ACELRX PHARMACEUTICALS INC

Form 10-Q

November 02, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended September 30, 2016
or
TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to
Commission File Number: 001-35068
ACELRX PHARMACEUTICALS, INC.

(Exact name	of registrant	as specified	in its	charter
L'Aact Haine	or region am	as succincu	111 163	CHAI tel

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

351 Galveston Drive

Redwood City, CA 94063

(650) 216-3500

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

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

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

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

Large accelerated filer

Accelerated filer

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

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

As of October 21, 2016, the number of outstanding shares of the registrant's common stock was 45,333,790.							
	•						
1							

## ACELRX PHARMACEUTICALS, INC.

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

### **Table of Contents**

Part I. F	inancial Information	Page
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015	3
	Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015 (unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015 (unaudited)	5
	Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	35
Item 4.	Controls and Procedures	35
Part II. (	OTHER Information	36
Item 1.	Legal Proceedings	36
Item 1A	. Risk Factors	36
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	65
Item 3.	Defaults Upon Senior Securities	65
Item 4.	Mine Safety Disclosures	65
Item 5.	Other Information	65

Item 6. Exhibits 66

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

### PART I. FINANCIAL INFORMATION

### **Item 1. Financial Statements**

# AcelRx Pharmaceuticals, Inc.

### **Condensed Consolidated Balance Sheets**

## (In thousands, except share data)

	September 30, 2016 (Unaudited)	December 31, 2015 <sup>(1)</sup>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 92,462	\$107,922
Short-term investments		5,542
Accounts receivable, net	2,009	3,286
Inventories	1,384	466
Prepaid expenses and other current assets	1,067	1,731
Total current assets	96,922	118,947
Property and equipment, net	8,848	8,610
Restricted cash	178	178
Other assets	50	50
Total Assets	\$ 105,998	\$127,785
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,351	\$1,561
Accrued liabilities	4,140	3,956
Long-term debt, current portion	9,180	4,541
Deferred revenue, current portion	362	2,604
Liability related to the sale of future royalties, current portion	497	118
Total current liabilities	15,530	12,780
Deferred rent, net of current portion	96	245
Long-term debt, net of current portion	12,145	16,381
Deferred revenue, net of current portion	3,915	593
Liability related to the sale of future royalties, net of current portion	70,033	63,494

Contingent put option liability	175		266
Warrant liability	832		913
Total liabilities	102,726		94,672
Commitments and Contingencies			
Stockholders' Equity:			
Common stock, \$0.001 par value—100,000,000 shares authorized as of September 30, 2016	)		
and December 31, 2015; 45,333,790 and 45,273,772 shares issued and outstanding as of	45		45
September 30, 2016 and December 31, 2015			
Additional paid-in capital	239,906		236,274
Accumulated deficit	(236,680	)	(203,205)
Accumulated other comprehensive income (loss)	1		(1)
Total stockholders' equity	3,272		33,113
Total Liabilities and Stockholders' Equity	\$ 105,998	9	\$127,785

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

See notes to condensed consolidated financial statements.

## AcelRx Pharmaceuticals, Inc.

## **Condensed Consolidated Statements of Comprehensive Loss**

# (Unaudited)

# (In thousands, except share and per share data)

		nree Months eptember 30,		ed			Nine Months I September 30		ed		
	20	16		20	15	2	016		20	15	
Revenue:											
Collaboration agreement	\$	1,562		\$	13,863	9	4,669		\$	14,530	
Contract and other		1,804			1,565		6,253			3,003	
Total revenue		3,366			15,428		10,922			17,533	
Operating costs and expenses:											
Cost of goods sold		2,579					9,154				
Research and development		4,617			5,393		15,068			19,009	
General and administrative		4,145			2,930		11,519			10,186	
Restructuring costs										756	
Total operating costs and expenses		11,341			8,323		35,741			29,951	
(Loss) income from operations		(7,975	)		7,105		(24,819	)		(12,418	)
Other (expense) income:											
Interest expense		(702	)		(713	)	(2,069	)		(2,296	)
Interest income and other income		(260	`		(260	`	200			1.015	
(expense), net		(360	)		(269	)	300			1,915	
Non-cash interest expense on liability		(2.401	`		(282	`	(6,921	`		(282	`
related to future sale of royalties		(2,401	)		(282	)	(0,921	)		(282	)
Total other expense		(3,463	)		(1,264	)	(8,690	)		(663	)
Net (loss) income before income		(11 420	`		5,841		(22.500	`		(12.001	`
taxes		(11,438	)		3,041		(33,509	)		(13,081	)
Benefit (provision) for income taxes		36			(772	)	34			(772	)
Net (loss) income		(11,402	)		5,069		(33,475	)		(13,853	)
Other comprehensive (loss) income:											
Unrealized gains on available-for-sale		(5	`		1		2			6	
securities		(3	)		1		2			O	
Comprehensive (loss) income	\$	(11,407	)	\$	5,070	9	(33,473	)	\$	(13,847	)
Net (loss) income per share of	\$	(0.25	)	\$	0.11	9	(0.74	)	\$	(0.31	)
common stock, basic	Ψ	(0.23	,	Ψ	0.11	4	(0.74	,	Ψ	(0.51	,
Net (loss) income per share of	\$	(0.25	)	\$	0.11	9	(0.74	)	\$	(0.37	)
common stock, diluted	Ψ	`	,	Ψ		4	`	,	Ψ	`	,
Shares used in computing net (loss)		45,319,269			44,406,933		45,306,177			44,209,726	
income per share of common stock,											

basic

Shares used in computing net (loss)

income per share of common stock, 45,319,269 45,049,258 45,306,177 44,399,387

diluted – see Note 11

See notes to condensed consolidated financial statements.

## AcelRx Pharmaceuticals, Inc.

### **Condensed Consolidated Statements of Cash Flows**

(Unaudited)

(In thousands)

	Nine Mo Ended S 30,		
	2016	2	2015
Cash flows from operating activities:			
Net loss	\$(33,475	5) 5	\$(13,853)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash royalty revenue related to royalty monetization	(3	)	
Non-cash interest expense on liability related to royalty monetization	6,921		282
Depreciation and amortization	1,545		1,502
Amortization of premium/discount on investments, net	17		81
Interest expense related to debt financing	653		691
Stock-based compensation	3,408		3,820
Revaluation of put option and PIPE warrant liabilities	(172	)	(2,363)
Loss on disposal and impairment of property and equipment			509
Changes in operating assets and liabilities:			
Accounts receivable	1,277		(17,376)
Inventories	(918	)	
Prepaid expenses and other assets	664		65
Restricted cash			72
Accounts payable	(112	)	(564)
Accrued liabilities	184		(1,289)
Income taxes payable			771
Deferred revenue	1,080		792
Deferred rent	(149	)	(88)
Net cash used in operating activities	(19,080	))	(26,948)
Cash flows from investing activities:			
Purchase of property and equipment	(1,881	)	(1,122)
Purchase of investments	(998	)	(7,264)
Proceeds from maturities of investments	6,525		13,210
Net cash provided by investing activities	3,646		4,824
Cash flows from financing activities:			
Net proceeds from sale of future royalties			61,184
Payment of long-term debt	_		(4,534)
Payment of debt modification transaction costs	(205	)	(215)
Net proceeds from issuance of common stock through equity plans and exercise of warrants	179	-	693

Net cash (used in) provided by financing activities	(26)	57,128
Net (decrease) increase in cash and cash equivalents	(15,460)	35,004
Cash and cash equivalents—Beginning of period	107,922	60,038
Cash and cash equivalents—End of period	\$92,462	\$95,042

See notes to condensed consolidated financial statements.

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**Notes to Condensed Consolidated Financial Statements** 

(Unaudited)

### 1. Organization and Summary of Significant Accounting Policies

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

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

The Company has two late-stage development candidates based on sublingual sufentanil. The first, ARX-04, is a 30 mcg sufentanil sublingual tablet in a single-dose applicator intended for the treatment of moderate-to-severe acute pain administered by a healthcare professional. ARX-04 was initially developed at the request of the U.S. Department of Defense as a replacement for injections of morphine on the battlefield. In addition to the military application, AcelRx is developing ARX-04 as an investigational product for the treatment of patients suffering from moderate-to-severe acute pain in multiple settings, such as emergency room patients; patients who are recovering from short-stay or ambulatory surgery and do not require more long-term patient-controlled analgesia; post-operative patients who are transitioning from the operating room to the recovery floor; and patients being transported by paramedics. The Company has completed the Phase 3 clinical program for ARX-04 and intends to submit to the U.S. Food and Drug Administration, or FDA, a New Drug Application, or NDA, for ARX-04 for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional in medically-supervised settings by the end of 2016.

The Company's other late-stage investigational product candidate, Zalvis®, delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the European Union, or EU, as well as Norway, Iceland and Liechtenstein and is in late-stage development in the

U.S. In response to the NDA the Company submitted to the FDA seeking approval for Zalviso, the Company received a Complete Response Letter, or CRL, on July 25, 2014. Subsequently, the FDA requested an additional clinical study, IAP312, which the Company initiated in September 2016.

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015 and September 20, 2016, or the Amended License Agreement, which grants Grünenthal rights to commercialize Zalviso, the Company's novel sublingual patient-controlled analgesia, or PCA, system, or the Product, in the countries of the EU, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. In September 2015, the European Commission approved the Marketing Authorization Application, or MAA, previously submitted to the European Medicines Agency, or EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. The approval allows Grünenthal to market Zalviso in the 28 EU member states as well as for the European Economic Area countries, Norway, Iceland and Liechtenstein, or EEA. Also on December 16, 2013, AcelRx and Grünenthal, entered into a related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. Under the MSA, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory. On July 22, 2015, the Company entered into an amendment to the MSA, or the MSA Amendment, and together with the MSA, the Amended MSA, between the Company and Grünenthal, effective as of July 17, 2015, and together with the Amended License Agreement, the Amended Agreements.

Zalviso is currently commercially available for sale in Germany, France and the United Kingdom. Grünenthal currently has pilot programs in Belgium, Italy, the Netherlands and Ireland. Pilot programs are expected to last several months after which Zalviso may be available for commercial sale. Royalty revenues and non-cash royalty revenues from the commercial sales of Zalviso in the EU are expected to be minimal for 2016.

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

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

#### **Principles of Consolidation**

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

#### Basis of Presentation

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

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

#### Use of Estimates

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

#### Significant Accounting Policies

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

#### Recently Issued Accounting Standards

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 31, 2017, and for interim periods within those years. Early adoption is permitted. The Company does not expect the amended guidance to have a material impact on its statements of cash flows.

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

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

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

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

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

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

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

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

#### 2. Investments and Fair Value Measurement

Investments

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

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

	As of September 30, 2016							
	Amortizo Cost	Unrealized		Gross Unrealized Losses		Fair Value		
Cash and cash equivalents:								
Cash	\$62,036	\$		\$	_	\$62,036		
U.S. government agency securities	30,425		1		_	30,426		
Total cash and cash equivalents	92,461		1			92,462		
Marketable securities:								
U.S. government agency securities						_		
Total marketable securities								
Total cash, cash equivalents and investments	\$92,461	\$	1	\$		\$92,462		

	As of December 31, 2015						
	Amortize Cost	ed Gross Unrealized Gains		Un	oss realized sses	Fair Value	
Cash and cash equivalents:							
Cash	\$83,112	\$	_	\$	_	\$83,112	
U.S. government agency securities	24,809		1			24,810	
Total cash and cash equivalents	107,921		1			107,922	
Marketable securities:							
U.S. government agency securities	5,544				(2	) 5,542	
Total marketable securities	5,544				(2	) 5,542	
Total cash, cash equivalents and investments	\$113,465	\$	1	\$	(2	) \$113,464	

As of September 30, 2016 and December 31, 2015, 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, 2016 or December 31, 2015. 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, 2016 and 2015.

As of September 30, 2016 and December 31, 2015, the contractual maturity of all investments held was less than one year.

#### Fair Value Measurement

The Company's financial instruments consist of Level I and Level II assets and Level III liabilities. Level I securities include highly liquid money market funds and are valued based on quoted market prices. For Level II instruments, the Company estimates fair value by utilizing third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. treasury and U.S. government agency obligations. As of September 30, 2016 and December 31, 2015, the Company held, in addition to Level I and Level II assets, a contingent put option liability associated with the Company's Amended and Restated Loan and Security Agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Capital, Inc., formerly known as Hercules Technology Growth Capital, Inc., collectively referred to as Hercules or the Lenders, which amends and restates the loan and security agreement with Hercules dated as of June 29, 2011, or the Original Loan Agreement, and which was classified as a Level III liability. See Note 6 "Long-Term Debt" for further description. The Company's estimate of fair value of the contingent put option liability was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the

contingent put option. Changes to the estimated fair value of these liabilities are recorded in interest income and other income, net in the condensed consolidated statements of comprehensive loss. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. As of September 30, 2016 and December 31, 2015, the Company also held a Level III liability associated with warrants, or PIPE warrants, issued in connection with the Company's private placement equity offering, completed in June 2012. For a detailed description, see Note 8 "Warrants." The PIPE warrants are considered a liability and are valued using the Black-Scholes option-pricing model, the inputs for which include exercise price of the PIPE warrants, market price of the underlying common shares, expected term, volatility based on a group of the Company's peers and the risk-free rate corresponding to the expected term of the PIPE warrants. Changes to any of these inputs can have a significant impact to the estimated fair value of the PIPE warrants. The following table sets forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy (in thousands):

C

	As of September 30, 2016			
	Fair Value	Level I	Level II	Level III
<u>Assets</u>				
Money market funds	\$79	\$ 79	\$	\$
U.S. government agency obligations	30,347		30,347	
Total assets measured at fair value	\$30,426	\$ 79	\$30,347	<b>\$</b> —
<u>Liabilities</u>				
PIPE warrants	\$832		_	\$832
Contingent put option liability	175		_	175
Total liabilities measured at fair value	\$1,007	\$ —	<b>\$</b> —	\$1,007
	As of De	cember	31, 2015	
	As of De Fair Value	cember Level I	•	Level III
<u>Assets</u>	Fair	Level	-	
Assets Money market funds	Fair	Level I \$ 2	Level II \$—	III \$—
Money market funds U.S. government agency obligations	<b>Fair Value</b> \$2 30,352	Level I \$ 2	Level II \$— 30,352	## S— — — — — — — — — — — — — — — — — —
Money market funds	Fair Value \$2	Level I \$ 2	Level II \$— 30,352	## S— — — — — — — — — — — — — — — — — —
Money market funds U.S. government agency obligations	<b>Fair Value</b> \$2 30,352	Level I \$ 2	Level II \$— 30,352	## S— — — — — — — — — — — — — — — — — —
Money market funds U.S. government agency obligations Total assets measured at fair value	<b>Fair Value</b> \$2 30,352	Level I \$ 2	Level II \$— 30,352	## S— — — — — — — — — — — — — — — — — —
Money market funds U.S. government agency obligations Total assets measured at fair value  Liabilities	Fair Value \$2 30,352 \$30,354	Level I \$ 2	Level II \$— 30,352	\$— - \$—

The following table sets forth the assumptions used in the Black-Scholes option-pricing model to estimate the fair value of the PIPE warrants as of September 30, 2016:

Market price	\$3.89
Exercise price	\$3.40
Risk-free interest rate	0.59%
Expected volatility	89.0%
Expected life (in years)	1.19
Expected dividend yield	0.0 %

The following table sets forth the assumptions used in the Black-Scholes option-pricing model to estimate the fair value of the PIPE warrants as of December 31, 2015:

Market price	\$3.85
Exercise price	\$3.40
Risk-free interest rate	1.06%
Expected volatility	80.0%
Expected life (in years)	1.92
Expected dividend yield	0.0 %

The following tables set forth a summary of the changes in the fair value of the Company's Level III financial liabilities for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three	Nine	
	Months	Months	
	Ended	Ended	
	September	Septembo	er
	30,	30,	
	2016	2016	
Fair value—beginning of period	\$ 605	\$ 1,179	
Change in fair value of PIPE warrants	392	(81	)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	10	(91	)
Fair value—end of period	\$ 1,007	\$ 1,007	

	M En Se 30	),	er	Nine Months Ended Septemb 30,	er
Fair value—beginning of period Change in fair value of PIPE warrants Exercise of PIPE warrants		1,167 (283		<b>2015</b> \$ 5,859 (2,401 (2,543	)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules Fair value—end of period		68 952		37 \$ 952	

### 3. Inventories

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

	Balance as of					
	Septem 30, 2016	ber December 31, 2015				
Raw materials	\$1,015	\$	140			
Work-in-process	194		181			
Finished goods	175		145			