

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 2, 2018

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State of incorporation)

001-35068

(Commission File No.)

41-2193603

(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 November 2, 2018, AcelRx Pharmaceuticals, Inc. (the “Company”), issued a press release entitled “AcelRx Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update” regarding its financial results for the third quarter ended September 30, 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	<u>Press Release dated November 2, 2018 entitled “AcelRx Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update”</u>

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 2, 2018

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian

Raffi Asadorian
Chief Financial Officer



AcelRx Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

- *FDA approved DSUVIA™ for use in adults in a certified medically supervised healthcare setting for the management of acute pain*
- *September 30, 2018 cash, cash equivalents and short-term investments balance of \$63.6 million*
- *Combined R&D and G&A expenses declined 17% from YTD 2017*

REDWOOD CITY, Calif., November 2, 2018 – 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 third quarter 2018 financial results.

“The FDA’s previously announced approval of DSUVIA is a notable achievement for all AcelRx stakeholders, which we anticipate will lead to improved care for patients in acute pain,” said Vince Angotti, Chief Executive Officer of AcelRx. “Our third-quarter results demonstrate sustained discipline in our financial management, which we expect to continue as we plan for the commercial launch of DSUVIA, targeted for the first quarter of next year,” continued Angotti.

Third Quarter and Recent Highlights

- In the third quarter, the Company completed an underwritten public offering of 8,363,636 shares of common stock for approximately \$21.7 million of net proceeds after deducting underwriting discounts and commissions and other offering expenses.
 - On October 12, 2018, the Anesthetic and Analgesic Drug Products Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 10-3 in favor of recommending the approval of DSUVIA™.
 - On November 2, 2018, the FDA approved the New Drug Application (NDA) for DSUVIA for use in adults in a certified medically supervised healthcare setting for the management of acute pain.
 - Analyst and investor day planned for December 11, 2018.
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Financial Information

- September 30, 2018 cash, cash equivalents and short-term investments balance of \$63.6 million;
- R&D and G&A expenses for the quarter ended September 30, 2018 totaled \$8.8 million compared to \$8.3 million for the prior year period. Excluding stock-based compensation expense, these figures were \$7.1 million for the third quarter of 2018 compared to \$7.4 million for the prior year period. R&D and G&A expenses for the first nine months of 2018 totaled \$23.6 million compared to \$28.4 million in the first nine months of 2017. Excluding stock-based compensation expense, these figures were \$19.9 million for the first nine months of 2018 compared to \$25.4 million for the prior year period. The decrease in R&D and G&A expenses in both periods is primarily due to lower Zalviso-related expenses attributed to the Phase 3 clinical program completed in 2017. 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 the net proceeds from the public equity offering of \$21.7 million, net cash use during the third quarter 2018 was \$8.2 million, which included \$2.3 million of debt service; and
- For the third quarter of 2018 net loss was \$12.5 million, or \$0.21 per basic and diluted share, compared to \$13.0 million, or \$0.28 per basic and diluted share, for the third quarter of 2017. Net loss for the first nine months of 2018 was \$34.6 million, or \$0.64 basic and diluted net loss per share, compared to \$41.6 million, or \$0.91 basic and diluted net loss per share, for the prior year period.

Conference Call and Webcast Information

As previously announced, AcclRx will conduct an investment-community conference call Monday, November 5, 2018 at 8:30 a.m. Eastern Time (5:30 a.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.acclrx.com and clicking on the webcast link on the Investors home page. The webcast will be archived on the AcclRx 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.

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.acerlx.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 the expected timing of a commercial launch of DSUVIA in the United States, as well as the Company's expected financial discipline as it continues preparation for commercial launch. 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		Nine Months Ended	
	September 30		September 30	
	2018	2017	2018	2017
Statement of Comprehensive Loss Data				
Revenue:				
Collaboration agreement revenue	\$ 177	\$ 1,225	\$ 802	\$ 6,444
Contract and other revenue	200	262	736	811
Total revenue	<u>377</u>	<u>1,487</u>	<u>1,538</u>	<u>7,255</u>
Operating costs and expenses:				
Cost of goods sold ⁽¹⁾	875	2,029	2,738	9,697
Research and development ⁽¹⁾	3,642	3,913	10,433	15,733
General and administrative ⁽¹⁾	5,188	4,406	13,117	12,700
Total operating costs and expenses	<u>9,705</u>	<u>10,348</u>	<u>26,288</u>	<u>38,130</u>
Loss from operations	<u>(9,328)</u>	<u>(8,861)</u>	<u>(24,750)</u>	<u>(30,875)</u>
Other (expense) income:				
Interest expense	(529)	(919)	(1,758)	(2,596)
Interest income and other income (expense), net	312	(465)	643	(215)
Non-cash interest expense on liability related to sale of future royalties	(2,913)	(2,768)	(8,724)	(7,935)
Total other expense	<u>(3,130)</u>	<u>(4,152)</u>	<u>(9,839)</u>	<u>(10,746)</u>
Provision for income taxes	-	-	(2)	(2)
Net loss	<u>\$ (12,458)</u>	<u>\$ (13,013)</u>	<u>\$ (34,591)</u>	<u>\$ (41,623)</u>
Basic and diluted net loss per common share	<u>\$ (0.21)</u>	<u>\$ (0.28)</u>	<u>\$ (0.64)</u>	<u>\$ (0.91)</u>
Shares used in computing basic and diluted net loss per common share	<u>60,004</u>	<u>46,365</u>	<u>54,292</u>	<u>45,701</u>

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

Cost of goods sold	\$ 119	\$ 80	\$ 280	\$ 243
Research and development	769	458	1,578	1,442
General and administrative	920	480	2,078	1,555
Total	<u>\$ 1,808</u>	<u>\$ 1,018</u>	<u>\$ 3,936</u>	<u>\$ 3,240</u>

	September 30, 2018	December 31, 2017
Selected Balance Sheet Data		
Cash, cash equivalents and investments	\$ 63,561	\$ 60,469
Total assets	77,744	75,552
Total liabilities	115,531	112,061
Total stockholders' deficit	(37,787)	(36,509)

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Operating expenses (GAAP):				
Research and development	\$ 3,642	\$ 3,913	\$ 10,433	\$ 15,733
General and administrative	5,188	4,406	13,117	12,700
Total operating expenses	8,830	8,319	23,550	28,433
<i>Less associated stock-based compensation expense</i>	1,689	938	3,656	2,997
<i>Operating expenses (non-GAAP)</i>	<u>\$ 7,141</u>	<u>\$ 7,381</u>	<u>\$ 19,894</u>	<u>\$ 25,436</u>