**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 7, 2019**

# 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))

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 7, 2019, AcelRx Pharmaceuticals, Inc. (the "*Company*"), issued a press release entitled "AcelRx Pharmaceuticals Announces Commercial Launch of DSUVIA and Reports Fourth Quarter and Full Year 2018 Financial Results" regarding its financial results for the fourth quarter and year ended December 31, 2018, a business update and certain other information. The full text of the press release concerning the foregoing is furnished herewith as Exhibit 99.1.

The information contained in this Item 2.02 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 to this Current Report shall not be incorporated by reference into any filing with the Securities and Exchange Commission (the *"SEC"*) 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.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated March 7, 2019 entitled "AcelRx Pharmaceuticals Announces Commercial Launch of DSUVIA and Reports Fourth Quarter and Full Year 2018 Financial Results" |

**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 7, 2019

ACELRX PHARMACEUTICALS, INC.

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

**Exhibit 99.1**


# AcelRx Pharmaceuticals Announces Commercial Launch of DSUVIA and Reports Fourth Quarter and Full Year 2018 Financial Results

- *DSUVIA now available for use in certified medically supervised healthcare settings, with initial shipments to wholesalers completed in the second half of February 2019*
- *Executed contracts with Group Purchasing Organizations (GPOs) covering approximately 80% of commercial launch targets*
- *Cash, cash equivalents and short-term investments of $105.7 million as of December 31, 2018*

REDWOOD CITY, Calif., March 7, 2019 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, today provided a business update and reported its fourth quarter and full year 2018 financial results.

"This past year was a tremendous success for the Company, highlighted by the FDA approval of DSUVIA in the U.S., followed by our staged launch last month," said Vince Angotti, Chief Executive Officer of AcelRx. "Our recent efforts with the wholesalers and GPOs have laid the foundation for DSUVIA's use in certified medically supervised healthcare settings. While the launch is only one month old, we are pleased with the initial response by healthcare professionals to DSUVIA as an effective and efficient new option for the management of acute pain in these settings," continued Angotti.

**Fourth Quarter and Recent Highlights**

- Following the positive recommendation from the FDA advisory committee in October 2018, the FDA approved DSUVIA in November 2018 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.

- AcelRx now has 14 Orange Book listed patents with exclusivity dates ranging from 2027 through 2031.

- The staged DSUVIA launch was initiated with fifteen hospital account managers hired, trained and placed in the field beginning in second half of January 2019.

- Commercial launch of DSUVIA with initial contracted wholesaler orders received and shipped in the second half of February, as planned.

- Contracts executed with GPO targets covering approximately 80% of the hospital customers included in the DSUVIA initial launch markets.

**Financial Information**

- Cash, cash equivalents and short-term investments balance of $105.7 million as of December 31, 2018;

- Combined R&D and G&A expenses for the fourth quarter 2018 totaled $10.4 million compared to $7.6 million for the prior year period. Excluding stock-based compensation expense, these amounts were $9.2 million for the fourth quarter of 2018 compared to $6.6 million for the prior year period. The increase in R&D and G&A expenses is primarily due to increased personnel-related expenses in preparation for the commercial launch of DSUVIA. R&D and G&A expenses for the year ended December 31, 2018 totaled $33.9 million compared to $36.0 million in the year ended December 31, 2017. Excluding stock-based compensation expense, these amounts were $29.1 million for 2018 compared to $32.0 million for the prior year. The decrease in R&D and G&A expenses is primarily due to lower Zalviso-related expenses attributed to the Phase 3 clinical program completed in 2017, partially offset by increased personnel-related expenses in preparation 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;

- Excluding $53.4 million in net proceeds raised from the issuance of equity, the Company used $11.3 million in cash, including $2.3 million in debt service, during the quarter ended December 31, 2018; and

- For the fourth quarter of 2018, net loss was $12.6 million, or $0.18 per basic and diluted share, compared to $9.9 million, or $0.20 per basic and diluted share, for the fourth quarter of 2017. Net loss for the year ended December 31, 2018 was $47.1 million, or $0.81 basic and diluted net loss per share, compared to $51.5 million, or $1.10 basic and diluted net loss per share, for the prior year.

**2019 Guidance**

Based on the initial month of experience in the field with its commercial team, the Company is increasing its expected number of formulary approval wins by the end of 2019 to 125, up from the previous guidance of 100. In addition, the Company plans to accelerate the hiring of the next stage of 25 hospital account managers to the third quarter from the fourth quarter to better cover the initial indications of interest in DSUVIA by hospitals. Quarterly combined R&D and SG&A expense in 2019 is expected to range from $15 million to $18 million, depending on the quarter, which includes approximately $2 million of non-cash stock-based compensation per quarter. Annual debt service is expected to approximate $9 million. Annual capital expenditures are expected to range from $5-$7 million attributed mainly to the installation of a new high-volume, automated packaging line at our contract manufacturer.

2019 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 "Safe Harbor Statement" below.

**Conference Call and Webcast Information**
As previously announced, AcelRx will conduct an investment-community conference call Thursday, March 7, 2019 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates. 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. Those interested in listening to a webcast of the conference call live via the Internet may do so by visiting the Company's website at www.acelrx.com and clicking on the webcast link on the Investors home page. The webcast will be archived on the AcelRx website for 90 days following the call.

**About DSUVIA (sufentanil sublingual tablet), 30 mcg**
DSUVIA™, known as DZUVEO™ outside the United States, approved by the FDA in November 2018, is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain in adult patients 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 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 currently marketed for intravenous (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 Medicines Agency (EMA) 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) 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 this non-GAAP financial measure provides useful supplementary information to, and facilitates additional analysis by, investors and analysts. In particular, the Company believes that this non-GAAP financial measure, 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, this type of non-GAAP financial measure is regularly used by investors and analysts to model and track the Company's financial performance. AcelRx's management also regularly uses this non-GAAP financial measure 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 anticipated commercial growth of DSUVIA in the United States, and 2019 guidance regarding potential acceleration of sales force growth, formulary approvals, quarterly operating expenses and stock-based compensation expense, annual debt service and annual capital expenditures, . 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.*


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

| | Three Months Ended December 31 | | Twelve Months Ended December 31 | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| **Statement of Comprehensive Loss Data** | | | | |
| Revenue: | | | | |
| Collaboration agreement revenue | $ 511 | $ 699 | $ 1,313 | $ 7,143 |
| Contract and other revenue | 102 | 41 | 838 | 852 |
| Total revenue | 613 | 740 | 2,151 | 7,995 |
| | | | | |
| Operating costs and expenses: | | | | |
| Cost of goods sold [1] | 1,238 | 962 | 3,976 | 10,659 |
| Research and development [1] | 2,704 | 3,676 | 13,137 | 19,409 |
| General and administrative [1] | 7,648 | 3,909 | 20,765 | 16,609 |
| Total operating costs and expenses | 11,590 | 8,547 | 37,878 | 46,677 |
| Loss from operations | (10,977) | (7,807) | (35,727) | (38,682) |
| | | | | |
| Other (expense) income: | | | | |
| Interest expense | (459) | (720) | (2,217) | (3,316) |
| Interest income and other income (expense), net | 495 | 725 | 1,138 | 510 |
| Non-cash interest expense on liability related to sale of future royalties | (1,617) | (2,786) | (10,341) | (10,721) |
| Total other expense | (1,581) | (2,781) | (11,420) | (13,527) |
| (Benefit) provision for income taxes | - | (703) | 2 | (701) |
| Net loss | $ (12,558) | $ (9,885) | $ (47,149) | $ (51,508) |
| | | | | |
| Basic and diluted net loss per common share | $ (0.18) | $ (0.20) | $ (0.81) | $ (1.10) |
| | | | | |
| Shares used in computing basic and diluted net loss per common share | 70,623 | 50,391 | 58,409 | 46,884 |
| | | | | |
| (1) Includes the following non-cash, stock-based compensation expense: | | | | |
| Cost of goods sold | $ 78 | $ 80 | $ 358 | $ 324 |
| Research and development | 392 | 459 | 1,970 | 1,901 |
| General and administrative | 762 | 514 | 2,840 | 2,069 |
| Total | $ 1,232 | $ 1,053 | $ 5,168 | $ 4,294 |

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Selected Balance Sheet Data** | | |
| Cash, cash equivalents and investments | $ 105,715 | $ 60,469 |
| Total assets | 120,533 | 75,552 |
| Total liabilities | 116,280 | 112,061 |
| Total stockholders' equity (deficit) | 4,253 | (36,509) |

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

| | Three Months Ended December 31 | | Twelve Months Ended December 31 | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Operating expenses (GAAP): | | | | |
| Research and development | $ 2,704 | $ 3,676 | $ 13,137 | $ 19,409 |
| General and administrative | 7,648 | 3,909 | 20,765 | 16,609 |
| Total operating expenses | 10,352 | 7,585 | 33,902 | 36,018 |
| *Less associated stock-based compensation expense* | 1,154 | 973 | 4,810 | 3,970 |
| *Operating expenses (non-GAAP)* | $ 9,198 | $ 6,612 | $ 29,092 | $ 32,048 |