ACELRX PHARMACEUTICALS INC
Form 10-Q
August 11, 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 June 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 August 1, 2011, the number of outstanding shares of the registrant s common stock was 19,419,665.

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ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 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 a trademark application pending for our tagline, ACCELERATE, INNOVATE, ALLEVIATE in Class 5, 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)

	June 30, 2011 (Unaudited)	December 31, 2010[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 18,760	$ 3,055
Short-term investments	19,042	627
Prepaid expenses and other current assets	1,206	2,097
Total current assets	39,008	5,779
Property and equipment, net	1,670	800
Restricted cash	205	205
Other assets	104	46
TOTAL ASSETS	$ 40,987	$ 6,830
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 1,847	$ 543
Accrued liabilities	1,779	859
Convertible notes		6,805
Long-term debt, current portion		5,204
Other current liabilities	151	
Total current liabilities	3,777	13,411
Contingent put option liability	62	
Call option liability		596
Convertible preferred stock warrant liability		2,529
Long-term debt	8,733	
Other liabilities		245
Total liabilities	12,572	16,781
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value 10,000,000 shares and 46,736,125 shares authorized as of June 30, 2011 and December 31, 2010, respectively; no shares and 7,151,802 shares issued and outstanding as of June 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 June 30, 2011 and December 31, 2010, respectively; 19,419,665 and 674,353 shares issued and outstanding as of June 30, 2011 and December 31, 2010, respectively		
Additional paid-in capital	104,926	2,668
Deficit accumulated during the development stage	(76,530)	(68,563)
Accumulated other comprehensive loss	(2)	
Total stockholders equity (deficit)	28,415	(65,892)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)	$ 40,987	$ 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 June 30, 2011	Three Months Ended June 30, 2010	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	Period from July 13, 2005 (Inception) Through June 30, 2011
Research grant revenue	$ 40	$	$ 40	$	$ 40
Operating expenses:					
Research and development	3,029	2,033	4,975	4,795	58,772
General and administrative	1,630	1,276	3,220	1,948	15,714
Total operating expenses	4,659	3,309	8,195	6,743	74,486
Loss from operations	(4,619)	(3,309)	(8,155)	(6,743)	(74,446)
Interest expense	(156)	(214)	(1,514)	(458)	(4,644)
Interest income and Other income (expense), net	12	(14)	1,702	(18)	2,560
Net loss	$ (4,763)	$ (3,537)	$ (7,967)	$ (7,219)	$ (76,530)
Net loss per share of common stock, basic and diluted	$ (0.25)	$ (5.41)	$ (0.53)	$ (11.26)	
Shares used to compute basic and diluted net loss per share of common stock	19,374,909	653,637	15,058,546	641,391	

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)

	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	Period from July 13, 2005 (Inception) Through June 30, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (7,967)	$ (7,219)	$ (76,530)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	232	240	1,797
Amortization of premium/discount on investments, net	78	42	78
Interest expense related to debt financing	1,306	117	2,514
Stock-based compensation	789	866	3,302
Revaluation of convertible preferred stock warrant liability and write off of call option liability	(1,682)		(254)
Other non-cash items			(10)
Changes in operating assets and liabilities:			
Prepaids and other assets	892	18	343
Restricted cash			(205)
Accounts payable	863	(147)	1,406
Accrued liabilities	557	(471)	(353)
Deferred rent	(94)	(88)	150
Net cash used in operating activities	(5,026)	(6,642)	(67,762)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(237)	(4)	(2,606)
Purchase of investments	(19,809)	(478)	(65,109)
Proceeds from maturities and sales of investments	1,316	3,975	46,040
Net cash provided by (used in) investing activities	(18,730)	3,493	(21,675)
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)	(2,313)	(13,222)
Proceeds from issuance of convertible promissory notes			9,000
Proceeds from issuance of common stock upon exercise of options	58	13	156
Proceeds from issuance of convertible preferred stock, net of issuance costs		70	54,941
Net cash provided by (used in) financing activities	39,461	(2,230)	108,197
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	15,705	(5,379)	18,760
CASH AND CASH EQUIVALENTS Beginning of period	3,055	7,150	
CASH AND CASH EQUIVALENTS End of period	$ 18,760	$ 1,771	$ 18,760

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 196	$ 341	$ 1,936
NONCASH INVESTING AND FINANCING ACTIVITIES:			
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
Purchase of property and equipment through accounts payable and accrued liabilities	$ 865	$	$ 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 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 June 30, 2011. In addition, the Company had an accumulated deficit of $76.5 million and $68.6 million as of June 30, 2011 and December 31, 2010. Through June 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 facility 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 six months ended June 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 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 June 30, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 10,089	$	$	$ 10,089
Corporate debt securities	5,000			5,000
U.S. government agency securities	3,671			3,671
Total cash and cash equivalents	$ 18,760	$	$	$ 18,760
Marketable securities:				
Corporate debt securities	1,700			1,700
U.S. government agency securities	17,344		(2)	17,342
Total marketable securities	$ 19,044	$	$ (2)	$ 19,042
Total cash, cash equivalents and investments	$ 37,804	$	$ (2)	$ 37,802

	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 June 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 six months ended June 30, 2011. The gross unrealized losses above are a result of interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the Company s investment securities. There were no other-than-temporary impairments for these securities at June 30, 2011.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

As of June 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 the liability associated with previously outstanding warrants to purchase convertible preferred stock 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 June 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 June 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 June 30, 2011			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 1,864	$ 1,864	$	$
Corporate debt securities	6,700		6,700	
U.S. government agency obligations	19,149		19,149	
Total assets measured at fair value	$ 27,713	$ 1,864	$ 25,849	$
Liabilities				
Contingent put option liability	$ 62			$ 62
Total liabilities measured at fair value	$ 62	$	$	$ 62

	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):

	Six Months Ended June 30, 2011
Fair value beginning of period	$ 3,125
Exercise of warrants	(536)
Reclassification of warrant liability	(906)
Change in fair value of Level III liabilities	(1,683)
Addition of contingent put option liability	62
Fair value end of period	$ 62

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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 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 $40,000 for the three months ended June 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 June 30, 2011, the estimated fair value of the contingent put option liability was $62,000 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 June 30, 2011 while applying estimated probabilities to each scenario value. As of June 30, 2011 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.

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 June 30, 2011, the Company had outstanding borrowings under the Hercules loan and security agreement of $8.7 million, net of debt discounts of $1.3 million, and had an accrued balance of $74,000 related to deferred financing costs.

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 June 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 June 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.

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 June 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 June 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Expenses:				
Research and development	$ 204	$ 423	$ 325	$ 547
General and administrative	262	317	464	319
Total stock-based compensation expense	$ 466	$ 740	$ 789	$ 866

As of June 30, 2011 there were 1,031,227 shares available for grant, 2,416,877 options outstanding and 343,815 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 six months ended June 30, 2011 and 2010 (in thousands, except for share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net loss	$ (4,763)	$ (3,537)	$ (7,967)	$ (7,219)
Shares used in computing net loss per share of common stock, basic and diluted	19,374,909	653,637	15,058,546	641,391
Net loss per share of common stock, basic and diluted	$ (0.25)	$ (5.41)	$ (0.53)	$ (11.26)

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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:

	June 30,	
	2011	2010
Convertible preferred stock (as-if converted)		7,151,802
Stock options to purchase common stock	2,416,877	1,954,735
Restricted Stock Units	343,815	
Restricted shares of common stock subject to repurchase		33,277
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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net loss	$ (4,763)	$ (3,537)	$ (7,967)	$ (7,219)
Changes in unrealized gain (loss) on available-for-sale securities	(2)		(2)	
Comprehensive loss	$ (4,765)	$ (3,537)	$ (7,969)	$ (7,219)

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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.

Overview

We are a 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 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.

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 June 30, 2011, we have received net proceeds of $54.9 million from the sale of convertible preferred stock and $31.6 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 $7.9 million and $7.2 million during the six months ended June 30, 2011 and 2010. As of June 30, 2011, we had cash, cash equivalents and investments totaling $37.8 million compared to $3.7 million as of December 31, 2010. As of June 30, 2011, we had an accumulated deficit of $76.5 million.

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Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations. We expect to incur significant and increasing expenses over the next several years, principally to develop ARX-01, including completion of the three planned Phase 3 clinical trials, as well as to further increase our spending to manufacture, sell and market our product candidates. Contingent on our ability to secure additional funding, we plan to submit a new drug application, or NDA, to the U.S. Food & Drug Administration, or FDA, following the completion of our three Phase 3 clinical trials. In addition, based on the availability of additional financial resources, we plan to advance one or more of our other product candidates into Phase 3 trials. Based on the funding provide by USAMRMC, we have adequate funds to advance ARX-04 through a Phase 2 clinical study and Phase 3 preparatory activities, however, additional funds would be required to advance ARX-04 into Phase 3 clinical studies. Furthermore, as a result of our IPO, we expect to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future.

Financial Overview

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 acute pain. Reimbursement of related research and development expenses will be recorded as revenue as incurred over the duration of the grant. To date, we have recognized $40,000 as revenue associated with the grant.

Research and Development Expenses

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 consisted of:

- 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.

Conducting research and development is central to our business model. Though we have yet to initiate our first ARX-01 Phase 3 clinical trial, we have made progress, and expenses have increased, as we advance toward initiating the first Phase 3 clinical trial. Examples of these activities include:

- PharmaNet has been engaged as the contract research organization, or CRO, to conduct the first two ARX-01 Phase 3 studies and clinical sites have been identified for the abdominal surgery study and are engaged in the site selection process;
- The ARX-01 system design for the dispensing device has been finalized, and we have completed two of a total of four planned user studies. The remaining two user studies, and final software validation, are planned to be completed in the second half of 2011 and are

required for review by FDA prior to initiation of ARX-01 Phase 3 studies;

Construction of the NanoTab commercial manufacturing facility which will manufacture clinical and commercial supplies in a dedicated room at our contract manufacturer, Patheon, Inc., has been completed with facility qualification underway; and

PharmaNet has been retained as the CRO to conduct the ARX-04 Phase 2 study that will evaluate two different doses of sufentanil in patients suffering from moderate-to-severe acute pain, and the clinical trial sites for this study have been selected.

We have completed multiple Human Factors and clinical tests during the course of development of the device for ARX-01. In 2011, we plan to complete 4 Human Factors studies that are required for review by the FDA prior to software validation, which is the last step in device development prior to initiation of Phase 3 studies. Two of the 4 Human Factor studies have been completed:

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.

In addition, there are 2 user studies expected to be completed over the next few months:

A Usability Study with Nurses - A usability study with nurses to demonstrate that the Sufentanil NanoTab PCA System can be set up safely and effectively by nurses, and to assess the effectiveness of the device labeling and instructions for use.

Usability Study with Nurses and Patients - A usability study with nurses and patients to demonstrate that the Sufentanil NanoTab PCA System can be used by representative users under simulated use conditions, including normal use conditions and unanticipated use conditions, and to validate the effectiveness of the Instructions for Use and training.

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 six months ended June 30, 2011 and 2010 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
ARX-01	$ 1,466	$ 48	$ 2,355	$ 116
ARX-02		295		592
ARX-03		424		1,578
ARX-04	14		14	
Overhead	1,549	1,266	2,606	2,509
Total research and development expenses	$ 3,029	$ 2,033	$ 4,975	$ 4,795

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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, finance and business development. 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.

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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 six months ended June 30, 2011 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2011 and 2010

Revenue

Revenue for the three and six months ended June 30, 2011 was $40,000 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 six months ended June 30, 2010.

Operating Expenses

	Three Months Ended June 30, (in thousands, except percentage values)				Six Months Ended June 30, (in thousands, except percentage values)			
	2011	2010	Change	%	2011	2010	Change	%
Operating expenses:								
Research and development	$ 3,029	$ 2,033	$ 996	49%	$ 4,975	$ 4,795	$ 180	4%
General and administrative	1,630	1,276	354	28%	3,220	1,948	1,272	65%
Total expenses	$ 4,659	$ 3,309	$ 1,350	41%	$ 8,195	$ 6,743	$ 1,452	22%

Research and Development

The $1.0 million increase during the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 was primarily attributable to a $1.4 million increase in our development expenses for ARX-01 related to the planned Phase 3 trials, partially offset by a decrease in development expenses of $0.3 million related to the completion of Phase 2 clinical trials for our ARX-02 and ARX-03 programs.

There was not a significant change in research and development expenses for the six months ended June 30, 2011 as compared to the six months ended June 30, 2010. The increase in ARX-01 development expenses of $2.2 million was largely offset by decreases in development expenses related to the completion of Phase 2 clinical trials for our ARX-02 and ARX-03 programs.

General and Administrative Expenses

The $0.4 million increase during the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 was primarily due to an increase in legal, investor relations and other consulting fees associated with our operations as a public company.

The $1.3 million increase during the six months ended June 30, 2011 as compared to the six months ended June 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 June 30, (in thousands, except percentage values)				Six Months Ended June 30, (in thousands, except percentage values)			
	2011	2010	Change	%	2011	2010	Change	%
Interest expense	$ 156	$ 214	$ (58)	(27)%	$ 1,514	$ 458	$ 1,056	231%

The $58,000 decrease during the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 was due to decreased interest expense associated with the Pinnacle Ventures note, as it neared maturity. The Pinnacle Ventures note was paid off in full in June 2011.

The $1.1 million increase during the six months ended June 30, 2011 as compared to the six months ended June 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 six months ended June 30, 2011 in connection with conversion of these notes immediately prior to the IPO.

Interest Income and Other Income (Expense), net

	Three Months Ended June 30, (in thousands, except percentage values)				Six Months Ended June 30, (in thousands, except percentage values)			
	2011	2010	Change	%	2011	2010	Change	%
Interest Income and Other Income (Expense), net.	$ 12	$ (14)	$ 26	NA%	$ 1,702	$ (18)	$ (1,720)	NA%

The change during the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 was not significant.

The $1.7 million change during the six months ended June 20, 2011 as compared to the six months ended June 30, 2010 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.

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 June 30, 2011, we have received net proceeds of $54.9 million from the sale of convertible preferred stock, $34.9 million from our IPO and $31.6 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.

As of June 30, 2011, we had cash, cash equivalents and investments totaling $37.8 million compared to $3.7 million as of December 31, 2010. The increase was primarily attributable to proceeds from our IPO, during which we sold 8,000,000 shares at $5.00 per share and received net proceeds of $34.9 million, after underwriting discounts, commissions and offering expenses. Additionally, we drew down $10.0 million in the current quarter from our loan and security agreement with Hercules which was established in June 2011. A portion of the proceeds were used to pay down the remaining obligations of $2.8 million under our loan and security agreement with Pinnacle Ventures upon termination of the agreement.

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, corporate debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity.

Cash Flows

	Six Months Ended June 30, (in thousands)	
	2011	2010
Net cash used in operating activities	$ (5,026)	$ (6,642)
Net cash provided by (used in) investing activities	(18,730)	3,493
Net cash provided by (used in) financing activities	39,461	(2,230)

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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.

Net cash used in operating activities for the six months ended June 30, 2011 primarily reflects the net loss for the period, partially offset by a net change of $2.2 million in our operating assets and liabilities primarily related to prepaid expenses and other assets and accounts payable and accrued liabilities. In addition, we had non-cash charges of $1.3 million for interest on our debt and $0.8 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.

Net cash used in operating activities for the six months ended June 30, 2010 primarily reflects the net loss for the period, partially offset by $0.9 million in stock-based compensation.

Cash Flows from Investing Activities. Net cash used in investing activities for both periods primarily reflect purchases and maturities of investments. During the six months ended June 30, 2011 we had $0.9 million in fixed asset additions which were reflected in accounts payable and accrued liabilities as of June 30, 2011. The additions for the six months ended June 30, 2011 primarily relate to the construction of the NanoTab commercial manufacturing facility.

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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.

During the six months ended June 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 debt agreement with Hercules, partially offset by principal repayments on our long-term debt of $5.2 million, including payment in full of our remaining obligations under the Pinnacle agreement, which was terminated upon executing the Hercules loan agreement.

During the six months ended June 30, 2010, cash used in financing activities was primarily a result of principal repayments on our long-term debt of $2.3 million.

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 activities. We believe that the available cash resources, including proceeds received from our IPO, debt financings, including full utilization of the $20.0 million Hercules loan and USAMRMC research grant will enable us to maintain our currently planned operations into the first quarter of 2013, including support for our continuing development of our product candidates, clinical trials and manufacturing scale-up and commercial readiness activities. Future capital requirements will be substantial and if our capital resources are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations, including product candidate development activities. 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 in 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.

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

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and

the possible costs of litigation.

Contractual Obligations

We are obligated to make principal and interest payments on our loan and security agreement with Hercules entered into in June 2011, as provided below.

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	Payment by Period				
Contractual Obligations:	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Principle Payments on Long-term debt	$ 10,000	$	$ 10,000	$	
Interest Payments on Long-term debt	$ 2,152	$ 798	$ 1,354	$	
Total	$ 12,152	$ 798	$ 11,354	$	

As of June 30, 2011, we had operating lease obligations totaling $0.4 million for our office and laboratory facilities in Redwood City, California. The lease expires in April 2012.

Off-Balance Sheet Arrangements

Through June 30, 2011, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

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Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved, and you are cautioned not to place undue reliance on such statements, which speak only as of the date made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities.

Our market risks at June 30, 2011 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2010 as filed with the SEC.

Item 4. Controls and Procedures

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

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

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

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

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2010.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. *

We are a development stage company with limited operating history. To date, we have focused primarily on developing our lead product candidate, the Sufentanil NanoTab PCA System, or ARX-01. We have three additional product candidates, the Sufentanil NanoTab BTP Management System, or ARX-02, the Sufentanil/Triazolam NanoTab, or ARX-03 and Sufentanil Single-Dose Acute Pain NanoTab, or ARX-04. We have incurred significant net losses in each year since our inception in July 2005 and as of June 30, 2011, we had an accumulated deficit of $76.5 million.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenues are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success.

We expect to continue to incur substantial and increased expenses as we expand our research and development activities and advance our clinical programs. We also expect an increase in our expenses associated with preparing for the potential commercialization of ARX-01 and creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future.

We have never generated any product or commercial revenue and may never be profitable.

Our ability to generate revenue from commercial sales and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals and commercialize our product candidates. Other than the revenue received from the USAMRMC for research and development reimbursement under the terms of the grant for ARX-04, we do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing the clinical development of ARX-01, initially for the treatment of post-operative pain in the hospital setting;

obtaining regulatory approval for ARX-01;

- launching and commercializing ARX-01, including building a hospital-directed sales force in the U.S. and collaborating with third parties internationally; and

- completing the clinical development, obtaining regulatory approval, launching and commercializing ARX-02, ARX-03 and ARX-04, which will require additional funding.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses, when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations.

We have a limited operating history that may make it difficult to predict our future performance or evaluate our business and prospects.

We were incorporated in 2005. Since inception, our operations have been primarily limited to organizing and staffing our company, developing our technology and undertaking preclinical studies and clinical trials for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Consequently, any predictions you make about our future success or viability or evaluation of our business and prospects may not be accurate.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs. As of June 30, 2011, we had working capital of $35.3 million.

We believe that our current cash, cash equivalents and investments and available funds under the $20.0 million debt facility with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, will be sufficient to fund our current operations into the first quarter of 2013. We will need to raise substantial additional funds to support our future operations, and such funding may not be available to us on acceptable terms, or at all. Additionally, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, we believe our existing cash resources are adequate to complete all three ARX-01 Phase 3 clinical trials, however, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expected. In any event, we will require substantial additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment, when the capital markets have been affected by the global recession, may present additional challenges.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;

- seek corporate partners for ARX-01 at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from continuing operations well into 2013 allowing for the completion the development efforts required to submit an NDA to the FDA and pursuing commercialization efforts, which will have a material adverse effect on our business, operating results and prospects

We may sell additional equity or debt securities to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which would result in dilution to all of our stockholders or impose restrictive covenants that adversely impact our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our debt service obligations.

We might be unable to service our current debt due to a lack of cash flow and might be subject to default.*

In June 2011, we entered into a loan and security agreement with 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 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., 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. Any notes issued pursuant to the loan and security agreement mature on December 1, 2014, which would be extended until March 1, 2015 if certain ARX-01 clinical development milestones are met. We granted to Hercules a first priority security interest in substantially all of our assets, with the exception of our intellectual property, where the security interest is limited to proceeds of intellectual property.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, if we breach the agreement or become insolvent, Hercules could elect to declare all amounts outstanding, together with accrued and unpaid interest and penalty, to be immediately due and payable. Even if we were able to prepay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, Hercules will have a first claim on our assets pledged under the loan agreement. If Hercules should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the loan agreement and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Risks Related to Clinical Development and Regulatory Approval

We depend substantially on the success of our product candidate, ARX-01, which is still under clinical development, and may not obtain regulatory approval or be successfully commercialized.*

We have not marketed, distributed or sold any products. The success of our business depends primarily upon our ability to develop and commercialize ARX-01, which has completed Phase 2 clinical trials for the treatment of post-operative pain. We expect to initiate one of the three planned Phase 3 clinical trials for ARX-01 in the second half of 2011 with a second Phase 3 clinical trial initiating in early 2012. We plan to begin a third Phase 3 clinical trial in the second half of 2012. We believe or existing capital resources will be adequate to support operations into the first quarter of 2013 and will be adequate to complete all three ARX-01 Phase 3 clinical trials. Contingent on our ability to raise additional funding, we intend to use these completed trials as a basis to submit an NDA for ARX-01 later in 2013. There is no guarantee that our Phase 3 clinical trials, or any of the remaining Phase 1 or non-clinical studies to be included in the NDA, will be completed, or if completed, will be successful.

Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing ARX-01, generating revenues and achieving profitability. If any of these events occur, we may be forced to abandon our development efforts for ARX-01, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We depend substantially on the successful completion of Phase 3 clinical trials for our product candidates. The positive clinical results obtained for our product candidates in Phase 2 clinical studies may not be repeated in Phase 3.

We have completed Phase 2 clinical studies and participated in three separate End of Phase 2 meeting with the FDA for ARX-01, ARX-02 and ARX-03, while ARX-04 is about to enter a Phase 2 clinical study. However, we have never conducted a Phase 3 clinical trial. Our product candidates are subject to the risks of failure inherent in pharmaceutical and medical device development. Before

obtaining regulatory approval for the commercial sale of any product candidate, we must successfully complete Phase 3 clinical trials. Negative or inconclusive results of a Phase 3 clinical study could cause the FDA to require that we repeat it or conduct additional clinical studies. Furthermore, while we have obtained positive safety and efficacy results for our sufentanil-based product candidates during our prior clinical trials, we cannot be certain that these results will be duplicated when our product candidates are tested in a larger number of patients in our Phase 3 clinical trials.

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Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales. *

We may experience delays in clinical trials of our product candidates. We expect to initiate one of the three planned Phase 3 clinical trials of ARX-01 in the second half of 2011 with a second Phase 3 study being initiated in the first half of 2012 and a third Phase 3 study starting in the second half of 2012. In addition, we expect to enter Phase 2 clinical studies with ARX-04 in the second half of 2011. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in pharmacokinetic studies required to submit an NDA;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- delays in completing the required device Human Factor studies and software validation to the satisfaction to the FDA in order to initiate clinical trials;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the device components of our product candidates;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or

delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of the planned Phase 3 trials or Phase 2 trial are delayed for our product candidates for any of the above reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.*

Adverse events, or AEs, caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. Phase 2 clinical studies conducted by us with our ARX-01, ARX-02 and ARX-03 product candidates have generated some AEs, but no serious adverse events, or SAEs, related to the study drug. For example, in ARX-01 clinical studies completed to date, 11% of the patients experienced vomiting and 8% experienced itching for 10 mcg and 15 mcg treated groups, as compared to the placebo treated subjects, of which 6% experienced vomiting and none experienced itching. If SAEs related to the study drug are observed in any of our clinical studies, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Further, if our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

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Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

Additional time may be required to obtain regulatory approval for our ARX-01 product candidate because it is a drug/device combination.

ARX-01 is a drug/device combination. We have filed an IND for ARX-01. Based on our discussions with the FDA, we believe that ARX-01 will be reviewed as a combination product, with both drug and device components submitted in the IND, and both components will eventually be part of an NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as ARX-01. As a result, we may experience delays in regulatory approval for ARX-01 due to uncertainties in the approval process, in particular as it relates to device approval under an NDA.

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize any of our product candidates, and we cannot, therefore, predict the timing of any future revenue.*

We cannot commercialize any of our product candidates, including ARX-01, until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for ARX-01. Additional delays may result if ARX-01 is taken before an FDA Advisory Committee which may recommend restrictions on approval or recommend non-approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process.

Even if we obtain regulatory approval for ARX-01 and our other product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties. *

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for ARX-01 and our other product candidates will likely include restrictions on use due to the opioid nature of sufentanil. ARX-01 and our other product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;

suspend any ongoing clinical trials;

refuse to approve a pending NDA or supplements to an NDA submitted by us;

seize product; or

refuse to allow us to enter into supply contracts, including government contracts.

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Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

Even if we obtain FDA approval for ARX-01 or any of our product candidates in the United States, we may never obtain approval for or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

ARX-01 and our other product candidates will require Risk Evaluation and Mitigation Strategies.

The FDA Amendments Act of 2007 implemented safety-related changes to product labeling and require the adoption of REMS. Our product candidates will require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. While we have received information from the FDA regarding certain aspects of the required REMS for ARX-01, we cannot predict the specific REMS to be required as part of the FDA s approval of ARX-01. Depending on the extent of the REMS requirements, our costs to commercialize ARX-01 may increase significantly. ARX-02, ARX-03 and ARX-04, if approved, will also require REMS programs that may increase our costs to commercialize these product candidates. Furthermore, risks of sufentanil that are not adequately addressed through proposed REMS for our product candidates may also prevent or delay their approval for commercialization.

Risks Related to Our Reliance on Third Parties

We rely on third party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidates. *

Reliance on third party manufacturers entails many risks including:

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;

the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;

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- the lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

We rely on limited sources of supply for the drug component of our product candidates and any disruption in the chain of supply may cause delay in developing and commercializing our product candidates.

Currently we use two established suppliers of sufentanil citrate for our NanoTabs. For each product candidate, only one of the two suppliers will be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. The alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new sufentanil supplier is relied upon for commercial production. In addition, the Drug Enforcement Administration, or the DEA, may reduce, delay or refuse our quota for sufentanil, which would disrupt our supply of sufentanil citrate and cause delay in the development and commercialization of our product candidates.

Currently, we use one supplier of triazolam for our ARX-03 NanoTabs. Switching triazolam suppliers may involve substantial cost and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacture of sufentanil NanoTabs requires specialized equipment and expertise.*

Ethanol, which is used in the manufacturing process, is flammable, and sufentanil is a highly potent, Schedule II compound. These factors necessitate the use of specialized equipment and facilities for manufacture of sufentanil NanoTabs. There are a limited number of facilities that can accommodate our manufacturing process and we need to use dedicated equipment throughout development and commercial manufacturing to avoid the possibility of cross-contamination. If our equipment breaks down or needs to be repaired or replaced, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Furthermore, we are using one facility to manufacture our sufentanil NanoTabs and have not identified a back-up commercial facility to date. We are currently moving our equipment from one manufacturing facility to another. If equipment is damaged during the moving process, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Any problems with our existing facility or equipment may delay or impair our ability to complete our clinical trials or commercialize our product candidates and increase our cost.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with our planned clinical trials and obtain regulatory approval for commercial marketing. In the past we have identified impurities in our product candidates. In the future we may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our products.

Historically we have manufactured all our NanoTab supplies at Patheon in Toronto, Canada. We are currently in the process of transferring our manufacturing capabilities to Patheon s facility in Cincinnati, Ohio where we are building out a dedicated room within their existing buildings, that will serve as the manufacturing facility for clinical and commercial supplies of NanoTabs. In order to successfully produce the NanoTab supplies, the new facility must first be qualified and all equipment must successfully be transferred and qualified to produce the necessary clinical supplies and subsequently commercial supplies.

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Our designs for the device components of our product candidates for Phase 3 clinical trials may not be fully functional or commercially viable.

The ARX-01 device we plan to use in Phase 3 clinical trials and commercially, or Phase 3 device, has more features than the device used in Phase 2, including additional software and functionality. Although we have conducted multiple human factor and usability studies, the design of the ARX-01 Phase 3 device is still under development. We plan to complete additional user testing studies prior to the release of the device for Phase 3 clinical trials. However, we cannot predict if the Phase 3 device will be fully functional or acceptable for commercial use. If we need to modify the Phase 3 device either during or after the completion of the Phase 3 studies, we may incur higher costs and experience delay in regulatory approval and commercialization of ARX-01. Furthermore, if the changes to the device are substantial, we may need to conduct further clinical studies in order to have the commercial device approved by the FDA.

The dispensing components of all of our product candidates are under development. We cannot be certain that the dispensing components will be fully functional or acceptable for commercial use or that we will be able to effectively scale up the manufacturing process. Failure to do so may delay or prevent regulatory approval or commercialization of our product candidates.

We have limited experience manufacturing the ARX-01 Phase 3 device on a clinical scale, no experience on a commercial scale and do not own or operate a manufacturing facility.

While we have manufactured Phase 3 devices internally on a small scale, we plan to rely on contract manufacturers, component fabricators and secondary service providers to produce ARX-01 devices for Phase 3 clinical trials and the commercial marketplace. We currently outsource manufacturing and packaging of the controller, dispenser and cartridge components of the ARX-01 device to third parties and intend to continue to do so. We may encounter unanticipated problems in the scale-up and automation process that will result in delays in the manufacturing of the ARX-01 cartridge, dispenser or controller.

We do not currently have any agreements with third party manufacturers for the manufacture of the Phase 3 device. We may not be able to enter into agreements for commercial supply of ARX-01 with third party manufacturers, or may be unable to do so on acceptable terms.

We may not be able to establish additional sources of supply for device manufacture. Such suppliers are subject to FDA regulations requiring that materials be produced under cGMPs, or Quality System Regulations, or QSR, and subject to ongoing inspections by regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in delays and interruptions to our product candidate supply while we seek to secure another supplier that meets all regulatory requirements.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

We rely on third parties to conduct, supervise and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.*

We recently selected and executed agreements with our CRO to conduct our first two Phase 3 clinical studies for ARX-01 and for the Phase 2 study for ARX-04. We will rely on this CRO, along with other CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical programs for ARX-01 and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CROs activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Since our drug products are controlled substances, all of our contract manufacturing organizations, or CMOs, and CROs must follow proper DEA rules and procedures or comparable rules and procedures in other countries. Failure to properly follow these rules and procedures could result in DEA action, up to and including losing their license to work with controlled substances. This would result in a major delay in our clinical studies and/or NDA submission.

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We and our CROs are required to comply with the FDA s current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA may determine that our Phase 3 clinical trials do not comply with cGCPs. In addition, our Phase 3 clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of ARX-01. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat the Phase 3 clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may allow our potential competitors to access our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize ARX-01, or our other product candidates. As a result, our financial results and the commercial prospects for ARX-01 and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Development of ARX-04 is dependent on funding from our government grant with the US Army Medical Research and Material Command, or USAMRMC.*

In May, 2011, we entered into an award contract with the USAMRMC, effective June 1, 2011, in which the USAMRMC granted approximately $5.6 million to us in order to support the development of our new product candidate, ARX-04, a sufentanil NanoTab for the treatment of acute pain. Under the terms of the grant, the USAMRMC will reimburse us 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.

Development of ARX-04 is dependent on the continued performance by the USAMRMC of its responsibilities under this agreement, including adequate continued funding of USAMRMC programs. We have no control over the resources and funding that USAMRMC may devote to this or future agreements, which may be subject to annual renewal and which generally may be terminated by USAMRMC at any time.

USAMRMC may fail to perform their responsibilities under the agreement, which may cause them to be terminated. In addition, we may fail to perform our responsibilities under the agreement. Our government agreement is subject to audits, which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful in entering, or ineligible to enter, into future government agreements.

There can be no assurances that this agreement will continue or that we will be able to enter into new contracts with USAMRMC or obtain funding from other sources to continue to support development of ARX-04 beyond the Phase 2 clinical study and preparation for Phase 3 activities. The process of obtaining USAMRMC contracts is lengthy and uncertain and we will have to compete with other companies for each contract. Further, changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting research and development programs, including ARX-04.

Risks Related to Commercialization of Our Product Candidates

The commercial success of ARX-01 and our other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors.

The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

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

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

the prevalence and severity of any AEs;

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- overcoming the perception of sufentanil as a potentially unsafe drug due to its high potency;
- limitations or warnings contained in the FDA-approved label for ARX-01;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators sales and marketing strategies;
- our ability to obtain hospital formulary approval;
- our ability to obtain and maintain sufficient third party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third party coverage.

If ARX-01 is approved, but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue from ARX-01 and we may not become or remain profitable.

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

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We will also consider the option to enter into strategic partnerships for our product candidates in the United States.

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To date, we have not entered into any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. Our strategy for ARX-01 is to develop a hospital-directed sales force and/or collaborate with third parties to promote the product to healthcare professionals and third party payors in the United States. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for ARX-02 or ARX-03, we may be forced to curtail the development of ARX-02 or ARX-03, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. We are developing ARX-04 under a grant from USAMRMC and if a follow on grant from USAMRMC to cover Phase 3 costs is not obtained, we may be required to curtail all activities associated with ARX-04. In addition, without a partnership or additional grant funding, we would bear all the risk related to the development of ARX-02, ARX-03 or ARX-04. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring ARX-02, ARX-03 or ARX-04 to market or generate product revenue.

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

If we obtain approval to commercialize our products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market ARX-01 outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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If we are unable to compete effectively, our product candidates may not reach their commercial potential. *

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates obtain FDA approval, they will compete with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations.

The primary competition for ARX-01 is the IV PCA pump, which is widely used in the post-operative setting. Leading manufacturers of IV PCA pumps include Hospira Inc., CareFusion Corporation, Baxter International Inc., Curlin Medical, Inc. and Smiths Medical. The most common opioids used to treat post-operative pain are morphine, hydromorphone and fentanyl, all of which are available as generics. Also available on the market is the Avancen Medication on Demand, or MOD, Oral PCA Device developed by Avancen MOD Corporation. Also in development is MoxDuo, an orally administered, fixed ratio combination of morphine and oxycodone being developed by QRx Pharma, an Australian company. This product is also in development as an IV product.

Additional potential competitors for ARX-01 include products in development, including the fentanyl iontophoretic transdermal system, IONSYS, originally developed by ALZA Corporation and Ortho-McNeil Pharmaceutical, Inc., both Johnson & Johnson subsidiaries, and currently under development by Incline Therapeutics, Inc.; and Rylomine, an intranasal morphine product developed by Javelin Pharmaceuticals, Inc.

Our potential competitors for ARX-02 include products approved in the United States for cancer breakthrough pain, including: ACTIQ and FENTORA, currently manufactured by Cephalon Inc.; Onsolis, currently manufactured by BioDelivery Sciences International, Inc.; and Abstral, currently manufactured by ProStrakan Group plc; as well as products approved in Europe, including: Instanyl, currently manufactured by Nycomed International Management GmbH. The active ingredient in all approved products for cancer breakthrough pain is fentanyl. Additional potential competitors for ARX-02 include products in late stage development for cancer breakthrough pain, such as: PecFent, currently manufactured by Archimedes Pharma Limited; Fentanyl TAIFUN, currently manufactured by Akela Pharma, Inc.; and SL Spray, currently manufactured by Insys Therapeutics, Inc.

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

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approval of products and the commercialization of those products. Accordingly, our competitors may be more successful than we are in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors drugs or drug delivery systems may be more effective, have fewer adverse effects, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product candidate we may commercialize. This may render our product candidates obsolete or non-competitive before we can recover our losses. We anticipate that we will face intense and increasing competition as new drugs enter the market and additional technologies become available. These entities may also establish collaborative or licensing relationships with our competitors, which may adversely affect our competitive position. Finally, the development of different methods for the treatment of post-operative pain or breakthrough pain could render ARX-01 and ARX-02, respectively, non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

Hospital formulary approval and reimbursement may not be available for ARX-01 and our other product candidates, which could make it difficult for us to sell our products profitably.

Obtaining formulary approval can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell our products into our target markets. Failure to obtain timely formulary approval will limit our commercial success.

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Furthermore, market acceptance and sales of ARX-01, or any future product candidates that we develop, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for ARX-01, or any future product candidates. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize ARX-01, or any future product candidates that we develop.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell our products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for ARX-01. The potential application of user fees to generic drug products may expedite the approval of additional pain medication generic drugs. We expect to experience pricing pressures in connection with the sale of ARX-01 and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Risks Related to Our Business Operations and Industry

Failure to comply with the Drug Enforcement Administration regulations, or the cost of compliance with these regulations, may adversely affect our business. *

Our sufentanil-based products are subject to extensive regulation by the DEA, due to their status as scheduled drugs. Sufentanil is a Schedule II opioid, considered to present the highest risk of abuse. The manufacture, shipment, storage, sale and use of controlled substances are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA. This high degree of regulation can result in significant costs in order to comply with the required regulations, which may have an adverse effect on the development and commercialization of our product candidates.

The DEA limits the availability and production of all Schedule II substances, including sufentanil, through a quota system. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. At present, our contract manufacturers have applied for a quota on our behalf which allocates a sufficient quantity of sufentanil to meet our planned clinical and pre-clinical needs during 2011 and 2012. In future years, we may need greater amounts of sufentanil to sustain and complete our Phase 3 development program for ARX-01, and we will need significantly greater amounts of sufentanil to implement our commercialization plans if the FDA approves ARX-01. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in our quota for sufentanil or a failure to increase it over time as we anticipate could delay or stop the clinical development or commercial sale of ARX-01. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, historically we have purchased sufentanil in the United States and have shipped it to our third party manufacturer, Patheon Inc. in Toronto, Canada, where much of our clinical trial manufacturing has been completed to date. Shipping across international borders is a bureaucratic process that takes a minimum of three months and requires permits for both import and export. If we fail to comply with applicable regulatory requirements or fail to submit permit applications in a timely manner, the government could refuse to permit sufentanil to be exported and imported between Canada and the United States. Our failure to comply with these requirements could result in increased costs, delayed shipments, the loss of DEA registration for one of our suppliers, significant restrictions on ARX-01 or any of our product candidates, civil penalties or criminal prosecution and delays in conducting our clinical trials.

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Drug Enforcement Administration regulations require that sufentanil be manufactured in the United States if sufentanil-based products are to be marketed in the United States, and there is no guarantee that we will secure a commercial supply agreement with a manufacturer based in the United States.*

A substantial portion of our clinical trial manufacturing to date has been completed at Patheon Inc. in Toronto, Canada. Because the DEA requires that sufentanil be manufactured in the United States if our product candidates are marketed in the United States, we are in the process of transferring our manufacturing capability from Patheon in Toronto, Canada to Patheon s production facility in Cincinnati, Ohio. There can be no assurance that there will be a successful transfer of the manufacturing capability to the Cincinnati facility, including the successful qualification of the NanoTab manufacturing equipment and the qualification of the new manufacturing facility.

In addition, we do not yet have a commercial supply contract in place. If we cannot establish a supply contract on commercially reasonable terms, or if facility modifications, equipment manufacture or modification do not meet expected deadlines, we may not be able to successfully commercialize our product candidates.

Switching or adding commercial manufacturing capability can involve substantial cost and require extensive management time and focus, as well as additional regulatory filings. In addition, there is a natural transition period when a new manufacturing facility commences work. As a result, delays may occur, which can materially impact our ability to meet our desired commercial timelines, thereby increasing our costs and reducing our ability to generate revenue.

The facilities of any of our future manufacturers of sufentanil-containing NanoTabs must be approved by the FDA after we submit our NDA and before approval of ARX-01 and our other product candidates. We do not control the manufacturing process of sufentanil NanoTabs and are completely dependent on these third party manufacturing partners for compliance with the FDA s requirements for manufacture. In addition, although our third party manufacturers are well established commercial manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their process. If our manufacturers cannot successfully produce material that conforms to our specifications and the FDA s strict regulatory requirements, they will not be able to secure FDA approval for their manufacturing facilities. If the FDA does not approve these facilities for the commercial manufacture of sufentanil NanoTabs, we will need to find alternative suppliers, which would result in significant delays in obtaining FDA approval for ARX-01. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

Business interruptions could delay us in the process of developing our products and could disrupt our sales.

Our headquarters is located in the San Francisco Bay Area, near known earthquake fault zones and is vulnerable to significant damage from earthquakes. We are also vulnerable to other types of natural disasters and other events that could disrupt our operations. We do not carry insurance for earthquakes or other natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are at will employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

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We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. *

As of June 30, 2011, we had 21 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize ARX-01 and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related to Our Intellectual Property

We have numerous pending patent applications in the United States, and one issued patent in Europe. If our pending patent applications fail to issue, our business will be adversely affected.*

Our commercial success will depend in part on obtaining and maintaining patent protection for our product candidates, as well as successfully defending our current and future patents against third party challenges. To protect our proprietary technology, we rely on patents as well as other intellectual property protections, including trade secrets, nondisclosure agreements and confidentiality provisions.

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In addition, there can be no assurance that our pending patent applications will result in issued patents. As of June 30, 2011, we are the owner of record and are pursuing 16 U.S. non-provisional patent applications, three pending international Patent Cooperation Treaty applications, 49 National Phase applications and ten European Regional Phase applications foreign directed to our product candidates. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents.

The opposition period ended for our European patent, EP2114383 on April 21, 2011. On May 30, 2011 we received formal notification from the European patent authority that the opposition period ended with no opposition filed.

The patent positions of pharmaceutical companies, including us, can be highly uncertain and involve complex and evolving legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. Legal developments may preclude or limit the scope of available patent protection.

Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing our product candidates to market and interfere with our business.

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to, or may include compositions or methods that encompass our technology, allowing them to claim that the use of our technologies infringes these patents.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and/or invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to successful in our defense. Our business may suffer if a finding of infringement is established.

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It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. The pharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications. *

We have systems in place, including use of third party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business. *

We have registered our ACELRX mark in Class 5, Pharmaceutical preparations for treating pain; pharmaceutical preparations for treating anxiety, and Class 10, Drug delivery systems; medical device, namely, a mechanical and electronic device used to administer medications, perform timed medication delivery, and to provide secure access to and delivery of medications, in the United States. Our ACELRX mark has also been registered in the European Community and in Canada, and is pending in India. We have registered our NANOTAB mark and a trademark application is pending for our tagline, ACCELERATE, INNOVATE, ALLEVIATE in Class 5, in the United States. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications could be subject to opposition or cancellation after the marks are registered. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols other than ACELRX that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile.

Prior to our IPO in February 2011, there was no public market for our common stock. An active public trading market may not develop or, if developed, may not be sustained. Moreover, the trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding, including funding necessary to complete the third ARX-01 Phase 3 clinical trial required to submit an NDA;
- any delay in submitting an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA s filing or review of that NDA;
- failure to successfully develop and commercialize our product candidates;

changes in laws or regulations applicable to our products;

inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;

adverse regulatory decisions;

introduction of new products, services or technologies by our competitors;

failure to meet or exceed financial projections we provide to the public;

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- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and the NASDAQ Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our common stock is thinly traded and in the future, may continue to be thinly traded, and our stockholders may be unable to sell at or near ask prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares. *

To date, we have a low volume of daily trades in our common stock on the NASDAQ Global Market. For example, the average daily trading volume in our common stock on the NASDAQ Global Market during the second quarter of 2011 was approximately 15,000 shares per day. Our stockholders may be unable to sell their common stock at or above their respective purchase prices if at all, which may result in substantial losses to our stockholders.

The market for our common shares may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. As noted above, our common shares may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval. *

Our executive officers and directors, together with the stockholders with whom our executive officers and directors are affiliated or associated, beneficially owned approximately 78% of our outstanding voting stock as of August 1, 2011. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders are able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Stock Market have imposed various requirements on public companies. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

As a public company, we are subject to the requirements of Section 404 of the Sarbanes-Oxley Act. If we are unable to comply with Section 404 in a timely manner, it may affect the reliability of our internal control over financial reporting. Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process.

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We plan to continue to assess our internal controls and procedures and intend to take further action as necessary or appropriate to address any other matters we identify. In addition, our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2012, unless we qualify for an exemption as a non-accelerated filer under the applicable SEC rules and regulations.

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We have been and will continue to be involved in a substantial effort to implement appropriate processes, document the system of internal control over key processes, assess their design, remediate any deficiencies identified and test their operation. We cannot be certain at this time whether our measures to improve internal controls will be successful, that we will be able to successfully complete the procedures, certification and attestation requirements of Section 404 or that we or our independent registered public accounting firm will not identify material weaknesses in our internal control over financial reporting. If we fail to comply with the requirements of Section 404, it may affect the reliability of our internal control over financial reporting and negatively impact the quality of disclosure to our investors. If we or our independent registered public accounting firm identify and report a material weakness, it could adversely affect our stock price.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of August 1, 2011, we had 19,419,665 shares of common stock outstanding.

Substantially all of our stockholders that held stock prior to our IPO are subject to lock-up agreements with the underwriters of our IPO that restrict the stockholders ability to transfer shares of our common stock until at least August 10, 2011. The lock-up agreements limit the number of shares of common stock that may be sold until the expiration of the lock-up period. Upon the expiration of the lock-up period, approximately 16,219,665 of the shares outstanding as of August 1, 2011 will become eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. The remaining 3,200,000 shares of common stock outstanding as of August 1, 2011 are freely tradable without restriction or further registration. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by our existing stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2011 Equity Incentive Plan, or the 2011 Incentive Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under our 2011 Incentive Plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under our 2011 Incentive Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which

the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 10, 2011, our registration statement on Form S-1 (File No. 333-170594) was declared effective for our initial public offering, or IPO, pursuant to which we sold 8,000,000 shares of common stock at a public offering price of $5.00 per share for an aggregate public offering price of $40.0 million. As a result of the IPO, we received net proceeds of $35.2 million, after deducting underwriting discounts and commissions and other offering expenses totaling $4.8 million. None of the expenses associated with the IPO were paid to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

Approximately $27.8 million of the net proceeds are expected to fund our pharmaceutical and engineering activities in anticipation of our Phase 3 studies. The net proceeds will also fund two of our three planned ARX-01 Phase 3 clinical trials, with the balance of the proceeds to be used for general corporate purposes. As of June 30, 2011, the net offering proceeds have been invested in high credit quality U.S. government agency obligations, corporate debt obligations and commercial paper. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on February 11, 2011.

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Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. (Removed and Reserved)

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of the Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.[1]
3.2	Bylaws of the Registrant, currently in effect.[2]
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2	Specimen Common Stock Certificate of the Registrant.[3]
4.3	Amended and Restated Investor s Rights Agreement, among the Registrant and certain of its security holders, dated as of November 23, 2009.[4]
4.4	Warrant to Purchase Stock of the Registrant, issued to Wells Fargo Bank, N.A., dated March 15, 2007.[5]
4.5	Warrant to Purchase Preferred Stock of the Registrant, issued to Pinnacle Ventures II Equity Holdings, L.L.C., dated September 16, 2008.[6]
4.6	Warrant to Purchase Stock issued to Hercules Technology II, L.P., dated as of June 29, 2011. [7]
4.7	Warrant to Purchase Stock issued to Hercules Technology Growth Capital, Inc., dated as of June 29, 2011.[8]
10.1	2011 Cash Bonus Plan Summary. [9]
10.2	Loan and Security Agreement among AcelRx Pharmaceuticals, Inc., Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., dated as of June 29, 2011. [10]
10.3	Award contract with the US Army Medical Research and Material Command dated May 26, 2011.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document **
101.LAB	XBRL Taxonomy Extension Label Linkbase Document **
101.PRE	XBRL Taxonomy Extension Presentation Document **

(1) Incorporated herein by reference to Exhibit 3.1 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on February 18, 2011.

(2) Incorporated herein by reference to Exhibit 3.4 to the Registrant s registration statement on Form S-1, as amended (File No. 333-170594), as filed with the SEC on January 7, 2011.

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(3) Incorporated herein by reference to Exhibit 4.2 to the Registrant s registration statement on Form S-1, as amended (File No. 333-170594), as filed with the SEC on January 31, 2011.

(4) Incorporated herein by reference to Exhibit 4.3 to the Registrant s registration statement on Form S-1, as amended (File No. 333-170594), as filed with the SEC on November 12, 2010.

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(6) Incorporated herein by reference to Exhibit 4.5 to the Registrant s registration statement on Form S-1, as amended (File No. 333-170594), as filed with the SEC on November 12, 2010.

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(8) Incorporated herein by reference to Exhibit 4.5 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on June 30, 2011.

(9) Incorporated by reference to Exhibit 10.1 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on May 16, 2011.

(10) Incorporated herein by reference to Exhibit 10.1 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on June 30, 2011.

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or Prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 11, 2011

AcelRx Pharmaceuticals, Inc.

/s/ James H. Welch
James H. Welch

Chief Financial Officer

(Duly Authorized and Principal Financial and Accounting Officer)

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