

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 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 August 2, 2018, AcelRx Pharmaceuticals, Inc. (the “*Company*”), issued a press release regarding its financial results for the second quarter ended June 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 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 August 2, 2018.

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 2, 2018

ACELRX PHARMACEUTICALS, INC.

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



AcelRx Pharmaceuticals Reports Second Quarter 2018 Financial Results

- *European Commission approved DZUVEO (sufentanil sublingual tablet, 30 mcg) for the management of acute moderate-to-severe pain in adults in medically monitored settings*
- *June 30, 2018 cash and short-term investments balance of \$50.1 million*
- *Combined R&D and G&A expenses declined 27% from H1 2017*

REDWOOD CITY, Calif., August 2, 2018 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, today reported its second quarter 2018 financial results.

“The first half of the year has been productive on all fronts as we have accomplished all the milestones we established for the period. We’re very focused on reaching our remaining milestones for the year and, if DSUVIA is approved in November, eager to start commercializing our first U.S. product in Q1 2019,” said Vince Angotti, Chief Executive Officer of AcelRx. “We continue to believe we have a unique product for the management of moderate to severe acute pain that can fulfill an unmet need within appropriate healthcare settings. We look forward to continued dialogue with the FDA during the coming months to achieve these objectives,” continued Angotti.

Recent Highlights

- The U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for DSUVIA in May.
 - Received approval from the European Commission for DZUVEO™ for the management of acute moderate-to-severe pain in medically monitored settings.
 - Completed an underwritten public offering of 7,272,727 shares of common stock, at a price of \$2.75 per share to the public with estimated net proceeds to the company of \$18.7 million.
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Financial Information

- June 30, 2018 cash and short-term investment balance of \$50.1 million;
- R&D and G&A expenses for the quarter ended June 30, 2018 totaled \$7.2 million compared to \$9.1 million for the prior year period. Excluding stock-based compensation expense, these figures were \$6.2 million for the second quarter of 2018 compared to \$8.1 million for the prior year period. R&D and G&A expenses for the first half of 2018 totaled \$14.7 million compared to \$20.1 million in the first half of 2017. Excluding stock-based compensation expense, these figures were \$12.8 million for the first half of 2018 compared to \$18.1 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;
- Net cash use during the second quarter 2018 was \$8.5 million excluding proceeds from ATM facility, included \$2.3 million of debt service; and
- For the second quarter of 2018 net loss was \$10.5 million, or \$0.20 per basic and diluted share, compared to \$13.1 million, or \$0.29 per basic and diluted share, for the second quarter of 2017. Net loss for the first half of 2018 was \$22.1 million, or \$0.43 basic and diluted net loss per share, compared to \$28.6 million, or \$0.63 basic and diluted net loss per share, for the prior year period.

2018 Remaining Milestones

- Expected FDA advisory committee meeting for DSUVIA in late Q3/early Q4 2018;
- Prescription Drug User Fee Act, PDUFA, date for DSUVIA on November 3, 2018; and
- Anticipated resubmission of NDA for Zalviso in Q4 2018.

Conference Call and Webcast Information

As previously announced, AcclRx will conduct an investment-community conference call today, August 2, 2018 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.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 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. AcclRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The company has two product candidates including DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, and 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.

For additional information about AcclRx's clinical programs, please visit www.acelrx.com.

Non-GAAP Financial Measures

To supplement AcclRx'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. AcclRx'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 AcclRx'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 process and timing of anticipated future development of AcclRx's product candidates, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ outside the United States, and Zalviso® (sufentanil sublingual tablet system), including the anticipated resubmission of the Zalviso NDA, and the Company's anticipated conservation of cash in expectation of a potential commercial launch of DSUVIA, if approved. These forward-looking statements are based on AcclRx's current expectations and inherently involve significant risks and uncertainties. AcclRx's actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA and Zalviso in the United States; the possibility that the FDA may dispute or interpret differently the results of the company's Human Factors study to validate the effectiveness of the changes in the Directions for Use, or the supplemental information included in the resubmission of the NDA for DSUVIA; the possibility that the FDA may dispute or interpret differently the results of the Zalviso development program, including the results from the IAP312 clinical trial; the accuracy of AcclRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcclRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 10, 2018. AcclRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations, except as required by law.

Investors

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Statement of Comprehensive Loss Data				
Revenue:				
Collaboration agreement revenue	\$ 351	\$ 2,192	\$ 625	\$ 5,219
Contract and other revenue	467	467	536	549
Total revenue	<u>818</u>	<u>2,659</u>	<u>1,161</u>	<u>5,768</u>
Operating costs and expenses:				
Cost of goods sold ⁽¹⁾	749	3,543	1,863	7,668
Research and development ⁽¹⁾	3,278	4,901	6,791	11,820
General and administrative ⁽¹⁾	3,944	4,156	7,929	8,294
Total operating costs and expenses	<u>7,971</u>	<u>12,600</u>	<u>16,583</u>	<u>27,782</u>
Loss from operations	<u>(7,153)</u>	<u>(9,941)</u>	<u>(15,422)</u>	<u>(22,014)</u>
Other (expense) income:				
Interest expense	(586)	(903)	(1,229)	(1,677)
Interest income and other income (expense), net	195	396	331	250
Non-cash interest expense on liability related to sale of future royalties	(2,995)	(2,609)	(5,811)	(5,167)
Total other expense	<u>(3,386)</u>	<u>(3,116)</u>	<u>(6,709)</u>	<u>(6,594)</u>
Benefit (provision) for income taxes	(2)	(2)	(2)	(2)
Net loss	<u>\$ (10,541)</u>	<u>\$ (13,059)</u>	<u>\$ (22,133)</u>	<u>\$ (28,610)</u>
Basic and diluted net loss per common share	<u>\$ (0.20)</u>	<u>\$ (0.29)</u>	<u>\$ (0.43)</u>	<u>\$ (0.63)</u>
Shares used in computing basic and diluted net loss per common share	<u>51,842</u>	<u>45,379</u>	<u>51,389</u>	<u>45,364</u>
(1) Includes the following non-cash, stock-based compensation expense:				
Cost of goods sold	\$ 74	\$ 79	\$ 161	\$ 163
Research and development	377	448	809	985
General and administrative	597	551	1,158	1,074
Total	<u>\$ 1,048</u>	<u>\$ 1,078</u>	<u>\$ 2,128</u>	<u>\$ 2,222</u>
	June 30, 2018	December 31, 2017		
Selected Balance Sheet Data				
Cash, cash equivalents and investments	\$ 50,122	\$ 60,469		
Total assets	64,620	75,552		
Total liabilities	113,586	112,061		
Total stockholders' deficit	(48,966)	(36,509)		

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses (GAAP):				
Research and development	\$ 3,278	\$ 4,901	\$ 6,791	\$ 11,820
General and administrative	3,944	4,156	7,929	8,294
Total operating expenses	7,222	9,057	14,720	20,114
<i>Less associated stock-based compensation expense</i>	974	999	1,967	2,059
<i>Operating expenses (non-GAAP)</i>	<u>\$ 6,248</u>	<u>\$ 8,058</u>	<u>\$ 12,753</u>	<u>\$ 18,055</u>