ACELRX PHARMACEUTICALS INC
Form 10-Q
November 05, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

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 every Interactive Data File required to be submitted 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 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	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 October 30, 2018, the number of outstanding shares of the registrant's common stock was 61,907,272.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share data)

	September 30, 2018	**December 31, 2017[(1)]**
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 57,566	$ 52,902
Short-term investments	5,995	7,567
Accounts receivable, net	187	1,533
Tax receivable	352	—
Inventories	856	956
Prepaid expenses and other current assets	1,048	455
Total current assets	66,004	63,413
Property and equipment, net	11,004	11,051
Restricted cash	178	178
Long-term tax receivable	351	703
Other assets	207	207
Total Assets	$ 77,744	$ 75,552
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,775	$ 1,424
Accrued liabilities	3,621	3,543
Long-term debt, current portion	8,372	7,727
Deferred revenue, current portion	326	362
Liability related to the sale of future royalties, current portion	377	604
Total current liabilities	14,471	13,660
Deferred rent, net of current portion	442	378
Long-term debt, net of current portion	5,502	11,369
Deferred revenue, net of current portion	3,227	3,463

Liability related to the sale of future royalties, net of current portion	91,745	82,984
Contingent put option liability	144	207
Total liabilities	115,531	112,061
Commitments and Contingencies		
Stockholders' Deficit:		
Common stock, $0.001 par value—100,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 61,790,346 and 50,899,154 shares issued and outstanding as of September 30, 2018 and December 31, 2017	61	51
Additional paid-in capital	294,613	261,310
Accumulated deficit	(332,461)	(297,870)
Total stockholders' deficit	(37,787)	(36,509)
Total Liabilities and Stockholders' Deficit	$ 77,744	$ 75,552

(1) The condensed consolidated balance sheet as of December 31, 2017 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, 2017.

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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue:				
Collaboration agreement	$177	$1,225	$802	$6,444
Contract and other	200	262	736	811
Total revenue	377	1,487	1,538	7,255
Operating costs and expenses:				
Cost of goods sold	875	2,029	2,738	9,697
Research and development	3,642	3,913	10,433	15,733
General and administrative	5,188	4,406	13,117	12,700
Total operating costs and expenses	9,705	10,348	26,288	38,130
Loss from operations	(9,328)	(8,861)	(24,750)	(30,875)
Other (expense) income:				
Interest expense	(529)	(919)	(1,758)	(2,596)
Interest income and other income (expense), net	312	(465)	643	(215)
Non-cash interest expense on liability related to future sale of royalties	(2,913)	(2,768)	(8,724)	(7,935)
Total other expense	(3,130)	(4,152)	(9,839)	(10,746)
Net loss before income taxes	(12,458)	(13,013)	(34,589)	(41,621)
Provision for income taxes	—	—	(2)	(2)
Net loss	(12,458)	(13,013)	(34,591)	(41,623)
Other comprehensive loss:				
Unrealized losses on available-for-sale securities	—	—	—	(3)
Comprehensive loss	$(12,458)	$(13,013)	$(34,591)	$(41,626)
Net loss per share of common stock, basic and diluted	$(0.21)	$(0.28)	$(0.64)	$(0.91)
Shares used in computing net loss per share of common stock, basic and diluted	60,004,416	46,365,436	54,292,206	45,701,446

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$(34,591)	$(41,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	(220)	(89)
Non-cash interest expense on liability related to royalty monetization	8,724	7,935
Depreciation and amortization	435	1,388
Non-cash interest expense related to debt financing	489	1,060
Stock-based compensation	3,936	3,240
Revaluation of put option and PIPE warrant liabilities	(63)	435
Inventory impairment charge	—	369
Other	(84)	(3)
Changes in operating assets and liabilities:		
Accounts receivable	1,346	4,490
Inventories	100	1,060
Prepaid expenses and other assets	(563)	(224)
Accounts payable	403	220
Accrued liabilities	236	(1,300)
Deferred revenue	(272)	(271)
Deferred rent	39	224
Net cash used in operating activities	(20,085)	(23,089)
Cash flows from investing activities:		
Purchase of property and equipment	(573)	(2,495)
Purchase of investments	(12,844)	—
Proceeds from maturities of investments	14,500	—
Net cash provided by (used in) investing activities	1,083	(2,495)
Cash flows from financing activities:		
Principal payments on long-term debt	(5,711)	—
Net proceeds from issuance of common stock in connection with equity financings	29,073	13,120
Payment of debt modification transaction costs	—	(204)
Net proceeds from issuance of common stock through equity plans	304	294
Net cash provided by financing activities	23,666	13,210

Net increase (decrease) in cash, cash equivalents and restricted cash	4,664	(12,374)
Cash, cash equivalents and restricted cash—Beginning of period	53,080	80,488
Cash, cash equivalents and restricted cash—End of period	$57,744	$68,114

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statement of cash flows (in thousands):

	September 30, 2018	**September 30, 2017**
Cash and cash equivalents	57,566	67,936
Restricted cash	178	178
Cash, cash equivalents and restricted cash shown in the statement of cash flows	57,744	68,114

Amounts included in restricted cash represent letters of credit required to be maintained under the Company’s facility lease and corporate credit card agreements as security for performance under these agreements. The letters of credit are secured by certificates of deposit in amounts equal to the letters of credit.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(In thousands, except where otherwise noted)

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. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, approved the resubmitted New Drug Application, or NDA, for DSUVIA™ (known as DZUVEO™ outside of the United States). DSUVIA and the Company's follow-on product candidate, Zalviso®, each utilize sufentanil, delivered via a non-invasive route of sublingual administration. DSUVIA is a 30 mcg sufentanil sublingual tablet in a single-dose applicator approved for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia, or PCA, system. AcelRx anticipates developing a distribution capability and commercial organization in the United States to market and sell DSUVIA in the United States by itself. The Company anticipates launching commercial sales of DSUVIA in the United States in the first quarter of 2019. In geographies where AcelRx decides not to commercialize products by itself, the Company may seek to out-license commercialization rights. The Company currently intends to commercialize and promote DZUVEO in Europe with a strategic partner. 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. Zalviso is approved in Europe and is currently being commercialized by Grünenthal GmbH, or Grünenthal.

DSUVIA/DZUVEO

DSUVIA is a 30 mcg sufentanil sublingual tablet in a single-dose applicator intended for use in adults in a certified medically supervised healthcare setting for the management of 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 developed DSUVIA for the treatment of patients suffering from 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; and certain types of hospital-based procedures.

The Company filed a Marketing Authorisation Application, or MAA, for DZUVEO (sufentanil sublingual tablet, 30 mcg) for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting with the European Medicines Agency, or EMA. In June 2018, the Company announced that the European Commission, or EC, had granted marketing approval of DZUVEO for the treatment of patients with moderate-to-severe acute pain in medically monitored settings.

Zalviso

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 Europe 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 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. The Company is currently evaluating the timing of the NDA resubmission for Zalviso.

On December 16, 2013, AcelRx and 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 EC approved the MAA, previously submitted to the EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. 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 and Grünenthal amended the MSA, or the Amended MSA, effective as of July 17, 2015. The Amended MSA and the Amended License Agreement are referred to as the Amended Agreements.

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception. Although Zalviso has been approved for sale in Europe, on September 18, 2015, 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, in a transaction referred to as the Royalty Monetization. Although the FDA recently approved DSUVIA, we have not yet commercially launched the product. As a result, the Company expects to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

Except as the context otherwise requires, when we refer to "we," "our," "us," the "Company" or "AcelRx" in this document, we mean AcelRx Pharmaceuticals, Inc., and its consolidated subsidiary. “DSUVIA” and “DZUVEO” are trademarks, 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.

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 Europe by the Company’s 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 8 “Liability Related to Sale of Future Royalties” for additional information.

Basis of Presentation

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

Operating results for the three and nine months ended September 30, 2018, are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The condensed consolidated balance sheet as of December 31, 2017, was derived from the Company’s audited financial statements as of December 31, 2017, 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, 2017, 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.

Revenue Recognition

Beginning January 1, 2018, the Company has followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

The Company generates revenue from collaboration agreements. These agreements typically include payments for upfront signing or license fees, cost reimbursements for development and manufacturing services, milestone payments, product sales, and royalties on licensee's future product sales.

The Company has entered into award contracts with U.S. Department of Defense, or the DoD, to support the development of DSUVIA. These contracts provide for the reimbursement of qualified expenses for research and development activities. Revenue under these arrangements is recognized when the related qualified research expenses are incurred. The Company is entitled to reimbursement of overhead costs associated with the study costs under the DoD arrangements. The Company estimates this overhead rate by utilizing forecasted expenditures. Final reimbursable overhead expenses are dependent on direct labor and direct reimbursable expenses throughout the life of each contract, which may increase or decrease based on actual expenses incurred.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. The Company's performance obligations include commercialization license rights, development services, services associated with the regulatory approval process, joint steering committee services, demo devices, manufacturing services, material rights for discounts on manufacturing services, and product supply.

The Company has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or the Company's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded in revenue when the customer obtains control of the goods or services.

Transaction Price

The Company has both fixed and variable consideration. Non-refundable upfront fees and product supply selling prices are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Funding of research and development activities is considered variable until such costs are reimbursed at which point they are considered fixed. The Company allocates the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by the Company) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not

considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. Estimated selling prices for license rights and material rights for discounts on manufacturing services are calculated using an income approach model and can include the following key assumptions: the development timeline, sales forecasts, costs of product sales, commercialization expenses, discount rate, the time which the manufacturing services are expected to be performed, and probabilities of technical and regulatory success. For all other performance obligations, the Company uses a cost-plus margin approach.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. The Company estimates the performance period or measure of progress at the inception of the arrangement and re-evaluates it each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. Changes to these estimates are recorded on a cumulative catch up basis. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time when control of the product is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer, and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the cost-to-cost input method.

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, 2017. Aside from the adoption of ASC Topic 606 described below under "Recently Adopted Accounting Standards" and explained more fully above in "Revenue Recognition," and in Note 4 "Adoption of ASC Topic 606, *Revenue from Contracts with Customers*" below, there have been no significant changes to the Company's significant accounting policies during the three and nine months ended September 30, 2018, from those previously disclosed in its 2017 Annual Report on Form 10-K.

Recently Adopted Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to provide guidance on revenue recognition. In August 2015 and March, April, May and December 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. Collectively these are referred to as ASC Topic 606, which replaces all legacy GAAP guidance on revenue recognition and eliminates all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principal of the guidance is that an entity should 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 applying ASC Topic 606, companies need to use more judgment and make more estimates than under legacy guidance. This includes 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 distinct performance obligation. ASC Topic 606 is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted one year earlier.

The Company adopted the new standard effective January 1, 2018 under the modified retrospective transition method, applying the new guidance in the first quarter of 2018 to those contracts which were not completed as of January 1, 2018. For contracts which were modified before the adoption date, the Company has elected to treat the contracts and their modifications as combined contracts. Upon adoption, there was no change to the units of accounting previously identified under legacy GAAP, which are now considered performance obligations under the new guidance, and there was no change to the revenue recognition pattern for each performance obligation. Therefore, the adoption of the new standard resulted in no cumulative effect to the opening accumulated deficit balance.

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 adoption of ASU 2017-09 effective January 1, 2018 did not have a material effect on the Company's 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. The Company adopted ASU No. 2016-18, and the guidance has been retrospectively applied to all periods presented. The adoption of the guidance did not have an impact on the Company's condensed consolidated balance sheets or statements of comprehensive loss.

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. The adoption of ASU 2016-15 effective January 1, 2018, did not have a material impact on the Company's condensed consolidated statements of cash flows.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU No. 2018-15 provides new guidance on a customer's accounting for implementation, set-up and other upfront costs incurred in a cloud computing arrangement that is hosted by a vendor, i.e., a service contract. The new guidance aligns the requirements for capitalizing implementation costs in a cloud computing arrangement service contract with the requirements for capitalizing implementation costs incurred for an internal-use software license under ASU No. 2015-05, *Customer's Accounting for Fees Paid in a Cloud Computing Arrangement*. The new guidance also prescribes the balance sheet, income statement, and cash flow classification of the capitalized implementation costs and related amortization expense, and requires additional quantitative and qualitative disclosures. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. Entities can choose to adopt the new guidance (1) prospectively to eligible costs incurred on or after the date this guidance is first applied or (2) retrospectively. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2018-15 on its condensed consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which establishes a new lease accounting model for lessees. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements* which provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented. The Company is currently in the process of evaluating the transition method. Unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new guidance will require both types of leases (i.e. operating and capital leases) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. 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 expects to adopt this standard beginning in 2019. The Company does not expect that this standard will have a material impact on its condensed consolidated statements of comprehensive loss; however, the Company does expect that upon adoption, this standard will impact the carrying value of its assets and liabilities on its condensed consolidated balance sheets as a result of the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. The Company is still evaluating whether there are other existing contracts that may become leases under the new lease standard, and the impact of the adoption of this standard on its condensed consolidated financial statements and disclosures. 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 lease 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 September 30, 2018			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash and cash equivalents:				
Cash	$394	$ —	$ —	$394
Money market funds	32,168	—	—	32,168
U.S. government agency securities	25,004	—	—	25,004
Total cash and cash equivalents	$57,566	$ —	$ —	$57,566
Marketable securities:				
U.S. government agency securities	$5,995	$ —	$ —	$5,995
Total marketable securities	$63,561	$ —	$ —	$63,561
Total cash, cash equivalents and investments	$63,561	$ —	$ —	$63,561

	As of December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$29,765	$ —	$ —	$29,765
U.S. government agency securities	23,137	—	—	23,137
Total cash and cash equivalents	$52,902	$ —	$ —	$52,902
Marketable securities:				
U.S. government agency securities	$7,567	$ —	$ —	$7,567
Total marketable securities	$7,567	$ —	$ —	$7,567
Total cash, cash equivalents and investments	$60,469	$ —	$ —	$60,469

As of September 30, 2018 and December 31, 2017, none of the available-for-sale securities held by the Company had material unrealized losses. There were no other-than-temporary impairments for these securities at September 30, 2018 or December 31, 2017. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income to earnings during the three and nine months ended September 30, 2018 and September 30, 2017.

As of September 30, 2018 and December 31, 2017, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets and Level III liabilities. Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. 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. On March 2, 2017, the Company entered into an amended and restated loan agreement, or the Amended Loan Agreement with Hercules Capital Funding Trust 2014-1 and Hercules Technology II, L.P., together, Hercules, which contains a contingent put option liability. 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.

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

	As of September 30, 2018			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$32,168	$32,168	$—	$—
U.S. government agency obligations	30,999	—	30,999	—
Total assets measured at fair value	$63,167	$32,168	$30,999	$—
Liabilities				
Contingent put option liability	$144	$—	$—	$144
Total liabilities measured at fair value	$144	$—	$—	$144

	As of December 31, 2017			
	Fair Value	Level I	Level II	Level III
Assets				
U.S. government agency obligations	$30,704	$ —	$30,704	$—
Total assets measured at fair value	$30,704	$ —	$30,704	$—
Liabilities				
Contingent put option liability	$207	$ —	—	$207
Total liabilities measured at fair value	$207	$ —	$—	$207

As of September 30, 2017, the Company also held a Level III liability associated with warrants, or PIPE warrants, issued in connection with the Company's private placement equity offering, completed in June 2012. The PIPE warrants were considered a liability and were valued using the Black-Scholes option-pricing model, the inputs for which included 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 could have a significant impact to the estimated fair value of the PIPE warrants. The PIPE warrants expired in November 2017.

The following tables set forth a summary of the changes in the fair value of the Company's Level III financial liabilities for the three and nine months ended September 30, 2018 and September 30, 2017 (in thousands):

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Fair value—beginning of period	$ 166	$ 207
Change in fair value of contingent put option associated with Amended Loan Agreement	(22)	(63)
Fair value—end of period	$ 144	$ 144

	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2017

Fair value—beginning of period	$ 288	$ 412
Change in fair value of PIPE warrants	612	352
Change in fair value of contingent put option associated with Amended Loan Agreement	(53)	83
Fair value—end of period	$ 847	$ 847

3. Inventories

Inventories consist of raw materials and work in process and are stated at the lower of cost or net realizable value and consist of the following (in thousands):

	Balance as of September 30, 2018	**December 31, 2017**
Raw materials	$585	$ 702
Work-in-process	271	254
Total	$856	$ 956

4. **Adoption of ASC Topic 606, *Revenue from Contracts with Customers***

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018, are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under Topic 605. The adoption of the new revenue recognition guidance resulted in no changes to deferred revenue or the accumulated deficit as of January 1, 2018.

Revenue Recognition

As described in Note 1 "Organization and Summary of Significant Accounting Policies," the Company has entered into the Amended Agreements with Grünenthal related to Zalviso. At September 30, 2018, approximately $3.5 million of the transaction price under the Amended Agreements is allocated to the discount on future manufacturing services, which the Company expects to be recognized through 2029.

For additional detail on the Company's accounting policy regarding revenue recognition, refer to Note 1 "Organization and Summary of Significant Accounting Policies - Revenue Recognition."

The following table presents changes in the Company's contract liabilities for the nine months ended September 30, 2018:

	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
	(in thousands)			
Contract liability:				
Deferred revenue	$3,825	$ -	$ (272)	$3,553

During the three and nine months ended September 30, 2018, the Company recognized the following revenue (in thousands):

	Three months ended September 30, 2018	Nine months ended September 30, 2018
Amounts included in contract liabilities at the beginning of the period:		
Performance obligations satisfied – Amended Agreements	$ 90	$ 272
New activities in the period from performance obligations satisfied:		
Performance obligations satisfied – Amended Agreements	—	237
Total revenue from performance obligations satisfied	90	509
Royalty revenue	87	293
Contract and other	200	736
Total revenue	$ 377	$ 1,538

5. U.S. Department of Defense

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 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. At December 31, 2017, the additional activities as outlined under the DoD Contract through February 28, 2018 were substantially complete. On February 28, 2018, the DoD contract was amended to incorporate additional services in the amount of $0.5 million and to extend the contract period by twelve months through February 28, 2019. 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 $0.2 million and $0.7 million for the three and nine months ended September 30, 2018, respectively, and $0.3 million and $0.8 million for the three and nine months ended September 30, 2017, respectively.

6. Collaboration Agreement

As described in Note 1 “Organization and Summary of Significant Accounting Policies,” the Company has entered into the Amended Agreements with Grünenthal related to Zalviso.

Amended License Agreement

Under the Amended License Agreement, the Company is eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, 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 8 “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. The Product will be supplied at prices approximating the Company’s manufacturing cost, subject to certain caps, as defined in the MSA Amendment. The MSA Amendment requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and, under certain specified conditions, permits Grünenthal to use a third-party back-up manufacturer to manufacture the Product for Grünenthal’s commercial sale in the Territory.

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

During the three and nine months ended September 30, 2018, the Company recognized $0.2 million and $0.8 million in revenue under the Amended Agreements, respectively, primarily product sales revenue. During the three and nine months ended September 30, 2017, the Company recognized $1.2 million and $6.4 million in revenue under the Amended Agreements, respectively, primarily product sales revenue. As of September 30, 2018, the Company had current and noncurrent portions of the deferred revenue balance under the Amended Agreements of $0.3 million and $3.2 million, respectively. The deferred revenue balance consists primarily of the significant and incremental discount on manufacturing services, which is being recognized on a straight-line basis over the period such discount is made available to Grünenthal, which began in February 2016 and is estimated to continue through 2029.

7. Long-Term Debt

Amended Loan Agreement

The Company has long-term debt with Hercules under the Amended Loan Agreement that requires equal monthly payments of principal and interest through the scheduled maturity date of March 1, 2020. A final payment equal to 6.5% of the aggregate principal amount of $20.5 million in loans funded under the Amended Loan Agreement, or the End of Term Fee, 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 accrued balance due under the Amended Loan Agreement was $13.9 million at September 30, 2018 and $19.1 million at December 31, 2017. Interest expense related to the Amended Loan Agreement was $0.5 million, $0.2 million of which represented amortization of the debt discount, for the three months ended September 30, 2018, and $1.7 million, $0.5 million of which represented amortization of the debt discount, for the nine months ended September 30, 2018. 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 September 30, 2017, and $2.6 million, $1.1 million of which represented amortization of the debt discount, for the nine months ended September 30, 2017.

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8. Liability Related to Sale of Future Royalties

On September 18, 2015, the Company entered into the Royalty Monetization with PDL for which it received gross proceeds of $65.0 million. Under the Royalty Monetization, PDL will receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), up to a capped amount of $195.0 million over the life of the arrangement.

The following table shows the activity within the liability account during the nine months ended and the period from inception to September 30, 2018 (in thousands):

	Nine months ended September 30, 2018	Period from inception to September 30, 2018
Liability related to sale of future royalties — beginning balance	$ 83,588	$ —
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	(190)	(317)
Non-cash interest expense recognized	8,724	31,255
Liability related to sale of future royalties as of September 30, 2018	92,122	92,122
Less: current portion	(377)	(377)
Liability related to sale of future royalties — net of current portion	$ 91,745	$ 91,745

As royalties are remitted to PDL from the Company's subsidiary, 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.

9. Warrants

Amended Loan Agreement Warrants

In connection with the Company's Amended Loan Agreement, warrants to purchase 176,730 shares of common stock at $3.07 per share were issued to Hercules. As of September 30, 2018, these warrants had not been exercised and were still outstanding. These warrants expire in December 2018.

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 September 30,		**Nine Months Ended September 30,**	
	2018	**2017**	**2018**	**2017**
Cost of goods sold	$119	$80	$280	$243
Research and development	769	458	1,578	1,442
General and administrative	920	480	2,078	1,555
Total	$1,808	$1,018	$3,936	$3,240

As of September 30, 2018, there were 1,140,133 shares available for grant, 11,628,345 options outstanding and no restricted stock units outstanding under the Company's 2011 Equity Incentive Plan and 858,889 shares available for grant under the ESPP.

11. Stockholders' Equity

Common Stock

2018 Underwritten Public Offering

On July 16, 2018, the Company completed an underwritten public offering of 7,272,727 shares of common stock, at a price of $2.75 per share to the public. On August 7, 2018, the underwriters exercised in full their option to purchase an additional 1,090,909 shares of common stock at the public offering price of $2.75 per share, less underwriting discounts and commissions. The total gross proceeds from this offering of an aggregate 8,363,636 shares were approximately $23.0 million with net proceeds to the Company of $21.7 million after deducting the underwriting discounts and commissions and other offering expenses payable by the Company.

2016 ATM Agreement

During the nine months ended September 30, 2018, the Company issued and sold 2.3 million shares of common stock pursuant to the 2016 ATM Agreement, for which the Company received net proceeds of approximately $7.4 million, after deducting commissions, fees and expenses of $0.2 million.

12. 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.

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:

	September 30,	
	2018	2017
ESPP and stock options to purchase common stock	12,003,600	8,922,456
Common stock warrants	176,730	689,186

13. Subsequent Event

On November 2, 2018, the FDA approved the resubmitted NDA for DSUVIA (sufentanil sublingual tablet, 30 mcg) for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

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 planned United States launch of DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ outside the United States; the process and timing of anticipated future development of Zalviso® (sufentanil sublingual tablet system), including the timing of the planned NDA resubmission for Zalviso; the accuracy of our estimates regarding expenses, capital requirements and the need for financing; the status of the Amended Agreements with Grünenthal, including potential milestones and royalty payments under the Amended Agreements, or any other future potential collaborations; and the therapeutic and commercial potential of our approved products and product candidates, including potential market opportunities for DSUVIA, DZUVEO and Zalviso.

Forward-looking statements are based on AcelRx'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 AcelRx'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.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

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, 2017.

About AcelRx Pharmaceuticals

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. DSUVIA™ (known as DZUVEO™ outside of the United States) and Zalviso®, are both focused on the treatment of acute pain, and each utilize sufentanil, delivered via a non-invasive route of sublingual administration, exclusively for use in medically supervised settings. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, approved our resubmitted New Drug Application, or NDA, for DSUVIA for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. In June 2018, the European Commission, or EC, granted marketing approval of DZUVEO for the treatment of patients with moderate-to-severe acute pain in medically monitored settings. We anticipate developing a distribution capability and commercial organization to market and sell DSUVIA in the United States by ourselves. We currently anticipate the commercial launch of DSUVIA in the United States in the first quarter of 2019. In geographies where we decide not to commercialize ourselves, including for DZUVEO in Europe, we may seek to out-license commercialization rights. We currently intend to commercialize and promote DZUVEO in Europe with a strategic partner, although we have not yet entered into such an arrangement. We are currently evaluating the timing of the resubmission of the NDA for Zalviso. If we are successful in obtaining approval of Zalviso in the United States, we plan to potentially promote Zalviso either by ourselves or with strategic partners. Zalviso is approved in Europe and is currently being commercialized by Grünenthal GmbH, or Grünenthal.

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, a high-therapeutic index opioid, which has no active metabolites, 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. Sufentanil has many pharmacological advantages over other opioids. Published studies demonstrate that sufentanil produces significantly less respiratory depressive effects relative to its analgesic effects compared to other opioids, including morphine and fentanyl. These third-party clinical results correlate well with preclinical trials demonstrating sufentanil’s high therapeutic index, or the ratio of the toxic dose to the therapeutic dose of a drug, used as a measure of the relative safety of the drug for a particular treatment. Accordingly, we believe that sufentanil can be developed to provide an effective and well-tolerated treatment for 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 predictable 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 DZUVEO outside the United States

DSUVIA is a non-invasive product consisting of 30 mcg sufentanil tablets delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator, or SDA. DSUVIA has been approved in both the United States and Europe for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional to a patient in medically supervised settings. 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 hospital-based procedures; 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 may provide an impediment to rapid discharge. Moreover, IV dosing results in high peak plasma levels, thereby limiting the opioid dose and requiring frequent redosing intervals to titrate to satisfactory analgesia. Oral pills and liquids generally have slow and erratic onset of 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 currently marketed oral pills and liquids, as well as IV-administered opioids, for moderate-to-severe acute pain. In addition, based on our recent interactions with healthcare providers, and also as reported in recent media coverage, the need for new acute pain treatment options is further highlighted by the current shortage of IV opioids in hospitals throughout the United States. We believe this situation creates an environment to demonstrate how DSUVIA could help U.S. hospitals manage through the intravenous opioid shortage they are experiencing in their facilities today.

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, to support the development of DSUVIA. Pursuant to the terms of the DoD Contract, the DoD has the option to purchase 112,000 units of commercial DSUVIA product.

We anticipate we may need comparator studies of DZUVEO in the EU to ensure premium reimbursement in certain countries. As mentioned above, we intend to commercialize and promote DZUVEO in Europe with a strategic partner, but we have not yet entered into such an arrangement.

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. Zalviso is designed to help address certain problems associated with post-operative IV patient-controlled analgesia, or PCA. Zalviso allows patients to self-administer sufentanil sublingual tablets via a pre-programmed, secure system designed in part to eliminate the risk of healthcare provider programming errors. While still under development in the U.S., as discussed further below, Zalviso is approved and marketed in Europe.

On December 16, 2013, AcelRx and Grünenthal entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. The License Agreement grants Grünenthal rights to commercialize Zalviso, our novel sublingual PCA system, or the Product, in the 28 EU member states, 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. 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 6 “Collaboration Agreement” in the accompanying notes to the condensed consolidated financial statements.

Zalviso was approved for commercial sale by the EC in September 2015 and Grünenthal began its European launch of Zalviso with its first commercial sale occurring in April 2016. On September 18, 2015, we sold a majority of the expected royalty stream and commercial milestones from the European sales of Zalviso by Grünenthal to PDL, or the Royalty Monetization. For additional information on the Royalty Monetization with PDL, see Note 8 “Liability Related to Sale of Future Royalties” in the accompanying notes to the condensed consolidated financial statements.

We submitted an NDA for Zalviso in September 2013, or the Zalviso NDA, and on July 25, 2014, the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA issued a 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. A total of 7,293 sufentanil tablets were dispensed by the 320 patients, of which 2.2% of these patients experienced a Zalviso device error over the course of the study. This error rate was statistically less than the 5% limit specified in the study objectives and none of these device errors resulted in an over-dosing event. Separate from device errors, and consistent with patient training, 6 patients called the nurse when they failed to properly self-administer a single tablet which allowed the nurse to properly retrieve and dispose of the tablet. Also, during inspection by the nurse, which occurred every two hours per protocol, a total of 7 misplaced tablets (<0.1% of total dispensed tablets) were discovered with 6 additional patients. Overall, efficacy and safety 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 the results from the IAP312 study, 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.

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 begin commercialization activities to support the U.S. launch of DSUVIA, continue our research and development activities and support Grünenthal’s European sales of Zalviso. As a result, we expect to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

Although Zalviso has been approved for sale in Europe, 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.

We currently anticipate the commercial launch of DSUVIA in the United States in the first quarter of 2019. As we begin the commercial launch of DSUVIA, we expect the business aspects of our company to become more complex. We plan to continue to add personnel and incur additional costs related to the maturation of our business and the commercialization of DSUVIA and potential commercialization of Zalviso in the United States, subject to FDA approval. In addition, we believe that continued investment in research and development is critical to attaining our strategic objectives. In order to develop Zalviso, and any future 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 Department of Defense, or DoD.

Our revenues since inception have consisted primarily of revenues from our Amended License Agreement with Grünenthal and our research contracts with the DoD. There can be no assurance that our relationship with Grünenthal will continue beyond the initial term or that we will be able to meet the milestones specified in the Amended License Agreement. Under the terms of the DoD Contract, the DoD has reimbursed 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.

We received approval of DZUVEO in Europe in June 2018, but we have not yet entered into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe. There can be no assurance that we will enter into a collaborative agreement for DZUVEO, or any other collaborative agreements, or receive research-related contract awards in the future. Accordingly, we expect revenues to continue to fluctuate from period-to-period. Although we have received approval of DSUVIA in the U.S., and Zalviso and DZUVEO in Europe, we cannot provide assurance that we will generate revenue from those products in excess of our operating expenses, nor that we will obtain marketing approval for Zalviso, or any future product candidates, and subsequently generate revenue from those product candidates in excess of our operating expenses.

Our net loss for the three months and nine months ended September 30, 2018 was $12.5 million and $34.6 million, respectively, compared to net losses of $13.0 million and $41.6 million for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $332.5 million. As of September 30, 2018, we had cash, cash equivalents and short-term investments totaling $63.6 million compared to $60.5 million as of December 31, 2017.

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, 2017. Aside from the adoption of *Revenue from Contracts with Customers (Topic 606*) explained more fully in Note 1 “Organization and Summary of Significant Accounting Policies - Revenue Recognition,” and in Note 4 “Adoption of ASC Topic 606, *Revenue from Contracts with Customers*,” in the accompanying notes to the condensed consolidated financial statements, there have been no significant changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2018, from those previously disclosed in our 2017 Annual Report on Form 10-K.

Results of Operations

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our commercial launch of DSUVIA, our research and development efforts and variations in the level

of expenses related to developmental efforts during any given period. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. We are subject to risks common to companies in our industry and at our stage of development, including risks inherent in our efforts to commercialize DSUVIA, our research and development efforts, reliance upon our collaborator, enforcement of our patent and proprietary rights, need for future capital, potential competition and uncertainty of clinical trial results or regulatory approvals or clearances. In order for a product candidate to be commercialized based on our research, we and our collaborators must conduct preclinical tests and clinical trials, demonstrate the efficacy and safety of our product candidates, obtain regulatory approvals or clearances and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance.

Three and Nine Months Ended September 30, 2018 and 2017

Revenue

Collaboration Agreement Revenue

In September 2015, the EC granted marketing approval for Zalviso to our commercial partner, Grünenthal, and Grünenthal commercially launched Zalviso in Europe, with the first commercial sale occurring in April 2016. We estimate and recognize royalty revenue and non-cash royalty revenue on a quarterly basis. Adjustments to estimated revenue are recognized in the subsequent quarter based on actual revenue earned per the royalty reports received from Grünenthal.

For the three months ended September 30, 2018, we recognized $0.2 million in revenue under the Amended Agreements, consisting primarily of product sales revenue. For the three months ended September 30, 2017, we recognized $1.2 million in revenue under the Amended Agreements, primarily product sales revenue. Revenue recognized under the Amended Agreements for the nine months ended September 30, 2018 was $0.8 million, $0.2 million of which was non-cash royalty revenue, with the remainder consisting primarily of product sales revenue, compared to $6.4 million for the nine months ended September 30, 2017, consisting primarily of product sales revenue. The decrease in collaboration agreement revenue for the three and nine months ended September 30, 2018, as compared to the prior year periods, was primarily the result of Grünenthal working down its existing inventories. While Grünenthal anticipates positive sales growth for Zalviso in fiscal year 2018, this trend will not always closely align with the timing of our product sales revenue as Grünenthal continues to work down its existing inventories. Therefore, despite Grünenthal's continued growth expectations for Zalviso, we expect our collaboration agreement revenue related to product sales to continue to decline in fiscal year 2018 before increasing modestly in 2019. In addition, under the Royalty Monetization, we sold a portion of the expected royalty stream and commercial milestones from the European sales of Zalviso by Grünenthal to PDL. As a result, collaboration agreement revenue is not expected to have a significant impact on our cash flows in the near-term since a significant portion of European Zalviso royalties and milestones were already monetized with PDL in 2015. We anticipate that royalty revenues and non-cash royalty revenues from the commercial sale of Zalviso in 2018 will continue to be minimal.

As of September 30, 2018, we had current and non-current portions of the deferred revenue balance under the Amended Agreements of $0.3 million and $3.2 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 nine months ended September 30, 2018, we recognized revenue of $0.2 million and $0.7 million, respectively, for services performed under the DoD Contract for DSUVIA, as compared to $0.3 million and $0.8 million during the three and nine months ended September 30, 2017, respectively. 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 nine months ended September 30, 2018 and 2017 was as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017
	(In thousands, except percentages)							
Cost of goods sold	$875	$2,029	$(1,154)	(57)%	$2,738	$9,697	$(6,959)	(72)%

In October 2015, we initiated commercial production of Zalviso for Grünenthal. Under the Amended Agreements, we will sell Zalviso at a predetermined transfer price. We will not recover internal indirect costs as part of the transfer price. At current low volume levels, our direct costs are in excess of the transfer prices we are receiving from Grünenthal. 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 yet resubmitted the NDA for Zalviso and sales by Grünenthal in Europe have not been substantial. If we do not timely resubmit the NDA for Zalviso and then receive timely approval and are unable to successfully launch Zalviso in the U.S., or the volume of Grünenthal sales does not increase significantly, we will not 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 $0.1 million and $0.6 million in the three and nine months ended September 30, 2018, respectively, and $1.1 million and $6.2 million in the three and nine months ended September 30, 2017, respectively. 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 $0.8 million and $2.1 million in the three and nine months ended September 30, 2018, respectively, and $0.9 million and $3.4 million in the three and nine months ended September 30, 2017, respectively. We periodically evaluate the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or net realizable value approach as that used to value the inventory. During the nine months ended September 30, 2017, we recorded an inventory impairment charge of $0.4 million, primarily for ZALVISO raw materials inventory on hand, plus related purchase commitments. For the foreseeable future, we anticipate negative gross margins on Zalviso product delivered to Grünenthal.

Research and Development Expenses

The majority of our operating expenses to date have been for research and development activities related to Zalviso and DSUVIA. 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.

While we completed the Phase 3 clinical development programs for DSUVIA and Zalviso in fiscal year 2017, we expect to incur future research and development expenditures to support the FDA regulatory review of the Zalviso NDA, once it is resubmitted.

We track external development expenses on a program-by-program basis. Our internal development resources are shared among all of our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead. Below is a summary of our research and development expenses during the three and nine months ended September 30, 2018 and 2017 (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Drug Indication/Description	**2018**	**2017**	**$ Change 2018 vs.**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**

			2018 vs. 2017	2018 vs. 2017				2017	2018 vs. 2017	
	(In thousands, except percentages)									
DSUVIA	$678	$843	$ (165)	(20)%		$2,163	$3,066	$ (903)	(29)%	
ZALVISO	65	692	(627)	(91)%		567	5,983	(5,416)	(91)%	
Overhead	2,899	2,378	521	22%		7,703	6,684	1,019	15%	
Total research and development expenses	$3,642	$3,913	$ (271)	(7)%		$10,433	$15,733	$ (5,300)	(34)%	

Due to the inherently unpredictable nature of product development, development timelines and the probability of success, development costs can differ materially from expectations. In addition, we cannot predict which product candidates may be subject to future collaborations, when these arrangements will be secured, if at all, and to what degree these arrangements would affect our development plans and capital requirements.

The $0.3 million decrease in research and development expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to a $0.6 million decrease in Zalviso-related expenses and a $0.2 million decrease in DSUVIA-related development spending, offset by a $0.5 million net increase in other research and development expenses. The $5.3 million decrease in research and development expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was mainly due to a $5.4 million decrease in Zalviso-related expenses and a $0.9 million decrease in DSUVIA-related development spending, offset by a $1.0 million net increase in other research and development expenses. The decrease in Zalviso-related spending in 2018 as compared to the prior year periods is primarily due to the completion of the Phase 3 clinical development program in 2017, while the decrease in DSUVIA-related spending in 2018 as compared to the prior year periods is primarily due to a decrease in development-related expenses. The increase in other research and development expenses in 2018 as compared to the prior year periods is primarily the result of increased personnel expenses as we prepare for the commercial launch of DSUVIA.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel engaged in administration, finance, pre-commercialization and business development activities. Other significant expenses included allocated facility costs and professional fees for general legal, audit and consulting services. We expect general and administrative expenses in the fiscal year 2018 to increase as compared to fiscal year 2017 expenses, as we focus our efforts on preparing for the commercialization of DSUVIA in the United States.

Total general and administrative expenses for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017
	(In thousands, except percentages)							
General and administrative expenses	$5,188	$4,406	$ 782	18 %	$13,117	$12,700	$ 417	3 %

General and administrative expenses during the three months ended September 30, 2018 increased by $0.8 million, as compared to the three months ended September 30, 2017 and increased by $0.4 million during the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. In both periods, the increases were primarily due to increased personnel-related expenses in preparation for the commercial launch of DSUVIA.

Other (Expense) Income

Total other (expense) income for the three and nine months ended September 30, 2018 and 2017 was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017	2018	2017	$ Change 2018 vs. 2017	% Change 2018 vs. 2017
	(In thousands, except percentages)							
Interest expense	$(529)	$(919)	$ 390	42 %	$(1,758)	$(2,596)	$ 838	(32)%
Interest income and other income (expense), net	312	(465)	777	(167)%	643	(215)	858	(399)%
	(2,913)	(2,768)	(145)	5 %	(8,724)	(7,935)	(789)	10 %

Non-cash interest expense on liability related to sale of future royalties								
Total other (expense) income	$(3,130)	$(4,152)	$ 1,022	(25	)%	$(9,839)	$(10,746)	$ 907	(8	)%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense pertains to interest on the Amended Loan Agreement with Hercules Capital Funding Trust 2014-1 and Hercules Technology II, L.P., together, Hercules. Refer to Note 7 “Long-Term Debt” in the accompanying notes to the condensed consolidated financial statements for additional information. Primarily as a result of the lower principal balance in the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017, the amount of interest expense incurred decreased. As of September 30, 2018, the accrued balance due to Hercules was $13.9 million.

Interest income and other income (expense), net, for the three and nine months ended September 30, 2018 primarily related to interest earned on our investments, while for the three and nine months ended September 30, 2017 it consisted primarily of the change in the fair value of our warrants, or PIPE warrants, which were issued in connection with the June 2012 private placement of our common stock and expired in November 2017, and the change in the fair value of the contingent put option related to the Amended Loan Agreement with Hercules.

The increase in non-cash interest expense on the liability related to the sale of future royalties for the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017, is attributable to the Royalty Monetization that we completed in September 2015. As described above, the Royalty Monetization has been recorded as debt under the applicable accounting guidance. We impute interest on the liability and record interest expense based on the amount and timing of royalty and milestone payments expected to be received by PDL over the life of the arrangement. There are a number of factors that could materially affect the estimated interest rate and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively. We anticipate that we will incur approximately $12 million in non-cash interest expense related to the Royalty Monetization during the year ended December 31, 2018.

Liquidity and Capital Resources

Liquidity

We have incurred losses and generated negative cash flows from operations since inception. We expect to continue to incur significant losses in 2018 and may incur significant losses and negative cash flows from operations for the foreseeable future. We have funded our operations primarily through issuance of equity securities, borrowings, payments from our commercial partner, Grünenthal, monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, and our contracts with the DoD.

As of September 30, 2018, we had cash, cash equivalents and investments totaling $63.6 million compared to $60.5 million as of December 31, 2017. The decrease was primarily due to cash required to fund our continuing operations, as we continue our research and development and pre-commercialization activities and support Grünenthal's European sales of Zalviso. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of the fourth quarter of 2019. However, our expectations may change depending on a number of factors including our expenditures related to the preparation for the United States commercial launch of DSUVIA, any changes or delays in the NDA resubmission of Zalviso and the FDA approval process for Zalviso. Our existing capital resources likely will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, or if the terms underlying potential funding sources are unfavorable, our business and our ability to develop our product candidates would be harmed.

On July 16, 2018, we completed an underwritten public offering of 7,272,727 shares of common stock, at a price of $2.75 per share to the public. On August 7, 2018, the underwriters exercised in full their option to purchase an additional 1,090,909 shares of common stock at the public offering price of $2.75 per share, less underwriting discounts and commissions. The total gross proceeds from this offering of an aggregate 8,363,636 shares were approximately $23.0 million with net proceeds to us of $21.7 million after deducting the underwriting discounts and commissions and other offering expenses payable by us.

On June 21, 2016, we entered into a Controlled Equity Offering^{SM} Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which AcelRx may offer and sell, from time to time through Cantor, shares of the Company's common stock, or the Common Stock, having an aggregate offering price of up to $40.0 million. During the nine months ended September 30, 2018, we issued and sold an aggregate of 2.3 million shares of common stock pursuant to the Sales Agreement, for which we received net proceeds of approximately $7.4 million, after deducting commissions, fees and expenses of $0.2 million. As of September 30, 2018, we had issued and sold an aggregate of 7.7 million shares of common stock pursuant to the Sales Agreement, for which we had received net proceeds of approximately $23.1 million, after deducting commissions, fees and expenses of $0.7 million.

On September 18, 2015, we sold a portion of the expected royalty stream and commercial milestone payments from the European sales of Zalviso by Grünenthal to PDL. The total liability related to sale of future royalties to PDL as of September 30, 2018 was $92.1 million.

Under the terms of the Amended Agreements with Grünenthal, we received an upfront cash payment of $30.0 million, 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 related to the EC approval of the MAA for Zalviso in September 2015. In addition, under the terms of the Amended Agreements, we are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, depending on the level of sales achieved, on net sales of Zalviso in the Territory. 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, as discussed above.

On March 2, 2017, we amended and restated the Original Loan Agreement with Hercules, which is referred to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, we borrowed approximately $20.5 million upon closing of the transaction on March 2, 2017, which is represented by secured term promissory notes, or the Notes. Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property. Loans under the Amended Loan Agreement now mature in March 2020. For more information, see Note 7 “Long-Term Debt” in the accompanying notes to the condensed consolidated financial statements.

As of September 30, 2018, the accrued balance due under the Amended Loan Agreement was $13.9 million, which includes the accrued portion of the End of Term Fee.

Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, money market funds and time deposits. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our condensed consolidated financial statements which are included elsewhere in this Form 10-Q (in thousands):

	Nine Months Ended September 30,	
	2018	**2017**
Net cash used in operating activities	$(20,085)	$(23,089)
Net cash provided by (used in) investing activities	1,083	(2,495)
Net cash provided by financing activities	23,666	13,210

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund the development of our product candidates, including commercial readiness activities for our approved product, DSUVIA, and our product candidate, Zalviso, in addition to the support of Grünenthal's European sales of Zalviso. Our cash used for operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, non-cash interest expense related to the sale of future royalties, interest expense related to our debt financings and the contingent put option liability.

Cash used in operating activities of $20.1 million during the nine months ended September 30, 2018, reflected a net loss of $34.6 million, partially offset by aggregate non-cash charges of $13.2 million. Non-cash charges included $8.7 million in non-cash interest expense on the liability related to the royalty monetization and $3.9 million for stock-based compensation expense. The net change in our operating assets and liabilities included a decrease in accounts receivable of $1.3 million.

Cash used in operating activities of $23.1 million during the nine months ended September 30, 2017, reflected a net loss of $41.6 million, partially offset by aggregate non-cash charges of $14.3 million, and a net change of $4.2 million in our net operating assets and liabilities. Non-cash charges included $7.9 million in non-cash interest expense on the liability related to the royalty monetization, $3.2 million for stock-based compensation, $1.4 million in depreciation expense, $1.1 million in non-cash interest expense related to the Amended Loan Agreement, $0.4 million in inventory impairment due to excess ZALVISO inventory and $0.4 million due to the change in fair value of our PIPE warrant liability and contingent put liability. The net change in our operating assets and liabilities included a decrease in accounts receivable of $4.5 million.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales and maturities of our available-for-sale investments.

During the nine months ended September 30, 2018, cash provided by investing activities of $1.1 million was the net result of $14.5 million in proceeds from maturity of investments, offset by $12.8 million for purchases of investments and purchases of property and equipment of $0.6 million. During the nine months ended September 30, 2017, cash used in investing activities of $2.5 million was due to purchases of property and equipment.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities and payments made on debt financings.

During the nine months ended September 30, 2018, cash provided by financing activities was primarily due to net proceeds of $29.1 million from the issuance of common stock, including $21.7 million in net proceeds from our underwritten public offering plus $7.4 million in net proceeds received under the Sales Agreement. In addition, we used $5.7 million during the nine months ended September 30, 2018 to repay our long-term debt with Hercules. During the nine months ended September 30, 2017, cash provided by financing activities of $13.2 million was primarily due to $13.1 million in net proceeds from the sale of our common stock under the 2016 ATM Agreement.

Operating Capital and Capital Expenditure Requirements

Our rate of cash usage may increase in the future, in particular to support our product development activities, including activities undertaken to prepare for the potential commercialization of our product candidates, to resubmit the Zalviso NDA to the FDA, and to support the anticipated FDA review of the resubmitted ZALVISO NDA. In the short-term, we anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of the fourth quarter of 2019. Our current operating plan includes anticipated activities required to resubmit the NDA for Zalviso, to support the FDA review of the resubmitted Zalviso NDA, once resubmitted, and expenditures related to our preparation for the commercialization of DSUVIA in the United States. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to successfully launch DSUVIA and gain approval of Zalviso in the United States and intend to update our cash forecasts accordingly. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, or if the terms underlying potential funding sources are unfavorable, our business and our ability to develop our product candidates would be harmed.

Our future capital requirements may vary materially from our expectations based on numerous factors, including, but not limited to, the following:

- expenditures related to our preparation for the commercialization of DSUVIA and potential commercialization of Zalviso;
- future manufacturing, selling and marketing costs related to DSUVIA and Zalviso, including our contractual obligations to Grünenthal for Zalviso;
- the outcome, timing and cost of the regulatory resubmission of Zalviso and any approval for Zalviso;
- the initiation, progress, timing and completion of any post-approval clinical trials for our product candidates, if approved;
- changes in the focus and direction of our business strategy and/or research and development programs;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- delays that may be caused by changing regulatory requirements;

- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the expenses associated with any possible litigation.

We will need substantial funds to:

- commercialize any products we market, including DSUVIA in the United States, and Zalviso, if approved in the United States;
- manufacture and market our products;
- conduct preclinical and clinical testing of our product candidates, and;
- conduct research and development programs.

In the long-term, our existing capital resources likely will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities, monetization of current and future assets, issuance of debt or debt-like securities or from development and licensing arrangements to continue our development programs. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

- significantly curtail or put on hold commercialization or development efforts of our product candidates or other operations;

- obtain funds through entering into collaboration agreements on unattractive terms; and/or

- delay, postpone or terminate planned clinical trials.

Off-Balance Sheet Arrangements

Through September 30, 2018, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our cash, cash equivalents and short-term investments as of September 30, 2018, consisted primarily of money market funds and U.S. government agency securities. We do not have any auction rate securities on our condensed consolidated balance sheet, as they are not permitted by our investment policy. Our cash is invested in accordance with an investment policy approved by our Board of Directors which specifies the categories, allocations, and ratings of securities we may consider for investment. We do not believe our cash, cash equivalents and short-term investments have significant risk of default or illiquidity.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. In an attempt to limit interest rate risk, we follow guidelines to limit the average and longest single maturity dates, place our investments with high quality issuers and follow internally developed guidelines to limit the amount of credit exposure to any one issuer. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. If a 10 percent change in interest rates were to have occurred on September 30, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

In addition, domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of disclosure controls and procedures. As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

From time to time we may be involved in legal proceedings arising in the ordinary course of business. We are not currently involved in any material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share. You should carefully consider these risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q as well as our other publicly available filings with the U.S. Securities and Exchange Commission, or SEC.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2017.

Risks Related to Commercialization of Our Approved Products and Our Product Candidates

Our success depends heavily on successful commercialization of DSUVIA, which received approval in November 2018 from the U.S. Food and Drug Administration, or FDA, for use in adults in a certified medically supervised healthcare setting, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. To the extent DSUVIA is not commercially successful, our business, financial condition and results of operations will be materially harmed.*

We have invested and continue to invest a significant portion of our efforts and financial resources in the development, approval and now commercialization of DSUVIA for use in adults in a certified medically supervised healthcare setting for the management of acute pain. The success of DSUVIA will depend on numerous factors, including:

- our success in commercializing DSUVIA, including the marketing, sales, and distribution of the product;
- successfully establishing and maintaining commercial manufacturing with third parties;
- acceptance of DSUVIA by physicians, patients and the healthcare community;
- the acceptance of pricing and placement of DSUVIA on payers' formularies;

- effectively competing with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;

- effective management of and compliance with the DSUVIA Risk Evaluation and Mitigation Strategies, or REMS program;

- continued demonstration of an acceptable safety profile of DSUVIA following approval; and

- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize DSUVIA, which would materially harm our business.

The commercial success of DSUVIA, and Zalviso®, if approved, in the United States, as well as DZUVEO and Zalviso in Europe, will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.*

The degree of market acceptance of DSUVIA, and Zalviso, if approved, in the United States, or DZUVEO and Zalviso in Europe, will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;

- the relative convenience, ease of administration and acceptance by physicians, patients and health care payors;

- the use of DSUVIA for the management of moderate-to-severe acute pain by a healthcare professional for patient types that were not specifically studied in our Phase 3 trials;

- the use of Zalviso for the management of moderate-to-severe acute pain in the hospital setting for patient types that were not specifically studied in our Phase 3 trials;

- the prevalence and severity of any adverse events, or AEs, or serious adverse events, or SAEs;

- overcoming any perceptions of sufentanil as a potentially unsafe drug due to its high potency;

- limitations or warnings contained in the FDA-approved label for DSUVIA, or the European Medicines Agency, or EMA-approved label for DZUVEO, or Zalviso;

- restrictions or limitations placed on DSUVIA due to the REMS;

- availability of alternative treatments;

- existing capital investment by hospitals in IV PCA technology;

- pricing and cost-effectiveness;

- the effectiveness of our or any future collaborators' sales and marketing strategies;

- our ability to obtain formulary approval; and,

- our ability to obtain and maintain sufficient third-party coverage and reimbursement.

If our approved products do not achieve an adequate level of acceptance by physicians, nurses, patients and pharmacy and therapeutics committees, we may not generate sufficient revenue and we may not become or remain profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any product revenue.*

In order to commercialize DSUVIA, and Zalviso, if approved, in the United States, we must build our internal sales, marketing, distribution, managerial and other capabilities or make arrangements with third parties to perform these services. In addition, we plan to enter into agreements with third parties for the distribution of approved product candidates; however, if there are delays in establishing such relationships or those third parties do not perform as expected, our ability to effectively distribute products would suffer.

We have entered into a collaboration with Grünenthal for the commercialization of Zalviso in Europe and Australia and intend to enter into additional strategic partnerships with third parties to commercialize our product candidates outside of the United States. DZUVEO was approved by the EC in June 2018, but we have not yet entered into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe, and there can be no assurance that we will successfully enter into such an agreement. We may also consider the option to enter into

strategic partnerships for our product candidates in the United States. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document.

We may not be able to negotiate future strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. Our current or future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of Zalviso or DZUVEO in Europe, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates, if approved, to healthcare professionals and in geographical regions that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, if approved, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our product candidates, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish and maintain successful collaborative relationships to obtain international sales, marketing and distribution capabilities for our product candidates. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;

- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;

- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully and timely transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Approval of Zalviso and DZUVEO in Europe has resulted, and any future approvals of our product candidates outside of the United States will result, in a variety of risks associated with international operations that could materially adversely affect our business.

Our existing collaboration with Grünenthal for Zalviso requires us to supply product to support the European commercialization of Zalviso. In addition, with the June 2018 approval of DZUVEO in Europe, we intend to enter into agreements with third parties to market DZUVEO in Europe, which may also require us to supply product to those third parties. We may be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we, or current and potential partners, are unable to compete effectively, our product candidates may not reach their commercial potential.

The U.S. market for DSUVIA and Zalviso is characterized by intense competition and cost pressure. DSUVIA, and Zalviso, if approved, will compete with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We or our current and potential partners will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies.

There are a wide variety of approved injectable and oral opioid products to treat moderate-to-severe acute pain, including IV opioids such as morphine, fentanyl, hydromorphone and meperidine or oral opioids such as oxycodone and hydrocodone. DSUVIA does not require placement of an IV line and therefore direct competitors in the

emergency department are other non-invasive, rapid-acting analgesics. In this environment, DSUVIA may compete with Egalet Corporation's SPRIX (intranasal ketorolac) or products that are in development, such as INSYS' sublingual buprenorphine spray. Transmucosal fentanyl products, such as ACTIQ or FENTORA (Cephalon, Inc., a subsidiary of Teva Pharmaceutical Products Ltd.), are approved for opioid-tolerant patients suffering from cancer pain and therefore are not a competitor for DSUVIA. Orally administered tablets or liquids containing oxycodone or hydrocodone often have slower absorption and slower analgesic onset than transmucosal opioids. Examples of oral opioids include Acura Pharmaceuticals, Inc.'s OXAYDO (marketed by Egalet Corporation), Collegium Pharmaceuticals, Inc.'s NUCYNTA, and Purdue Pharma, L.P.'s OXYFAST, or generic oral opioids which have moderate-to-severe acute pain labeling.

Often used in combination with opioids are generic injectable local anesthetics, such as bupivacaine, or branded formulations thereof, including Pacira Pharmaceuticals, Inc.'s EXPAREL. In addition, Heron Therapeutics, Inc. is in Phase 3 development of HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. These products may reduce the amount of opioids required to achieve adequate pain control but usually do not obviate the need for opioids completely. Similarly, there are many IV formulations of non-steroidal anti-inflammatory drugs, or NSAIDS, for treatment of acute pain, such as generic IV ketorolac, Pfizer's DYLOJECT, Cumberland Pharmaceuticals Inc.'s CALDOLOR and recently Recro Pharma, Inc. submitted a New Drug Application, or NDA, for IV meloxicam for the treatment of moderate-to-severe acute pain. These products are all invasively administered via an IV and, as a result, we do not believe they are direct competitors to the non-invasive DSUVIA.

We believe that Zalviso would compete with a number of opioid-based treatment options that are currently available, as well as some products that are in development. The hospital market for opioids for moderate-to-severe acute pain is large and competitive. The primary competition for Zalviso is the IV PCA pump, which is widely used in the moderate-to-severe acute pain in the hospital setting. Leading manufacturers of IV PCA pumps include Hospira, Inc. (sold by Pfizer, Inc. to ICU Medical), CareFusion Corporation (purchased by Becton, Dickinson and Company), Baxter International, Inc., Curlin Medical, Inc. and Smiths Medical. The most common opioids used to treat moderate-to-severe acute pain are morphine, hydromorphone and fentanyl, all of which are available as generics both from generic product manufacturers as well as from compounding pharmacies. In addition, branded manufacturers (e.g., Hospira, Inc.) sell pre-filled glass syringes of morphine to fit their IV PCA pump systems. These systems, however, are invasive and require programming, which can lead to dosing errors, and therefore, while they are commonly used, we do not believe they are direct competitors for Zalviso.

Also available on the market is the Avancen Medication on Demand, or MOD, an oral PCA device developed by Avancen MOD Corporation. Oral opioids and other agents can be used in this system. Oral opioids tend to have slower onset than transmucosal opioids, such as Zalviso. The Medicine Company's IONSYS is a non-invasive transdermal opioid PCA that could potentially compete with Zalviso; however, a worldwide recall of the product was announced due to a commercial refocusing of the company. Additional potential opioid competitors for Zalviso include Cara Therapeutics, Inc., who is developing a kappa opioid agonist, CR845, as an IV agent for the management of post-operative moderate-to-severe pain. Also, Trevena, Inc., has submitted an NDA for IV oliceridine, an intravenous G-protein biased ligand that targets the mu-opioid receptor for the treatment of moderate-to-severe acute pain, with a clinical development focus in acute post-operative pain. Both of these product candidates are invasive and, therefore, we do not believe they are direct competition to the non-invasive Zalviso.

It is possible that any of these competitors could develop or improve technologies or products that would render our product candidates obsolete or non-competitive, which could adversely affect our revenue potential. Key competitive factors affecting the commercial success of our product candidates are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approval of products and the commercialization of those products. Accordingly, our competitors may be more successful than we are in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs or drug delivery systems may be more effective, have fewer adverse effects, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product candidate we may commercialize. This may render our product candidates obsolete or non-competitive before we can recover our losses. We anticipate that we will face intense and increasing competition as new drugs enter the market and additional technologies become available. These entities may also establish collaborative or licensing relationships with our competitors, which may adversely affect our competitive position. Finally, the development of different methods for the treatment of moderate-to-severe acute pain could render our products non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

Formulary approval may not be available, or could be subject to certain restrictions for DSUVIA, or Zalviso, if approved, in the United States, which could make it difficult for us to sell our products profitably.*

Obtaining formulary approval can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell our products into our target markets. Failure to obtain timely formulary approval will limit our commercial success. If we are successful in obtaining formulary approval, we may need to complete evaluation programs whereby DSUVIA, or Zalviso, if approved, is used on a limited basis for certain patient types. Hospitals may seek to obtain DSUVIA or Zalviso devices at little or no cost during this evaluation period. Revenue generated from these hospitals during the evaluation period would be minimal. The evaluation period may last several months and there can be no assurance that use during the evaluation period will lead to formulary approval of DSUVIA, or Zalviso, if approved. Further, even successful formulary approval may be subject to certain restrictions based on patient type or hospital protocol. Failure to obtain timely formulary approval for DSUVIA, and/or Zalviso, if approved, would materially adversely affect our ability to attain or sustain profitable operations.

Coverage and adequate reimbursement may not be available for DSUVIA, or Zalviso, if approved, in the United States, or DZUVEO or Zalviso in Europe, which could make it difficult for us, or our partners, to sell our products profitably.*

Our ability to commercialize DSUVIA, or Zalviso, if approved, in the United States, any future collaboration partner's ability to commercialize DZUVEO in Europe, or Grünenthal's ability to expand sales of Zalviso in Europe successfully will depend, in part, on the extent to which coverage and adequate reimbursement will be available from government payer programs at the federal and state levels, authorities, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payers.

No uniform policy requirement for coverage and reimbursement for drug products exists among third-party payers in the United States or Europe. Therefore, coverage and reimbursement can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from third party payers could significantly harm our operating results, our ability to raise capital needed to commercialize any future approved drugs and our overall financial condition.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell our products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for DSUVIA, or Zalviso, if approved in the United States, and DZUVEO and Zalviso in Europe and elsewhere. The application of user fees to generic drug products may expedite the approval of additional pain medication generic drugs. We expect to experience pricing pressures in connection with our sales of DSUVIA, and Zalviso, if approved, in the United States, Grünenthal's European sales of Zalviso, future product sales of DZUVEO, and any other product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Furthermore, market acceptance and sales of our product candidates, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payers, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for DSUVIA in the United States, or DZUVEO or Zalviso in Europe or Zalviso, or any of our other product candidates, if approved in the United States. Also, reimbursement amounts may reduce the demand for, or the price of, our products. For example, as mentioned above, we anticipate we may need comparator studies of DZUVEO in Europe to ensure premium

reimbursement in certain countries. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize DSUVIA in the United States, or DZUVEO or Zalviso in Europe, or Zalviso, or any of product candidates, if approved in the United States.

Additionally, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. For example, although in September 2015 the EC approved the MAA for Grünenthal to market Zalviso in the European Economic Area countries, including the 28 EU member states as well as Norway, Iceland and Liechtenstein, separate pricing and reimbursement approvals may impact their ability to successfully commercialize Zalviso. Adverse pricing limitations may hinder our ability to recoup our investment in DSUVIA in the United States, or Zalviso and our other drug candidates, even if those drug candidates obtain marketing approval.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade, i.e. arbitrage between low-priced and high-priced countries. If any of these events occur, revenue from sales of Zalviso and DZUVEO in Europe would be negatively affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.*

If we are found to have improperly promoted off-label uses of our product candidates, including DSUVIA, or Zalviso, if approved in the United States, we ma