ACELRX PHARMACEUTICALS INC
Form 10-Q
July 29, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2016

or

TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-2193603**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

351 Galveston Drive

Redwood City, CA 94063

(650) 216-3500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2) Yes No

As of July 21, 2016, the number of outstanding shares of the registrant's common stock was 45,312,242.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2016

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Unless the context indicates otherwise, the terms “AcelRx,” “AcelRx Pharmaceuticals,” “we,” “us” and “our” refer to AcelRx Pharmaceuticals, Inc. “ACELRX,” “ZALVISO,” and “ACCELERATE, INNOVATE, ALLEVIATE” are U.S registered trademarks owned by AcelRx Pharmaceuticals, Inc. This report also contains other trademarks and trade names that are the property of their respective owners.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share data)

	June 30, 2016 (Unaudited)	December 31, 2015[(1)]
Assets		
Current Assets:		
Cash and cash equivalents	$ 97,800	$ 107,922
Short-term investments	1,000	5,542
Accounts receivable, net	4,185	3,286
Inventories	1,328	466
Prepaid expenses and other current assets	1,237	1,731
Total current assets	105,550	118,947
Property and equipment, net	7,794	8,610
Restricted cash	178	178
Other assets	50	50
Total Assets	$ 113,572	$ 127,785
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,857	$ 1,561
Accrued liabilities	2,914	3,956
Long-term debt, current portion	13,942	4,541
Deferred revenue, current portion	957	2,604
Liability related to the sale of future royalties, current portion	357	118
Total current liabilities	21,027	12,780
Deferred rent, net of current portion	148	245
Long-term debt, net of current portion	7,406	16,381

Deferred revenue, net of current portion	3,113	593
Liability related to the sale of future royalties, net of current portion	67,775	63,494
Contingent put option liability	165	266
Warrant liability	440	913
Total liabilities	100,074	94,672
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.001 par value—100,000,000 shares authorized as of June 30, 2016 and December 31, 2015; 45,312,242 and 45,273,772 shares issued and outstanding as of June 30, 2016 and December 31, 2015	45	45
Additional paid-in capital	238,725	236,274
Accumulated deficit	(225,278)	(203,205)
Accumulated other comprehensive income (loss)	6	(1)
Total stockholders' equity	13,498	33,113
Total Liabilities and Stockholders' Equity	$ 113,572	$ 127,785

(1) The condensed consolidated balance sheet as of December 31, 2015 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenue:				
Collaboration agreement	$1,314	$486	$3,107	$667
Contract and other	3,217	1,438	4,449	1,438
Total revenue	4,531	1,924	7,556	2,105
Operating costs and expenses:				
Cost of goods sold	2,976	—	6,575	—
Research and development	6,280	7,310	10,451	13,616
General and administrative	3,597	2,735	7,374	7,256
Restructuring costs	—	2	—	756
Total operating costs and expenses	12,853	10,047	24,400	21,628
Loss from operations	(8,322)	(8,123)	(16,844)	(19,523)
Other (expense) income:				
Interest expense	(687)	(777)	(1,367)	(1,583)
Interest income and other income, net	241	4	660	2,184
Non-cash interest expense on liability related to future sale of royalties	(2,324)	—	(4,520)	—
Total other (expense) income	(2,770)	(773)	(5,227)	601
Net loss before income taxes	(11,092)	(8,896)	(22,071)	(18,922)
Provision for income taxes	—	—	(2)	—
Net loss	(11,092)	(8,896)	(22,073)	(18,922)
Other comprehensive loss:				
Unrealized gains on available-for-sale securities	2	1	7	5
Comprehensive loss	$(11,090)	$(8,895)	$(22,066)	$(18,917)
Net loss per share of common stock, basic	$(0.24)	$(0.20)	$(0.49)	$(0.43)

Net loss per share of common stock, diluted	$(0.24)	$(0.20)	$(0.49)	$(0.47)
Shares used in computing net loss per share of common stock, basic	45,312,242	44,343,270	45,299,560	44,109,488
Shares used in computing net loss per share of common stock, diluted – see Note 11	45,312,242	44,343,270	45,299,560	44,397,471

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$(22,073)	$(18,922)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense on liability related to royalty monetization	4,520	—
Depreciation and amortization	1,029	997
Amortization of premium/discount on investments, net	17	47
Interest expense related to debt financing	426	472
Restructuring costs	—	(756)
Stock-based compensation	2,330	2,649
Revaluation of put option and PIPE warrant liabilities	(574)	(2,148)
Changes in operating assets and liabilities:		
Accounts receivable	(899)	—
Inventories	(862)	—
Prepaid expenses and other assets	494	(1,376)
Accounts payable	1,391	(834)
Accrued liabilities	(1,042)	(850)
Deferred revenue	873	(667)
Deferred rent	(97)	(50)
Net cash used in operating activities	(14,467)	(21,438)
Cash flows from investing activities:		
Purchase of property and equipment	(308)	(894)
Purchase of investments	(993)	(5,543)
Proceeds from maturities of investments	5,525	5,460
Net cash provided by (used in) investing activities	4,224	(977)
Cash flows from financing activities:		
Payment of long-term debt	—	(2,240)
Net proceeds from issuance of common stock through equity plans and exercise of warrants	121	459
Net cash provided by (used in) financing activities	121	(1,781)

Net decrease in cash and cash equivalents	(10,122)	(24,196)
Cash and cash equivalents—Beginning of period	107,922	60,038
Cash and cash equivalents—End of period	$97,800	$35,842

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

AcelRx Pharmaceuticals, Inc., or the Company or AcelRx, was incorporated in Delaware on July 13, 2005 as SuRx, Inc., and in January 2006, the Company changed its name to AcelRx Pharmaceuticals, Inc. The Company's operations are based in Redwood City, California.

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. AcelRx intends to commercialize its product candidates in the United States and license the development and commercialization rights to its product candidates for sale outside of the United States through strategic partnerships and collaborations. AcelRx may also consider the option to enter into strategic partnerships for its product candidates in the United States.

The Company has two late-stage development candidates based on sublingual sufentanil. The first, ARX-04, is a 30 mcg sufentanil sublingual tablet in a single-dose applicator intended for the treatment of moderate-to-severe acute pain administered by a healthcare professional. ARX-04 was initially developed at the request of the U.S. Department of Defense as a replacement for injections of morphine on the battlefield. In addition to the military application, AcelRx is developing ARX-04 as an investigational product for the treatment of patients suffering from moderate-to-severe acute pain in multiple settings, such as emergency room patients; patients who are recovering from short-stay or ambulatory surgery and do not require more long-term patient-controlled analgesia; post-operative patients who are transitioning from the operating room to the recovery floor; and patients being transported by paramedics. AcelRx has completed two placebo-controlled clinical studies (one Phase 2 and one Phase 3) demonstrating safety and efficacy of ARX-04. In October 2015, the Company initiated SAP302, an open-label Phase 3 study of ARX-04 for the treatment of adult patients who present in the emergency room with moderate-to-severe acute pain associated with trauma or injury, which treated 40 patients in the initial phase. In March 2016, the Company initiated the extension phase of the SAP302 study of ARX-04, which treated an additional 36 patients. Also in March 2016, the Company initiated SAP303, an open-label, single-arm study of ARX-04 in post-operative patients which treated 140 patients 40 years of age and older who had moderate-to-severe acute pain following a surgical procedure. The SAP303 study allowed for administration of ARX-04 for up to 12 hours. Both the SAP302 and SAP303 trials have had their last patient visits and data are currently being analyzed. The Company anticipates the top-line results for both studies will be available in the third quarter of 2016. Pending successful results of these two Phase 3 open-label studies, the Company intends to submit to the U.S. Food and Drug Administration, or FDA, a New Drug Application, or NDA, for ARX-04 for the treatment of moderate-to-severe acute pain to be administered by a

healthcare professional in medically-supervised settings by the end of 2016.

The Company's other late-stage investigational product candidate, Zalviso®, delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland and Liechtenstein and is in late-stage development in the U.S. In response to the NDA the Company submitted to the FDA seeking approval for Zalviso, the Company received a Complete Response Letter, or CRL, on July 25, 2014. Subsequently, the FDA requested an additional clinical study, IAP312, and the Company estimates that it may be able to begin IAP312 in September 2016. The Company does not intend to initiate the study until final supplies have been received and tested and clinical sites are ready. These activities may or may not occur in time to initiate the trial in September 2016. Timing of the completion of the IAP312 study will be dependent on the actual initiation date and other timing including, but not limited to, study enrollment.

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015, or the Amended License Agreement, which grants Grünenthal rights to commercialize Zalviso, the Company's novel sublingual patient-controlled analgesia, or PCA, system, or the Product, in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. In September 2015, the European Commission approved the Marketing Authorization Application, or MAA, previously submitted to the European Medicines Agency, or EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. The approval allows Grünenthal to market Zalviso in the 28 European Union member states as well as for the European Economic Area countries, Norway, Iceland and Liechtenstein, or EEA. Also on December 16, 2013, AcelRx and Grünenthal, entered into a related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. Under the MSA, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory. On July 22, 2015, the Company entered into an amendment to the MSA, or the MSA Amendment, and together with the MSA, the Amended MSA, between the Company and Grünenthal, each effective as of July 17, 2015, and together, with the Amended License Agreement, the Amended Agreements.

In April 2016, Grünenthal completed the first commercial sale of Zalviso. Grünenthal continues to sell Zalviso initially in a limited number of hospitals in Germany under a pilot program, whereby the hospital will use Zalviso in a small number of post-operative patients. The pilot program, which is expected to last approximately two months at each institution, is being made available to additional hospitals in Germany over the next several months. Pending success with the pilot program, Grünenthal expects to make the product widely available in Germany. With similar methodology, Grünenthal has also initiated the sale of Zalviso in France, the United Kingdom, Italy and Belgium, and intends to launch Zalviso in the Netherlands, Ireland and Portugal by the end of 2016.

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception and expects to continue to incur negative cash flows. Although Zalviso has been approved for sale in the European Union, the Company sold the majority of the royalty rights and certain commercial sales milestones it is entitled to receive under the Amended License Agreement with Grünenthal to PDL BioPharma, Inc., or PDL. As a result, the Company expects to continue to incur negative cash flows.

When we refer to "we," "our," "us," the "Company" or "AcelRx" in this document, we mean the current Delaware corporation, or AcelRx Pharmaceuticals, Inc., and its predecessor, as well as its consolidated subsidiary.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, ARPI LLC, which was formed in September 2015 for the sole purpose of facilitating the monetization transaction with PDL of the expected royalty stream and milestone payments due from the sales of Zalviso in the European Union by its commercial partner, Grünenthal, pursuant to the Amended License Agreement, or the Royalty Monetization. All intercompany accounts and transactions have been eliminated in consolidation. Refer to Note 7 “Liability Related to Sale of Future Royalties” for additional information.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the rules and regulations of the U.S. Securities and Exchange Commission, or SEC. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

Operating results for the three and six months ended June 30, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. The condensed consolidated balance sheet as of December 31, 2015, was derived from the Company's audited financial statements as of December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the SEC. These financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2015, which includes a broader discussion of the Company's business and the risks inherent therein.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management evaluates its estimates on an ongoing basis including critical accounting policies. Estimates are based on historical experience and on various other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Significant Accounting Policies

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2015. During the six months ended June 30, 2016, there have been no significant changes to the Company's significant accounting policies from those previously disclosed in its Annual Report on Form 10-K.

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-09, *Compensation - Stock Compensation (Topic 718)*, which is part of the FASB's Simplification Initiative. The updated guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which establishes a new lease accounting model for lessees. The updated guidance requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, to provide guidance on revenue recognition. ASU No. 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU No. 2014-09 is effective for the Company in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU No. 2014-09 can be applied retrospectively to all periods presented or only to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented. The FASB has also issued the following standards which clarify ASU No. 2014-09 and have the same effective date as the original standard:

ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*;

ASU No. 2016-10, *Identifying Performance Obligations and Licensing (Topic 606);*

ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting;* and

ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*.

The Company is currently evaluating the method of adoption and the impact of adopting ASU No. 2014-09 on its results of operations, cash flows and financial position.

2. Investments and Fair Value Measurement

Investments

The Company classifies its marketable securities as available-for-sale and records its investments at fair value. Available-for-sale securities are carried at estimated fair value based on quoted market prices or observable market inputs of almost identical assets, with the unrealized holding gains and losses included in accumulated other comprehensive income. Marketable securities which have maturities beyond one year as of the end of the reporting period are classified as non-current.

The table below summarizes the Company's cash, cash equivalents and investments (in thousands):

	As of June 30, 2016			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash and cash equivalents:				
Cash	$68,360	$ —	$ —	$68,360
U.S. government agency securities	29,434	6	—	29,440
Total cash and cash equivalents	97,794	6	—	97,800
Marketable securities:				
U.S. government agency securities	1,000	—	—	1,000
Total marketable securities	1,000	—	—	1,000
Total cash, cash equivalents and investments	$98,794	$ 6	$ —	$98,800

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				