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 16, 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 March 16, 2020, AcelRx Pharmaceuticals, Inc. (the "*Company*") issued a press release announcing its financial results for the three and twelve months ended December 31, 2019 (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

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated March 16, 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: March 16, 2020

ACELRX PHARMACEUTICALS, INC.

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

AcelRx Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

Exceeds 2019 metrics with 166 REMS-certified facilities and 148 formulary approvals through December 31, greater than the year-end goals of 125 for each

Reiterates year-end 2020 REMS-certified facilities and formulary approval goals of 465

223 formulary approvals and 218 REMS-certified facilities as of March 15

$66.1 million of cash and short-term investments at December 31, 2019

REDWOOD CITY, Calif., March 16, 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 fourth quarter and full year 2019 financial results.

“After only two quarters in 2019 with an expanded sales team, exceeding last year’s formulary and REMS objectives is a solid indicator of the growing acceptance of DSUVIA® as a treatment option for the management of acute pain. We fully expect DSUVIA’s success to continue and look forward to the Department of Defense’s Milestone C meeting, which we believe will provide even more opportunities,” continued Angotti. “I’m also excited about the announcement earlier today related to our acquisition of Tetraphase Pharmaceuticals, Inc., which will add a key, high growth product to the portfolio, enhancing our offering to healthcare institutions, while increasing the productivity of the commercial teams.”

Fourth Quarter and Recent Highlights

- Announced an agreement to acquire Tetraphase Pharmaceuticals in a stock for stock transaction at an exchange ratio of 0.6303 shares of AcelRx for each share of Tetraphase, valuing Tetraphase at $14.4 million as of the close of trading on March 13, 2020. Also entered into a co-promotion agreement to immediately begin realizing commercial combination benefits prior to closing of the acquisition.

- The Company is on track to achieve its previously communicated target of 465 REMS-certified facilities and formulary approvals by the end of 2020. As of March 15, 2020, 218 healthcare facilities are now REMS-certified and able to purchase DSUVIA and 223 formulary approvals have been achieved.

- Confirmed timing for April 2020 DSUVIA Milestone C meeting with the Department of Defense, with procurement recommendation expected post-meeting.

- Announced an agreement with Brigham and Women’s Hospital for an investigator-initiated study led by Richard D. Urman MD, MBA, Associate Professor of Anesthesia and co-director of the Center for Perioperative Research at Brigham and Women’s Hospital and Harvard Medical School. The study plans to examine the perioperative use of DSUVIA in the analgesic regimen for spine surgery.

Financial Information

- Cash, cash equivalents and short-term investments balance of $66.1 million as of December 31, 2019;

- Fourth quarter 2019 net revenues were $0.5 million, and for the full year 2019 were $2.3 million, as previously announced;

- Combined R&D and SG&A expenses for the fourth quarter of 2019 totaled $13.8 million compared to $10.4 million for the fourth quarter of 2018. Excluding stock-based compensation expense, these amounts were $12.6 million for the fourth quarter of 2019 compared to $9.2 million for the fourth quarter of 2018. R&D and SG&A expenses for the year ended December 31, 2019 totaled $49.7 million compared to $33.9 million for the year ended December 31, 2018. Excluding stock-based compensation expense, these figures were $44.9 million for the year ended December 31, 2019 compared to $29.1 million for the year ended December 31, 2018. The increase in combined R&D and SG&A expenses is primarily due to increased personnel-related expenses for the commercial launch of DSUVIA. 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;

- Net cash outflow for the fourth quarter of 2019 was $14.3 million, including $0.6 million in debt service, and for the year-ended December 31, 2019 was $39.6 million, and;

- For the fourth quarter of 2019, net loss was $14.4 million, or $0.18 per basic and diluted share, compared to $12.6 million, or $0.18 per basic and diluted share, for the fourth quarter of 2018. Net loss for the year ended December 31, 2019 was $53.2 million, or $0.67 per basic and diluted share, compared to $47.1 million, or $0.81 per basic and diluted share, for the year ended December 31, 2018.

2020 Guidance

As previously announced, the Company’s year-end goals include obtaining 465 REMS-certified facilities and 465 formulary approvals in 2020. Quarterly combined R&D and SG&A expense in 2020 is expected to range from $10 million to $13 million, depending on the quarter, and includes approximately $1 million of non-cash stock-based compensation per quarter ($9 million to $12 million excluding stock-based compensation expense). Annual debt service is expected to approximate $6 million. Annual capital expenditures are expected to range from $4-$5 million attributed mainly to the installation of a new high-volume, automated packaging line at our contract manufacturer. These amounts do not consider the impact from the previously announced acquisition of Tetraphase Pharmaceuticals but reflect the benefits of the co-promotion agreement.

2020 financial guidance is based on the Company's current expectations and are forward-looking statements. Actual results could differ materially depending on market conditions and the factors set forth under the "Forward-Looking Statements" heading below.

Webcast and Conference Call Information

As previously announced, AcelRx will host a live webcast Monday, March 16, 2020 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is accessible by visiting the Investors page of the Company'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 the Company'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 the Company is currently in discussions with potential European marketing partners.

For more information, 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.

Non-GAAP Financial Measures
To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the Company uses certain non-GAAP financial measures in this press release, in particular, excluding stock-based compensation expense from its operating expenses. The Company believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, the Company believes that these non-GAAP financial measures, when considered together with the Company's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare the Company'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 the Company's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate the Company'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 the number of REMS-certified facilities and formulary approvals expected by the end of 2020, the timing of the Department of Defense Milestone C meeting and procurement of DSUVIA by the military, opportunities that may result from the Milestone C meeting, the continuing success of DSUVIA, expected commencement of an investigator-initiated study, expected R&D and SG&A expenses, debt service and capital expenditures, expected benefits from the acquisition of Tetraphase and the co-promotion agreement, and the acquisition being consummated. 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. 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 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. 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 the Company's most recent annual, quarterly or current report as filed or furnished with the SEC. 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.

Media Contacts:
Theresa Dolge, Evoke
215-928-2748
theresa.dolge@evokegroup.com

Jessica Ross, Evoke
215-928-2346
jessica.ross@evokegroup.com

Investor Contacts:
Raffi Asadorian, CFO, AcelRx
investors@acelrx.com

Brian Korb, Solebury Trout
646-378-2923
investors@acelrx.com

###

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

	Three Months Ended December 31		Twelve Months Ended December 31	
	2019	2018	2019	2018
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 377	$ 390	$ 1,830	$ 825
Contract and other collaboration	98	223	459	1,326
Total revenue	475	613	2,289	2,151
Operating costs and expenses:				
Cost of goods sold (1)	1,618	1,238	6,806	3,976
Research and development (1)	1,063	2,704	4,661	13,137
Selling, general and administrative (1)	12,786	7,648	45,027	20,765
Total operating costs and expenses	15,467	11,590	56,494	37,878
Loss from operations	(14,992)	(10,977)	(54,205)	(35,727)
Other income (expense):				
Interest expense	(831)	(459)	(2,535)	(2,217)
Interest income and other income (expense), net	438	495	2,166	1,138
Non-cash interest income (expense) on liability related to sale of future royalties	962	(1,617)	1,337	(10,341)
Total other income (expense)	569	(1,581)	968	(11,420)
Provision for income taxes	-	-	(3)	(2)
Net loss	$ (14,423)	$ (12,558)	$ (53,240)	$ (47,149)
Basic and diluted net loss per common share	$ (0.18)	$ (0.18)	$ (0.67)	$ (0.81)
Shares used in computing basic and diluted net loss per common share	79,573	70,623	79,184	58,409
(1) Includes the following non-cash, stock-based compensation expense:				
Cost of goods sold	$ 63	$ 78	$ 260	$ 358
Research and development	221	392	920	1,970
Selling, general and administrative	994	762	3,877	2,840
Total	$ 1,278	$ 1,232	$ 5,057	$ 5,168

	December 31, 2019	December 31, 2018
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 66,137	$ 105,715
Total assets	91,356	120,533
Total liabilities	132,774	116,280
Total stockholders' (deficit) equity	(41,418)	4,253

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

	Three Months Ended December 31, 2019		Twelve Months Ended December 31, 2019	
	2019	**2018**	**2019**	**2018**
Operating expenses (GAAP):				
Research and development	$ 1,063	$ 2,704	$ 4,661	$ 13,137
Selling, general and administrative	12,786	7,648	45,027	20,765
Total operating expenses	13,849	10,352	49,688	33,902
Less associated stock-based compensation expense	1,215	1,154	4,797	4,810
Operating expenses (non-GAAP)	$ 12,634	$ 9,198	$ 44,891	$ 29,092