ACELRX PHARMACEUTICALS INC
Form 10-Q
August 02, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act.

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

As of July 26, 2017, the number of outstanding shares of the registrant's common stock was 45,380,473.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017

Table of Contents

Unless the context indicates otherwise, the terms “AcelRx,” “AcelRx Pharmaceuticals,” “we,” “us” and “our” refer to AcelRx Pharmaceuticals, Inc. “DSUVIA” is a trademark, and ACELRX and “ZALVISO” are registered trademarks, all owned by AcelRx Pharmaceuticals, Inc. This report also contains trademarks and trade names that are the property of their respective owners.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share data)

	June 30, 2017 (Unaudited)	December 31, 2016[(1)]
Assets		
Current Assets:		
Cash and cash equivalents	$ 62,148	$80,310
Accounts receivable, net	2,070	5,833
Inventories	1,580	2,154
Prepaid expenses and other current assets	971	756
Total current assets	66,769	89,053
Property and equipment, net	11,193	10,712
Restricted cash	178	178
Other assets	50	50
Total Assets	$ 78,190	$99,993
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,028	$1,558
Accrued liabilities	4,365	4,595
Long-term debt, current portion	7,129	2,912
Deferred revenue, current portion	362	362
Liability related to the sale of future royalties, current portion	677	764
Total current liabilities	13,561	10,191
Deferred rent, net of current portion	—	43
Long-term debt, net of current portion	14,891	18,637
Deferred revenue, net of current portion	3,643	3,824
Liability related to the sale of future royalties, net of current portion	77,431	72,223
Contingent put option liability	260	124
Warrant liability	28	288
Total liabilities	109,814	105,330
Commitments and Contingencies		

Stockholders' Deficit:		
Common stock, $0.001 par value—100,000,000 shares authorized as of June 30, 2017 and December 31, 2016; 45,380,473 and 45,333,790 shares issued and outstanding as of June 30, 2017 and December 31, 2016	45	45
Additional paid-in capital	243,303	240,977
Accumulated deficit	(274,972)	(246,362)
Accumulated other comprehensive income	—	3
Total stockholders' deficit	(31,624)	(5,337)
Total Liabilities and Stockholders' Deficit	$ 78,190	$ 99,993

(1) The condensed consolidated balance sheet as of December 31, 2016 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, 2016.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Collaboration agreement	$2,192	$1,314	$5,219	$3,107
Contract and other	467	3,217	549	4,449
Total revenue	2,659	4,531	5,768	7,556
Operating costs and expenses:				
Cost of goods sold	3,543	2,976	7,668	6,575
Research and development	4,901	6,280	11,820	10,451
General and administrative	4,156	3,597	8,294	7,374
Total operating costs and expenses	12,600	12,853	27,782	24,400
Loss from operations	(9,941)	(8,322)	(22,014)	(16,844)
Other (expense) income:				
Interest expense	(903)	(687)	(1,677)	(1,367)
Interest income and other income (expense), net	396	241	250	660
Non-cash interest expense on liability related to future sale of royalties	(2,609)	(2,324)	(5,167)	(4,520)
Total other expense	(3,116)	(2,770)	(6,594)	(5,227)
Net loss before income taxes	(13,057)	(11,092)	(28,608)	(22,071)
Provision for income taxes	(2)	—	(2)	(2)
Net loss	(13,059)	(11,092)	(28,610)	(22,073)
Other comprehensive loss:				
Unrealized gains (losses) on available-for-sale securities	2	2	(3)	7
Comprehensive loss	$(13,057)	$(11,090)	$(28,613)	$(22,066)
Net loss per share of common stock, basic	$(0.29)	$(0.24)	$(0.63)	$(0.49)
Net loss per share of common stock, diluted	$(0.29)	$(0.24)	$(0.63)	$(0.49)
Shares used in computing net loss per share of common stock, basic	45,379,471	45,312,242	45,363,949	45,299,560
Shares used in computing net loss per share of common stock, diluted – see Note 11	45,379,471	45,312,242	45,363,949	45,299,560

See notes to condensed consolidated financial statements.

4

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$(28,610)	$(22,073)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	(46)	—
Non-cash interest expense on liability related to royalty monetization	5,167	4,520
Depreciation and amortization	948	1,029
Non-cash interest expense related to debt financing	471	426
Stock-based compensation	2,222	2,330
Revaluation of put option and PIPE warrant liabilities	(124)	(574)
Inventory impairment charge	369	—
Other	(3)	17
Changes in operating assets and liabilities:		
Accounts receivable	3,763	(899)
Inventories	574	(862)
Prepaid expenses and other assets	(276)	494
Accounts payable	2	1,391
Accrued liabilities	(538)	(1,042)
Deferred revenue	(181)	873
Deferred rent	(43)	(97)
Net cash used in operating activities	(16,305)	(14,467)
Cash flows from investing activities:		
Purchase of property and equipment	(1,961)	(308)
Purchases of investments	—	(993)
Proceeds from maturities of investments	—	5,525
Net cash (used in) provided by investing activities	(1,961)	4,224
Cash flows from financing activities:		
Net proceeds from issuance of common stock through equity plans	104	121
Net cash provided by financing activities	104	121
Net decrease in cash and cash equivalents	(18,162)	(10,122)
Cash and cash equivalents—Beginning of period	80,310	107,922
Cash and cash equivalents—End of period	$62,148	$97,800

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

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

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. AcelRx's lead product candidate, DSUVIA™ (known as ARX-04 outside of the United States), and its product candidate, ZALVISO®, utilize sublingual sufentanil, delivered via a non-invasive route of sublingual administration. Subject to obtaining regulatory approvals, AcelRx anticipates developing a distribution capability and commercial organization in the United States to market and sell DSUVIA in the United States by itself, and potentially, in certain European Economic Area, or EEA, countries with strategic partners. In geographies where AcelRx decides not to commercialize products by itself, the Company may seek to out-license commercialization rights. AcelRx intends to seek regulatory approval for ZALVISO in the United States and, if successful, potentially promote ZALVISO either by itself or with strategic partners.

DSUVIA, is a 30 mcg sufentanil sublingual tablet in a single-dose applicator intended for the treatment of moderate-to-severe acute pain administered by a healthcare professional. DSUVIA was initially developed at the request of the U.S. Department of Defense as a replacement for injections of morphine on the battlefield. In addition to the military application, AcelRx is developing DSUVIA for the treatment of patients suffering from moderate-to-severe acute pain in multiple settings, such as emergency room patients; patients who are recovering from short-stay or ambulatory surgery and do not require more long-term analgesia; post-operative patients who are transitioning from the operating room to the recovery floor; certain types of office-based or hospital-based procedures; patients being treated and transported by paramedics. The Company has completed the Phase 3 clinical program for DSUVIA and in February 2017 a New Drug Application, or NDA, was accepted for filing by the U.S. Food and Drug Administration, or FDA, for DSUVIA for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional in medically supervised settings. The Prescription Drug User Fee Act or, PDUFA, goal date for completion of the review of the NDA is October 12, 2017. In March 2017, the European Medicines Agency, or EMA, notified the Company that the ARX-04 (sufentanil sublingual tablet, 30 mcg) Marketing Authorisation Application, or MAA, has passed validation, and that the scientific review of the MAA is underway. The MAA for ARX-04 (known as DSUVIA in the United States) was filed for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting. AcelRx expects an opinion on the MAA from the Committee for

Medicinal Products for Human Use, or CHMP, in the first half of 2018.

ZALVISO delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia, or PCA, system. ZALVISO is approved in the EEA, Norway, Iceland and Liechtenstein and is in late-stage development in the U.S. The Company had initially submitted to the FDA an NDA seeking approval for ZALVISO in September 2013 but received a Complete Response Letter, or CRL, on July 25, 2014. Subsequently, the FDA requested an additional clinical study, IAP312, designed to evaluate the effectiveness of changes made to the functionality and usability of the ZALVISO device and to take into account comments from the FDA on the study protocol. In the IAP312 study, for which top-line results were announced in August 2017, ZALVISO met safety, satisfaction and device usability expectations. These results will supplement the three Phase 3 trials already completed in the ZALVISO NDA resubmission which the Company anticipates resubmitting to the FDA by the end of 2017.

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015 and September 20, 2016, or the Amended License Agreement, which grants Grünenthal rights to commercialize ZALVISO PCA system, or the Product, in the countries of the EU, Switzerland, Liechtenstein, Iceland, Norway and Australia (collectively, the Territory) for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings, or the Field. In September 2015, the European Commission, or EC, 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 EEA, Norway, Iceland and Liechtenstein, or EEA. Also on December 16, 2013, AcelRx and Grünenthal, entered into a related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. Under the MSA, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory. On July 22, 2015, the Company entered into an amendment to the MSA, or the MSA Amendment, and together with the MSA, the Amended MSA, between the Company and Grünenthal, effective as of July 17, 2015, and together with the Amended License Agreement, the Amended Agreements.

Grünenthal has initially deployed the ZALVISO System in a limited number of hospitals in targeted countries under a pilot program, whereby the hospital will use ZALVISO in a small number of post-operative patients. Pilot programs are expected to last several months after which ZALVISO may be available for commercial sale. ZALVISO has been commercially launched in Germany, France, Belgium, Netherlands, Italy, the UK, Spain and Portugal, and is expected to be commercially launched in 2017 in Ireland and Austria. Royalty revenues and non-cash royalty revenues from the commercial sales of ZALVISO in the EU are expected to be minimal for 2017.

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception. Although ZALVISO has been approved for sale in the EU, 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 operating losses and negative cash flows.

When we refer to "we," "our," "us," the "Company" or "AcelRx" in this document, we mean AcelRx Pharmaceuticals, Inc. and its consolidated subsidiary.

Principles of Consolidation

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

Basis of Presentation

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

Operating results for the six months ended June 30, 2017, are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. The condensed consolidated balance sheet as of December 31, 2016, was derived from the Company’s audited financial statements as of December 31, 2016, 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, 2016, 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, 2016. During the six months ended June 30, 2017, there have been no significant changes to the Company’s significant accounting policies from those previously disclosed in its Annual Report on Form 10-K.

Recently Adopted Accounting Standards

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)*, which is part of the FASB's Simplification Initiative. The updated guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. Under this guidance, on a prospective basis, companies will no longer record excess tax benefits and certain tax deficiencies as additional paid-in capital. Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. In addition, the guidance eliminates the requirement that excess tax benefits be realized before companies can recognize them. The ASU requires a cumulative-effect adjustment for previously unrecognized excess tax benefits in opening retained earnings in the annual period of adoption. Effective January 1, 2017, the Company adopted this updated guidance. Upon adoption, the Company recognized additional excess tax benefit as a deferred tax asset with a corresponding increase to our deferred tax asset valuation allowance, which did not result in a net impact to retained earnings, and elected to recognize forfeitures when they occur using a modified retrospective approach, which did not have a material impact on its condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330) Related to Simplifying the Measurement of Inventory,* which applies to all inventory measured using first-in, first-out ("FIFO") or average cost. Inventory within the scope of the new guidance should be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU No. 2015-11 was adopted by the Company beginning in fiscal 2017, and did not have a material impact on its condensed consolidated financial statements.

Recently Issued Accounting Standards

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*, to clarify which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under ASC 718. Under the new guidance, an entity will not apply modification accounting to a share-based payment award if all of the following remain unchanged immediately before and after the change of terms and conditions:

•The award's fair value (or calculated value or intrinsic value, if those measurement methods are used),

•The award's vesting conditions, and

•The award's classification as an equity or liability instrument.

ASU 2017-09 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017 for all entities. Early adoption is permitted, including adoption in any interim period for which financial statements have not yet been issued or made available for issuance. The ASU will be applied prospectively to awards modified on or after the adoption date. The Company has not yet selected a transition date. The Company does not expect the adoption of ASU 2017-09 to have a material effect on its results of operations, financial condition or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU No. 2016-18 is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the condensed consolidated statement of cash flows. The ASU requires that the condensed consolidated statement of cash flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The ASU also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the

condensed consolidated statement of cash flows and the cash and equivalents balance presented on the condensed consolidated balance sheet. ASU 2016-18 is effective retrospectively on January 1, 2018, with early adoption permitted. The Company has not yet selected a transition date. The Company does not expect the adoption of ASU 2016-18 to have a material effect on its results of operations, financial condition or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 15, 2017, and for interim periods within those years. Early adoption is permitted. The Company does not expect the amended guidance to have a material impact on its statements of cash flows.

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

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

ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*;
ASU No. 2016-10, *Identifying Performance Obligations and Licensing (Topic 606);*
ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting;*
ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and*
ASU No. 2016-20, *Revenue from Contracts with Customers (Topic 606): Technical Corrections and Improvements*.

The Company currently anticipates adoption of the new standard effective January 1, 2018 under the modified retrospective transition method. The initial analysis identifying areas that will be impacted by the new guidance is substantially complete, and the Company is currently analyzing the potential impacts to the condensed consolidated financial statements and related disclosures, including the areas of variable consideration and new disclosure requirements. While the Company is still in the process of its evaluation of its contract with the U.S. Department of Defense and the Amended Agreements with its collaboration partner Grünenthal, the Company currently believes that the impact of adoption of the new standard to its financial statements will not be material. As the Company completes its evaluation of the new standard, new information may arise that could change the Company's understanding of the impact to its financial statements. The Company will continue to monitor additional modifications, clarifications or interpretations undertaken by the FASB that may impact its current conclusions, and will expand its analysis to include any new revenue arrangements initiated prior to adoption.

2. Investments and Fair Value Measurement

Investments

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

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

	As of June 30, 2017			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash and cash equivalents:				
Cash	$31,581	$ —	$ —	$31,581
U.S. government agency securities	30,567	—	—	30,567
Total cash and cash equivalents	62,148	—	—	62,148
Total cash, cash equivalents and investments	$62,148	$ —	$ —	$62,148

	As of December 31, 2016			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash and cash equivalents:				
Cash	$49,833	$ —	$ —	$49,833
U.S. government agency securities	30,474	3	—	30,477
Total cash and cash equivalents	80,307	3	—	80,310
Total cash, cash equivalents and investments	$80,307	$ 3	$ —	$80,310

As of June 30, 2017 and December 31, 2016, 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 June 30, 2017 or December 31, 2016. 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 six months ended June 30, 2017 and 2016.

As of June 30, 2017 and December 31, 2016, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company's financial instruments consist of Level II assets and Level III liabilities. 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 June 30, 2017 and December 31, 2016, the Company held, in addition to Level II assets, a contingent put option liability associated with the Company's Amended and Restated Loan and Security Agreement, or the Original Loan Agreement, with Hercules Technology II, L.P. and Hercules Capital, Inc., formerly known as Hercules Technology Growth Capital, Inc., collectively referred to as the Lenders, which amended and restated the Loan and Security Agreement dated as of June 29, 2011, which was classified as a Level III liability. On March 2, 2017, the Company entered into an Amended and Restated Loan and Security Agreement, or the Amended Loan Agreement with Hercules Capital Funding Trust 2014-1 and Hercules Technology II, L.P., together, Hercules. The Amended Loan Agreement amends and restates the Original Loan Agreement. See Note 6 "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 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 June 30, 2017 and December 31, 2016, 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. For a detailed description, see Note 8 "Warrants." 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 these inputs can have a significant impact to the estimated fair value of the PIPE warrants. 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 June 30, 2017			
	Fair Value	Level I	Level II	Level III
Assets				
U.S. government agency obligations	$30,567	$ —	$30,567	$—
Total assets measured at fair value	$30,567	$ —	$30,567	$—
Liabilities				
PIPE warrants	$28	—	—	$28
Contingent put option liability	260	—	—	260
Total liabilities measured at fair value	$288	$ —	$—	$288

	As of December 31, 2016			
	Fair Value	Level I	Level II	Level III
Assets				
U.S. government agency obligations	$30,477	$ —	$30,477	$—
Total assets measured at fair value	$30,477	$ —	$30,477	$—
Liabilities				
PIPE warrants	$288	—	—	$288
Contingent put option liability	124	—	—	124
Total liabilities measured at fair value	$412	$ —	$—	$412

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 June 30, 2017 and December 31, 2016:

	As of June 30, 2017	As of December 31, 2016
Market Price	$2.15	$ 2.60
Exercise Price	$3.40	$ 3.40
Risk-free interest rate	1.14%	0.85 %
Expected volatility	58.0%	81.0 %
Expected life (in years)	0.42	0.92
Expected dividend yield	0.0 %	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 six months ended June 30, 2017 and June 30, 2016 (in thousands):

	Three Months Ended June 30, 2017	Six Months Ended June 30, 2017
Fair value—beginning of period	$ 609	$ 412
Change in fair value of PIPE warrants	(267)	(260)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	(54)	136
Fair value—end of period	$ 288	$ 288

	Three Months Ended June 30, 2016	Six Months Ended June 30, 2016
Fair value—beginning of period	$ 804	$ 1,179

Change in fair value of PIPE warrants	(142)	(473)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	(57)	(101)
Fair value—end of period	$ 605	$ 605

3. Inventories

Inventories consist of finished goods, raw materials and work in process and are stated at the lower of cost or market and consist of the following (in thousands):

	Balance as of	
	June 30, 2017	**December 31, 2016**
Raw materials	$860	$ 1,126
Work-in-process	520	296
Finished goods	200	732
Total	$1,580	$ 2,154

The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. During the three months ended June 30, 2017, the Company recorded an inventory impairment charge of $369,000, primarily for ZALVISO raw materials inventory on hand, plus related purchase commitments.

4. U.S. Department of Defense Contract

On May 11, 2015, the Company entered into an award contract (referred to as the DoD Contract) supported by the Clinical and Rehabilitative Medicine Research Program, or CRMRP, of the United States Army Medical Research and Materiel Command, or the 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 DSUVIA (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. Under the terms of the DoD Contract, the DoD has and continues to reimburse the Company for costs incurred for development, manufacturing, regulatory and clinical costs outlined in the DoD Contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the DoD Contract began on May 11, 2015. The DoD Contract gives the DoD the option to extend the term of the DoD Contract and provide additional funding for the research. On March 2, 2016, the DoD Contract was amended to approve enrollment of additional patients in the SAP302 study, approve the addition of the SAP303 study, and extend the DoD Contract period of performance by four months from November 10, 2016 to March 9, 2017, to accommodate the increased SAP302 patient enrollment and the SAP303 study. The costs for these changes were absorbed within the current DoD Contract value. On March 9, 2017, the DoD Contract was amended to incorporate additional activities including the development and testing of packaging changes; additional stability testing; and preparation for any FDA advisory committee meeting for DSUVIA. The amendment also extends the DoD Contract period of performance by 11 months through February 28, 2018 to accommodate these additional activities. If DSUVIA 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 DoD 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 and other revenue in the condensed consolidated statements of comprehensive loss, was $0.5 million and $0.6 million for the three and six months ended June 30, 2017, respectively, and $3.2 million and $4.4 million for the three and six months ended June 30, 2016, respectively.

5. Collaboration Agreement

As described in Note 1 “Organization and Summary of Significant Accounting Policies,” the Company has entered into amendments to the Agreements with Grünenthal related to ZALVISO. 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, which was fully delivered by the end of 2016.

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 described above. 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. A CE Mark for ZALVISO was obtained in the fourth quarter of 2014 which specifies AcelRx as the device design authority and manufacturer. In September 2015, the EC approved the MAA for ZALVISO (15 mcg sufentanil sublingual tablets) for the management of acute moderate-to-severe post-operative pain in adult patients for the 28 EU member states as well as for the EEA. In April 2016, Grünenthal completed the first commercial sale of ZALVISO.

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, and an additional $15.0 million milestone payment upon the EC approval. 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 to be agreed between Grünenthal and the Company ($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, depending on the level of sales achieved, on net sales of ZALVISO. A portion of the tiered royalty payment, exclusive of the supply and trademark fee payments, will be paid to PDL in connection with the Royalty Monetization. For additional information on the Royalty Monetization with PDL, see Note 7 “Liability Related to Sale of Future Royalties”. 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, or December 16, 2013 through December 15, 2018, 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 direct 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 BESP, 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. BESP 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, a cash payment of $5.0 million. In September of 2015, the MAA was approved by the EC, triggering the second of these two milestones, a cash payment of $15.0 million. Amounts received under these non-substantive milestones were 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 totaling $54.4 million, 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. 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 six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Product sales	$1,993	$1,302	$4,914	$2,702
Joint steering committee, research and development services and demonstration devices	166	12	244	405
Non-cash royalty revenue related to Royalty Monetization (See Note 7)	25	—	46	—
Royalty revenue	8	—	15	—
Total	$2,192	$1,314	$5,219	$3,107

As of June 30, 2017, the Company had current and noncurrent portions of the deferred revenue balance under the Amended Agreements of $0.4 million and $3.6 million, respectively.

6. Long-Term Debt

Amended and Restated Loan and Security Agreement

In June 2011, AcelRx entered into the Loan and Security Agreement, with 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 the Lenders seven-year warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share, all of which have been exercised.

On December 16, 2013, AcelRx entered into an Amended and Restated Loan and Security Agreement with the Lenders, or the Original Loan Agreement, under which the Company was provided the ability to borrow up to $40.0

million in three tranches. The loans were represented by secured convertible term promissory notes, collectively, the 2013 Notes. The Original Loan Agreement amended and restated the prior Loan and Security 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 prior 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. In connection with the Original Loan Agreement, the Company issued to the Lenders warrants exercisable for an aggregate of 176,730 shares of common stock at an exercise price of $6.79 per share.

On September 24, 2014, the Company entered into Amendment No. 1 to the Original Loan Agreement with the Lenders. 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 Original Loan Agreement with the Lenders. Amendment No. 2 includes an interest-only period from October 1, 2015 through March 31, 2016, with 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 was extended through September 30, 2016. Loans under the Original Loan Agreement were scheduled to mature on October 1, 2017. In connection with Amendment No. 2, the Company reduced the exercise price of the previously issued warrants to $3.88 per share.

On September 30, 2016, the Company entered into Amendment No. 3 to the Original Loan Agreement with the Lenders. Among other things, Amendment No. 3 extended the interest-only period from October 1, 2016 to April 1, 2017. In connection with Amendment No. 3, the Company further reduced the exercise price of the existing warrants held by the Lenders to $3.07 per share.

On March 2, 2017, the Company amended and restated the Original Loan Agreement with the Lenders, which is referred to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, the Company may borrow up to approximately $30.5 million in two tranches, which are represented by secured convertible term promissory notes, or the Notes. The Company borrowed the first tranche of approximately $20.5 million upon closing of the transaction on March 2, 2017. The Company used or will use all of the proceeds from the first tranche to repay its obligations under the Original Loan Agreement (a final payment of $1.7 million on the earliest of (i) October 1, 2017, (ii) prepayment in full of the loans (other than by a refinancing with Hercules) or (iii) the date on which the loans under the Amended Loan Agreement become due and payable). The second tranche, of up to $10.0 million, can be drawn at any time between April 1, 2017 and December 31, 2017, but only if (a) the Company has obtained approval for the NDA for DSUVIA on or before December 31, 2017, or the Tranche 2 Milestone, and (b) the extension of the second tranche has been approved by Agent's investment committee, such approval to be granted or withheld in its sole discretion. The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 9.55% plus the prime rate as reported from time to time in The Wall Street Journal minus 3.50%, and (ii) 9.55%. Payments under the Amended Loan Agreement are interest-only until October 1, 2017 (which will be extended until April 1, 2018 if the Company shall have received at least $40.0 million in net proceeds raised as a combination of up-front cash proceeds from out-licensing or commercial partnering relating to DSUVIA and ZALVISO and from the issuance and sale of new equity after March 2, 2017 and on or before December 31, 2017, or the Liquidity Milestone, and which will be further extended until October 1, 2018 if the Company has achieved the Liquidity Milestone and the Tranche 2 Milestone) followed by equal monthly payments of principal and interest through the scheduled maturity date on March 1, 2020 (which would be extended until September 1, 2020 if the Company achieves the Liquidity Milestone and March 1, 2021 if the Company achieves the Liquidity Milestone and the Tranche 2 Milestone) as applicable, or the Maturity Date. A final payment equal to 6.5% of the aggregate principal amount of loans funded under the Amended Loan Agreement will be due on the earliest of (i) the maturity date, (ii) prepayment in full of the loans (other than by a refinancing with Hercules) or (iii) the date on which the loans under the Amended Loan Agreement become due and payable. 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.

If the Company prepays the loans under the Amended Loan Agreement prior to the maturity date, it will pay Hercules a prepayment charge, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs prior to March 2, 2018, 2% if the prepayment occurs after March 2, 2018, but prior to March 2, 2019, or 1% if the prepayment occurs after March 2, 2019.

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.

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. This option is considered a

contingent put option liability, as the holder of the loan has the ability to 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 Original Loan Agreement entered into on December 16, 2013 was considered an extinguishment, the contingent put option liability associated with the prior Loan and Security 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 June 30, 2017, the estimated fair value of the contingent put option liability was $260,000 under the Amended Loan Agreement and as of December 31, 2016, the estimated fair value of the contingent put option liability was $124,000 under the Original Loan Agreement. The estimated fair values were 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 related to the Amended Loan Agreement will be revalued at the end of each reporting period and any change in the fair value will be recognized in interest income and other income (expense), net in the condensed consolidated statements of comprehensive loss.

The Company performed an analysis of Amendments No. 2 and No. 3 to determine if each amendment was a modification or extinguishment of the debt under the Original 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 Amendments No. 2 and No. 3 were each modifications rather than extinguishments of the debt. In connection with the Amended Loan Agreement, the Company performed an analysis to determine if the amendment and restatement of the Original Loan Agreement was a modification or extinguishment of the debt. The Company assumed immediate prepayment of both the pre-modification debt and post-modification debt and concluded the Amended Loan Agreement was a modification rather than extinguishment of the debt under the Original Loan Agreement.

The accrued balance due under the Amended Loan Agreement was $22.0 million at June 30, 2017 and the accrued balance due under the Original Loan Agreement was $21.5 million at December 31, 2016. Interest expense related to the Amended Loan Agreement was $0.9 million, $0.4 million of which represented amortization of the debt discount, for the three months ended June 30, 2017 and $1.7 million, $0.7 million of which represented amortization of the debt discount, for the six months ended June 30, 2017. Interest expense related to the Original Loan Agreement was $0.7 million, $0.2 million of which represented amortization of the debt discount, for the three months ended June 30, 2016, and $1.4 million, $0.4 million of which represented amortization of the debt discount, for the six months ended June 30, 2016.

7. 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 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 $28.5 million.

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. Due to 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 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 six months ended June 30, 2017 (in thousands):

	Six months ended June 30, 2017	**Period from inception to June 30, 2017**
Liability related to sale of future royalties — beginning balance	$72,987	$—
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	(46)	(53)
Non-cash interest expense recognized	5,167	16,977
Liability related to sale of future royalties as of June 30, 2017	78,108	78,108
Less: current portion	(677)	(677)
Liability related to sale of future royalties — net of current portion	$77,431	$77,431

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 loss over the term of the Royalty Monetization.

8. Warrants

Hercules Warrants

In connection with the Original Loan Agreement, executed in December 2013, the Company issued warrants to the Lenders 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 Original Loan Agreement, the Company reduced the exercise price of the warrants already held by the Lenders from the exercise price of $6.79 per share to $3.88 per share, or the First Warrant Amendments. In connection with Amendment No. 3 to the Original Loan Agreement, the Company further reduced the exercise price of the warrants already held by the Lenders to $3.07 per share, or the Second 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 Company estimated the fair value of the warrants after modification by the First 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 in September 2015 and was recorded as equity. The Company estimated the fair value of the warrants after modification by the Second Warrant Amendments, as of the issuance date to be $45,000, and which was used in estimating the fair value of the amended debt instrument in September 2016 and was recorded as equity.

As of June 30, 2017, the Lenders' warrants had not been exercised. These warrants expire in December 2018.

2012 Private Placement Warrants

In connection with a 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. 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 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."

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 June 30, 2017, the fair value of the PIPE warrants was estimated to be $28,000. The change in fair value during the three months ended June 30, 2017 and 2016, which was recorded as other income, was $0.3 million, and $0.2 million, respectively. The change in fair value for the six months ended June 30, 2017 and 2016, which was recorded as other income, was $0.3 million, and $0.5 million, respectively.

As of June 30, 2017, 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.

9. Commitments and Contingencies

Operating Leases

On June 14, 2017, the Company entered into a second amendment, or the Second Lease Amendment, to that certain lease dated December 21, 2011, as amended by a first amendment, dated as of May 2, 2014, or the Existing Lease, and as amended by the Second Lease Amendment, the Lease, with Metropolitan Life Insurance Company, or the Landlord, for the Company's current principal executive offices, approximately 26,000 square feet located at 301 – 351 Galveston Drive, Redwood City, California. Pursuant to the Second Lease Amendment, the term of the Existing Lease has been extended for a period of seventy-two (72) months, or the Extended Term, beginning February 1, 2018 and expiring January 31, 2024, or the Expiration Date, unless sooner terminated pursuant to the terms of the Lease.

Pursuant to the Lease Amendment, the Company will pay on a monthly basis annual rent of approximately $1.2 million, with annual increases each 12-month period beginning February 1st, and the first two months to be abated provided that the Company is not in default thereunder. In addition, the Company will pay the Landlord specified percentages of certain operating expenses related to the leased facility incurred by the Landlord.

10. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of goods sold	$79	$77	$163	$148
Research and development	448	586	985	1,186
General and administrative	551	482	1,074	996
Total	$1,078	$1,145	$2,222	$2,330

As of June 30, 2017, there were 2,311,579 shares available for grant, 8,570,011 options outstanding and no restricted stock units outstanding under the Company's 2011 Equity Incentive Plan and 1,101,331 shares available for grant under the ESPP.

11. 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 six months ended June 30, 2017 and the three and six months ended June 30, 2016, the exercise price of the PIPE warrants exceeded the average of AcelRx's closing share price during each of the periods. As a result, the PIPE warrants were anti-dilutive during the three and six months ended June 30, 2017 and 2016, respectively. 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. As the average market prices during the three and six months ended June 30, 2017 and 2016, respectively, did not exceed the exercise price of the PIPE warrants, no such

adjustments were made.

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 six months ended June 30, 2017 and 2016 (in thousands, except for share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands, except share and per share amounts)			
Numerator				
Net loss used to compute net loss per share:				
Basic	$(13,059)	$(11,092)	$(28,610)	$(22,073)
Adjustments for change in fair value of warrant liability	—	—	—	—
Diluted	$(13,059)	$(11,092)	$(28,610)	$(22,073)
Denominator				
Weighted average shares outstanding used to compute net loss per share:				
Basic	45,379,471	45,312,242	45,363,949	45,299,560
Dilutive effect of warrants	—	—	—	—
Diluted	45,379,471	45,312,242	45,363,949	45,299,560
Net loss per share — basic	$(0.29)	$(0.24)	$(0.63)	$(0.49)
Net loss per share — diluted	$(0.29)	$(0.24)	$(0.63)	$(0.49)

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:

	June 30,	
	2017	2016
ESPP and stock options to purchase common stock	8,700,169	6,537,180
Convertible debt into common stock	—	553,763
Common stock warrants	689,186	692,611

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 the Company's product candidates, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including FDA review and potential approval of the NDA for DSUVIA; the EMA's scientific review of the ARX-04 MAA; the DSUVIA and ARX-04 clinical trial results; the Company's pathway forward towards gaining approval of ZALVISO in the United States, including the anticipated resubmission of the ZALVISO NDA to the FDA, the scope and timing of the resubmission, and FDA review time; the status of the Amended Agreements with Grünenthal or any other future potential collaborations, including potential milestones and royalty payments under the Amended Agreements; and the therapeutic and commercial potential of the Company's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO.

Forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. Actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of various factors. For a more detailed discussion of the potential risks and uncertainties that may impact the accuracy of these forward-looking statements, see the "Risk Factors" section in Part II, Item 1A of this Quarterly Report on Form 10-Q. You should not place undue reliance on these forward-looking statements, which reflect the Company's view 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, 2016.

About AcelRx Pharmaceuticals

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. Our lead product candidate, DSUVIA™ (known as ARX-04 outside of the United States), and our product candidate, ZALVISO®, utilize sublingual sufentanil, delivered via a non-invasive route of sublingual administration. We anticipate developing a distribution capability and commercial organization to market and sell DSUVIA in the United States by ourselves, and potentially, in certain European Economic Area, or EEA, countries with strategic partners. In geographies where we decide not to commercialize ourselves, we may seek to out-license commercialization rights. We intend to seek regulatory approval for ZALVISO in the United States and, if successful, potentially promote ZALVISO either by ourselves or with strategic partners.

We have chosen sufentanil as the therapeutic ingredient for our current product candidates. Opioids have been utilized for pain relief for centuries and are the standard-of-care for the treatment of moderate-to-severe acute pain. Sufentanil is available as an injectable in several markets around the world and is used by anesthesiologists for induction of sedation or as an epidural; however, the injectable formulation is not suitable for the treatment of acute pain. We have created a proprietary sublingual (under the tongue) formulation of sufentanil intended for the treatment of moderate-to-severe acute pain. The sublingual formulation retains the therapeutic value of sufentanil and novel delivery devices provide a non-invasive route of administration. Sufentanil is highly lipophilic which provides for rapid absorption in the mucosal tissue, or fatty cells, found under the tongue, and for rapid transit across the blood-brain barrier to reach the mu-opioid receptors in the brain. The sublingual route of delivery used by DSUVIA and ZALVISO provides a recognized onset of analgesia. The sublingual delivery system also eliminates the risk of intravenous, or IV, complications, such as catheter-related infections. In addition, because patients do not require direct connection to an IV infusion pump, or IV line, DSUVIA and ZALVISO may allow for ease of patient mobility.

DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States

DSUVIA is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator, or SDA. We are developing DSUVIA for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional to a patient in medically supervised settings. If approved, examples of potential patient populations and settings in which DSUVIA could be used include: emergency room patients; patients who are recovering from short-stay or ambulatory surgery and do not require more long-term analgesia; post-operative patients who are transitioning from the operating room to the recovery floor; certain types of office-based or hospital-based procedures; patients being treated and transported by paramedics; and for battlefield casualties. In the emergency room and in ambulatory care environments, patients often do not have immediate IV access available, or maintaining IV access can be an impediment to rapid discharge. Oral pills and liquids generally have slow and erratic onset of analgesia. Moreover, IV dosing results in high peak plasma levels, thereby limiting the opioid dose and requiring frequent redosing intervals to titrate to satisfactory analgesia. Based on internal market research conducted to date, we believe that additional treatment options are needed that can safely and effectively treat acute trauma pain, in both civilian and military settings, and that can provide an alternative to IV opioids for moderate-to-severe acute pain.

With the completion of the clinical program for DSUVIA, and the positive data obtained from all the clinical studies, we submitted an NDA under section 505(b)(2) with the FDA for DSUVIA for the treatment of adult patients experiencing moderate-to-severe acute pain in a medically supervised setting. The NDA was accepted for filing by the FDA in February 2017. The NDA contains results of the entire DSUVIA clinical program, including data from four (three Phase 3 and one Phase 2) clinical trials in which DSUVIA was assessed as a treatment for moderate-to-severe acute pain in post-operative and emergency department patients. In each of these clinical studies, patients treated with DSUVIA demonstrated mean improvements in pain intensity as early as 15-to-30 minutes after the start of dosing. Adverse events reported in the studies were typical of opioid therapy, with the most common being nausea, headache, vomiting and dizziness. In June 2017, the Company was advised that the FDA would not be holding a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee for DSUVIA, originally anticipated to be held in summer 2017. The Prescription Drug User Fee Act, or PDUFA, date for completion of the review of the NDA remains October 12, 2017.

On May 11, 2015, we entered into an award contract (referred to as the DoD Contract) supported by the Clinical and Rehabilitative Medicine Research Program, or CRMRP, of 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 DSUVIA. Under the terms of the DoD Contract, the DoD has and continues to reimburse us for costs incurred for development, manufacturing, regulatory and clinical costs outlined in the DoD Contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the DoD Contract began on May 11, 2015. The DoD Contract gives the DoD the option to extend the term and provide additional funding. On March 2, 2016, the DoD Contract was amended to approve enrollment of additional patients in the SAP302 study, approve the addition of the SAP303 study, and extend the DoD Contract period of performance by four months from November 10, 2016 to March 9, 2017, to accommodate the increased SAP302 patient enrollment and the SAP303 study. The costs for these changes were absorbed within the current DoD Contract value. On March 9, 2017, the DoD Contract was amended to incorporate additional activities including the development and testing of packaging changes; additional stability testing; and preparation for any FDA advisory committee meeting for DSUVIA. The amendment also extended the DoD Contract period of performance by 11 months through February 28, 2018 to accommodate these additional activities. If DSUVIA is approved by the FDA, the DoD has the option to purchase 112,000 units of commercial product pursuant to the terms of the DoD Contract.

In March 2017, the European Medicines Agency, or EMA, notified us that the Marketing Authorisation Application, or MAA, for ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting has passed validation, and that the scientific review of the MAA is underway. We anticipate an opinion on the MAA from the Committee for Medicinal Products for Human Use, or CHMP, in the first half of 2018. We held various meetings with Health Authorities in Europe, including from Iceland and Hungary who have been designated as rapporteur and co-rapporteur, respectively, prior to the submission of the MAA. Based on feedback from these discussions, we submitted a hybrid application for a label indication for ARX-04 in the EU for acute moderate-to-severe pain in adult patients in medically supervised settings. At the time of the MAA submission, we had completed one study in the emergency room for acute pain patients, in addition to two Phase 3 and one Phase 2 post-operative pain studies. We may need an additional controlled study in the emergency department with ARX-04 to obtain a label that includes trauma-related pain in addition to post-operative pain. We also anticipate we may need comparator studies in the EU to ensure premium reimbursement in certain countries.

ZALVISO® (sufentanil sublingual tablet system)

ZALVISO is intended for the management of moderate-to-severe acute pain in hospitalized adult patients. ZALVISO consists of a pre-filled cartridge of 40 sufentanil sublingual tablets, 15 mcg, delivered by the ZALVISO System, a needle-free, handheld, patient-administered, pain management system. While still under development in the U.S., as discussed further below, ZALVISO is approved and marketed in the EU.

ZALVISO is a 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 (IV) patient-controlled analgesia (PCA). ZALVISO

allows patients to self-administer sufentanil sublingual tablets via a pre-programmed, secure system designed in part to eliminate the risk of programming errors.

On December 16, 2013, AcelRx and Grünenthal GmbH, or 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, our novel sublingual patient-controlled analgesia, or PCA, system, or the Product, in the countries of the European Union, or EU, 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. We retain 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. 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. We entered into amendments to the License Agreement, effective July 17, 2015 and September 20, 2016, or the License Amendments, and together with the License Agreement, the Amended License Agreement, and entered into an amendment to the MSA, or the MSA Amendment, and together with the MSA, the Amended MSA, effective as of July 17, 2015, and together, the Amended Agreements. For additional information on the Amended Agreements, see Note 5 "Collaboration Agreement" in the accompanying notes to the condensed consolidated financial statements.

ZALVISO was approved for commercial sale by the European Commission in September 2015. Grünenthal has initially deployed the ZALVISO System in a limited number of hospitals in targeted countries under a pilot program, whereby the hospital will use ZALVISO in a small number of post-operative patients. Pilot programs are expected to last several months after which ZALVISO may be available for commercial sale. ZALVISO has been commercially launched in Germany, France, Belgium, Netherlands, Italy, the UK, Spain and Portugal, and is expected to be commercially launched in 2017 in Ireland and Austria. On September 18, 2015, we sold a majority of the expected royalty stream and commercial milestones from the sales of ZALVISO in the EU and EEA by Grünenthal to PDL, or the Royalty Monetization. For additional information on the Royalty Monetization with PDL, see Note 7 “Liability Related to Sale of Future Royalties” in the accompanying notes to the condensed consolidated financial statements. Royalty revenues and non-cash royalty revenues from the commercial sales of ZALVISO in the EU are expected to be minimal for 2017.

We submitted an NDA for ZALVISO in September 2013, and on July 25, 2014, the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA issued a Complete Response Letter, or CRL, for the ZALVISO NDA. The CRL contained 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 device errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. In March 2015, we received correspondence from the FDA stating that, in addition to the work we had performed to address the items in the CRL, a clinical study would be required to test the modifications to the ZALVISO device and mitigations put in place to reduce the risk of inadvertent dosing/misplaced tablets.

Our IAP312 study was designed to evaluate the effectiveness of changes made to the functionality and usability of the ZALVISO device and to take into account comments from the FDA on the study protocol. In the IAP312 study, 320 hospitalized, post-operative patients used ZALVISO to self-administer 15 mcg sublingual sufentanil tablets as often as once every 20 minutes for 24-to-72 hours to manage their moderate-to-severe acute pain. Throughout the study, for which top-line results were announced in August 2017, 2.2% of patients experienced a ZALVISO device error, which was statistically less than the 5% limit specified in the study objectives. None of these device errors resulted in an over-dosing event. This 2.2% rate was lower ($p < 0.001$) than the 7.9% rate of device errors during patient use previously reported for the earlier version of the ZALVISO device in the Phase 3 IAP311 study. In addition, results of this study supported earlier clinical findings, with favorable tolerability and a significant majority of “good” or “excellent” ratings provided by both patients and healthcare providers when assessing the method of pain control. We intend to submit these results, together with our earlier Phase 3 studies (IAP309, IAP310 and IAP311), all of which met safety and efficacy endpoints, as part of our resubmission of the NDA for ZALVISO by the end of 2017.

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 and pre-commercialization activities and support Grünenthal’s launch of ZALVISO in the EU. As a result, we expect to continue to incur operating losses and negative cash flows. Although ZALVISO has been approved for sale in the EU, we sold the majority of the royalty rights and

certain commercial sales milestones we are entitled to receive under the Grünenthal Agreements to PDL in September 2015. 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. We plan to add personnel and incur additional costs related to the maturation of our business and the potential commercialization of DSUVIA 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 funding from the DoD.

Our revenues since inception have consisted primarily of revenues from our Amended License Agreement with Grünenthal and our research contracts with the DoD. As mentioned above, in May 2015, the DoD agreed to provide us up to $17.0 million to support the development of DSUVIA. Under the terms of the DoD Contract, the DoD has and continues to reimburse us for certain costs incurred for development, manufacturing, regulatory and clinical costs outlined in the DoD Contract, including reimbursement for certain personnel and overhead expenses.

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 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 loss for the three months and six months ended June 30, 2017 was $13.1 million and $28.6 million, respectively, compared to net losses of $11.1 million and $22.1 million for the three and six months ended June 30, 2016, respectively. As of June 30, 2017, we had an accumulated deficit of $275.0 million. As of June 30, 2017, we had cash and cash equivalents totaling $62.1 million compared to $80.3 million as of December 31, 2016.

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, 2016. There have been no significant changes in our critical accounting policies and estimates during the three and six months ended June 30, 2017 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Three and Six Months Ended June 30, 2017 and 2016

Revenue

In September 2015, the European Commission, or EC, granted marketing approval for ZALVISO in the European Union to our commercial partner, Grünenthal. ZALVISO has been commercially launched in Germany, France, Belgium, Netherlands, Italy, the UK, Spain and Portugal, and is expected to be commercially launched in 2017 in Ireland and Austria. We anticipate that royalty revenues and non-cash royalty revenues from the commercial sale of ZALVISO in 2017 will be minimal.

During the three months ended June 30, 2017, we recognized revenues of $2.7 million, including $2.2 million in collaboration agreement revenue recognized under our Amended Agreements with Grünenthal, plus $0.5 million in revenue under the DoD Contract. Revenue during the six months ended June 30, 2017, was $5.8 million, including $5.2 million in collaboration agreement revenue recognized under our Amended Agreements with Grünenthal, plus $0.6 million in revenue under the DoD Contract.

During the three months ended June 30, 2016, we recognized revenues of $1.3 million under our Amended Agreements with Grünenthal, plus $3.2 million for services performed under the DoD Contract. Revenue during the six months ended June 30, 2016, consisted of $3.1 million recognized under our Amended Agreements with Grünenthal, plus $4.4 million in revenue for services performed under the DoD Contract.

Collaboration Agreement Revenue

Below is a summary of revenue recognized under the Amended Agreements during the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Product sales	$1,993	$1,302	$4,914	$2,702
Joint steering committee, research and development services and demonstration devices	166	12	244	405
Non-cash royalty revenue related to Royalty Monetization (See Note 8)	25	—	46	—
Royalty revenue	8	—	15	—
Total	$2,192	$1,314	$5,219	$3,107

As a result of the launch of ZALVISO in Europe by our licensee, Grünenthal, we recognized $2.0 million and $4.9 million in product sales during the three and six months ended June 30, 2017, respectively, consisting of ZALVISO devices, drug product and accessories.

The first commercial sale of ZALVISO occurred in April 2016. As mentioned above, under the Royalty Monetization, we sold a portion of the expected royalty stream and commercial milestones from the sales of ZALVISO in the EU by Grünenthal to PDL. As the royalty amounts are not currently reasonably estimable without the royalty reports, we recognize royalty revenue and non-cash royalty revenue on a quarterly basis in arrears.

As of June 30, 2017, we had current and non-current portions of the deferred revenue balance under the Amended Agreements of $0.4 million and $3.6 million, respectively. The estimated margin we expect to receive on transfer prices under the Amended Agreements was deemed to be a significant and incremental discount on manufacturing services, as compared to market rates for contract manufacturing margin. The value assigned to this portion of the total allocated consideration was $4.4 million. We anticipate that the long-term deferred revenue balance will decline on a straight-line basis through 2029, as we recognize collaboration revenue under the Amended Agreements.

Contract and Other Revenue

During the three and six months ended June 30, 2017, we recognized revenue of $0.5 million and $0.6 million, respectively, for services performed under the DoD Contract for DSUVIA. During the three and six months ended June 30, 2016, we recognized revenue of $3.2 million and $4.4 million, respectively, for services performed under the DoD Contract.

Under the terms of the DoD Contract, the DoD reimburses us for costs incurred for development, manufacturing, regulatory and clinical costs as outlined in the DoD Contract, including reimbursement for certain personnel and overhead expenses.

Cost of goods sold

Total cost of goods sold for the three and six months ended June 30, 2017 and 2016 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	$ Change 2017 vs. 2016	% Change 2017 vs. 2016	2017	2016	$ Change 2017 vs. 2016	% Change 2017 vs. 2016
	(In thousands, except percentages)							
Cost of goods sold	$3,543	$2,976	$ 567	19 %	$7,668	$6,575	$ 1,093	17 %

In October 2015, we initiated commercial production of ZALVISO for Grünenthal. Under the Amended Agreements, we will sell ZALVISO at a predetermined transfer price that approximates the direct cost of manufacture at our contract manufacturers. We will not recover internal indirect costs as part of the transfer price. In addition, the Amended Agreements include declining maximum transfer prices over the term of the contract with Grünenthal. These transfer prices were agreed to assuming economies of scale that would occur with increasing production volumes (from the potential approval of ZALVISO in the U.S. and an increase in demand in Europe) and corresponding decreases in manufacturing costs. We do not have long-term supply agreements with our contract manufacturers and prices are subject to periodic changes. To date, we have not received U.S. approval of ZALVISO and the Grünenthal launch is in the very early stages. If we do not receive timely approval of ZALVISO in the U.S., are unable to successfully launch ZALVISO in the U.S. or the volume of Grünenthal sales does not increase significantly, we are not likely to achieve the manufacturing cost reductions required in order to accommodate these declining transfer prices without a corresponding decrease in our gross margin.

Cost of goods sold for ZALVISO delivered to Grünenthal includes the inventory costs of the active pharmaceutical ingredient, or API, third-party contract manufacturing costs, estimated warranty costs, packaging and distribution costs, shipping, handling and storage costs and impairment charges. These direct costs included in costs of goods sold totaled $2.3 million and $5.1 million in the three and six months ended June 30, 2017, respectively, and $1.7 million and $3.7 million in the three and six months ended June 30, 2016, respectively. We periodically evaluate the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or market approach as that used to value the inventory. During the three months ended June 30, 2017, we recorded an inventory impairment charge of $369,000, primarily for ZALVISO raw materials inventory on hand, plus related purchase commitments. The indirect costs to manufacture include internal personnel and related costs for purchasing, supply chain, quality assurance, depreciation and related expenses. Indirect costs included in costs of goods sold totaled $1.3 million and $2.6 million in the three and six months ended June 30, 2017, respectively, and $1.3 million and $2.9 million in the three and six months ended June 30, 2016, respectively. We anticipate that at future production levels, indirect costs included in costs of goods sold for 2017 will be approximately $1.4 million per quarter. For the foreseeable future, we anticipate negative gross margins on ZALVISO product delivered to Grünenthal.

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; however, in 2016 research and development expenses related to DSUVIA, known as ARX-04 outside the United States, were greater than those for 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.