ACELRX PHARMACEUTICALS INC
Form 10-Q
November 03, 2015

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 September 30, 2015

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 October 21, 2015, the number of outstanding shares of the registrant's common stock was 44,445,109.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2015

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Unless the context indicates otherwise, the terms “AcelRx,” “AcelRx Pharmaceuticals,” “we,” “us” and “our” refer to AcelRx Pharmaceuticals, Inc. “ACELRX” 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)

	September 30, 2015 (Unaudited)	December 31, 2014[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 95,042	$60,038
Short-term investments	9,291	15,312
Accounts receivable, net	17,376	—
Prepaid expenses and other current assets	883	948
Total current assets	122,592	76,298
Property and equipment, net	8,740	9,818
Restricted cash	178	250
Other assets	50	50
Total Assets	$ 131,560	$86,416
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,701	$2,431
Accrued liabilities	2,342	3,654
Income taxes payable	771	—
Long-term debt, current portion	—	6,859
Deferred revenue, current portion	3,012	787
Liability related to the sale of future royalties, current portion	59	—
Total current liabilities	7,885	13,731
Deferred rent	441	529

Long-term debt, net of current portion	20,716	18,015
Deferred revenue, net of current portion	193	1,626
Liability related to the sale of future royalties, net of current portion	61,407	—
Contingent put option liability	319	282
Warrant liability	633	5,577
Total liabilities	91,594	39,760
Stockholders' Equity:		
Common stock, $0.001 par value—100,000,000 shares authorized as of September 30, 2015 and December 31, 2014; 44,445,109 and 43,712,363 shares issued and outstanding as of September 30, 2015 and December 31, 2014	44	43
Additional paid-in capital	232,579	225,423
Accumulated deficit	(192,659)	(178,806)
Accumulated other comprehensive income (loss)	2	(4)
Total stockholders' equity	39,966	46,656
Total Liabilities and Stockholders' Equity	$ 131,560	$ 86,416

(1) The condensed consolidated balance sheet as of December 31, 2014 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, 2014.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Collaboration agreement	$13,863	$ 4,825	$ 14,530	$ 4,991
Contract	1,565	—	3,003	—
Total revenue	15,428	4,825	17,533	4,991
Operating expenses:				
Research and development	5,393	5,244	19,009	17,239
General and administrative	2,930	4,650	10,186	13,622
Restructuring costs	—	—	756	—
Total operating expenses	8,323	9,894	29,951	30,861
Income (loss) from operations	7,105	(5,069)	(12,418)	(25,870)
Other (expense) income:				
Interest expense	(713)	(816)	(2,296)	(1,818)
Interest income and other income (expense), net	(269)	6,556	1,915	8,153
Non-cash interest expense on liability related to sale of future royalties	(282)	—	(282)	—
Total other (expense) income	(1,264)	5,740	(663)	6,335
Net income (loss) before income taxes	5,841	671	(13,081)	(19,535)
Provision for income taxes	(772)	—	(772)	—
Net income (loss)	5,069	671	(13,853)	(19,535)
Other comprehensive income (loss):				
Unrealized gains (losses) on available-for-sale securities	1	1	6	(1)
Comprehensive income (loss)	$5,070	$ 672	$ (13,847)	$ (19,536)
Net income (loss) per share of common stock, basic	$0.11	$ 0.02	$ (0.31)	$ (0.45)
Net income (loss) per share of common stock, diluted	$0.11	$ (0.13)	$ (0.37)	$ (0.63)
Shares used in computing net loss per share of common stock, basic	44,406,933	43,469,354	44,209,726	43,332,013
	45,049,258	44,263,492	44,399,387	44,287,959

Shares used in computing net loss per share of common stock, diluted – see Note 10

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$(13,853)	$(19,535)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense on liability related to royalty monetization	282	—
Depreciation and amortization	1,502	469
Amortization of premium/discount on investments, net	81	187
Interest expense related to debt financing	691	514
Stock-based compensation	3,820	3,068
Revaluation of put option and PIPE warrant liabilities	(2,363)	(8,796)
Loss on disposal and impairment of property and equipment	509	—
Changes in operating assets and liabilities:		
Accounts receivable	(17,376)	—
Prepaid expenses and other assets	65	(226)
Restricted cash	72	—
Accounts payable	(564)	528
Accrued liabilities	(1,289)	(1,744)
Income taxes payable	771	—
Deferred revenue	792	9
Deferred rent	(88)	(9)
Net cash used in operating activities	(26,948)	(25,535)
Cash flows from investing activities:		
Purchase of property and equipment	(1,122)	(4,756)
Purchase of investments	(7,264)	(14,884)
Proceeds from maturity of investments	13,210	14,629
Net cash provided by (used in) investing activities	4,824	(5,011)
Cash flows from financing activities:		

Net proceeds from sale of future royalties	61,184	—
Proceeds from issuance of long-term debt	—	10,000
Payment of long-term debt	(4,534)	—
Payment of debt modification transaction costs	(215)	—
Net proceeds from issuance of common stock through equity plans and exercise of warrants	693	2,386
Net cash provided by financing activities	57,128	12,386
Net increase (decrease) in cash and cash equivalents	35,004	(18,160)
Cash and cash equivalents—Beginning of period	60,038	88,401
Cash and cash equivalents—End of period	$95,042	$70,241

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

The Company

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.

In September 2015, the Company reported that SAP301, a pivotal Phase 3 study for ARX-04 (sufentanil sublingual tablet, 30 mcg), met primary and secondary endpoints in a multi-center, double-blind, placebo-controlled trial designed to study the short-term treatment of patients with moderate-to-severe acute pain following ambulatory abdominal surgery. The Company believes ARX-04 may be a candidate for use in a variety of medically supervised settings to manage moderate-to-severe acute pain, including in the emergency room, or for post-operative patients, following either short-stay or ambulatory surgery.

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. In response to the New Drug Application, or NDA, the Company submitted to the U.S. Food and Drug Administration, or FDA, seeking approval for Zalviso, the Company received a Complete Response Letter, or CRL, on July 25, 2014. The FDA has requested an additional clinical study and the Company has submitted a protocol to the FDA for review. The Company is planning to begin this study, IAP312, in the first quarter of 2016 but likely will await comments on the protocol prior to study initiation.

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, which was amended effective July 17, 2015, or the Amended License Agreement, which grants Grünenthal rights to commercialize Zalviso in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia. 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.

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.

The Company has one business activity, which is the development and commercialization of product candidates for the treatment of pain, and a single reporting and operating unit structure.

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.

Reclassifications

Certain prior year amounts in the condensed consolidated financial statements have been reclassified to conform to the current year's presentation.

Principles of Consolidation

The 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 6 “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 nine months ended September 30, 2015, are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The condensed consolidated balance sheet as of December 31, 2014, was derived from the Company's audited financial statements as of December 31, 2014, 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, 2014, 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, 2014. During the nine months ended September 30, 2015, the Company has updated its concentration of risk policy to include its reliance on third parties for product manufacturing obligations under the Grünenthal Manufacturing and Supply Agreement, and its revenue recognition policy to include contract revenue, and royalties as discussed below. There are no other significant changes to the Company's significant accounting policies from those previously disclosed in its Annual Report on Form 10-K.

Concentration of Risk

The Company relies on a single third-party supplier for the supply of sufentanil, the active pharmaceutical ingredient in Zalviso, and various sole-source third-party contract manufacturer organizations to manufacture the Zalviso drug cartridge and device components, including the controller, the dispenser kit and the accessories.

Revenue Recognition - Contract Revenue

In May 2015, the Company entered into an award contract with the United States Army Medical Research and Materiel Command, or USAMRMC, to support the development of the Company's product candidate, ARX-04, referred to as DoD Contract. The DoD Contract provides for the reimbursement of qualified expenses for research and development activities as defined under the terms of the contract. Revenue under the contract is recognized when the related qualified research expenses are incurred. The Company is entitled to reimbursement of overhead costs associated with the study costs incurred under the DoD Contract. The Company estimates this overhead rate by utilizing forecasted expenditures. Final reimbursable overhead expenses are dependent on direct labor and direct reimbursable expenses throughout the life of the DoD Contract, so it may increase or decrease based on actual expenses incurred.

Non-Cash Interest Expense on Liability Related to Sale of Future Royalties

In September 2015, the Company sold certain royalty and milestone payment rights from the sales of Zalviso in the European Union by its commercial partner, Grünenthal, pursuant to the Collaboration and License Agreement, dated as of December 16, 2013, as amended, to PDL for an upfront cash purchase price of $65.0 million, referred to as the Royalty Monetization. The Company continues to have significant continuing involvement in the Royalty Monetization primarily due to an obligation to act as the intermediary for the supply of Zalviso to Grünenthal. Under the relevant accounting guidance, because of the Company's significant continuing involvement, the Royalty Monetization has been accounted for as a liability that will be amortized using the interest method over the life of the arrangement. In order to determine the amortization of the liability, the Company is required to estimate the total amount of future royalty and milestone payments to be received by PDL and payments the Company is required to make to PDL, up to a capped amount of $195.0 million, over the life of the arrangement. The sum of the capped amount of $195.0 million, less the $61.2 million of net proceeds the Company received will be recorded as interest expense over the life of the liability. Consequently, the Company imputes interest on the unamortized portion of the liability and record interest expense using an estimated interest rate for an arms-length debt transaction. The Company's estimate of the interest rate under the arrangement is based on the amount of royalty and milestone payments expected to be received by PDL over the life of the arrangement. The Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 14%. The Company will periodically assess the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than its initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the liability and the interest rate.

The Company will record non-cash royalty revenues and non-cash interest expense within its condensed consolidated statement of operations over the term of the PDL agreement.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, to provide guidance on revenue recognition. ASU 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 Update No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU-2015-14, that provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU 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 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 Company is currently evaluating the method of adoption and the impact of adopting ASU 2014-09 on its results of operations, cash flows and financial position.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest—Imputation of Interest*, or ASU 2015-03. ASU 2015-03 will more closely align the presentation of debt issuance costs under U.S. GAAP with the presentation under comparable IFRS standards by requiring that debt issuance costs be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015 and is required to be applied retrospectively to all prior periods presented. As permitted by ASU 2015-03, the Company elected to early adopt this guidance beginning with the first quarter of fiscal 2015, in order to simplify the presentation of its debt issuance costs. The resulting reclassifications of unamortized debt issuance costs from other assets to long-term debt, net of current portion on the condensed consolidated balance sheets as of September 30, 2015 and December 31, 2014, was $23,000 and $31,000, respectively. Refer to Note 5 "Long Term Debt" for additional information.

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 September 30, 2015			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash and cash equivalents:				
Cash	$88,994	$ —	$ —	$88,994
Money market funds	6,047	1	—	6,048
Total cash and cash equivalents	95,041	1	—	95,042
Marketable securities:				
U.S. government agency securities	9,290	1	—	9,291
Total marketable securities	9,290	1	—	9,291
Total cash, cash equivalents and investments	$104,331	$ 2	$ —	$104,333

	As of December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$60,005	$ —	$ —	$60,005
Money market funds	33	—	—	33
Total cash and cash equivalents	60,038	—	—	60,038
Marketable securities:				
U.S. government agency securities	15,316	—	(4)	15,312
Total marketable securities	15,316	—	(4)	15,312
Total cash, cash equivalents and investments	$75,354	$ —	$ (4)	$73,350

As of September 30, 2015 and December 31, 2014, none of the available-for-sale securities held by the Company had material unrealized losses. There were no other-than-temporary impairments for these securities at September 30, 2015 or December 31, 2014. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income to earnings during the three and nine months ended September 30, 2015 and 2014.

As of September 30, 2015 and December 31, 2014, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company's financial instruments consist of Level I and Level II assets and Level III liabilities. Level I securities include highly liquid money market funds and are valued based on quoted market prices. For Level II instruments, the Company estimates fair value by utilizing third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. treasury and U.S. government agency obligations. As of September 30, 2015 and December 31, 2014, the Company held, in addition to Level I and Level II assets, a contingent put option liability associated with the Company's Amended and Restated Loan and Security Agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which amends and restates the loan and security agreement with Hercules dated as of June 29, 2011, or the Original Loan Agreement, and which was classified as a Level III liability. See Note 5 "Long-Term Debt," for further description. The Company's estimate of fair value of the contingent put option liability was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair

values is the estimated fair value of the default provisions, or the contingent put option. Changes to the estimated fair value of these liabilities are recorded in interest income and other income (expense), net in the condensed consolidated statements of comprehensive income (loss). The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. As of September 30, 2015 and December 31, 2014, the Company also held a Level III liability associated with warrants, or PIPE warrants, issued in connection with the Company's private placement equity offering, completed in June 2012. The PIPE warrants are considered a liability and are valued using the Black-Scholes option-pricing model, the inputs for which include exercise price of the PIPE warrants, market price of the underlying common shares, expected term, volatility based on a group of the Company's peers and the risk-free rate corresponding to the expected term of the PIPE warrants. Changes to any of the inputs can have a significant impact to the estimated fair value of the PIPE warrants. As of September 30, 2015, the Company remeasured on a non-recurring basis a portion of its leasehold improvements in its corporate offices using Level III valuation techniques. The write down to fair value of these long-lived assets resulted in an impairment charge of $0.5 million in the three months ended September 30, 2015, which was recorded in interest income and other income (expense), net in the condensed consolidated statements of comprehensive income (loss).

The following table sets forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy (in thousands):

	As of September 30, 2015			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$6,048	$6,048	$—	$—
U.S. government agency obligations	9,291	—	9,291	—
Total assets measured at fair value	$15,339	$6,048	$9,291	$—
Liabilities				
PIPE warrants	$633	—	—	$633
Contingent put option liability	319	—	—	319
Total liabilities measured at fair value	$952	$—	$—	$952

	As of December 31, 2014			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$33	$ 33	$—	$—
U.S. government agency obligations	15,312	—	15,312	—
Total assets measured at fair value	$15,345	$ 33	$15,312	$—
Liabilities				
PIPE warrants	$5,577	—	—	$5,577
Contingent put option liability	282	—	—	282
Total liabilities measured at fair value	$5,859	$ —	$—	$5,859

The following table sets forth the assumptions used in the Black-Scholes option-pricing model to estimate the fair value of the PIPE warrants as of September 30, 2015:

Market price	$3.05
Exercise price	$3.40
Risk-free interest rate	0.64%
Expected volatility	78.0%
Expected life (in years)	2.17
Expected dividend yield	0.0 %

The following table sets forth the assumptions used in the Black-Scholes option-pricing model to estimate the fair value of the PIPE warrants as of December 31, 2014:

Market price	$6.73
Exercise price	$3.40
Risk-free interest rate	1.10%
Expected volatility	61.0%
Expected life (in years)	2.92
Expected dividend yield	0.0 %

The following tables set forth a summary of the changes in the fair value of the Company's Level III financial liabilities for the three and nine months ended September 30, 2015 and September 30, 2014 (in thousands):

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Fair value—beginning of period	$ 1,167	$ 5,859
Change in fair value of PIPE warrants	(283)	(2,401)
Exercise of PIPE warrants	—	(2,543)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	68	37
Fair value—end of period	$ 952	$ 952

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Fair value—beginning of period	$ 11,726	$ 13,445
Change in fair value of PIPE warrants	(6,964)	(8,241)
Exercise of PIPE warrants	—	(546)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	(113)	(9)
Fair value—end of period	$ 4,649	$ 4,649

3. U.S. Department of Defense Contract

On May 11, 2015, the Company entered into an award contract supported by the United States Army Medical Research and Materiel Command, or USAMRMC, within the U.S. Department of Defense, or the DoD, in which the DoD agreed to provide up to $17.0 million to the Company in order to support the development of the Company's product candidate, ARX-04 (sufentanil sublingual tablet, 30 mcg), a proprietary, non-invasive, single-use tablet in a disposable, pre-filled single-dose applicator, or SDA, for the treatment of moderate-to-severe acute pain. The DoD Contract supports development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse the Company for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on

November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

Revenue is recognized based on expenses incurred by the Company in conducting research and development activities, including overhead, as set forth in the agreement. Revenue attributable to the research and development performed under the DoD Contract, recorded as contract revenue in the condensed consolidated statements of comprehensive income (loss), was $1.6 million and $3.0 million for the three and nine months ended September 30, 2015, respectively. There was no such revenue recognized for the three and nine months ended September 30, 2014.

4. Collaboration Agreement

On December 16, 2013, AcelRx and Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. The License Agreement 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. The Company retains rights with respect to the Product in countries outside the Territory, including the United States, Asia and Latin America. 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 amendments to the License Agreement, or the License Amendment, and together with the License Agreement, the Amended License Agreement, and 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, the Amended Agreements.

In the Amended Agreements, the parties amended the Product supply configurations and packaging of Product components and accessories, and associated pricing therefor, which the Company will manufacture and supply to Grünenthal for the Territory. The parties agreed to increase the pricing of the Product components and accessories in exchange for a reduction of $5.5 million in the total milestone payments due from Grünenthal contingent upon achieving specified net sales targets from a total of $171.5 million to $166.0 million. The parties also updated the development plan for the Product in the Territory, providing for additional near-term development services to be rendered by AcelRx in exchange for payments by Grünenthal of $0.7 million. In accordance with the terms of the Amended MSA, AcelRx also received a binding Product forecast from Grünenthal for approximately $3.7 million.

Amended License Agreement

Under the terms of the Amended License Agreement, Grünenthal has the exclusive right to commercialize the Product in the Field in the Territory. The Company retains control of clinical development, while Grünenthal and the Company will be responsible for certain development activities pursuant to a development plan as agreed between the parties. The Company will not receive separate payment for such development activities, apart from the $0.7 million included under the Amended Agreements. Grünenthal is exclusively responsible for marketing approval applications and other regulatory filings relating to the sufentanil sublingual tablet drug cartridge for the Product in the Field in the Territory, while the Company is responsible for the CE Mark and other regulatory filings relating to device portions of the Product. In July 2014, Grünenthal submitted an MAA to the European Medicines Agency, or EMA, for Zalviso™ (15 micrograms sufentanil sublingual tablets) for the management of acute moderate-to-severe post-operative pain in adult patients. A CE Mark for Zalviso was obtained in the fourth quarter 2014 which specifies AcelRx as the device design authority and manufacturer. In September 2015, the European Commission approved the MAA for Zalviso for the 28 European Union member states as well as for the EEA.

The Company received an upfront non-refundable cash payment of $30.0 million in December 2013, and a milestone payment of $5.0 million related to the MAA submission in the third quarter of 2014. The Company was entitled to receive an additional $15.0 million milestone payment upon the approval of the MAA. The MAA was approved in September 2015. Under the Amended License Agreement, the Company is eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range on net sales of Zalviso.

Unless earlier terminated, the Amended License Agreement continues in effect until the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments, which supply and trademark fee continues for so long as the Company continues to supply the Product to Grünenthal. The Amended License Agreement is subject to earlier termination in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party, upon the bankruptcy or insolvency of either party, or by Grünenthal for convenience.

Amended MSA

Under the terms of the Amended MSA, the Company will manufacture and supply the Product for use in the Field for the Territory exclusively for Grünenthal. Grünenthal shall purchase from AcelRx, during the first five years after the effective date of the MSA, 100% and thereafter 80% of Grünenthal's and its sublicensees' and distributors' requirements of Product for use in the Field for the Territory. The Product will be supplied at prices approximating the Company's manufacturing cost, subject to certain caps, as defined in the MSA Amendment. The MSA Amendment requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and, under certain specified conditions, permits Grünenthal to use a third party back-up manufacturer to manufacture the Product for Grünenthal's commercial sale in the Territory.

Unless earlier terminated, the Amended MSA continues in effect until the later of the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments or the end of any transition period for manufacturing obligations due to the expiration or termination of the Amended License Agreement. The Amended MSA is subject to earlier termination in connection with certain termination events in the Amended License Agreement, in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

The Company identified the following four significant non-contingent performance deliverables under the original Agreements: 1) intellectual property (license), 2) the obligation to provide research and development services, 3) the significant and incremental discount on the manufacturing of Zalviso for commercial purposes, and 4) the obligation to participate on the joint steering committee.

At the time the Amended Agreements were executed, with the exception of the intellectual property license, these obligations remained partially undelivered. Additionally, the Company identified the following three performance deliverables under the License Amendment and the MSA Amendment: 1) the obligation to provide additional research and development services, 2) the obligation to provide Zalviso demonstration device systems, and 3) the obligation to manufacture and deliver Product under the binding forecast. The Company determined that the License Amendment and MSA Amendment are modifications to the original Agreements.

The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value and thus should be treated as separate units of accounting. The Company's management determined that the license under the original License Agreement had standalone value and represented a separate unit of accounting because the rights conveyed permitted Grünenthal to perform all efforts necessary to commercialize and begin selling the product upon regulatory approval. In addition, Grünenthal has the appropriate development, regulatory and commercial expertise with products similar to the product licensed under the agreement and has the ability to engage third parties to manufacture the product allowing Grünenthal to realize the value of the license without receiving any of the remaining deliverables. Grünenthal can also sublicense its license rights to third parties. Also, the Company's management determined that the research and development services, Zalviso demonstration device systems, joint steering committee participation, the significant and incremental discount on the manufacturing of Zalviso, and the obligation to manufacture and deliver Products each represent individual units of accounting, as Grünenthal could perform such services and/or could acquire these on a separate basis.

The Company believes that none of the deliverables have vendor-specific objective evidence, or VSOE, or sufficient third-party evidence, or TPE, of selling price, as none of them have been sold separately by the Company, and as there is only limited information about third party pricing for similar deliverables. Accordingly, the Company developed best estimates of selling prices, or ESP, for each deliverable in order to allocate the noncontingent arrangement consideration to the units of accounting, based on current information available as of the modification date.

The Company's management determined the best estimate of selling price for the license based on Grünenthal's estimated future cash flows arising from the arrangement. Embedded in the estimate were significant assumptions regarding regulatory expenses, revenue, including potential customer market for the product and product price, costs to manufacture the product and the discount rate. The Company's management determined the best estimate of selling price of the research and development services and committee participation based on the nature and timing of the services to be performed and in consideration of personnel and other costs incurred in the delivery of the services. For the discount on manufacturing services, the Company's management estimated the selling price based on the market level of contract manufacturing margin it could have received if it were engaged to supply products to a customer in a separate transaction, the estimated cost of manufacturing, and the anticipated volume of Grünenthal's orders over the course of the agreement, to which the discount would apply. For the Zalviso demonstration devices and the obligation to manufacture and deliver Product, the Company's management estimated the selling price based on the binding volume of such devices and Products, the estimated cost of manufacturing, and the market level of contract manufacturing margin. ESP of the license, research and development and committee participation services and the discount on manufacturing services were updated at the time the Amended Agreements were executed for purposes of allocating the amended arrangement consideration.

The Amended Agreements entitle the Company to receive additional payments upon the achievement of certain development and sales milestones. Based on ASC Topic 605-28, *Revenue Recognition — Milestone Method*, the Company evaluates contingent milestones at inception or modification of the agreement, and recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is considered substantive in its entirety. Milestones are events which have the following characteristics: (i) they can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) there was substantive uncertainty at the date the agreement was entered into that the event would be achieved and, (iii) they would result in additional payments due to the Company. A milestone is considered substantive if the following criteria are met: (i) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item (s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (ii) the consideration relates solely to past performance and, (iii) the consideration is reasonable relative to all of the other deliverables and payment terms, including other potential milestone consideration, within the arrangement.

The substantive milestone payments will be recognized as revenue in their entirety upon the achievement of each substantive milestone. Based on the criteria noted above, the identified substantive milestones in the original Agreements pertain to post approval product enhancements, expanded market opportunities and manufacturing efficiencies for Zalviso. Each of these potential achievements is based primarily on the Company's performance and involves substantive uncertainty as achievement of these milestones requires future research, development and regulatory activities, which are inherently uncertain in nature. The Company determined that the consideration for each milestone was commensurate with the Company's performance to achieve the milestone, including future research, development, manufacturing and regulatory activities and that the consideration is reasonable relative to all of the other deliverables and payments within the arrangement. Aggregate potential payments for these milestones total $28.5 million.

In addition to substantive milestones, two milestones associated with the original Agreements were deemed not to be substantive. These milestones pertain to regulatory developments for Zalviso in Europe, which the Company's management deemed to be not substantive due to the high likelihood of achievement, both at inception of the original Agreements and at the time the Amended Agreements were executed. Aggregate potential payments for these milestones totaled $20.0 million. In July 2014, Grünenthal submitted an MAA to the EMA for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients, triggering the first of these two milestones. Under the terms of the Amended License Agreement with Grünenthal, the Company received a cash payment of $5.0 million in the third quarter of 2014. In September of 2015, the MAA was approved by the European Commission, triggering the second of these two milestones and making the Company entitled to receive $15.0 million. Amounts received under non-substantive milestones are allocated to performance deliverables based on the relative selling price method and recognized as appropriate for such deliverables.

The Amended Agreements also include milestone payments related to specified net sales targets, totaling $166.0 million. These milestones do not meet the definition of a milestone under ASU 2010-17 because the achievement of these milestones is solely dependent on counter-party performance and not on any performance obligations of the Company.

At the time the Amended Agreements were executed, approximately $33.3 million of revenue had been recognized, and $1.7 million remained unrecognized from the aggregate to-date consideration of $35.0 million received under the original Agreements. Upon execution of the Amended Agreements, the Company updated the allocation of this arrangement consideration, along with the consideration owed under the Amended Agreements, consisting of $0.7 million related to research and development services and the demonstration device systems, and $3.7 million related to the Product binding purchase forecast, to all of the identified deliverables in the arrangement (both delivered and undelivered) using their relative selling prices. Further, the $15.0 million non-substantive milestone achieved in September of 2015 was also allocated to the deliverables in the same manner. As a result of such allocations, additional amounts of $13.2 million and $0.5 million were allocated to the previously delivered license and research and development and committee participation services, respectively. A total of $4.4 million was allocated to the significant and incremental discount on manufacturing services, and is expected to be recognized over the period such discount is made available to Grünenthal, beginning in February 2016, on a straight-line basis over the estimated period through 2029. An additional $0.2 million has been allocated to committee participation services and is recognized on a straight-line basis over the performance obligation period extending through 2018. A total of $2.3 million was allocated to manufacturing services for the binding forecast of Products, and is expected to be recognized when the Products are delivered in the first quarter of 2016. The remaining $0.5 million was allocated to the additional research and development services under the Amended License Agreement and demonstration device systems, and manufacturing and delivery of the Products, and will be recognized as those services are performed or as the devices are delivered, as applicable.

Below is a summary of revenue recognized under the Amended Agreements during the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
License	$13,167	$4,560	$13,167	$4,560
Joint steering committee and research and development services	696	265	1,363	431
Total	$13,863	$4,825	$14,530	$4,991

As of September 30, 2015, the Company had current and noncurrent portions of the deferred revenue balance of $3.0 million and $0.2 million, respectively.

5. Long-Term Debt

Hercules Loan and Security Agreements

In June 2011, AcelRx entered into the Loan and Security Agreement, or the Loan Agreement, between the Company and with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., together, the Lenders, under which AcelRx borrowed $20.0 million in two tranches of $10.0 million each, represented by secured convertible term promissory notes. The Company's obligations associated with the agreement are secured by a security interest in substantially all of its assets, other than its intellectual property and those assets sold under the Royalty Monetization.

The Company borrowed the first tranche of $10.0 million upon the closing of the transaction on June 29, 2011 and borrowed the second tranche of $10.0 million in December 2011. The Company used a portion of the proceeds from the first tranche to repay the remaining obligations under that certain loan and security agreement between the Company and Pinnacle Ventures, L.L.C., or Pinnacle Ventures, dated September 16, 2008. The interest rate for each tranche was 8.50%. In connection with the loan, the Company issued Hercules seven-year warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share. See Note 7 "Warrants," for further description.

On December 16, 2013, AcelRx entered into an Amended and Restated Loan and Security Agreement with the Lenders, or the Amended Loan Agreement, under which the Company may borrow up to $40.0 million in three tranches. The loans are represented by secured convertible term promissory notes, collectively, the Notes. The Amended Loan Agreement amends and restates the Loan Agreement between the Company and the Lenders dated as of June 29, 2011. The Company borrowed the first tranche of $15.0 million upon closing of the transaction on December 16, 2013, and the second tranche of $10.0 million on June 16, 2014. The Company used approximately $8.6 million of the proceeds from the first tranche to repay its obligations under the Loan and Security Agreement with the Lenders. The Company recorded the new debt at an estimated fair value of $24.9 million as of December 31, 2014.

On September 24, 2014, the Company entered into Amendment No. 1 to the Amended Loan Agreement with Hercules. Amendment No. 1 extended the time period under which the Company could draw down the third tranche, of up to $15.0 million, from March 15, 2015 to August 1, 2015, subject to the Company obtaining approval for Zalviso from the FDA. The Company did not receive FDA approval of Zalviso by August 1, 2015 and as such, did not have access to the third tranche.

On September 18, 2015, concurrently with the closing of the Royalty Monetization, the Company entered into a Consent and Amendment No. 2, or Amendment No. 2, to the Amended Loan Agreement with the Lenders.

Amendment No. 2 includes an interest only period from October 1, 2015 through March 31, 2016, with the potential for further extension to September 30, 2016 upon satisfaction of certain conditions. These conditions were satisfied in the third quarter of 2015 and the interest only period under the Amended Loan Agreement is October 1, 2015 through September 30, 2016. Loans under the Amended Loan Agreement mature on October 31, 2017. In connection with Amendment No. 2, the Company reduced the exercise price of the warrants already held by the Lenders, which are exercisable for an aggregate of 176,730 shares of Common Stock, from the previous exercise price of $6.79 per share to $3.88 per share, or the Warrant Amendments.

The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 9.10% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.10%. Payments under the Amended Loan Agreement were interest only until April 1, 2015, followed by equal monthly payments of principal and interest through September 30, 2015, to be followed by an interest only period from October 1, 2015 through September 30, 2016, and by equal monthly payments of principal and interest from October 1, 2016 through the scheduled maturity date on October 1, 2017, or the Loan Maturity Date. In addition, a final payment equal to $1.7 million will be due on the Loan Maturity Date, or such earlier date specified in the Amended Loan Agreement. The Company's obligations under the Amended Loan Agreement are secured by a security interest in substantially all of its assets, other than its intellectual property and those assets sold under the Royalty Monetization.

If the Company prepays the Amended Loan Agreement prior to maturity, it will pay Hercules a prepayment charge, based on a percentage of the then outstanding principal balance, 2% if the prepayment occurs after December 16, 2014, but prior to December 16, 2015, or 1% if the prepayment occurs after December 16, 2015.

Subject to certain conditions and limitations set forth in the Amended Loan Agreement, the Company has the right to convert up to $5.0 million of scheduled principal installments under the Notes into freely tradeable shares of the Company's common stock, or Common Stock. The number of shares of Common Stock that would be issued upon conversion of the Amended Notes would be equal to the number determined by dividing (x) the product of (A) the principal amount to be paid in shares of Common Stock and (B) 103%, by (y) $9.30 (subject to certain proportional adjustments as provided for in the Amended Loan Agreement).

The Amended Loan Agreement includes customary affirmative and restrictive covenants, but does not include any financial maintenance covenants, and also includes standard events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Hercules' security interest or in the value of the collateral, and events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Amended Loan Agreement.

In connection with the Amended Loan Agreement, the Company issued a warrant to each Lender which, collectively, are exercisable for an aggregate of 176,730 shares of common stock and each carried an exercise price of $6.79 per share. As mentioned above, in connection with Amendment No. 2, the Company reduced the exercise price of these warrants from the previous exercise price of $6.79 per share to $3.88 per share. See Note 7 “Warrants,” for further description.

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the Amended Loan Agreement, including payment of any applicable prepayment charges, which range from 1%-3% of the outstanding loan balance and accrued interest, as well as a final payment fee of $1.7 million. This option is considered a contingent put option liability, as the holder of the loan may exercise the option in the event of default, and is considered an embedded derivative, which must be valued and separately accounted for in the Company’s financial statements. As the Amended Loan Agreement entered into on December 16, 2013 was considered an extinguishment, the contingent put option liability associated with the Loan Agreement, which had an estimated fair value of $32,000 at the time of the amendment, was written off as a part of the loss on extinguishment, and a new contingent put option liability was established. As of September 30, 2015 and December 31, 2014, the estimated fair value of the contingent put option liability was $319,000 and $282,000, respectively, which was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. The contingent put option liability was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The contingent put option liability is revalued at the end of each reporting period and any change in the fair value is recognized in interest income and other income (expense), net in the condensed consolidated statements of comprehensive income (loss).

The Company performed an analysis of Amendment No. 2 to determine if it was a modification or extinguishment of the debt under the Amended Loan Agreement. The Company assumed immediate prepayment of both the pre-modification debt and post-modification debt, including the change in the fair value due to the Warrant Amendments, and concluded that Amendment No. 2 was a modification rather than an extinguishment of the debt.

As of September 30, 2015, the Company had outstanding borrowings under the Amended Loan Agreement of $20.7 million. Interest expense related to the Amended Loan Agreement was $0.7 million and $2.3 million for the three and nine months ended September 30, 2015, respectively.

6. Liability Related to Sale of Future Royalties

On September 18, 2015, the Company consummated the Royalty Monetization, in which it sold certain royalty and milestone payment rights to its newly formed wholly owned subsidiary, ARPI LLC, pursuant to a Purchase and Sale Agreement, or PSA. Subsequently, ARPI LLC sold the royalty and milestone payment rights to PDL for an upfront cash purchase price of $65.0 million, subject to a capped amount of $195.0 million pursuant to the Subsequent Purchase and Sale Agreement, or SPSA. Under the SPSA, PDL will receive 75% of the European royalties under the Amended License Agreement as well as 80% of the first four commercial milestones, worth $35.6 million (or 80% of $44.5 million), subject to the capped amount. The Company is entitled to receive 25% of the royalties, 20% of the first four commercial milestones, 100% of the remaining commercial milestones and all remaining development milestones of $43.5 million, including the $15.0 million payment for the approval of the Zalviso MAA.

The Company and ARPI LLC continue to retain certain duties and obligations under the Amended License Agreement. These include the collection of the royalty and milestones amounts due and enforcement of related provisions under the Amended License Agreement, among others. In addition, the Company must prepare a quarterly distribution report relating to the Amended License Agreement, containing among other items, the amount of royalty and milestone payments received, reimbursable expenses and set-offs. The Company and ARPI LLC must also provide PDL with notice of certain communications, events or actions with respect to the Amended License Agreement and infringement of any underlying intellectual property.

The Company has significant continuing involvement in the Royalty Monetization primarily due to an obligation to act as the intermediary for the supply of Zalviso to Grünenthal. Under the relevant accounting guidance, because of its significant continuing involvement, the Royalty Monetization has been accounted for as a liability that will be amortized using the interest method over the life of the arrangement. In order to determine the amortization of the liability, the Company is required to estimate the total amount of future royalty and milestone payments to be received by PDL and payments the Company is required to make to PDL, up to a capped amount of $195.0 million, over the life of the arrangement. The sum of the capped amount of $195.0 million, less the $61.2 million of net proceeds the Company received will be recorded as interest expense over the life of the liability. Consequently, the Company imputes interest on the unamortized portion of the liability and records interest expense. The Company’s estimate of the interest rate under the arrangement is based on the amount of royalty and milestone payments expected to be received by PDL over the life of the arrangement. The Company’s estimate of this total interest expense resulted in an effective annual interest rate of approximately 14%.

The Company will periodically assess the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, the Company will prospectively adjust the amortization of the liability and the interest rate.

The following table shows the activity within the liability account during the nine months ended September 30, 2015 (in thousands):

Liability related to sale of future royalties—beginning balance	$—
Net proceeds from sale of future royalties	61,184
Non-cash interest expense recognized	282
Payments from AcelRx to PDL	—
Total liability related to sale of future royalties as of September 30, 2015	61,466
Less: current portion	(59)
Liability related to sale of future royalties, less current portion	$61,407

As royalties are remitted to PDL from ARPI LLC as described in Note 1 “Organization and Summary of Significant Accounting Policies,” the balance of the liability will be effectively repaid over the life of the agreement. The Company will record non-cash royalty revenues and non-cash interest expense within its condensed consolidated statements of comprehensive income (loss) over the term of the Royalty Monetization.

7. Warrants

Series A Warrants

As of September 30, 2015, warrants to purchase 3,425 shares of common stock had not been exercised and were still outstanding. These warrants expire in March 2017.

Hercules Warrants

In connection with the Amended Loan Agreement, executed in December 2013, the Company issued warrants to Hercules which were exercisable for an aggregate of 176,730 shares of common stock with an exercise price of $6.79 per share, or the Warrants. In connection with Amendment No. 2 to the Amended Loan Agreement, the Company reduced the exercise price of the warrants already held by the Lenders, which are exercisable for an aggregate of 176,730 shares of Common Stock, from the previous exercise price of $6.79 per share to $3.88 per share, or the Warrant Amendments. Each Warrant may be exercised on a cashless basis. The Warrants are exercisable for a term beginning on the date of issuance and ending on the earlier to occur of five years from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the Warrants. The number of shares for which the Warrants are exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in the Warrants. The Company estimated the fair value of these Warrants as of the issuance date to be $1.1 million, which was used in the estimating the fair value of the amended debt instrument and was recorded as equity. The fair value of the Warrants was calculated using the Black-Scholes option-valuation model, and was based on the original strike price of $6.79, the stock price at issuance of $9.67, the five-year contractual term of the warrants, a risk-free interest rate of 1.55%, expected volatility of 71% and 0% expected dividend yield. The Company estimated the fair value of the modification of the Warrants, or the Warrant Amendments, as of the issuance date to be $0.1 million, which was used in estimating the fair value of the amended debt instrument and was recorded as equity.

As of September 30, 2015, warrants to purchase 176,730 shares of common stock issued to Hercules had not been exercised and were still outstanding. These warrants expire in December 2018.

In connection with the Loan Agreement with Hercules, executed in June 2011, the Company issued to Hercules warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share, which were net exercised for 183,404 shares of common stock during the year ended December 31, 2013.

2012 Private Placement Warrants

In connection with the Private Placement, completed in June 2012, the Company issued PIPE warrants to purchase up to 2,630,103 shares of common stock. The per share exercise price of the PIPE warrants was $3.40 which equals the closing consolidated bid price of the Company’s common stock on May 29, 2012, the effective date of the Purchase Agreement. The PIPE warrants issued in the Private Placement became exercisable six months after the issuance date, and expire on the five year anniversary of the initial exercisability date. Under the terms of the PIPE warrants, upon certain transactions, including a merger, tender offer, sale of all or substantially all of the assets of the Company or if a person or group shall become the owner of 50% of the Company’s issued and outstanding common stock, which is outside of the Company’s control, each PIPE warrant holder may elect to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option-pricing model. Accordingly, the PIPE warrants were recorded as a liability at fair value, as determined by the Black-Scholes option-pricing model, and then marked to fair value each reporting period, with changes in estimated fair value recorded through the condensed consolidated statements of comprehensive income (loss) in interest income and other income (expense), net. The Black-Scholes assumptions used to value the PIPE warrants are disclosed in Note 2 “Investments and Fair Value Measurement.”

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Upon execution of the Purchase Agreement, the fair value of the PIPE warrants was estimated to be $5.8 million, which was recorded as a liability. As of September 30, 2015, the fair value of the PIPE warrants was estimated to be $0.6 million. The change in fair value for the three months ended September 30, 2015 was $0.3 million, which was recorded as other income, and the change in fair value for the nine months ended September 30, 2015 was $2.4 million, which was recorded as other income.

In March 2015, PIPE warrants to purchase 847,058 shares were net exercised for 527,101 shares of common stock. As of September 30, 2015, PIPE warrants to purchase 512,456 shares of common stock issued in connection with the Private Placement had not been exercised and were outstanding. These warrants expire in November 2017.

8. Stock-Based Compensation

The Company recorded total stock-based compensation expense for stock options, stock awards and the 2011 Employee Stock Purchase Plan as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expenses:				
Research and development	$636	$568	$1,967	$1,607
General and administrative	535	631	1,853	1,461
Total stock-based compensation expense	$1,171	$1,199	$3,820	$3,068

As of September 30, 2015 there were 2,425,285 shares available for grant, 5,676,630 options outstanding and no restricted stock units outstanding under the Company’s 2011 Equity Incentive Plan.

9. Restructuring Costs

On March 19, 2015, the Board of Directors of the Company, in connection with its efforts to reduce operating costs, conserve capital, focus the Company's financial and development resources on working with the FDA to seek marketing approval for Zalviso, and continuing development of ARX-04, implemented a cost reduction plan. The cost reduction plan reduced the Company’s workforce by 19 employees, approximately 36% of total headcount, in the first quarter of 2015. Employee termination benefits related to this restructuring, are charged to restructuring costs in the

condensed consolidated statements of comprehensive income (loss).

Restructuring costs for the three and nine months ended September 30, 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Employee termination benefits	$ —	$ —	$ 756	$ —
Total restructuring costs	$ —	$ —	$ 756	$ —

The following table presents activities related to a cost reduction plan during the three and nine months ended September 30, 2015 (in thousands):

	Employee severance and related costs
Balance of restructuring liability at December 31, 2014	$ —
Charges	754
Payments	—
Balance of restructuring liability at March 31, 2015	754
Charges	2
Payments	(753)
Balance of restructuring liability at June 30, 2015	3
Charges	—
Payments	(3)
Balance of restructuring liability at September 30, 2015	$ —

The restructuring liability has been fully disbursed as of September 30, 2015.

10. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock and warrants to purchase common stock were considered to be common stock equivalents. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive.

During the three and nine months ended September 30, 2015, the PIPE warrants had a dilutive impact to net loss per share due to a lower share price at September 30, 2015, compared to the closing share price on June 30, 2015 and December 31, 2014. Similarly, during the three and nine months ended September 30, 2014, the PIPE warrants had a dilutive impact to net loss per share due to a lower share price at September 30, 2014, compared to the closing share price on June 30, 2014 and December 31, 2013. The decrease in share price created a lower Black-Scholes value and lower liability for the PIPE warrants, which resulted in other income during the three and nine months ended September 30, 2015, and the three and nine months ended September 30, 2014. The calculation of diluted net loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the

exercise price of the PIPE warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the PIPE warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

The following table sets forth the computation of the Company's basic and diluted net loss per share of common stock during the three and nine months ended September 30, 2015 and 2014 (in thousands, except for share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except share and per share amounts)			
Numerator				
Net income (loss) used to compute net income (loss) per share:				
Basic	$5,069	$671	$(13,853)	$(19,535)
Adjustments for change in fair value of warrant liability	(283)	(6,418)	(2,401)	(8,241)
Diluted	$4,786	$(5,747)	$(16,254)	$(27,776)
Denominator				
Weighted average shares outstanding used to compute net income (loss) per share:				
Basic	44,406,933	43,469,354	44,209,726	43,332,013
Dilutive effect of warrants	88,494	794,138	189,661	955,946
Dilutive effect of ESPP and stock options	553,831	—	—	—
Diluted	45,049,258	44,263,492	44,399,387	44,287,959
Net income (loss) per share — basic	$0.11	$0.02	$(0.31)	$(0.45)
Net income (loss) per share — diluted	$0.11	$(0.13)	$(0.37)	$(0.63)

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
ESPP and stock options to purchase common stock	3,606,683	5,381,477	5,784,402	5,381,447
Convertible debt into common stock	553,763	553,763	553,763	553,763
Common stock warrants	180,155	180,155	180,155	180,155

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11. Commitments and Contingencies

Purchase Obligations

Purchase obligations consist of agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. These include obligations for product manufacturing and research and development.

We have purchase commitments with various sole source vendors for commercial inventory for Zalviso totaling $2.8 million at September 30, 2015 to supply raw materials in the fourth quarter of 2015 of approximately $0.7 million, and finished goods in the first quarter of 2016 of approximately $2.1 million.

Manufacturing Agreements

Patheon

In January 2013, the Company and Patheon Pharmaceuticals Inc., or Patheon, entered into a Manufacturing Services Agreement, or the Services Agreement, and a related Amended and Restated Capital Expenditure and Equipment Agreement, or the Capital Agreement, relating to the manufacture of sufentanil tablets, or the Product, for use with the Company's Zalviso drug product.

Under the terms of the Services Agreement, the Company has agreed to purchase, subject to Patheon's continued material compliance with the terms of the Services Agreement, all of its Product requirements for the United States, Canada and Mexico from Patheon during the Initial Term of the Services Agreement (as defined below), and at least eighty percent (80%) of its Product requirements for such territories after the Initial Term. In addition, Patheon will manufacture Product for the Company to support Grünenthal's commercialization of Zalviso in the European Union.

The term of the Services Agreement extends until December 31, 2017, or the Initial Term, and will automatically renew thereafter for periods of two years, unless terminated by either party upon eighteen months' prior written notice; provided, however, that the Services Agreement may not be terminated without cause prior to the end of the Initial Term.

The Company also entered into a Capital Expenditure and Equipment Agreement, or the Capital Agreement. Under the terms of the Capital Agreement, as amended in January 2014, or the Amended Capital Agreement, the Company has made and has the option to make certain future modifications to Patheon's Cincinnati facility and which would be the responsibility of the Company. If additional equipment and facility modifications are required to meet the Company's Product needs, the Company may be required to contribute to the cost of such additional equipment and facility modifications.

12. Related Party Transactions

Stephen Hoffman is a Senior Advisor to PDL and a member of the Company's Board of Directors, or the Board. The Board was aware of Dr. Hoffman's status as an interested party in the Royalty Monetization and Dr. Hoffman recused himself from all deliberations and actions taken by the Board with respect to the Royalty Monetization. Dr. Hoffman's consulting compensation from PDL is composed, in part, of a success fee which is formula driven based on a minimum dollar value of deals and the total dollar value of the deals concluded or funded in 2015. This determination is made at the end of 2015. Because the total dollar value of deals concluded or funded by PDL in 2015 is not known, the exact amount of the success fee potentially attributable to the AcelRx transaction is indeterminate. Depending on the total dollar value of deals concluded or funded in 2015 and subject to Dr. Hoffman rendering services for the entire fiscal year of 2015, PDL estimates the potential range attributable to the AcelRx transaction could be from $190,000 to $260,000.

13. Subsequent Events

On October 2, 2015, the Company executed an agreement to sublease 11,871 sq. of its space located at 301 Galveston Drive, Redwood City, California for a term of 26 months commencing on December 1, 2015. The sublessee is entitled to abatement of the first monthly installment of rent. Subsequent monthly installments of rent start at a rental rate of $2.05 per square foot (subject to agreed nominal increases). Upon the completion of the sublease, the Company has the option to take back the subleased space.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso™ (sufentanil sublingual tablet system), including AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the additional clinical trial for Zalviso; anticipated resubmission of the Zalviso New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, including the scope of the resubmission and the timing of the resubmission, and FDA review time; the anticipated timing of the Phase 3 SAP302 study for ARX-04; ability to fund ARX-04 development from the contract with the Department of Defense; the status of the Collaboration and License Agreement with Grünenthal or any other future potential collaborations, including potential milestones and royalty payments under the Grünenthal agreement; and the therapeutic and commercial potential of AcelRx's product candidates, including ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitations, risks related to AcelRx Pharmaceuticals' ability to finalize the pathway towards a resubmission of the Zalviso NDA to the FDA; potential additional clinical studies, Human Factor studies and/or additional data analysis necessary in order to resubmit the Zalviso NDA; AcelRx's ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; AcelRx's ability to receive any milestones or royalty payments under the Grünenthal agreement and the timing thereof; ability to manufacture and supply sufficient quantities of Zalviso to Grünenthal on a timely basis; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the additional clinical trial for Zalviso and the Phase 3 ARX-04 SAP302 trial and the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; AcelRx's ability to complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; the market potential for AcelRx's product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need for financing. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2014.

About AcelRx Pharmaceuticals

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

ARX-04 (sufentanil sublingual tablet, 30 mcg)

ARX-04 is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually via a disposable, pre-filled, single-dose applicator, or SDA. We are developing ARX-04, a proprietary, non-invasive, single-use tablet in a disposable, pre-filled, single-dose applicator for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional to a patient in medically supervised settings of acute pain. If approved, examples of potential settings where ARX-04 could be used include: emergency room patients; post-operative patients who are transitioning from the operating room to the recovery floor; patients who are recovering from either short-stay or ambulatory surgery and do not require more long-term patient-controlled analgesia; treatment of battlefield casualties; and patients being transported by paramedics. In December 2013, we completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, to identify a Phase 3 program pathway forward for evaluation of ARX-04.

On May 11, 2015, we entered into an award contract supported by the United States Army Medical Research and Materiel Command, or USAMRMC, within the U.S. Department of Defense, or the DoD, in which the DoD agreed to provide up to $17.0 million to support the development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an New Drug Application, or NDA, to the FDA, referred to as the DoD Contract. Under the terms of the contract, the DoD will reimburse us for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the DoD Contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

In September 2015, we reported that SAP301, a pivotal Phase 3 multi-center, double-blind, placebo-controlled study of ARX-04, met primary and secondary endpoints in the short-term treatment of patients with moderate-to-severe acute pain following ambulatory abdominal surgery.

In October 2015, we announced the initiation of an open-label Phase 3 study, SAP302, 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. The primary efficacy endpoint is the summed pain intensity difference, or SPID, over 1-hour, or SPID-1. Safety endpoints, such as adverse events and vital signs will also be assessed, as will the patients' and healthcare providers' satisfaction with the method of pain control. The study is expected to be completed in early 2016.

As part of our development program, we expect to meet with the FDA in December 2015 to review plans for an NDA for ARX-04.

Zalviso

Our product candidate, Zalviso™, is intended for the management of moderate-to-severe acute pain in hospitalized adult patients. Zalviso consists of sufentanil sublingual tablets, 15 mcg, delivered by the Zalviso System, a needle-free, handheld, patient-administered, pain management system (together, "Zalviso").

Zalviso is an investigational, pre-programmed, non-invasive, system to allow hospital patients with moderate-to-severe acute pain to self-dose with sufentanil sublingual tablets, 15 mcg, to manage their pain. Zalviso is designed to help address certain problems associated with post-operative intravenous patient-controlled analgesia, by offering:

- **A high therapeutic index opioid:** Zalviso uses sufentanil, an opioid that has a high therapeutic index. The therapeutic index is the ratio of the effective dose versus the lethal dose. In animal studies, the therapeutic index for sufentanil was approximately 100 times larger than fentanyl and 300 times larger than morphine.

- **A non-invasive route of delivery:** Zalviso utilizes a sufentanil tablet which allows for a sublingual (under the tongue) route of delivery. Sufentanil is highly lipophilic which provides for rapid absorption in the fatty cells (or mucosal tissue) found under the tongue, and for rapid transit across the blood-brain barrier to reach the mu-opioid receptors in the brain. The sublingual delivery used by Zalviso provides rapid onset of analgesia. The sublingual delivery system also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients do not require direct connection to an IV patient-controlled analgesia, or PCA, infusion pump through IV tubing, Zalviso allows for ease of patient mobility.

- **A simple, pre-programmed PCA solution:** Zalviso allows patients to self-dose sufentanil sublingual tablets via a pre-programmed, secure system designed to eliminate the risk of programming errors.

We submitted an NDA for Zalviso in September 2013 and, in December 2013, we announced that the FDA accepted for filing the Zalviso NDA. On July 25, 2014, the FDA issued a Complete Response Letter, or CRL, for our NDA for Zalviso. The CRL contains requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of optical system errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. There were no requests for additional clinical studies in the CRL. In the third quarter of 2014, we held a Type A meeting with the FDA to discuss the Zalviso CRL. During the meeting we discussed the resubmission of the Zalviso NDA and the steps necessary for the resubmission. In advance of resubmitting our Zalviso NDA, we agreed with the FDA to submit protocols for the bench testing and Human Factors, or HF, studies for their review and comment. In addition, the FDA requested in the minutes of the meeting that we provide a risk assessment that analyzes the risks associated with inadvertent dosing and the rationale that bench testing and HF studies are sufficient to address the specific items included in the CRL. We submitted the protocols and this rationale in the fourth quarter of 2014. In January 2015, we received feedback from the FDA on the protocol and the planned analysis of the results of the bench test. Based on the FDA feedback, no modifications to the conduct of the bench test were necessary; however, in response to the FDA's request, we refined the planned analysis of the bench test results. In February 2015, we received feedback from the FDA on the HF protocols. In this feedback, the FDA confirmed that the HF studies as proposed were acceptable to evaluate the design changes related to inadvertent dispensing of tablets. In March 2015, we received correspondence from the FDA stating that, in addition to the work we had performed to address items in the CRL, a clinical study is required to test the modifications to the Zalviso device. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we were granted a Type C meeting (previously identified as a General Advice meeting) with the FDA, which took place in early September 2015, to discuss their request for an additional clinical trial and our planned response to the CRL. We recently received formal minutes of this meeting. In the minutes, the FDA provided some additional details about the type of clinical data they would like us to provide, as a complement to the other data we already have provided, to assess the overall performance of Zalviso. We have submitted a protocol to the FDA for a clinical study in post-operative patients designed to evaluate the effectiveness of changes made to enhance product performance. We expect to be ready to initiate the study in the first quarter of 2016, but likely will await comments on the protocol from the FDA prior to study initiation.

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On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, which was amended effective July 17, 2015, or the Amended License Agreement, which grants Grünenthal rights to commercialize Zalviso in the countries of the European Union, or EU, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory. 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 EU member states as well as for the European Economic Area countries, Norway, Iceland and Liechtenstein, or EEA. For additional information on the collaboration agreement with Grünenthal, see Note 4 “Collaboration Agreement” in the accompanying notes to the condensed consolidated financial statements.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue our research and development activities and pre-commercialization activities. As we pursue development of our product candidates, including regulatory review and potential commercial development, subject to FDA approval, of our product candidates, we expect the business aspects of our company to become more complex. In the future, we plan to add personnel and incur additional costs related to the maturation of our business and the potential commercialization of ARX-04 and Zalviso in the United States. In addition, we believe that continued investment in research and development is critical to attaining our strategic objectives. In order to develop our product candidates as commercially viable therapeutics, we expect to expend significant resources for expertise in manufacturing, regulatory affairs, clinical research and other aspects of pharmaceutical development.

To date, we have funded our operations primarily through the issuance of equity securities, borrowings, payments from our commercial partner, Grünenthal, monetization of certain future royalties and commercial sales milestones from the sales of Zalviso by Grünenthal, and our contracts with the DoD.

Our revenues since inception have consisted primarily of revenues from our Amended License Agreement with Grünenthal and our research contracts with the USAMRMC within the DoD. As mentioned above, in May 2015, the DoD agreed to provide us up to $17.0 million to support the development of ARX-04. The DoD Contract will support development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA.

There can be no assurance that we will enter into other collaborative agreements or receive research-related contract awards in the future. We expect revenues to continue to fluctuate from period-to-period. There can be no assurance that our relationship with our existing commercial partner, Grünenthal, will continue beyond the initial term, or that we will be able to meet the milestones specified in the Amended License Agreement, or that the DoD Contract will result in an NDA submission for ARX-04, or that we will obtain marketing approval for any of our product candidates

outside of Zalviso in the EU and EEA and subsequently generate revenue from those product candidates in excess of our operating expenses.

Our net income for the three months ended September 30, 2015 was $5.1 million and our net loss for the nine months ended September 30, 2015 was $13.9 million, respectively. As of September 30, 2015, we had an accumulated deficit of $192.7 million. As of September 30, 2015, we had cash, cash equivalents and investments totaling $104.3 million compared to $75.4 million as of December 31, 2014.

On September 18, 2015, we sold a portion of the expected royalty stream and commercial milestones from the sales of Zalviso in the EU by Grünenthal to PDL BioPharma, Inc., or PDL, or the Royalty Monetization. The Company received gross proceeds of $65.0 million in the Royalty Monetization.

In the first step of the Royalty Monetization, we sold certain royalty and milestone payment rights to our newly formed wholly owned subsidiary, ARPI LLC, pursuant to a Purchase and Sale Agreement, or PSA. In the second step of the Royalty Monetization, ARPI LLC sold the royalty and milestone payment rights to PDL for an upfront cash purchase price of $65.0 million, subject to a capped amount of $195.0 million pursuant to the Subsequent Purchase and Sale Agreement, or SPSA. Under the SPSA, PDL will receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), subject to the capped amount of $195.0 million. We are entitled to receive all remaining amounts under the Amended License Agreement which include 25% of the European royalties, 20% of the first four commercial milestones, 100% of the remaining commercial milestones and all development milestones of $43.5 million, including the $15.0 million payment for the approval of the Zalviso MAA, which the European Commission approved in September 2015.

The total liability related to sale of future royalties to PDL as of September 30, 2015 was $61.5 million.

On December 16, 2013, we entered into an Amended and Restated Loan and Security Agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., together, the Lenders, or the Amended Loan Agreement, under which we may borrow up to $40.0 million in three tranches. The loans are represented by secured convertible term promissory notes, collectively, the Notes. The Amended Loan Agreement amends and restates the Loan and Security Agreement between AcelRx and the Lenders dated as of June 29, 2011. We borrowed the first tranche of $15.0 million upon closing of the transaction on December 16, 2013, and the second tranche of $10.0 million on June 16, 2014. We used approximately $8.6 million of the proceeds from the first tranche to repay our obligations under the Loan and Security Agreement with the Lenders. We recorded the new debt at an estimated fair value of $24.9 million as of December 31, 2014.

On September 24, 2014, we entered into Amendment No. 1 to the Amended Loan Agreement with Hercules. Amendment No. 1 extended the time period under which we could draw down the third tranche, of up to $15.0 million, from March 15, 2015 to August 1, 2015, subject to AcelRx obtaining approval for Zalviso from the FDA. We did not receive FDA approval of Zalviso by August 1, 2015 and as such, did not have access to the third tranche.

On September 18, 2015, concurrently with the closing of the Royalty Monetization, we entered into a Consent and Amendment No. 2, or Amendment No. 2, to the Amended Loan Agreement with the Lenders. Amendment No. 2 includes an interest only period from October 1, 2015 through March 31, 2016, with the potential for further extension to September 30, 2016 upon satisfaction of certain conditions. These conditions were satisfied in the third quarter of 2015 and the interest only period under the Amended Loan Agreement is October 1, 2015 through September 30,

2016. After the expiration of the interest only period, we will make 13 monthly payments of $1.7 million beginning in October 2016 through October 2017. In addition, a final payment equal to $1.7 million will be due in October 2017.Loans under the Amended Loan Agreement mature on October 31, 2017. In consideration for the modifications made in Amendment No. 2, we reduced the exercise price of the warrants already held by the Lenders, which are exercisable for an aggregate of 176,730 shares of Common Stock, from the previous exercise price of $6.79 per share to $3.88 per share, or the Warrant Amendments. These warrants expire on the earlier to occur of five years from the date of issuance, or December 16, 2018, or the consummation of certain acquisitions of AcelRx, as set forth in the warrants.

The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 9.10% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.10%. Payments under the Amended Loan Agreement are interest only until April 1, 2015 followed by equal monthly payments of principal and interest through the scheduled maturity date on October 1, 2017, or the Loan Maturity Date. In addition, a final payment equal to $1.7 million will be due on the Loan Maturity Date, or such earlier date specified in the Amended Loan Agreement. Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property and those assets sold under the Royalty Monetization.

As of September 30, 2015, the outstanding principal owed to Hercules was $20.7 million.

On December 16, 2013, we and Grünenthal entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. The License Agreement grants Grünenthal rights to commercialize Zalviso, or the Product, in the Territory for human use in pain treatment within or dispensed by hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. The Company retains rights with respect to the Product in countries outside the Territory, including the United States, Asia and Latin America. Under the MSA, we will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory. On July 22, 2015, we entered into amendments to the License Agreement, or the License Amendment, and together with the License Agreement, the Amended License Agreement, and the MSA, or the MSA Amendment, and together with the MSA, the Amended MSA, between AcelRx and Grünenthal, each effective as of July 17, 2015, and together, the Amended Agreements.

In the Amended Agreements, the parties amended the Product supply configurations and packaging of Product components and accessories, and associated pricing therefor, which we will manufacture and supply to Grünenthal for the Territory. The parties agreed to increase the pricing of the Product components and accessories, while reducing the total milestone payments due from Grünenthal contingent upon achieving specified net sales targets from a total of $171.5 million to $166.0 million. As mentioned above, PDL will receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), subject to the capped amount of $195.0 million. The parties also updated the development plan for the Product in the Territory, providing for additional near-term development services to be rendered by AcelRx in exchange for payments of approximately $0.7 million, primarily in 2015. Simultaneously, AcelRx also received a binding Product forecast from Grünenthal for approximately $3.7 million.

Under the terms of the Amended Agreements with Grünenthal, we received an upfront cash payment of $30.0 million in December 2013, and in the third quarter of 2014, we received a milestone payment of $5.0 million related to the MAA submission to EMA. We became entitled to receive an additional $15.0 million milestone payment upon the approval of the MAA in September 2015. Under the Amended License Agreement, we are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales of Zalviso in the Territory.

Grünenthal will be responsible for all commercial activities for Zalviso, including obtaining and maintaining pharmaceutical product regulatory approval in the Territory. We will be responsible for obtaining and maintaining device regulatory approval in the Territory and manufacturing and supply of Zalviso to Grünenthal for commercial sales.

In association with the impending commercialization of Zalviso in the European Union, we underwent a Conformite Europeenne approval process for the Zalviso device, more commonly known as a CE Mark approval process. We received CE Mark approval in December 2014, which permits the commercial sale of the Zalviso device in the European Union. In connection with the CE Mark approval, we were also granted International Standards Organization, or ISO, 13485:2003 certification of our quality management system in November 2014. This is an internationally recognized quality standard for medical devices. Certification of our quality management system was issued by the British Standards Institution, or BSI, a Notified Body.

ISO 13485:2003 certification recognizes that consistent quality policies and procedures are in place for the development, design and manufacturing of medical devices. The certification indicates that we have successfully implemented a quality system that conforms to ISO 13485 standards for medical devices. Certification to this standard is one of the key regulatory requirements for a CE Mark in the European Union as well as to meet equivalent requirements in other international markets. The certification applies to the Redwood City, California location which designs, manufactures and distributes finished medical devices, and includes critical suppliers.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe 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 may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2014. During the nine months ended September 30, 2015, we updated our concentration of risk policy to include our reliance on third parties for product manufacturing obligations under the Grünenthal Amended MSA, and our revenue recognition policy to include contract revenue, and added a policy for non-cash interest expense on liability related to sale of future royalties, as discussed below. There are no other significant changes to our significant accounting policies from those previously disclosed in our Annual Report on Form 10-K.

Concentration of Risk

We rely on a single third-party supplier for the supply of sufentanil, the active pharmaceutical ingredient in Zalviso, and various sole-source third-party contract manufacturer organizations to manufacture the Zalviso drug cartridge and device components, including the controller, the dispenser kit and the accessories.

Revenue Recognition - Contract Revenue

In May 2015, we entered into an award contract with the United States Army Medical Research and Materiel Command, or USAMRMC, to support the development of ARX-04. The contract provides for the reimbursement of qualified expenses for research and development activities as defined under the terms of the contract. Revenue under the contract is recognized when the related qualified research expenses are incurred. We are entitled to reimbursement of overhead costs associated with the study costs incurred under the DoD Contract. We estimate this overhead rate by utilizing forecasted expenditures. Final reimbursable overhead expenses are dependent on direct labor and direct reimbursable expenses throughout the life of the contract, so may increase or decrease based on actual expenses incurred.

Non-Cash Interest Expense on Liability Related to Sale of Future Royalties

In September 2015, we sold certain royalty and milestone payment rights from the sales of Zalviso in the European Union by our commercial partner, Grünenthal, pursuant to the Collaboration and License Agreement, dated as of December 16, 2013, as amended, to PDL for an upfront cash purchase price of $65.0 million. We continue to have significant continuing involvement in the Royalty Monetization primarily due to our obligation to act as the intermediary for the supply of Zalviso to Grünenthal. Under the relevant accounting guidance, because of our significant continuing involvement, the Royalty Monetization has been accounted for as a liability that will be amortized using the interest method over the life of the arrangement. In order to determine the amortization of the liability, we are required to estimate the total amount of future royalty and milestone payments to be received by PDL and payments we are required to make to PDL, up to a capped amount of $195.0 million, over the life of the arrangement. The sum of the capped amount of $195.0 million, less the $61.2 million of net proceeds we received will be recorded as interest expense over the life of the liability. Consequently, we impute interest on the unamortized portion of the liability and record interest expense using an estimated interest rate for an arms-length debt transaction. Our estimate of the interest rate under the arrangement is based on the amount of royalty and milestone payments expected to be received by PDL over the life of the arrangement. Our estimate of this total interest expense resulted in an effective annual interest rate of approximately 14%. We will periodically assess the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the liability and the interest rate.

We will record non-cash royalty revenues and non-cash interest expense within our condensed consolidated statement of operations over the term of the PDL agreement.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, to provide guidance on revenue recognition. ASU 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 Update No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU-2015-14, that provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU 2014-09 is effective for AcelRx in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU 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. We are currently evaluating the method of adoption and the impact of adopting ASU 2014-09 on our results of operations, cash flows and financial position.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest—Imputation of Interest*, or ASU 2015-03. ASU 2015-03 will more closely align the presentation of debt issuance costs under U.S. GAAP with the presentation under comparable IFRS standards by requiring that debt issuance costs be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015 and is required to be applied retrospectively to all prior periods presented. As permitted by ASU 2015-03, we elected to early adopt this guidance beginning with the first quarter of fiscal 2015, in order to simplify the presentation of our debt issuance costs. The resulting reclassifications of unamortized debt issuance costs from other assets to long-term debt, net of current portion on the condensed consolidated balance sheets as of September 30, 2015 and December 31, 2014, was $23,000 and $31,000, respectively. Refer to Note 5 "Long Term Debt" for additional information.

Results of Operations

Three and Nine Months Ended September 30, 2015 and 2014

Revenue

To date, we have not generated any commercial product revenue. In September 2015, the European Commission granted marketing approval for Zalviso in the European Union to our commercial partner, Grünenthal. We do not expect to receive any commercial sales revenue until after Grünenthal launches Zalviso in the European Union, which is expected in 2016.

Revenue for the three and nine months ended September 30, 2015, was $15.4 million and $17.5 million, respectively, the majority of which was recognized under our Amended License Agreement with Grünenthal, including revenue associated with the $15.0 million milestone payment for the MAA approval of Zalviso, which we expect to receive in the fourth quarter of 2015. In addition, in the three and nine months ended September 30, 2015, $1.6 million and $3.0 million, respectively, in revenue was recognized under the DoD Contract, while $0.7 million and $1.4 million, respectively, were recognized related to development work associated with our Amended License Agreement with Grünenthal. Revenue for the three and nine months ended September 30, 2014, was $4.8 million and $5.0 million, respectively, which was primarily due to the recognition of the milestone payment for the MAA submission under our Amended License Agreement with Grünenthal.

Contract Revenue

On May 11, 2015, we entered into an award contract supported by the USAMRMC within the DoD, in which the DoD agreed to provide up to $17.0 million to support the development of our product candidate ARX-04, a proprietary, non-invasive, single-use tablet in a disposable, pre-filled, single-dose applicator for the treatment of moderate-to-severe acute pain. The DoD Contract will support development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse us for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

Collaboration Agreement Revenue

Under the terms of the Amended Agreements with Grünenthal, we received an upfront cash payment of $30.0 million, and a milestone payment of $5.0 million related to the MAA submission, which occurred in July 2014. We are entitled to an additional $15.0 million milestone payment due to the European Commission approval of the Zalviso MAA in September 2015, of which $13.2 million was recognized in the three months ended September 30, 2015. We are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). PDL will receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), subject to the capped amount of $195.0 million. Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range on net sales of Zalviso.

In September 2015, we sold certain royalty and milestone payment rights from the sales of Zalviso in the European Union by Grünenthal, pursuant to the Amended Agreements, to PDL for an upfront cash purchase price of $65.0 million. Due to our significant continuing involvement in the Royalty Monetization, primarily due to an obligation to act as the intermediary for the supply of Zalviso to Grünenthal, the Royalty Monetization has been accounted for as a liability that will be amortized using the interest method over the life of the arrangement. As the portion of the royalties and milestone payments sold to PDL are remitted by Grünenthal, the balance of the liability related to the Royalty Monetization will be effectively reduced over the life of the agreement. As such, we will record non-cash royalty revenues and non-cash interest expense within our condensed consolidated statements of comprehensive income (loss) over the term of the PDL agreement. There was no such non-cash royalty revenue in the three and nine months ended September 30, 2015. We do not expect to receive any non-cash royalty revenue, or other commercial sales revenue, until after Grünenthal launches Zalviso in the European Union.

Research and Development Expenses

Conducting research and development is central to our business model. The majority of our operating expenses to date have been for research and development activities related to Zalviso. Research and development expenses included the following:

- expenses incurred under agreements with contract research organizations and clinical trial sites;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party pharmaceutical and engineering development contractors;
- payments to third party manufacturers;
- depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and equipment and laboratory and other supply costs; and
- costs for equipment and laboratory and other supplies.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We will incur substantial future expenditures as we seek to continue development of Zalviso, including activities to address issues raised by the FDA during their regulatory review process, as well as activities associated with potential preparation for commercialization of Zalviso, should we receive approval from the FDA. In addition, we plan to continue to incur significant research and development expenses, including the expenses associated with the continued development of ARX-04 and the additional clinical trial for Zalviso. We do not plan to continue development of ARX-02 and ARX-03, unless additional funding or corporate partnership resources are available to support these programs.

We track external development expenses on a program-by-program basis. Our development resources are shared among all of our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead. Below is a summary of our research and development expenses during the three and nine months ended September 30, 2015 and 2014 (in thousands):

Drug Indication/Description	Three Months Ended September 30, 2015	2014	2015 vs. 2014 Increase/ (Decrease)		Nine Months Ended September 30, 2015	2014	2015 vs. 2014 Increase/ (Decrease)	
	(In thousands, except percentages)							
ARX-04	$912	$523	74	%	$5,069	$2,223	128	%
Zalviso	1,291	2,241	(42	)%	4,043	7,541	(46	)%
Overhead	3,190	2,480	29	%	9,897	7,475	32	%
Total research and development expenses	$5,393	$5,244	3	%	$19,009	$17,239	10	%

Due to the inherently unpredictable nature of product development, development timelines and the probability of success, development costs can differ materially from expectations. While we are currently focused on the continued development of ARX-04 and advancing Zalviso, our future research and development expenses will depend on the clinical success of each product candidate as well as ongoing assessments of the commercial potential of our product candidates. In addition, we cannot predict which product candidates may be subject to future collaborations, when these arrangements will be secured, if at all, and to what degree these arrangements would affect our development plans and capital requirements.

Total research and development expenses for the three and nine months ended September 30, 2015 and 2014 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015	2014	Change	%	2015	2014	Change	%
	(In thousands, except percentages)							
Research and development expenses	$5,393	$5,244	$ 149	3%	$19,009	$17,239	$ 1,770	10%

Research and development expenses during the three months ended September 30, 2015, as compared to the three months ended September 30, 2014, included an increase of $0.4 million in ARX-04 costs, primarily due to the initiation of the SAP302 study which began in the third quarter of 2015, and $0.7 million in research and development overhead expenses, compared to the three months ended September 30, 2014. These increases were partially offset by a $0.9 million reduction in Zalviso development program expenses during the three months ended September 30, 2015, as compared to the three months ended September 30, 2014.

The $1.8 million increase in research and development expenses during the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014, was primarily attributable to a $2.8 million increase related to the ARX-04 development program, a $1.2 million increase in manufacturing facilities expense, and an increase of $1.3 million in personnel-related expenses, including stock-based compensation, partially offset by a $3.5 million decrease related to the Zalviso development program.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel in administration, finance, marketing and business development activities. Other significant expenses included legal expenses related to litigation and patent protection of our intellectual property, allocated facility costs and professional fees for general legal, audit and consulting services. We expect general and administrative expenses to continue to decrease in the next quarter as a result of the cost reduction plan and then remain flat as we focus our efforts on further development and seeking marketing approval for Zalviso, and the continued development of ARX-04.

Total general and administrative expenses for the three and nine months ended September 30, 2015 and 2014 were as follows (in thousands, except percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,	
	2015	2014	Change	%	2015	2014