ACELRX PHARMACEUTICALS INC
Form 10-Q
November 06, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012

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 x 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 x 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 x

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

As of October 15, 2012, the number of outstanding shares of the registrant s common stock was 22,646,773.

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ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2012

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

ACELRX, NANOTAB and ACCELERATE, INNOVATE, ALLEVIATE, are registered trademarks of AcelRx Pharmaceuticals, Inc. Other trademarks of AcelRx Pharmaceuticals, Inc. appearing in this report are the property of AcelRx Pharmaceuticals, Inc.

This report also contains trademarks and trade names that are the property of their respective owners.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Balance Sheets

(In thousands, except share data)

	September 30, 2012 (Unaudited)	December 31, 2011[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,721	$ 7,794
Short-term investments	19,654	27,991
Prepaid expenses and other current assets	1,922	2,361
Total current assets	25,297	38,146
Property and equipment, net	2,524	2,306
Restricted cash	205	205
Other assets	125	178
TOTAL ASSETS	$ 28,151	$ 40,835
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,858	$ 1,530
Accrued liabilities	2,143	2,565
Long-term debt, current portion	7,226	3,750
Total current liabilities	12,227	7,845
Deferred rent	341	15
Long-term debt, net of current portion	10,456	15,275
Warrant liability	5,345	
Contingent put option liability	109	232
Total liabilities	28,478	23,367
STOCKHOLDERS EQUITY:		
Common stock, $0.001 par value 100,000,000 shares authorized as of September 30, 2012 and December 31, 2011; 22,646,773 and 19,567,778 shares issued and outstanding as of September 30, 2012 and December 31, 2011	23	22
Additional paid-in capital	111,154	106,110
Deficit accumulated during the development stage	(111,505)	(88,664)
Accumulated other comprehensive income	1	
Total stockholders equity (deficit)	(327)	17,468

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 28,151	$ 40,835

(1) The condensed balance sheet as of December 31, 2011 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, 2011.

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Comprehensive Loss

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2012	2011	2012	2011	2012
Research grant revenue	$ 166	$ 408	$ 719	$ 448	$ 1,791
Operating expenses:					
Research and development	6,948	3,947	17,113	8,922	84,534
General and administrative	1,410	1,866	5,290	5,086	24,584
Total operating expenses	8,358	5,813	22,403	14,008	109,118
Loss from operations	(8,192)	(5,405)	(21,684)	(13,560)	(107,327)
Interest expense	(573)	(377)	(1,765)	(1,891)	(7,204)
Interest income and Other income (expense), net	183	21	608	1,722	3,026
Net loss	(8,582)	(5,761)	(22,841)	(13,729)	(111,505)
Other comprehensive loss:					
Unrealized gains on available for sale securities	4	5	1	3	1
Comprehensive loss	$ (8,578)	$ (5,755)	$ (22,840)	$ (13,726)	$ (111,504)
Net loss per share of common stock, basic and diluted	$ (0.38)	$ (0.30)	$ (1.09)	$ (0.83)	
Shares used to compute basic and diluted net loss per share of common stock	22,632,573	19,458,640	20,961,886	16,594,051	

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2012	2011	2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (22,841)	$ (13,729)	$ (111,505)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	467	348	2,545
Amortization of premium/discount on investments, net	339	196	534
Interest expense related to debt financing	497	1,462	3,324
Stock-based compensation	1,633	1,346	5,979
Revaluation of convertible preferred stock warrant, call option, put option and private placement warrant liabilities	(606)	(1,688)	(690)
Other	38		28
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	459	(133)	(524)
Restricted cash			(205)
Accounts payable	1,328	2,083	2,858
Accrued liabilities	(478)	961	400
Deferred rent	381	(142)	450
Net cash used in operating activities	(18,783)	(9,296)	(96,806)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(723)	(1,777)	(5,111)
Purchase of investments	(23,528)	(33,280)	(108,195)
Proceeds from sale of investments			21,815
Proceeds from maturity of investments	31,527	3,516	66,243
Net cash provided by (used in) investing activities	7,276	(31,541)	(25,248)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from initial public offering, net of costs		34,939	34,939
Proceeds from private placement of common stock, net of costs	9,077		9,077
Proceeds from the issuance of long-term debt		9,762	32,383
Payments of long-term debt	(1,806)	(5,298)	(15,027)
Proceeds from issuance of convertible promissory notes			9,000
Proceeds from issuance of common stock pursuant to equity plans	163	204	462
Proceeds from issuance of convertible preferred stock, net of issuance costs			54,941
Net cash provided by financing activities	7,434	39,607	125,775

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(4,073)	(1,230)	3,721
CASH AND CASH EQUIVALENTS Beginning of period	7,794	3,055	
CASH AND CASH EQUIVALENTS End of period	$ 3,721	$ 1,825	$ 3,721
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 1,255	$ 347	$ 4,157
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Contingent put option liability	$	$ 62	$ 62
Issuance of convertible preferred stock warrants	$	$	$ 1,223
Beneficial conversion features related to convertible notes	$	$	$ 1,699
Issuance of call option related to convertible note	$	$	$ 476
Conversion of convertible promissory notes into common stock	$	$ 8,137	$ 8,137
Issuance of common stock upon cashless exercise of warrants	$	$ 536	$ 536
Reclassification of warrant liability and call option liability to equity	$	$ 906	$ 906
Issuance of warrants for common stock	$ 5,828	$ 967	$ 6,795
Purchase of property and equipment through accounts payable and accrued liabilities	$	$ 865	$

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

AcelRx Pharmaceuticals, Inc., or AcelRx or the Company, is a development stage company that was incorporated in Delaware on July 13, 2005 as SuRx, Inc. In January 2006, the Company changed its name to AcelRx Pharmaceuticals, Inc. The Company s operations are based in Redwood City, California.

The Company is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. Since incorporation, primary activities have consisted of establishing facilities, recruiting personnel, conducting research and development of its product candidates, developing intellectual property and raising capital. To date, the Company has not yet commenced primary operations or generated any significant revenues and, accordingly, the Company is considered to be in the development stage.

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

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception through September 30, 2012. In addition, the Company had an accumulated deficit of $111.5 million and $88.7 million as of September 30, 2012 and December 31, 2011, respectively. Through September 30, 2012, the Company has relied primarily on the proceeds from equity offerings and loan proceeds to finance its operations. Management believes that the Company s current cash, cash equivalents and investments will be sufficient to fund the Company s current operations into the second quarter of 2013, including support for the continuing development of ARX-01, our lead product candidate. The Company will need to raise additional funding or otherwise enter into collaborations to fund future operations. However, there is no assurance that additional funding will be available to the Company on acceptable terms on a timely basis, if at all, or that the Company will achieve profitable operations. If the Company is unable to raise additional capital to fund its operations, it will need to curtail planned activities, such as completion of our final planned ARX-01 Phase 3 trial, to reduce costs. Doing so may affect the Company s ability to operate effectively. The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis of Presentation

The accompanying unaudited condensed 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 the 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The condensed balance sheet as of December 31, 2011 was derived from the Company s audited financial statements as of December 31, 2011, 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, 2011, which include a broader discussion of the Company s business and the risks inherent therein.

Initial Public Offering

On February 10, 2011, the Company sold 8,000,000 shares of common stock at a price of $5.00 per share in its initial public offering, or the IPO. The shares began trading on the NASDAQ Global Market on February 11, 2011. The Company received $34.9 million in net proceeds from the IPO, after deducting an estimated $5.1 million in underwriting discounts and commissions and other offering-related expenses payable

by the Company. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 8,555,713 shares of common stock. In addition, the principal and accrued interest under the 2010 Convertible Notes, as defined in Note 6 Convertible Notes, converted into 2,034,438 shares of common stock immediately prior to the closing of the IPO and the 2010 Warrants, as defined in Note 7 Warrants, were net exercised for 107,246 shares of Series C convertible preferred stock, which shares were converted to common stock immediately prior to the closing of the IPO. All other outstanding warrants to purchase convertible preferred stock became exercisable for shares of common stock.

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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 financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, 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.

Newly Adopted Accounting Pronouncements

In June of 2011, Accounting Standards Codification Topic 220, *Comprehensive Income* was amended to increase the prominence of items reported in other comprehensive income. Accordingly, a company can present all non-owner changes in stockholders equity either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The Company adopted this guidance as of January 1, 2012 on a retrospective basis and this adoption did not have a material effect on the Company s financial statements.

In May of 2011, Accounting Standards Codification Topic 820, *Fair Value Measurement* was amended to develop common requirements for measuring fair value and for disclosing information about fair value measurements in accordance with U.S. generally accepted accounting principles and International Financial Reporting Standards. The Company adopted this guidance as of January 1, 2012 on a retrospective basis and this adoption did not have a material effect on the Company s financial statements.

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, 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, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,241	$	$	$ 1,241
Money market funds	2,280			2,280
U.S. government agency securities	200			200
Total cash and cash equivalents	3,721			3,721
Marketable securities:				
U.S. government agency securities	19,653	1		$ 19,654
Total marketable securities	19,653	1		$ 19,654
Total cash, cash equivalents and investments	$ 23,374	$ 1	$	$ 23,375

	As of December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value

Cash and cash equivalents:			
Cash	$ 641	$	$ 641
Money market funds	6,883		6,883
U.S. government agency securities	270		270
Total cash and cash equivalents	7,794		$ 7,794

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	As of December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. government agency securities	27,991			27,991
Total marketable securities	27,991			$ 27,991
Total cash, cash equivalents and investments	$ 35,785	$	$	$ 35,785

As of September 30, 2012 and December 31, 2011 none of the available-for-sale securities held by the Company had material unrealized losses and there were no realized losses for the nine months ended September 30, 2012. There were no other-than-temporary impairments for these securities at September 30, 2012 or December 31, 2011.

As of September 30, 2012, 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, 2012 and December 31, 2011, the Company held, in addition to Level I and Level II assets, a contingent put option liability associated with the Company s loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which was classified as a Level III liability. As of September 30, 2012 and December 31, 2011, the estimated fair value of the contingent put option liability was $109,000 and $232,000, respectively, which was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. As of September 30, 2012, 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 5 Stockholders Equity. 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 one, or any, of the inputs impact the estimated fair value of the PIPE warrants.

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

	As of September 30, 2012			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 2,280	$ 2,280	$	$
U.S. government agency obligations	19,854		19,854	
Total assets measured at fair value	$ 22,134	$ 2,280	$ 19,854	$
Liabilities				
PIPE warrants	$ 5,345			$ 5,345
Contingent put option liability	109			109
Total liabilities measured at fair value	$ 5,454	$	$	$ 5,454

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	As of December 31, 2011			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 6,883	$ 6,883	$	$
U.S. government agency obligations	28,261		28,261	
Total assets measured at fair value	$ 35,144	$ 6,883	$ 28,261	$

	As of December 31, 2011			
	Fair Value	Level I	Level II	Level III
Liabilities				
Contingent put option liability	$ 232			$ 232
Total liabilities measured at fair value	$ 232	$	$	$ 232

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, 2012:

Risk-free interest rate	0.62%
Expected volatility	81.0%
Expected life (in years)	5.2
Expected dividend yield	0.0%

The following table sets forth a summary of the changes in the fair value of the Company s Level III financial liabilities (in thousands):

	Nine Months Ended September 30, 2012
Fair value beginning of period	$ 232
Addition of PIPE warrants on June 1, 2012	5,828
Change in fair value of PIPE warrants	(483)
Change in fair value of contingent put option	(123)
Fair value end of period	$ 5,454

3. Research Grant Agreement

In May 2011, AcelRx received a grant from the US Army Medical Research and Materiel Command, or USAMRMC, in which the USAMRMC granted $5.6 million to the Company in order to support the development of a new product candidate, ARX-04, a Sufentanil NanoTab for the treatment of moderate-to-severe acute pain. Under the terms of the grant, the USAMRMC will reimburse the Company for development, manufacturing and clinical costs necessary to prepare for and complete the planned Phase 2 dose-finding trial in a study of acute moderate-to-severe pain, and to prepare to enter Phase 3 development. The period of research under the grant was originally scheduled to end on August 31, 2012, with a final report due on September 30, 2012. In June 2012, due to a longer than expected administrative review process by the USAMRMC, the Company was awarded a no-cost extension of the grant whereby the period of research was extended through May 31, 2013, with a final report due on June 30, 2013. The grant gives the USAMRMC the option to extend the term of the grant and provide additional funding for the research.

Revenue is recognized based on expenses incurred by AcelRx in conducting research and development activities set forth in the grant agreement. Revenue attributable to the research and development performed under the USAMRMC grant was $166,000 and $719,000 for the three and nine months ended September 30, 2012, respectively, and $408,000 and $448,000 for the three and nine months ended September 30, 2011. Revenue attributable to the research and development performed under the USAMRMC grant since inception was $1.8 million.

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4. Long-Term Debt

Hercules Loan and Security Agreement

On June 29, 2011, AcelRx entered into a loan and security agreement with Hercules, under which AcelRx borrowed $20.0 million in two tranches of $10.0 million each, represented by secured convertible term promissory notes. The Company s obligations associated with the agreement are secured by a security interest in substantially all of its assets, other than its intellectual property.

The interest rate for each tranche is 8.50% and the Company made interest only payments until June 30, 2012 followed by equal monthly payments of $0.7 million, consisting of principal and interest, through the scheduled maturity date on December 1, 2014.

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the notes, including payment of any applicable prepayment charges, which range from 1%-3% of the outstanding loan balance and accrued interest, as well as a final payment fee of $0.2 million. This option is considered a contingent put option liability as the holder of the notes may exercise the option in the event of default and, is considered an embedded derivative which must be valued and separately accounted for in the Company s financial statements. The contingent put option liability was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The contingent put option liability will be revalued at the end of each reporting period and any change in the fair value will be recognized in the statement of comprehensive loss. As of September 30, 2012, the estimated fair value of the contingent put option liability was $109,000. See Note 2 Investments and Fair Value Measurement for further description of the contingent put option liability.

In connection with the loan, the Company issued Hercules seven-year warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share. See Note 7 Warrants for further description.

As of September 30, 2012, the Company had outstanding borrowings under the Hercules loan and security agreement of $17.7 million, net of debt discounts of $0.6 million. Amortization of the debt discounts, which was recorded as Interest Expense, was $134,000 and $406,000 for the three and nine months ended September 30, 2012, respectively and $126,000 for both the three and nine months ended September 30, 2011.

Pinnacle Loan and Security Agreement

In September 2008, the Company entered into a $12.0 million loan and security agreement with Pinnacle. In November 2008, the Company drew down all $12.0 million of the loan facility. On June 29, 2011, upon execution of the Hercules loan and security agreement, the Pinnacle agreement was terminated and the outstanding balance of $2.8 million was repaid. The unamortized portions of the final payment and deferred financing costs were recorded to interest expense upon termination of the Pinnacle agreement.

5. Stockholders Equity

2012 Private Placement Offering

On June 1, 2012, or the Issuance Date, the Company issued an aggregate of 2,922,337 shares of common stock and warrants to purchase up to 2,630,103 shares of common stock, or the PIPE warrants, for aggregate gross proceeds of $10.0 million, or the Private Placement. Costs related to the offering were $0.9 million. The shares of common stock and PIPE warrants issued in the Private Placement were sold pursuant to a Securities Purchase Agreement, or Purchase Agreement, dated May 29, 2012, between the Company and certain purchasers, including certain entities affiliated with Mark Wan and Stephen J. Hoffman, members of the Company s board of directors. Pursuant to the Purchase Agreement, AcelRx sold shares of common stock and PIPE warrants to purchase common stock in immediately separable Units, with each Unit consisting of (i) one share of common stock and (ii) a PIPE warrant to purchase 0.9 of a share of common stock. The per share exercise price of the PIPE warrants was $3.40. The offering price per Unit was $3.40 for non-affiliated investors, and $3.5125 for affiliated investors, which equals the sum of (i) $3.40, the closing consolidated bid price of our common stock on May 29, 2012, plus (ii) $0.1125 (which is equal to $0.125 per PIPE warrant

share, multiplied by 0.9), for an aggregate amount of $10.0 million. The PIPE warrants issued in the Private Placement become exercisable six months after the Issuance Date, and expire on the five year anniversary of the initial exercisability date.

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In connection with the Private Placement, the Company agreed to file a registration statement with the U.S. Securities and Exchange Commission, or SEC, registering for resale the shares of common stock and shares of common stock issuable upon exercise of the warrants sold in the Private Placement. The Company filed such registration statement with the SEC on June 21, 2012 and it was declared effective by the SEC on July 2, 2012.

2012 ATM Agreement

On August 31, 2012, the Company entered into an At Market Issuance Sales Agreement, or Sales Agreement, or ATM, with MLV & Co. LLC, or MLV, pursuant to which the Company may elect to issue and sell shares of its common stock having an aggregate offering price equal to the lesser of (i) the amount that the Company may continue to offer and sell under the eligibility requirements for use of Form S-3 (including, if applicable, Instruction I.B.6 thereof) or (ii) $7,500,000. The Company is not obligated to make any sales of common stock under the Sales Agreement. Unless earlier terminated, the Sales Agreement will automatically terminate upon the earlier of (1) the sale of all common stock subject to the Sales Agreement or (2) August 31, 2015. The Company will pay MLV an aggregate commission rate equal to up to 3.0% of the gross proceeds for common stock sold through MLV under the Sales Agreement. The Company has also provided MLV with customary indemnification rights and expense reimbursements for up to $25,000 of expenses. The Company did not sell any shares of common stock pursuant to the Purchase Agreement during the three and nine months ended September 30, 2012.

6. Convertible Notes

2010 Convertible Notes

On September 14, 2010, the Company sold convertible promissory notes, or the 2010 Convertible Notes, to certain existing investors for an aggregate purchase price of $8.0 million, with an option for the holders of the 2010 Convertible Notes to purchase an additional $4.0 million of the 2010 Convertible Notes. This option was determined to be a call option that was recorded at its fair value of $476,000 as a debt discount that would have been amortized to interest expense over the one-year term of the 2010 Convertible Notes. The fair value of the call option was determined by evaluating multiple potential outcomes using a market approach and an income approach depending on the scenario and discounting these values back to the appropriate date while applying estimated probabilities to each scenario value. The call option was revalued to its fair value as of the IPO date and was written off upon its expiration with a benefit of $596,000 being recognized through other income (expense) during the nine months ended September 30, 2011. In addition, the unamortized debt discount in the amount of $1.1 million at the time of the IPO was recognized as interest expense in connection with the conversion of the notes.

In connection with the IPO, the outstanding principal and accrued interest under the 2010 Convertible Notes automatically converted into 2,034,438 shares of common stock immediately prior to the closing of the IPO.

7. Warrants

Series A Warrants

In March 2007, the Company entered into an equipment financing agreement in which the Company issued immediately exercisable and fully vested warrants to purchase 2,500 shares of its Series A convertible preferred stock, or the Series A warrants, with an exercise price of $10.00 per share. The fair value of the Series A warrants on the date of issuance was $1,000, as determined using the Black-Scholes option-pricing model. This fair value was recorded as a convertible preferred stock warrant liability and as a deferred financing cost in other assets. The fair value was remeasured at the end of each reporting period. In connection with the IPO, the Series A warrants were automatically converted into warrants to purchase 3,425 shares of common stock. As a result of the conversion, these common stock warrants were no longer recorded as liabilities and were, therefore, no longer remeasured as of the end of each reporting period.

As of September 30, 2012, warrants to purchase 3,425 shares of common stock had not been exercised and were outstanding. These warrants expire in March 2017.

Series B and Series C Warrants

Upon the closing of the Series C convertible preferred stock financing during the year ended December 31, 2009, the Series B warrants underlying the loan and security agreement with Pinnacle Ventures became exercisable for 228,264 shares of Series C convertible preferred stock with an exercise price of $3.94 per share, or the Series C warrants. The Company

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revalued the convertible preferred stock warrant liability related to the Series B warrants and Series C warrants during each reporting period using the Black-Scholes option-pricing model and the fair value was estimated to be $894,000 as of the IPO date in February 2011.

In connection with the Company s IPO in February 2011, the Series C warrants were automatically converted into warrants to purchase 228,264 shares of common stock. Immediately before the conversion to common stock warrants, the Series C warrants were remeasured to fair value with the change in the fair value of these warrants of $323,000 being recorded as a benefit through other income (expense), net during the nine months ended September 30, 2011. Immediately after the conversion to common stock warrants, the remaining liability of $894,000 was reclassified to additional paid-in capital. As a result of the conversion, these common stock warrants were no longer recorded as liabilities and were therefore no longer remeasured as of the end of each reporting period.

As of September 30, 2012, warrants to purchase 228,264 shares of common stock had not been exercised and were outstanding. These warrants expire in September 2018.

2010 Warrants

The Company issued warrants in connection with the 2010 Convertible Notes in September 2010, or the 2010 Warrants. The 2010 Warrants were exercisable into shares of convertible preferred stock. The 2010 Warrants would have terminated if not exercised immediately prior to the IPO. The 2010 Warrants allowed for cashless exercises.

The Company determined the fair value of the 2010 Warrants to be $1.2 million upon issuance, as determined using the Black-Scholes option-pricing model which was recorded as a convertible preferred stock warrant liability and a debt discount. As of December 31, 2010, the related warrant liability was $1.3 million. In connection with the IPO, the 2010 Warrants were net exercised into shares of Series C convertible preferred stock, which shares were automatically converted to 107,246 shares of common stock immediately prior to the IPO. Immediately before the exercise into Series C convertible preferred stock, the 2010 Warrants were remeasured to fair value with the change in the fair value of these warrants of $796,000 being recorded as a benefit through other income (expense), net during the nine months ended September 30, 2011. Immediately after the exercise into Series C convertible preferred stock, the remaining liability of $536,000 was reclassified to additional paid-in capital.

Hercules Warrants

In connection with the loan and security agreement with Hercules, the Company issued to Hercules warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share. The warrants may be exercised on a cashless basis. The warrants are exercisable for a term beginning on the date of issuance and ending on the earlier to occur of seven years from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the warrants. The Company estimated the fair value of these warrants as of the issuance date to be $967,000, which was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The fair value of the warrants was calculated using the Black-Scholes option-pricing model. The Company also recorded fees paid to Hercules as a debt discount, which further reduced the carrying value of the loan. The debt discount is being amortized to interest expense.

As of September 30, 2012, warrants to purchase 274,508 shares of common stock issued to Hercules had not been exercised and were outstanding.

2012 Private Placement Warrants

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

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Upon execution of the Purchase Agreement, the fair value of the PIPE warrants was estimated to be $5.8 million, which was recorded as a liability. As of September 30, 2012, the fair value of the PIPE warrants was estimated to be $5.3 million. The change in fair value for the three and nine months ended September 30, 2012, which was recorded as other income, was $0.1 million and $0.5 million, respectively.

As of September 30, 2012, PIPE warrants to purchase 2,630,103 shares of common stock issued in connection with the Private Placement had not been exercised and were outstanding.

8. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2012	2011	2012	2011	2012
Expenses:					
Research and development	$ 258	$ 253	$ 762	$ 578	$ 3,142
General and administrative	304	304	871	768	2,837
Total stock-based compensation expense	$ 562	$ 557	$ 1,633	$ 1,346	$ 5,979

As of September 30, 2012 there were 866,969 shares available for future grant, 3,321,038 options outstanding and 161,096 restricted stock units outstanding under the Company s 2011 Equity Incentive Plan.

9. Net Loss per Share of Common Stock

The following table sets forth the computation of the Company s basic and diluted net loss per share of common stock during the three and nine months ended September 30, 2012 and 2011 (in thousands, except for share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	$ (8,582)	$ (5,761)	$ (22,841)	$ (13,729)
Shares used in computing net loss per share of common stock, basic and diluted	22,632,573	19,458,640	20,961,886	16,594,051
Net loss per share of common stock, basic and diluted	$ (0.38)	$ (0.30)	$ (1.09)	$ (0.83)

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,	
	2012	2011
Stock options to purchase common stock	3,321,038	2,395,968
Restricted stock units	161,096	257,868
Common stock warrants	3,136,300	506,197

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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 regarding: the timing, release and implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2011.

About AcelRx Pharmaceuticals

We are a development stage specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. Our lead product candidate, the Sufentanil NanoTab PCA System, or ARX-01, is designed to improve the management of post-operative pain in patients in the hospital setting. Although widely used, the current standard of care for patients with post-operative pain, intravenous patient-controlled analgesia, or IV PCA, has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the inherent potential for programming and delivery errors associated with the complexity of infusion pumps. We are conducting three Phase 3 trials for ARX-01. We completed enrollment of the final subject in our Phase 3 clinical trial comparing ARX-01 to IV PCA with morphine and we expect top-line data from this trial in November 2012. Top-line data from the other two Phase 3 trials are expected in the first quarter of 2013.

ARX-01 is designed to improve the management of post-operative pain in patients by utilizing:

- sufentanil, a high therapeutic index opioid;
- NanoTabs, our proprietary, non-invasive sublingual dosage form; and
- our novel handheld PCA device that enables simple patient-controlled delivery of NanoTabs in the hospital setting and eliminates the risk of programming errors.

We have completed Phase 2 clinical development for two additional product candidates, the Sufentanil NanoTab BTP Management System, or ARX-02, for the treatment of cancer breakthrough pain, or BTP, and the Sufentanil/Triazolam NanoTab, or ARX-03, designed to provide mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician s office. In May 2011, we announced that the US Army Medical Research and Materiel Command, or USAMRMC, awarded us a $5.6 million grant to support the development of a new product candidate, ARX-04, a Sufentanil NanoTab for the treatment of moderate-to-severe acute pain. Under the terms of the grant, the USAMRMC will reimburse us for development, manufacturing and clinical expenses necessary to prepare for and complete the planned Phase 2 dose-finding trial in a study of moderate-to-severe acute pain, and to prepare to enter Phase 3 development. Future development of ARX-02 and ARX-03 product candidates is contingent upon obtaining additional funding or establishing corporate partnerships.

We have established and continue to build proprietary positions for our product candidates and related technology in the United States and abroad. We continue to seek and expand our patent protection for both compositions of matter and delivery devices, as well as methods of treatment related to our product candidates. In particular, we are pursuing patent protection for our ARX-01, ARX-02, ARX-03 and ARX-04 NanoTabs and formulations, our ARX-01 PCA devices, the combination of drugs and our ARX-01 PCA devices, our ARX-02, ARX-03 and ARX-04 SDAs, as well as to methods of treatment using such drug and device compositions.

Development of therapeutic products is costly and is subject to a lengthy and uncertain regulatory process by the United States Food and Drug Administration, or FDA. Adverse events in both our own clinical program and other programs may have a negative impact on regulatory approval, the willingness of potential commercial partners to enter into agreements and the perception of the public.

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Product Development Update

ARX-01

We continue to make progress in the development of our lead product candidate, ARX-01, including the following activities:

In April 2012, we initiated a Phase 3 open-label active-comparator study comparing ARX-01 to the current standard of care, IV PCA morphine, in patients with post-operative pain following open-abdominal surgery or major orthopedic surgery. We completed enrollment of the final subject for this trial and expect top-line data in November 2012; and

In March 2012, we initiated a Phase 3 double-blind, placebo-controlled efficacy and safety trial of patients with post-operative pain following open-abdominal surgery. We expect top-line data for this trial in the first quarter of 2013;

In August 2012, we initiated our third planned Phase 3 clinical trial, a double-blind, placebo-controlled efficacy and safety study of patients with post-operative pain following hip and knee replacement surgeries. We expect top-line data for this trial in the first quarter of 2013.

ARX-04

ARX-04 is our product candidate for management of moderate-to-severe acute pain. In November 2012, following approval from the USAMRMC, we initiated a Phase 2 dose-finding clinical trial for ARX-04. The Phase 2 trial is a multicenter, double-blind, placebo-controlled efficacy and safety trial in patients with post-operative pain following bunionectomy surgery.

Financial Overview

We are a development stage company with a limited operating history. We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily from private placements of convertible preferred stock, proceeds from our initial public offering, or IPO, proceeds from our recent private placement equity offering and proceeds received from our debt financings. We will need to raise additional capital to fund our operations, including product candidate development activities. 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 technology and product candidates would be harmed.

Since our inception in July 2005, we have not generated any revenue from the sale of our products and do not anticipate generating any product revenues for the foreseeable future. We have recognized revenue associated with our grant from the USAMRMC of $1.8 million since inception of the grant, but continued funding from the USAMRMC is contingent upon their review and approval of our continued research and development activities associated with the grant. In addition, there can be no assurance that we will receive other research-related grant awards or produce other collaborative agreement revenues in the future. We have incurred losses and generated negative cash flows from operations since inception. Our net losses were $22.8 million for the nine months ended September 30, 2012 and $20.1 million during the year ended December 31, 2011. As of September 30, 2012, we had cash, cash equivalents and investments totaling $23.4 million compared to $35.8 million as of December 31, 2011. As of September 30, 2012, we had an accumulated deficit of $111.5 million.

On June 1, 2012, we issued an aggregate of 2,922,337 shares of common stock and warrants to purchase up to 2,630,103 shares of common stock, or the PIPE warrants, for aggregate gross proceeds of $10.0 million, in a private placement equity offering, or the Private Placement. On August 31, 2012, we entered into At Market Issuance Sales Agreement, or the Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of the lesser of (i) an amount we can continue to offer and sell under the eligibility requirements of the Form S-3 and (ii) $7.5 million, from time to time through MLV as our sales agent. We are not obligated to make any sales of common stock under the Sales Agreement and, to date, we have not sold any common stock pursuant to this agreement.

We believe that our current cash, cash equivalents and investments will be sufficient to fund the Company s current operations into the second quarter of 2013, including support for the continuing development of our lead product candidate, ARX-01. We will need to raise additional

funding or otherwise enter into collaborations to fund future operations. If we are unable to raise additional capital to fund our operations, we may not be able to complete our final planned ARX-01 Phase 3 study, which we initiated in August 2012, and will need to curtail planned activities to reduce costs. Doing so may affect our ability to operate effectively. See Liquidity and Capital Resources for additional discussion.

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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, 2011. There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2012 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2012 and 2011

Revenue

To date, we have not generated any revenue from commercial sales. We do not expect to receive any such revenue from any product candidate that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties. In May 2011, we received a grant award of $5.6 million from the USAMRMC for the development of ARX-04, a Sufentanil NanoTab for the treatment of moderate-to-severe acute pain. Revenue related to this grant award is recognized as the related research and development expenses are incurred.

Revenue from the grant award for the three and nine months ended September 30, 2012 was $0.2 million and $0.7 million, respectively, compared to $0.4 million and $0.4 million for the three and nine months ended September 30, 2011. From inception of the grant through September 30, 2012, we have generated grant revenue of $1.8 million.

Research and Development Expenses

Conducting research and development is central to our business model. The majority of our operating expenses in 2012 and 2011 have been for research and development activities related to ARX-01. Research and development expenses included the following:

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

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of ARX-01, execute activities associated with the clinical work related to ARX-04 and subsequently advance the development of ARX-02 and ARX-03, provided that additional funding or corporate partnership

resources are available to support the two latter programs.

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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, 2012 and 2011 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
ARX-01	$ 5,546	$ 2,566	$ 12,354	$ 4,942
ARX-04	86	168	380	182
Overhead	1,316	1,213	4,379	3,798
Total research and development expenses	$ 6,948	$ 3,947	$ 17,113	$ 8,922

Due to the inherently unpredictable nature of product development, development timelines and the probability of success, development costs can differ materially from expectations. While we are currently focused on advancing ARX-01 and ARX-04, and subsequently ARX-02 and ARX-03, our future research and development expenses will depend on the clinical success of each product candidate as well as ongoing assessments of the commercial potential of our product candidates. In addition, we cannot predict which product candidates may be subject to future collaborations, when these arrangements will be secured, if at all, and to what degree these arrangements would affect our development plans and capital requirements. We expect our research and development expenses to increase as we progress with our ARX-01 Phase 3 clinical trials, and subject to additional funding, complete all the requisite preparatory activities to submit a new drug application, or NDA, to the FDA. Additionally, our research and development expenses will increase as we conduct the ARX-04 Phase 2 clinical trial.

Total research and development expenses for the three and nine months ended September 30, 2012 and 2011 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change	%	2012	2011	Change	%
Research and development expenses	$ 6,948	$ 3,947	$ 3,001	76%	$ 17,113	$ 8,922	$ 8,191	92%

The $3.0 million increase during the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily attributable to an increase of $3.0 million related to Phase 3 clinical trial development for our ARX-01 program. We are conducting three ARX-01 Phase 3 trials, all of which were initiated in 2012.

The $8.2 million increase during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was primarily attributable to an increase of $7.4 million related to Phase 3 clinical trial development for our ARX-01 program. In addition, there was an increase of $0.2 million related to our ARX-04 development program, which we initiated in the second quarter of 2011. There were also increases in personnel-related expenses, including stock-based compensation of $0.2 million and in allocated overhead expenses of $0.3 million.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel in administration and finance and business development activities. Other significant expenses included legal expenses to pursue patent protection of our intellectual property, allocated facility costs and professional fees for general legal, audit and consulting services. We expect general and administrative expenses to increase as we continue to build our corporate infrastructure in support of continued development of our product candidates.

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Total general and administrative expenses for the three and nine months ended September 30, 2012 and 2011 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change	%	2012	2011	Change	%
General and administrative	$ 1,410	$ 1,866	$ (456)	(24)%	$ 5,290	$ 5,086	$ 204	4%

The $0.5 million decrease during the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily due to decreases in personnel related expenses, including consulting, of $0.2 million, and decreases in marketing research efforts associated with ARX-01 of $0.1 million and legal expenses, including patent prosecution, of $0.1 million.

There were no significant changes in general and administrative related expenses during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011.

Interest Expense

Total interest expense for the three and nine months ended September 30, 2012 and 2011 was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change	%	2012	2011	Change	%
Interest expense	$ 573	$ 377	$ 196	52%	$ 1,765	$ 1,891	$ (126)	(7)%

The $0.2 million increase in interest expense was due to a higher average debt balance during the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. During both periods we incurred interest expense related to our $20.0 million loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which we entered into on June 29, 2011. We borrowed $20.0 million in two tranches of $10.0 million; $10.0 million was borrowed upon execution of the agreement in June 2011 and the second $10.0 million was borrowed in December 2011.

The $0.1 million decrease in interest expense during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was primarily attributable to interest and the debt discount amortization recorded during the nine months ended September 30, 2011 related to convertible promissory notes issued in September 2010 which converted immediately prior to the IPO in February 2011. While the average debt balance during the nine months ended September 30, 2012 was higher than during the same period in 2011, the nine months ended September 30, 2011 included a $1.1 million charge to interest expense related to the unamortized debt discounts associated with the conversion of the aforementioned promissory notes.

Interest Income and Other Income (Expense), net

Total interest income and other income (expense), net for the three and nine months ended September 30, 2012 and 2011 was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Change	%	2012	2011	Change	%
Interest Income and Other Income (Expense), net.	$ 183	$ 21	$ 162	771%	$ 608	$ 1,722	$ (1,114)	(65%)

The $0.2 million increase in interest income and other income (expense) during the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily due to the decrease in estimated fair value of the PIPE warrants issued in connection with our Private Placement, completed in June 2012. A decrease in the estimated fair value of the PIPE warrants is recorded as other income.

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The $1.1 million decrease in interest income and other income (expense) during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was primarily attributable to the change in the fair value of our warrants to purchase convertible preferred stock and the write-off of the call option related to the convertible promissory notes issued in September 2010, which expired upon closing of the IPO in February 2011. Upon the completion of our IPO, all of our warrants to purchase convertible preferred stock were remeasured to fair value and were either exercised or converted into warrants to purchase common stock.

Interest income and other income (expense) during the nine months ended September 30, 2012 primarily reflects the decrease in estimated fair value of the PIPE warrants issued in connection with our Private Placement and the decrease in estimated fair value of the contingent put option liability associated with our loan and security agreement with Hercules.

Liquidity and Capital Resources

Liquidity

Since inception, we have incurred significant annual net losses and we have funded our operations primarily through the issuance of equity securities and debt financings. From inception through September 30, 2012, we have received net proceeds of $54.9 million from the sale of convertible preferred stock, $9.1 million from our Private Placement, $34.9 million from our IPO and $41.4 million from our debt arrangements. We have incurred losses and generated negative cash flows from operations since inception, and we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

On August 31, 2012, we entered into the Sales Agreement with MLV which provides that, upon the terms and subject to the conditions and limitations set forth in the agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of the lesser of (i) an amount we can continue to offer and sell under the eligibility requirements of the Form S-3 and (ii) $7.5 million, from time to time through MLV as our sales agent. The issuance and sale of shares by us under the Sales Agreement with MLV, if any, are subject to the continued effectiveness of our registration statement on Form S-3, which was declared effective by the SEC on August 31, 2012. We are not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Sales Agreement, (2) August 31, 2015 and (3) the termination of the Sales Agreement. To date, we have not sold any common stock pursuant to the Sales Agreement.

As of September 30, 2012, we had cash, cash equivalents and investments totaling $23.4 million compared to $35.8 million as of December 31, 2011. The decrease was primarily attributable to capital required to fund our continuing operations, including advancement of our lead product candidate, ARX-01, partially offset by proceeds from our Private Placement, which we completed in June 2012. Our most significant use of capital pertains to salaries and benefits for our employees and clinical trial expenses related to our development programs.

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

Cash Flows

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

	Nine Months Ended September 30,	
	2012	2011
Net cash used in operating activities	$ (18,783)	$ (9,296)
Net cash provided by (used in) investing activities	7,276	(31,541)
Net cash provided by financing activities	7,434	39,607

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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. Our cash used for operating activities also reflected changes in our working capital and adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, interest expense related to our debt financings, and the revaluation of our convertible preferred stock warrant liability.

Cash used in operating activities of $18.8 million during the nine months ended September 30, 2012 primarily reflected a net loss of $22.8 million, partially offset by a net change of $1.7 million in our operating assets and liabilities primarily related to accounts payable. In addition, we had non-cash charges of $1.6 million in stock-based compensation and $0.5 million for interest on our debt, partially offset by $0.6 million of non-cash benefits primarily related to the revaluation of the PIPE warrants.

Cash used in operating activities for the nine months ended September 30, 2011 primarily reflects the net loss for the period, partially offset by a net change of $2.7 million in our operating assets and liabilities primarily related to accounts payable and accrued liabilities. In addition, we had non-cash charges of $1.5 million for interest on our debt and $1.3 million in stock-based compensation, which were offset by $1.7 million of non-cash benefits for the revaluation of the warrant liability and the write off of the call option liability.

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, 2012, cash provided by investing activities of $7.3 million was primarily a result of $31.5 million in proceeds from maturity of investments, partially offset by $23.5 million for purchases of investments.

During the nine months ended September 30, 2011, cash used in investing activities of $31.5 million was primarily a result of $33.3 million used for purchases of investments and $1.8 million for purchases of property and equipment, partially offset by $3.5 million in proceeds from maturity of investments.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities, proceeds from our debt financings and payments made on such debt financings. As of September 30, 2012, we had outstanding debt of $17.7 million, net of debt discounts of $0.6 million.

During the nine months ended September 30, 2012, cash provided by financing activities was primarily a result of the Private Placement, pursuant to which, on June 1, 2012, we issued an aggregate of 2,922,337 shares of common stock and PIPE warrants to purchase up to 2,630,103 shares of common stock for net proceeds of $9.1 million. These proceeds were partially offset by payments of long-term debt of $1.8 million related to our loan and security agreement with Hercules.

During the nine months ended September 30, 2011, cash provided by financing activities was primarily a result of the receipt of $34.9 million in proceeds from our IPO, net of offering costs, proceeds of $9.8 million from our loan and security agreement with Hercules, partially offset by principal repayments on our long-term debt of $5.3 million, including payment in full of our remaining obligations under the Pinnacle agreement, which was terminated upon executing the Hercules loan and security agreement in June 2011.

Operating Capital and Capital Expenditure Requirements

We expect our rate of cash usage to increase in the future, in particular to support our product development and clinical trial activities. We believe that our available cash resources and funding from the USAMRMC grant, will support our currently planned operations into the second quarter of 2013, including support for our continuing development of our product candidates. Future capital requirements will be substantial and we will need to raise additional capital to fund our operations, including product candidate development activities. If we are unable to raise additional capital to fund our operations, we may not be able to complete our final planned ARX-01 Phase 3 study, which we initiated in August 2012, and will need to curtail planned clinical activities to reduce costs. Doing so may affect our ability to operate effectively.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 technology and product candidates would be harmed.

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Our future capital requirements will depend on many forward looking factors and are not limited to the following: