ACELRX PHARMACEUTICALS INC
Form 10-Q
November 08, 2011
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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, 2011

or

¨ **TRANSITION REPORT 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.)

575 Chesapeake 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.

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 Rule 12b-2 of the Exchange Act) Yes ¨ No x

As of November 1, 2011, the number of outstanding shares of the registrant s common stock was 19,552,992.

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ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2011

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Unless the context indicates otherwise, the terms AcelRx, AcelRx Pharmaceuticals, we, us and our refer to AcelRx Pharmaceuticals, Inc. Th name ACELRX is our trademark. NANOTAB is a registered trademark of AcelRx Pharmaceuticals, Inc. We have received a notice of allowance for our tagline, ACCELERATE, INNOVATE, ALLEVIATE in the United States. 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 and per share data)

	September 30, 2011 (Unaudited)	December 31, 2010[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,825	$ 3,055
Short-term investments	30,195	627
Prepaid expenses and other current assets	2,061	2,097
Total current assets	34,081	5,779
Property and equipment, net	2,229	800
Restricted cash	205	205
Other assets	188	46
TOTAL ASSETS	$ 36,703	$ 6,830
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 2,626	$ 543
Accrued liabilities	1,685	859
Convertible notes		6,805
Long-term debt, current portion	681	5,204
Other current liabilities	103	
Total current liabilities	5,095	13,411
Contingent put option liability	57	
Call option liability		596
Convertible preferred stock warrant liability		2,529
Long-term debt	8,196	
Other liabilities		245
Total liabilities	13,348	16,781
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value 10,000,000 shares and 46,736,125 shares authorized as of September 30, 2011 and December 31, 2010, respectively; no shares and 7,151,802 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively		55,941
STOCKHOLDERS EQUITY (DEFICIT):		
	21	3

Common stock, $0.001 par value 100,000,000 and 71,000,000 shares authorized as of September 30, 2011 and December 31, 2010, respectively; 19,552,992 and 674,353 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively		
Additional paid-in capital	105,623	2,668
Deficit accumulated during the development stage	(82,292)	(68,563)
Accumulated other comprehensive income	3	
Total stockholders equity (deficit)	23,355	(65,892)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)	$ 36,703	$ 6,830

(1) The condensed balance sheet as of December 31, 2010 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, 2010.

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Operations

(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,
	2011	2010	2011	2010	2011
Research grant revenue	$ 408	$	$ 448	$	$ 448
Operating expenses:					
Research and development	3,947	1,515	8,922	6,309	62,719
General and administrative	1,866	1,090	5,086	3,033	17,580
Total operating expenses	5,813	2,605	14,008	9,342	80,299
Loss from operations	(5,405)	(2,605)	(13,560)	(9,342)	(79,851)
Interest expense	(377)	(197)	(1,891)	(656)	(5,021)
Interest income and Other income (expense), net	21	(799)	1,722	(823)	2,580
Net loss	$ (5,761)	$ (3,601)	$ (13,729)	$ (10,821)	$ (82,292)
Net loss per share of common stock, basic and diluted	$ (0.30)	$ (5.38)	$ (0.83)	$ (16.63)	
Shares used to compute basic and diluted net loss per share of common stock	19,458,640	668,963	16,594,051	650,774	

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,
	2011	2010	2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (13,729)	$ (10,821)	$ (82,292)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	348	359	1,913
Amortization of premium/discount on investments, net	196		196
Interest expense related to debt financing	1,462	168	2,669
Stock-based compensation	1,346	1,107	3,859
Revaluation of convertible preferred stock warrant liability and write off of call option liability	(1,688)	827	(259)
Other non-cash items			(10)
Changes in operating assets and liabilities:			
Prepaids and other assets	(133)	(126)	(682)
Restricted cash			(205)
Accounts payable	2,083	(315)	2,626
Accrued liabilities	961	(106)	51
Deferred rent	(142)	(135)	102
Net cash used in operating activities	(9,296)	(9,042)	(72,032)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,777)	(4)	(4,146)
Purchase of investments	(33,280)	(4,823)	(78,581)
Proceeds from maturities and sales of investments	3,516	9,692	48,240
Net cash provided by (used in) investing activities	(31,541)	4,865	(34,487)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from initial public offering, net of costs	34,939		34,939
Proceeds from the issuance of long-term debt	9,762		22,383
Payments of long-term debt	(5,298)	(3,506)	(13,222)
Proceeds from issuance of convertible promissory notes		8,000	9,000
Proceeds from issuance of common stock pursuant to equity plans	204	21	303
Proceeds from issuance of convertible preferred stock, net of issuance costs		70	54,941
Net cash provided by financing activities	39,607	4,585	108,344
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,230)	408	1,825
CASH AND CASH EQUIVALENTS Beginning of period	3,055	7,150	

CASH AND CASH EQUIVALENTS End of period	$ 1,825	$ 7,558	$ 1,825
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 347	$ 521	$ 1,936
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Issuance of convertible preferred stock warrants	$	$ 1,223	$ 1,223
Beneficial conversion features related to convertible notes	$	$ 1,699	$ 1,699
Issuance of call option related to convertible notes	$	$ 476	$ 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	$ 967	$	$ 967
Contingent put option liability	$ 62	$	$ 62

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 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, the Company s 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, 2011. In addition, the Company had an accumulated deficit of $82.3 million and $68.6 million as of September 30, 2011 and December 31, 2010. Through September 30, 2011, 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, and funds from drawing down the second $10.0 million tranche pursuant to its loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which the Company entered into in June 2011, will be sufficient to fund the Company s current operations into the first quarter of 2013. The Company will need to raise additional funding or otherwise enter into collaborations to support 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 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 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, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The condensed balance sheet as of December 31, 2010 was derived from the Company s audited financial statements as of December 31, 2010, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC on March 30, 2011. These financial statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2010. Stockholders are encouraged to review the Company s Annual Report on Form 10-K for a broader discussion of the Company s business and the risks inherent therein.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Reverse Stock Split

In January 2011, the Company s board of directors and stockholders approved a 1-for-4 reverse stock split of the Company s issued and outstanding shares of common stock and convertible preferred stock, which became effective on January 28, 2011. The par value of the common stock and convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options exercisable for common stock, convertible preferred stock, warrants exercisable for common stock, warrants for convertible preferred stock, and per share amounts contained in the Company s condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

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 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 $5.1 million in underwriting discounts and commissions and other offering-related expenses payable by the Company. Upon the closing of the offering, 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 5 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 6 Warrants, were net exercised for 107,246 shares of Series C convertible preferred stock, which shares were converted to 107,246 shares of 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. Concurrently, the Company filed an amended and restated certificate of incorporation increasing the number of authorized shares of common stock to 100,000,000 with a par value of $0.001 per share and decreasing the number of authorized shares of preferred stock to 10,000,000 with a par value of $0.001 per share.

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 or estimates related to the fair value of common stock, stock-based compensation expense and the fair value of convertible preferred stock warrants. Estimates are based on historical experience and on various other market specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Revenue Recognition

The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

In May 2011, the Company entered into an award contract with the US Army Medical Research and Material Command, or USAMRMC, to support the development of the Company s new product candidate, ARX-04, a Sufentanil NanoTab for the treatment of moderate-to-severe acute pain. The grant provides for the reimbursement of qualified expenses for research and development activities as defined under the terms of the grant agreement. Revenue under the grant agreement is recognized when the related qualified research expenses are incurred.

Recent 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 plans to adopt this guidance as of January 1, 2012 on a retrospective basis and does not expect the adoption thereof to 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 plans to adopt this guidance as of January 1, 2012 on a prospective basis and does not expect the adoption thereof to have a material effect on the Company s financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

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 Company s investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the length of time and extent to which the fair value has been less than the Company s cost basis, the financial condition and near-term prospects of the investee, and the Company s intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in the market value.

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

	As of September 30, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 103	$	$	$ 103
Money market funds	1,522			1,522
U.S. government agency securities	200			200
Total cash and cash equivalents	$ 1,825	$	$	$ 1,825
Marketable securities:				
U.S. government agency securities	30,192	3		30,195
Total marketable securities	$ 30,192	$ 3		$ 30,195
Total cash, cash equivalents and investments	$ 32,017	$ 3	$	$ 32,020

	As of December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 103	$	$	$ 103
Money market funds	79			79
U.S. government agency securities	2,873			2,873
Total cash and cash equivalents	$ 3,055	$	$	$ 3,055
Marketable securities:				

U.S. government agency securities	627			627
Total marketable securities	$ 627	$	$	$ 627
Total cash, cash equivalents and investments	$ 3,682	$	$	$ 3,682

As of September 30, 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, 2011. There were no other-than-temporary impairments for these securities at September 30, 2011.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

As of September 30, 2011, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company measures and reports its cash equivalents, investments and financial liabilities at fair value. Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level I Unadjusted quoted prices in active markets for identical assets or liabilities;

Level II Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level III Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the 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. For Level II instruments, the Company estimates fair value by using benchmark yields, reported trades, broker dealer quotes and issuer spreads. Such Level II instruments include U.S. government agency and corporate obligations. As of September 30, 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, which was classified as a Level III liability. The fair value of the contingent put liability was determined by evaluating multiple potential outcomes using an income approach and discounting the values back to September 30, 2011 while applying estimated probabilities to each scenario value.

As of December 31, 2010, the Company held, in addition to Level I and Level II assets, convertible preferred stock warrant liabilities and call option liabilities, which were classified as Level III liabilities. Immediately prior to the closing of the IPO, the convertible preferred stock warrants were either converted into warrants to purchase common stock or exercised for shares of convertible preferred stock, which shares were automatically converted into common stock. As a result of the aforementioned conversions, the preferred stock warrant liabilities and call option liabilities were eliminated. The fair values of the then-outstanding convertible preferred stock warrants were measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair market value included the estimated fair value of the underlying stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. 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 the values back to December 31, 2010 while applying estimated probabilities to each scenario value.

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, 2011			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 1,522	$ 1,522	$	$
U.S. government agency obligations	30,395		30,395	
Total assets measured at fair value	$ 31,917	$ 1,522	$ 30,395	$
Liabilities				
Contingent put option liability	$ 57			$ 57
Total liabilities measured at fair value	$ 57	$	$	$ 57

	As of December 31, 2010			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 79	$ 79	$	$

U.S. government agency obligations	3,500		3,500	
Total assets measured at fair value	$ 3,579	$ 79	$ 3,500	$
Liabilities				
Convertible preferred stock warrant liability	$ 2,529	$	$	$ 2,529
Call option liability	$ 596			$ 596
Total liabilities measured at fair value	$ 3,125	$	$	$ 3,125

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

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, 2011
Fair value beginning of period	$ 3,125
Exercise of warrants	(536)
Reclassification of warrant liability	(906)
Contingent put option liability	62
Change in fair value of Level III liabilities	(1,688)
Fair value end of period	$ 57

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

3. Research Grant Agreement

In May 2011, AcelRx entered into an award contract with the US Army Medical Research and Material 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 ends on August 31, 2012, with a final report due on September 30, 2012. 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 agreement. Revenue attributable to the research and development performed under the USAMRMC grant was $408,000 for the three months ended September 30, 2011 and $448,000 for the nine months ended September 30, 2011.

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 may borrow up to $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 Company borrowed the first tranche of $10.0 million upon the closing of the transaction on June 29, 2011. The Company used a portion of the proceeds from the first tranche to repay the remaining obligations under that certain loan and security agreement between the Company and Pinnacle Ventures, L.L.C., or Pinnacle Ventures, dated September 16, 2008. The agreement with Pinnacle Ventures is described further below. The second tranche of up to $10.0 million can be drawn, at the Company s option, anytime prior to December 16, 2011. The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 8.50% plus the positive difference between the prime rate as reported from time to time in The Wall Street Journal and 5.25%, and (ii) 8.50%. The Company will make interest only payments until June 30, 2012 which would be extended until October 1, 2012 if the Company has initiated enrollment for its planned abdominal and comparator ARX-01 Phase 3 clinical trials on or before December 31, 2011, or the Extension Trigger Event, followed by equal monthly payments of principal and interest through the scheduled maturity date on December 1, 2014, which would be extended until March 1, 2015 upon the Extension Trigger Event.

Subject to certain conditions and limitations set forth in the Hercules loan and security agreement, the Company has the right to convert up to $3.0 million of scheduled principal installments under the notes into that number of freely tradable shares of common stock equal to (x) the product of (A) the principal amount to be so converted and (B) 103%, divided by (y) $5.70 per share.

In addition, Hercules was granted the right, in their discretion, to participate in certain future private offerings of securities by the Company occurring on or prior to June 29, 2013 by investing up to an aggregate of $2.0 million on the same terms, conditions and pricing afforded to others participating in such subsequent offerings.

The Hercules loan and security agreement includes customary affirmative and restrictive covenants, but does not include any financial maintenance covenants, and also includes standard events of default.

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the loan, 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 loan may exercise the option in the event of default and, is considered an embedded derivative which must be valued and separately accounted for in the Company s financial statements. As of September 30, 2011, the estimated fair value of the contingent put option liability was $57,000 which was determined by evaluating multiple potential outcomes of an event of default, including a change of control, using an income approach and discounting the values back to September 30, 2011 while applying estimated probabilities to each scenario value. 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 operations.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

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 6 Warrants, for further description.

As of September 30, 2011, the Company had outstanding borrowings under the Hercules loan and security agreement of $8.9 million, net of debt discounts of $1.1 million. Amortization of the debt discounts, which was recorded as Interest Expense, was $126,000 for both the three and nine month periods 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 agreement.

As of September 30, 2011 and December 31, 2010, the Company had outstanding borrowings under the Pinnacle loan and security agreement of $0 million and $5.2 million.

5. 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. The 2010 Convertible Notes bore interest at a rate of 4.0% per annum and had a maturity date of the earlier of (1) September 14, 2011 or (2) an event of default. 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.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Upon the election of the holders of a majority of the aggregate principal amount payable under the 2010 Convertible Notes outstanding, the Company was required to sell an additional $4.0 million of 2010 Convertible Notes. This additional $4.0 million 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. These scenarios included a potential initial public offering, merger or sale of the Company at different times during 2011 and 2012 as well as remaining private. The fair value of the call option as of December 31, 2010 was $596,000. During the three months ended March 31, 2011, the 2010 Convertible Notes were amended so that the note holders option to invest the second tranche of $4.0 million expired upon the closing of the IPO. 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 three months ended March 31, 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.

6. 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, 2011, warrants to purchase 3,425 shares of common stock had not been exercised and were still outstanding. These warrants expire in March 2017.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Series B and Series C Warrants

In September 2008, the Company entered into a $12.0 million loan and security agreement with Pinnacle Ventures. In November 2008, the Company drew down all $12.0 million of the loan facility. In connection with the loan and security agreement, the Company issued immediately exercisable and fully vested warrants, or the Series B warrants, to purchase 56,250 shares of Series B convertible preferred stock with an exercise price of $16.00 per share. 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 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 determined the fair value of the Series B warrants and Series C warrants on the dates of issuance to be $162,000, as determined using the Black-Scholes option-pricing model which was recorded as a convertible preferred stock warrant liability and as a deferred financing cost in other assets. The Company 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. The fair value of the convertible preferred stock warrant liability related to these Series B warrants and Series C warrants was estimated to be $894,000 and $1.2 million as of the IPO date in February 2011 and December 31, 2010.

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 three months ended March 31, 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, 2011, warrants to purchase 228,264 shares of common stock had not been exercised and were still 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 three months ended March 31, 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 valuation model, and was based on the contractual term of the warrants of seven years, a risk-free interest rate of 2.44%, expected volatility of 79% and 0% expected dividend yield. 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, 2011, warrants to purchase 274,508 shares of common stock issued to Hercules had not been exercised and were still outstanding.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

7. Stock-Based Compensation

Stock Option and Equity Incentive Plans

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Expenses:				
Research and development	$ 253	$ 92	$ 578	$ 638
General and administrative	304	148	768	469
Total stock-based compensation expense	$ 557	$ 240	$ 1,346	$ 1,107

As of September 30, 2011 there were 1,016,227 shares available for grant, 2,395,968 options outstanding and 257,868 restricted stock units outstanding under the Company s stock option and equity incentive plans.

8. 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, 2011 and 2010 (in thousands, except for share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (5,761)	$ (3,601)	$ (13,729)	$ (10,821)
Shares used in computing net loss per share of common stock, basic and diluted	19,458,640	668,963	16,594,051	650,774
Net loss per share of common stock, basic and diluted	$ (0.30)	$ (5.38)	$ (0.83)	$ (16.63)

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

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,	
	2011	2010
Convertible preferred stock (as-if converted)		7,151,802
Stock options to purchase common stock	2,395,968	1,892,860
Restricted Stock Units	257,868	
Convertible preferred stock warrants (as-if converted)		230,764
Common stock warrants	506,917	

9. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized gains and losses on available-for-sale securities that are excluded from net loss. Comprehensive loss and its components are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (5,761)	$ (3,601)	$ (13,729)	$ (10,821)
Changes in unrealized gain on available-for-sale securities	5		3	
Comprehensive loss	$ (5,756)	$ (3,601)	$ (13,726)	$ (10,821)

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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 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, 2010.

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. We were founded to solve the problems associated with post-operative intravenous patient-controlled analgesia, or IV PCA. Although widely used, 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 preparing to initiate three Phase 3 clinical trials for our lead product candidate, the Sufentanil NanoTab PCA System, or ARX-01. The system is designed to address these problems 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 Material 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 acute moderate-to-severe pain, and to prepare to enter Phase 3 development.

Product Development

ARX-01

We continue to make progress toward initiating the first Phase 3 clinical trial for ARX-01. Examples of these activities include:

The contract research organization, or CRO, PharmaNet, has been engaged to conduct the first two ARX-01 Phase 3 studies. Clinical sites have been engaged for the abdominal surgery study and a majority of the sites for the head-to-head comparator study have been identified.

We recently received correspondence from the FDA stating that a final planned Human Factors study, though required for final product approval, is not a prerequisite to initiating ARX-01 Phase 3 studies. There are, however, three additional device assessments focused on software verification, software validation and device reprocessing, originally planned as precursors to, or associated with, the final Human Factors Study, which remain as requirements from FDA prior to the start of Phase 3. Protocols for these assessments have been submitted to the FDA for review, and we await the agency s feedback. We plan to conduct the software verification and validation and device reprocessing studies prior to initiation of the Phase 3 clinical program. We currently expect that we

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will be in a position to dose the first patient in a Phase 3 placebo-controlled post-operative pain study following major abdominal surgery in late 2011 or early 2012. The remaining Phase 3 studies, an active comparator study comparing the sufentanil NanoTab PCA System to intravenous morphine patient-controlled analgesia in post-operative patients, and a placebo-controlled study in patients after major orthopedic surgery, are expected to be initiated and completed in 2012. We plan to complete the final Human Factors study, alongside the Phase 3 clinical program.

The NanoTab commercial manufacturing facility at AcelRx s contract manufacturer, Patheon, Inc., has been built, tested and qualified as a Good Manufacturing Practices, or GMP, facility. AcelRx will manufacture clinical and commercial supplies at this facility.

We have completed multiple Human Factors and clinical tests during the course of development of the device for ARX-01. Three of the four planned Human Factors studies have been completed. We plan to conduct the fourth Human Factors study in 2012.

Indicator Lights and Audio Tones (Sounds) User Study - We evaluated multiple sound options for various device functions (dose delivered sound, dose not available sound, low level alert, nurse confirmation, and power on/power off) and tested indicator lights through a user study where test subjects were simulated patients. This input allowed the design team to determine the preferred sounds for each device function.

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User Patient Study with Commercial System - A prototype Phase 3 system, fully featured from a patient use perspective, incorporating the ergonomics, indicator lights, audio tones and the graphical user interface, all preferred in previous Human Factor studies, was developed for a simulated patient user study.

All subjects completed the study and were able to successfully dose themselves over the 24-hour period. Subjects rated their overall satisfaction as 4.4 on a 5 point scale (1=very dissatisfied to 5=very satisfied), indicating high satisfaction with the training, ergonomics, indicator lights, and ease of use of the NanoTab PCA System. Additionally, the subjects rated the device on the system usability scale, or SUS, awarding the device a score of 85 on a 0-100 point scale. This score is in the top 10% of SUS scores based on more than 500 devices tested.

There were two areas of suggested change by the subjects: to increase the volume of tones and to redesign the cap covering the device dispenser tips to fit more securely. Both of these features will be modified prior to the final stages of Human Factors testing and initiation of Phase 3 clinical studies.

A Usability Study with Nurses - A fifteen nurse usability study was conducted to evaluate the usability of the Phase 3 System. Nurses were asked to conduct several tasks related to the set-up, operation and discontinuation of the System. They rated each task on a scale of 1 to 5 (very difficult to extremely easy). The average score for each of the tasks ranged from 4.07 to 4.67 out of 5. In addition, the nurses rated the device on the System Usability Scale, or SUS, awarding the device a score of 83 on a 0-100 point scale. This score is in the top 10% of SUS scores based on more than 500 devices tested.

The fourth Human Factors study is described as follows:

Usability Study with Nurses and Patients - In this study, nurse and patients will be asked to perform tasks to demonstrate that the Sufentanil NanoTab PCA System can be reliably used under a range of simulated use conditions to validate the usability of the System and the effectiveness of the Instructions for Use.

ARX-04

We continue to make advancements towards the initiation of our planned ARX-04 Phase 2 dose-finding clinical trial in the fourth quarter of 2011. Examples of these activities include:

The NanoTabs have been manufactured and packaged for the Phase 2 clinical trial.

In early October 2011, AcelRx filed an Investigational New Drug application for ARX-04, its product candidate for management of moderate-to-severe acute pain, with the FDA, and plans to initiate the Phase 2 study later this year with top line results available in the first half of 2012. AcelRx has retained a CRO to conduct the Phase 2 ARX-04 study and the clinical sites for this study have been selected and retained.

We have retained a CRO to conduct the Phase 2 randomized, double-blind, placebo-controlled clinical trial that will evaluate two different doses of ARX-04 in patients suffering from moderate-to-severe acute pain. The clinical trial sites for this study have been selected and retained.

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 the private placement of convertible preferred stock, proceeds from our initial public offering, or IPO, and proceeds received from our debt financings.

From inception through September 30, 2011, we have received net proceeds of $54.9 million from the sale of convertible preferred stock and $31.4 million from our debt financings. In February 2011, we completed our IPO, pursuant to which we sold 8,000,000 shares of our common stock at a public offering price of $5.00 per share for an aggregate offering price of $40.0 million. As a result of the offering, we received net proceeds of $34.9 million, after underwriting discounts, commissions and offering expenses totaling $5.1 million. In June 2011, we entered into

a loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we may borrow up to $20.0 million in two tranches of $10.0 million each, represented by secured convertible term promissory notes. We drew the first tranche of $10.0 million upon the closing of the transaction on June 29, 2011. We used a portion of the proceeds from the first tranche to repay the remaining obligations under that certain loan and security agreement between us and Pinnacle Ventures, L.L.C, or Pinnacle dated September 2008. The second tranche of up to $10.0 million can be drawn, at our option, anytime prior to December 16, 2011. The interest rate is initially 8.50%, with 12 months of interest only payments, which period can be extended to 15 months if certain ARX-01 clinical development milestones are met.

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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 incurred losses and generated negative cash flows from operations since inception. Our net losses were $13.7 million and $10.8 million during the nine months ended September 30, 2011 and 2010. As of September 30, 2011, we had cash, cash equivalents and investments totaling $32.0 million compared to $3.7 million as of December 31, 2010. As of September 30, 2011, we had an accumulated deficit of $82.3 million.

Revenue

To date, we have not generated any product revenue. We do not expect to receive any revenues from any product candidates 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. To date, we have recognized $448,000 as revenue associated with the grant.

Research and Development Expenses

Conducting research and development is central to our business model. The majority of our operating expenses to date have been for research and development activities related to ARX-01, ARX-02 and ARX-03. Research and development expenses included the following:

- expenses incurred under agreements with CROs 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 these programs.

We track external development expenses on a program-by-program basis. Our development resources are shared among all of our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead. Below is a summary of our research and development expenses during the three and nine months ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
ARX-01	$ 2,566	$ 441	$ 4,942	$ 564
ARX-02				591
ARX-03		78		1,657

ARX-04	168		182	
Overhead	1,213	996	3,798	3,497
Total research and development expenses	$ 3,947	$ 1,515	$ 8,922	$ 6,309

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Due to the inherently unpredictable nature of product development, development timelines, the probability of success and 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 substantially increase as we commence our planned ARX-01 Phase 3 clinical trials, and subject to additional funding, complete all the requisite preparatory activities to submit an NDA to the FDA. Additionally, our research and development expenses will increase as we initiate the planned ARX-04 Phase 2 clinical trial.

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 in connection with operating as a public company and as we continue to build our corporate infrastructure in support of continued development of our product candidates.

Interest Expense

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts.

Interest and Other Income (Expense), net

Interest income consisted of interest earned on our cash, cash equivalents and investments.

Other income (expense), net consisted primarily of the change in the fair value of our then-outstanding warrants to purchase convertible preferred stock. Our warrants to purchase convertible preferred stock were classified as liabilities and, as such, were remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded as other income (expense), net. 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. At that time, the then-current aggregate fair value of these warrants was reclassified from liabilities to additional paid-in capital and we will no longer remeasure the liability associated with these warrants to purchase convertible preferred stock to fair value. Other income (expense), net also consisted of the change in fair value of our contingent put option liability associated with our loan and security agreement with Hercules.

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Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States which requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. In many instances, we could have reasonably used different accounting estimates, and in other instances, changes in the accounting estimates are reasonably likely to occur from period-to-period. Accordingly, actual results could differ significantly from the estimates made by our management. 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, 2010. Aside from our revenue recognition policy related to our grant with the USAMRMC, as described in Note 1 on this Quarterly Report on Form 10-Q, there have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2011 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2011 and 2010

Revenue

Revenue for the three and nine months ended September 30, 2011 was $408,000 and $448,000, respectively, and was generated from our grant with the USAMRMC, which was awarded in May 2011. We did not generate any revenue for the three and nine months ended September 30, 2010.

Operating Expenses

	Three Months Ended September 30, (in thousands, except percentage values)				Nine Months Ended September 30, (in thousands, except percentage values)			
	2011	2010	Change	%	2011	2010	Change	%
Operating expenses:								
Research and development	$ 3,947	$ 1,515	$ 2,432	161%	$ 8,922	$ 6,309	$ 2,613	41%
General and administrative	1,866	1,090	776	71%	5,086	3,033	2,053	68%
Total expenses	$ 5,813	$ 2,605	$ 3,208	123%	$ 14,008	$ 9,342	$ 4,666	50%

Research and Development

The $2.4 million increase during the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was primarily attributable to a $2.1 million increase in our development expenses for ARX-01 related to the planned Phase 3 trials and a $0.2 million increase related to activities under our grant with the USAMRMC for ARX-04.

The $2.6 million increase during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 was primarily attributable to a $4.4 million increase in our development expenses for ARX-01 related to the planned Phase 3 trials and a $0.2 million increase related to activities under our grant with the USAMRMC for ARX-04, partially offset by a decrease in development expenses of $2.2 million related to the completion of Phase 2 clinical trials for our ARX-02 and ARX-03 programs.

General and Administrative Expenses

The $0.8 million increase during the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was primarily due to an increase in expenses related to investor relations, market research and other consulting fees associated with our operations as a public company.

The $2.1 million increase during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 was primarily due to an increase in legal, audit and consulting fees in connection with our annual audit and the costs associated with our operations as a public company.

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Interest Expense

	Three Months Ended September 30, (in thousands, except percentage values)				Nine Months Ended September 30, (in thousands, except percentage values)			
	2011	2010	Change	%	2011	2010	Change	%
Interest expense	$ 377	$ 197	$ 180	91%	$ 1,891	$ 656	$ 1,235	188%

The $180,000 increase during the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was due to interest expense associated with the Hercules loan and security agreement which was signed in June 2011.

The $1.2 million increase during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 was primarily attributable to interest and the debt discount amortization related to the $8.0 million principal amount of convertible promissory notes issued in September 2010. The $1.1 million in unamortized debt discounts was recognized as interest expense during the nine months ended September 30, 2011 in connection with conversion of these notes immediately prior to the IPO.

Interest Income and Other Income (Expense), net

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