986	2,502	375
Total other income (expense)	107	803	262	399
Provision for income taxes	-	-	(4)	(3)
Net loss	$ (8,930)	$ (12,731)	$ (31,461)	$ (38,817)
Basic and diluted net loss per common share	$ (0.10)	$ (0.16)	$ (0.38)	$ (0.49)
Shares used in computing basic and diluted net loss per common share	87,913	79,461	82,896	79,053

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

Cost of goods sold	$ 25	$ 68	$ 98	$ 197
Research and development	188	242	572	699
Selling, general and administrative	891	1,016	2,670	2,883
Total	$ 1,104	$ 1,326	$ 3,340	$ 3,779

	September 30, 2020	**December 31, 2019**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 43,023	$ 66,137
Total assets	66,179	91,356
Total liabilities	124,032	132,774
Total stockholders' (deficit) equity	(57,853)	(41,418)

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	**2019**	**2020**	**2019**
Operating expenses (GAAP):				
Research and development	$ 956	$ 1,058	$ 3,181	$ 3,598
Selling, general and administrative	7,598	10,936	28,484	32,241
Total operating expenses	8,554	11,994	31,665	35,839
Less associated stock-based compensation expense	1,079	1,258	3,242	3,582
Operating expenses (non-GAAP)	$ 7,475	$ 10,736	$ 28,423	$ 32,257