ACELRX PHARMACEUTICALS INC
Form 10-Q
May 16, 2011
Table of Contents

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 March 31, 2011

or

¨ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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 ¨ No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of May 1, 2011, the number of outstanding shares of the registrant s common stock was 19,371,750.

Table of Contents

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2011

TABLE OF CONTENTS

Table of Contents

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)

	March 31, 2011 (Unaudited)	December 31, 2010[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,206	$ 3,055
Short-term investments	3,032	627
Prepaid expenses and other current assets	758	2,097
Total current assets	36,996	5,779
Property and equipment, net	715	800
Restricted cash	205	205
Other assets	42	46
TOTAL ASSETS	$ 37,958	$ 6,830
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 1,309	$ 543
Accrued liabilities	499	859
Convertible notes		6,805
Long-term debt, current portion	3,994	5,204
Total current liabilities	5,802	13,411
Deferred rent	198	245
Call option liability		596
Convertible preferred stock warrant liability		2,529
Total liabilities	6,000	16,781
Commitments and Contingencies (Note 7)		
Convertible preferred stock, $0.001 par value no shares and 46,736,125 shares authorized as of March 31, 2011 and December 31, 2010; no shares and 7,151,802 shares issued and outstanding as of March 31, 2011 and December 31, 2010		55,941
STOCKHOLDERS EQUITY (DEFICIT):		
Common stock, $0.001 par value 100,000,000 and 71,000,000 shares authorized as of March 31, 2011 and December 31, 2010; 19,371,750 and 674,353 shares issued and outstanding as of March 31, 2011 and December 31, 2010	21	3

Additional paid-in capital	103,704	2,668
Deficit accumulated during the development stage	(71,767)	(68,563)
Total stockholders equity (deficit)	31,958	(65,892)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)	$ 37,958	$ 6,830

(1) The condensed consolidated 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.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended March 31,		Period from July 13, 2005 (Inception) Through March 31,
	2011	2010	2011
Operating Expenses:			
Research and development	$ 1,946	$ 2,761	$ 55,743
General and administrative	1,589	672	14,083
Total operating expenses	3,535	3,433	69,826
Loss from operations	(3,535)	(3,433)	(69,826)
Interest income	8	2	1,563
Interest expense	(1,359)	(244)	(4,489)
Other income (expense), net	1,682	(6)	985
Net loss	$ (3,204)	$ (3,681)	$ (71,767)
Net loss per share of common stock, basic and diluted	$ (0.30)	$ (5.85)	
Shares used in computing net loss per share of common stock, basic and diluted	10,742,182	629,006	

See notes to condensed financial statements.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Three Months Ended March 31,		Period from July 13, 2005 (Inception) Through March 31,
	2011	2010	2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (3,204)	$ (3,681)	$ (71,767)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	117	120	1,682
Interest expense related to debt financing	1,235	61	2,443
Stock-based compensation	323	129	2,836
Contributions of shares to charitable organizations			14
Revaluation of convertible preferred stock warrant liability and write off of call option liability	(1,682)	9	(254)
Realized gain on sale of investments			(29)
Loss on disposal of property and equipment			5
Changes in operating assets and liabilities:			
Prepaids and other assets	1,339	(18)	790
Restricted cash			(205)
Accounts payable	765	125	1,308
Accrued liabilities	(224)	(253)	(1,134)
Deferred rent	(44)	(44)	200
Net cash used in operating activities	(1,375)	(3,552)	(64,111)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(32)	4	(2,401)
Purchase of investments	(3,041)	(443)	(48,341)
Proceeds from sale of investments	636		45,360
Net cash used in investing activities	(2,437)	(439)	(5,382)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from initial public offering, net of costs	35,208		35,208
Proceeds from the issuance of long-term debt			12,621
Payment of long-term debt	(1,245)	(1,144)	(9,169)
Proceeds from issuance of convertible promissory notes			9,000
Proceeds from issuance of common stock upon exercise of options			98
Proceeds from issuance of convertible preferred stock, net of issuance costs		76	54,941
Net cash provided by (used in) financing activities	33,963	(1,068)	102,699
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	30,151	(5,059)	33,206
CASH AND CASH EQUIVALENTS Beginning of period	3,055	7,150	

CASH AND CASH EQUIVALENTS End of period	$ 33,206	$ 2,191	$ 33,206
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 82	$ 183	$ 1,822
NONCASH INVESTING AND FINANCE 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

See notes to condensed financial statements.

Table of Contents

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, 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 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 March 31, 2011. In addition, the Company had an accumulated deficit of $71.8 million and $68.6 million as of March 31, 2011 and December 31, 2010. Through March 31, 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 and cash equivalents including the net proceeds of $35.2 million from its initial public offering, or IPO, in February 2011, as detailed below, and the interest earned thereon, will be sufficient to fund the Company s current operations through the second quarter of 2012. The Company will need to raise additional funding or otherwise enter into collaborations to complete the third ARX-01 Phase 3 clinical trial required to submit a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, for ARX-01. 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 Securities and Exchange Commission. 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, the unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods indicated.

The condensed balance sheet as of December 31, 2010 is 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, filed with the Securities and Exchange Commission on March 30, 2011, but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

The unaudited condensed financial statements and the accompanying notes should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2010. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for any other interim period or for the full year ending December 31, 2011. 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.

Table of Contents

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 an amended and restated certificate of incorporation effecting a 1-for-4 reverse stock split of the Company s issued and outstanding shares of common stock and convertible preferred stock and on January 28, 2011, the Company filed an amended and restated certificate of incorporation effecting the 1-for-4 reverse stock split. The par value of the common and convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options for common stock, convertible preferred stock, warrants 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 $35.2 million in net proceeds from the IPO, after deducting an estimated $4.8 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 common stock. The 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 Company s 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 common stock immediately prior to the closing of the Company s 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. Such management estimates include the fair value of common stock, stock-based compensation expense, valuation of deferred tax assets and the fair value of convertible preferred stock warrants. The Company bases its estimates on historical experience and also on assumptions that it believes are reasonable, however, actual results could differ from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and restricted cash. The Company is exposed to credit risk in the event of default by the institutions holding the cash, cash equivalents and investments to the extent of the amounts recorded on the balance sheet. Cash, cash equivalents, short-term investments and restricted cash are invested with banks and other financial institutions in the United States and are only invested in high-credit quality instruments. Such deposits may be in excess of insured limits provided on such deposits.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Recently Issued Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board, or FASB, issued an amendment to an accounting standard which requires new disclosures for fair value measurements and provides clarification for existing fair value disclosure requirements. The amendment will require an entity to disclose separately the amounts of significant transfers in and out of Levels I and II fair value measurements and to describe the reasons for the transfers; and to disclose information about purchases, sales, issuances and settlements separately in the reconciliation for fair value measurements using significant unobservable inputs, or Level III inputs. This amendment clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and require disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level II and Level III inputs. This guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level III activity disclosure requirements that are effective for reporting periods beginning after December 15, 2010. The adoption of this amendment during the three months ended March 31, 2011 did not impact the Company s financial position or results of operations.

2. Cash, Cash Equivalents and Short-Term Investments

Cash, cash equivalents and short-term investments consist of the following (in thousands):

	As of March 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	$ 39	$	$	$ 39
Money market funds	292			292
U.S. government agency obligations	6,861			6,861
Commercial Paper	29,046			29,046
	$ 36,238	$	$	$ 36,238

	As of December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	$ 103	$	$	$ 103
Money market funds	79			79
U.S. government agency obligations	3,500			3,500
	$ 3,682	$	$	$ 3,682

As of March 31, 2011 and December 31, 2010, the contractual maturity of all investments held was less than one year.

3. Fair Value of Financial Instruments

Fair Value of Financial Instruments

The Company measures and reports its cash equivalents, short-term 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.

Table of Contents

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. If quoted market prices are not available for the specific security, then 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. Level III liabilities measured at fair value on a recurring basis consisted of convertible preferred stock warrant liabilities and call option liabilities. 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. Immediately prior to the closing of the Company s IPO, the convertible preferred stock warrants were either converted into warrants to purchase common stock or exercised into shares of convertible preferred stock, which shares where automatically converted into common stock.

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 March 31, 2011			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 292	$ 292	$	$
U.S. government agency obligations	6,861		6,861	
Commercial Paper	29,046		29,046	
Total assets measured at fair value	$ 36,199	$ 292	$ 35,907	$

	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

9

Table of Contents

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):

	Three Months Ended March 31, 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)
Fair value end of period	$

4. Long-Term Debt

Loan and Security Agreement

In September 2008, the Company entered into a $12.0 million loan and security agreement with Pinnacle Ventures L.L.C., or Pinnacle Ventures. In November 2008, the Company drew down all $12.0 million of the loan facility. The loan is repayable over 36 months, carries an interest rate of 8.5% per annum and is collateralized by the Company s tangible assets and proceeds from intellectual property. An additional $600,000 will be due as a final payment at the end of the loan term in November 2011, representing a 5.0% final payment fee. The final payment is being accreted on an effective interest basis over the term of the loan agreement. As of March 31, 2011 and December 31, 2010, the Company accrued $541,000 and $507,000 relating to this final payment, which is classified as a component of long-term debt in the condensed balance sheet. During the three months ended March 31, 2011, the Company made regular payments on the loan and security agreement of $1.2 million. As of March 31, 2011 and December 31, 2010, the Company had outstanding borrowings under the loan and security agreement of $4.0 million and $5.2 million.

During the three months ended March 31, 2011 and 2010, amortization of the deferred financing cost to interest expense was $4,000 and $4,000. As of March 31, 2011 and December 31, 2010, deferred financing cost on the condensed balance sheets related to this loan and security agreement was $12,000 and $16,000.

5. Convertible Notes

2010 Convertible Notes

On September 14, 2010, the Company sold convertible promissory notes, or 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 earliest of (1) September 14, 2011 or (2) an event of default. In connection with the Company s IPO in February 2011, 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 Company s IPO.

Table of Contents

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 IPO, merger or sale 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 an IPO by the Company. 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. These warrants expire in March 2017. 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. In connection with the Company s IPO in February 2011, the Series A warrants were automatically converted into warrants to purchase 3,425 shares of common stock. Immediately before the conversion to common stock warrants, the Series A warrants were remeasured to fair value with the immaterial change in the fair value of these warrants being recorded as other income (expense), net during the three months ended March 31, 2011. Immediately after the conversion to common stock warrants, the remaining liability of $13,000 was reclassified to additional paid-in capital. The Company revalued the convertible preferred stock warrant liability related to the Series A warrants during each reporting period using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2011	2010
Expected term (in years)	6.1	7.0
Risk-free interest rate	2.6%	1.9%
Expected volatility	80%	82%
Expected dividend rate	0%	0%

The fair value of the liability related to the Series A warrants was estimated to be $13,000 and $13,000 as of the IPO date in February 2011 and December 31, 2010. The change in the fair value of the Series A warrants during the three months ended March 31, 2011 and 2010 was insignificant. These common stock warrants will no longer be recorded as liabilities and will, therefore, no longer be remeasured as of the end of each reporting period. As of March 31, 2011, the 3,425 common stock warrants had not been exercised and were still outstanding.

Table of Contents

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 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 Series C warrants. 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. These warrants expire in September 2018. 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 with the following assumptions:

	Three Months Ended March 31,	
	2011	2010
Expected term (in years)	7.6	8.5
Risk-free interest rate	2.6%	2.2%
Expected volatility	80%	83%
Expected dividend rate	0%	0%

The fair value of the convertible preferred stock warrant liability related to these Series B 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. The change in the fair value of the warrants resulted in a charge to other income (expense), net of $9,000 during the three months ended March 31, 2010 and a benefit to other income (expense), net of $323,000 during the three months ended March 31, 2011. These common stock warrants will no longer be recorded as liabilities and will, therefore, no longer be remeasured as of the end of each reporting period. As of March 31, 2011, the 228,264 common stock warrants had not been exercised and were still outstanding.

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 (1) shares of convertible preferred stock sold in the Company s next equity financing with proceeds in excess of $15.0 million with an exercise price equal to the price of the convertible preferred stock sold in such equity financing or (2) shares of Series C at a price per share of the Series C (x) if the next equity financing with proceeds in excess of $15.0 million had not occurred prior to September 14, 2011, upon the election of holders of a majority of the aggregate principal amount of the 2010 Convertible Notes or (y) in the event of the IPO, a liquidation, sale of substantially all of the Company s assets, or merger. Each 2010 Warrant was exercisable for a number of shares equal to the quotient obtained by dividing 25% of the principal amount of the 2010 Convertible Note to which such 2010 Warrants related by the applicable per share price indicated above. The 2010 Warrants would have terminated if not exercised immediately prior to an IPO. The 2010 Warrants allowed for cashless exercises.

In order to determine a fair value for the 2010 Warrants on each respective measurement date, the Company evaluated multiple potential outcomes using the intrinsic value or Black-Scholes value depending on the scenario and discounted these values back to the appropriate date

while applying estimated probabilities to each scenario value. These scenarios included a potential IPO or potential merger or sale at different times during 2011 and 2012 as well as remaining private with estimated future qualifying equity financings. Accordingly, the Company determined the fair value of the 2010 Warrants to be $1.2 million upon issuance, 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 Company s IPO in February 2011, 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 Company s 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.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

7. Commitments and Contingencies

Operating Leases

In January 2007, the Company entered into a non-cancelable lease agreement for office and laboratory facilities in Redwood City, California. The lease term commenced in April 2007 and expires in April 2012. Rental expense from the facility lease is recognized on a straight-line basis from the inception of the lease in January 2007, the early access date, through the end of the lease. Rent expense was $39,000 and $39,000 during the three months ended March 31, 2011 and 2010. Future minimum payments under the lease agreement as of March 31, 2011 are as follows (in thousands):

Year Ending December 31:	
2011 (remainder)	$ 263
2012	97
Total minimum payments	$ 360

During 2007, the landlord provided a tenant improvement allowance of $746,000 to the Company to complete the office and lab facility. The Company has recorded the tenant improvement allowance paid by the landlord as a leasehold improvement asset and a deferred rent liability on the balance sheet. The allowance is amortized as a credit to rent expense over the term of the lease, and the leasehold improvements are amortized as depreciation expense over the period from when the improvements were placed in service until the end of their useful life, which is the end of the lease term. As of March 31, 2011 and December 31, 2010, the Company has an unamortized tenant improvement allowance of $199,000 and $245,000.

Litigation

The Company is not a party to any litigation and does not have contingent reserves established for any litigation liabilities.

8. Stock-Based Compensation

Stock Option and Equity Incentive Plans

2006 Stock Plan

As of December 31, 2010, the Company had one stock-based compensation plan, the 2006 Stock Plan, or the 2006 Plan. In August 2006, the Company established the 2006 Plan in which 342,000 shares of common stock were originally reserved for the issuance of incentive stock options, or ISOs, and nonstatutory stock options, or NSOs, to employees, directors or consultants of the Company. In February 2008, an additional 375,000 shares of common stock were reserved for issuance under the 2006 Plan and, in November 2009, an additional 1,376,059 shares of common stock were reserved for issuance under the 2006 Plan. Pursuant to the 2006 Plan, the exercise price of ISOs and NSOs granted to a stockholder who at the time of grant owns stock representing more than 10% of the voting power of all classes of the stock of the Company could not be less than 110% of the fair value per share of the underlying common stock on the date of grant.

The Company s stock options under the 2006 Plan generally vest over four years at a rate of 25% on the first anniversary and 1/48 per month thereafter. The stock options generally expire ten years from the date of grant. However, in the case of an ISO issued to an optionee who at the time of grant owned stock representing more than 10% of the voting power of all classes of the stock of the Company, the term of the option could be no more than five years. Stock bonus awards and rights to immediately purchase stock were also permitted to be granted under the 2006 Plan, with terms, conditions and restrictions determined by the board of directors. Effective upon the execution and delivery of the underwriting agreement for the Company s IPO, no additional stock options or other stock awards may be granted under the 2006 Plan.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

2011 Equity Incentive Plan

In January 2011, the board of directors adopted, and the Company s stockholders approved, the 2011 Equity Incentive Plan, or 2011 Plan, as a successor to the 2006 Plan. The 2011 Plan became effective immediately upon the execution and delivery of the underwriting agreement for the IPO on February 10, 2011. As of February 10, 2011, no more awards may be granted under the 2006 Plan, although all outstanding stock options and other stock awards previously granted under the 2006 Plan will continue to remain subject to the terms of the 2006 Plan. The 51,693 shares reserved under the 2006 Plan that remained available for future grant at the time of the IPO were transferred to the share reserve of the 2011 Plan. Shares granted under the 2006 Plan that are forfeited will not be added to the shares available for grant under the 2011 Plan.

The initial aggregate number of shares of the Company s common stock that may be issued pursuant to stock awards under the 2011 Plan is 1,875,000 shares, which number was the sum of (i) 51,693 shares remaining available for future grant under the 2006 Plan at the time of the execution and delivery of the underwriting agreement for the Company s IPO, and (ii) an additional 1,823,307 new shares. Then, the number of shares of common stock reserved for issuance under the 2011 Plan will automatically increase on January 1st each year, starting on January 1, 2012 and continuing through January 1, 2020, by 4% of the total number of shares of the Company s common stock outstanding on December 31 of the preceding calendar year, or such lesser number of shares of common stock as determined by the board of directors.

Pursuant to the 2011 Plan, the exercise price of ISOs and NSOs granted to a stockholder who at the time of grant owns stock representing more then 10% of the voting power of all classes of the stock of the Company cannot be less the 110% of the fair value per share of the underlying common stock on the date of grant.

The Company s stock options under the 2011 Plan generally vest over four years at a rate of 25% on the first anniversary and 1/48th per month thereafter. The stock options generally expire ten years from the date of the grant. However, in the case of an ISO issued to an optionee who at the time of the grant owned stock representing more than 10% of the voting power of all classes of the stock of the Company, the term of the option cannot be more than five years.

The following table summarizes option activity under the 2006 Plan and the 2011 Plan during the three months ended March 31, 2011:

	Shares Available for Grant	Number of Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding January 1, 2011	51,693	2,008,797	$ 2.91	8.3	$ 7,171
Additional options authorized	1,823,307				
Options granted	(444,958)	444,958	3.45		
Restricted Stock Units granted	(343,815)				
Options forfeited		(30,758)	2.55		
Outstanding March 31, 2011	1, 086,227	2,422,997	$ 3.02	8.7	$ 1,703
Vested options March 31, 2011		919,313	$ 2.71	7.7	$ 941
Vested and expected to vest March 31, 2011		2,422,997	$ 3.02	8.7	$ 1,703

Exercisable	March 31, 2011	919,313	$ 2.71	7.7	$	941

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Additional information regarding the Company s stock options outstanding and exercisable as of March 31, 2011 is summarized below:

	Options Outstanding			Options Exercisable	
Exercise Prices	Number of Stock Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price per Share	Shares Subject to Stock Options	Weighted-Average Exercise Price per Share
$1.20 - $2.56	1,061,666	8.3	$ 2.20	667,354	$ 2.06
$2.56 - $4.00	1,060,590	9.2	$ 3.15	152,828	$ 3.73
$5.32 - $5.52	300,741	8.6	$ 5.44	99,131	$ 5.52
	2,422,997	8.7	$ 3.02	919,313	$ 2.71

In March 2011, the Company granted 343,815 Restricted Stock Units, or RSUs, to employees and directors under the 2011 Plan. The fair value of the RSUs was determined on the date of grant based on the market price of the Company s common stock. The fair value of the RSUs is recognized as expense ratably over the vesting period, which is generally three years.

The Company s RSUs generally vest 25% on the 6 month anniversary of the vesting commencement date, 25% on the 12 month anniversary of the vesting commencement date, 25% on the 24 month anniversary of the vesting commencement date and 25% on the 36 month anniversary of the vesting commencement date, so long as the RSU recipient continues to provide services to the Company.

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company and its board of directors using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Valuation Method The Company estimates the fair value of its stock options using the Black-Scholes option-pricing model.

Expected Term The expected term represents the period that the stock-based awards are expected to be outstanding. For option grants that are considered to be plain vanilla, the Company used the simplified method to determine the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options

Expected Volatility The expected volatility was based on the historical stock volatilities of several of the Company s publicly listed peers over a period approximately equal to the expected terms of the options as the Company did not have a sufficient trading history to use the volatility of its own common stock.

Fair Value of Common Stock The fair value of the common stock underlying the stock options has historically been determined by the Company s board of directors. Because there had been no public market for the Company s common stock prior to the Company s IPO, the board of directors determined the fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including valuations of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, lack of liquidity of capital stock and general and industry-specific economic outlook, amongst other factors. The fair value of the

underlying common stock was determined by the board of directors until such time that the Company s common stock became listed on the NASDAQ Global Market.

Risk-Free Interest Rate The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term of the options.

Table of Contents

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements (Continued)

(Unaudited)

Expected Dividend The expected dividend has been zero as the Company has never paid dividends and does not expect to pay dividends.

Forfeiture Rate The Company estimates its forfeiture rate based on an analysis of its actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. The impact from a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from that estimated by the Company, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Summary of Assumptions The fair value of each employee stock option was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions during the three months ended March 31, 2011 (no options were granted during the three months ended March 31, 2010):

	Three Months Ended March 31, 2011
Expected term (in years)	6.25
Risk-free interest rate	2.5%
Expected volatility	80%
Expected dividend rate	0%

2011 Employee Stock Purchase Plan

In January 2011, the board of directors adopted, and the Company s stockholders approved, the 2011 Employee Stock Purchase Plan, or the ESPP, which also became effective immediately upon the execution and delivery of the underwriting agreement for the IPO.

Initially, 250,000 shares of common stock were authorized for issuance under the ESPP pursuant to purchase rights granted to the Company s employees or to employees of any of its designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1st each year, starting January 1, 2012 and continuing through January 1, 2020, in an amount equal to the lower of (1) 2% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (2) a number of shares of common stock as determined by the board of directors. If a purchase right granted under the ESPP terminates without having been exercised, the shares of common stock not purchased under such purchase right will be available for issuance under the ESPP.

During the three months ended March 31, 2011, compensation expense related to the ESPP was immaterial.

9. Net Loss per Share of Common Stock

The following table sets forth the computation of the Company s basic and diluted net loss per share of common stock during the three months ended March 31, 2011 and 2010 (in thousands, except for share and per share amounts):

	Three Months Ended March 31, 2011	2010
Net loss	$ (3,204)	$ (3,673)
	10,742,182	629,006

Shares used in computing net loss per share of common stock, basic and diluted		
Net loss per share of common stock, basic and diluted	$ (0.30)	$ (5.85)

Table of Contents

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:

	Three Months Ended March 31,	
	2011	2010
Convertible preferred stock (as-if converted)		7,151,802
Stock options to purchase common stock	2,422,997	640,834
RSUs	343,815	
Restricted shares of common stock subject to repurchase		17,032
Convertible preferred stock warrants (as-if converted)		230,764
Common stock warrants	231,689	

10. Income Taxes

The Company did not record a provision for income taxes during the three months ended March 31, 2011 and 2010.

As of March 31, 2011 and December 31, 2010, the Company had $603,000 and $603,000 of unrecognized tax benefits related to tax positions taken in prior periods, all of which would impact the Company s effective tax rate if recognized. Accrued interest and penalties related to unrecognized tax benefits are classified as income tax expense and were immaterial. The Company files income tax returns in the United States and in California. The tax years 2005 through 2008 remain open in both jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other foreign jurisdictions.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed financial statements and notes to condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part II Item 1A Risk Factors included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations see Cautionary Note Regarding Forward-Looking Statements that appears at the end of this discussion. These statements, like all statements in this report, speak only as of their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

The interim condensed financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2010 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2010, filed with the SEC on March 30, 2011.

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 two 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.

We are a development stage company with a limited operating history. We have funded our operations through March 31, 2011 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 March 31, 2011, we have received net proceeds of $54.9 million from the sale of convertible preferred stock and $21.6 million from proceeds of 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 $35.2 million, after underwriting discounts, commissions and offering expenses totaling $4.8 million. As of March 31, 2011, we had $4.0 million of debt outstanding related to our loan and security agreement.

Since our inception in July 2005, we have not generated any revenue from the sale of our products and do not anticipate generating any revenues for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. Our net losses were $3.2 million and $3.7 million during the three months ended March 31, 2011 and 2010. As of March 31, 2011, we had an accumulated deficit of $71.8 million.

18

Table of Contents

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. As of March 31, 2011, our principal sources of liquidity were our cash, cash equivalents and short-term investments, which totaled $36.2 million.

We expect to incur significant and increasing expenses over the next several years, principally to develop ARX-01, including completion of the first two planned Phase 3 clinical trials, as well as to further increase our spending to manufacture, sell and market our product candidates. For example, we continue to make progress toward initiating the first Phase 3 clinical trial as we have manufactured NanoTabs for all three Phase 3 studies and are in the process of manufacturing components for the ARX-01 device. In addition, we have selected the contract research organization, or CRO, to conduct the first two planned Phase 3 trials. Contingent on our ability to secure additional funding, we plan to complete the third planned ARX-01 Phase 3 clinical trial required to submit an NDA to the FDA. In addition, based on the availability of additional financial resources, we plan to advance ARX-02 into Phase 3 trials, submit an NDA to the FDA and commercialize it ourselves or with a partner in the United States. Further development of ARX-03 will depend on the identification of a partner to support this effort. Furthermore, as a result of our IPO in February 2011, 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 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.

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 consist 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. 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, and subsequently advance the development of ARX-02 and ARX-03.

Prior to January 1, 2009, we did not track our research and development costs including personnel and personnel-related costs on a project-by-project basis. Our development resources are shared among all of our programs. Since January 1, 2009, we have tracked external development expenses on a program-by-program basis. 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 months ended March 31, 2011 and 2010 (in thousands):

	Three months ended March 31,	
	2011	2010
ARX-01	$ 751	$ 68
ARX-02		268
ARX-03		1,140
Overhead	1,195	1,285
Total research and development expenses	$ 1,946	$ 2,761

Table of Contents

Due to the inherently unpredictable nature of product development, we are unable to estimate the costs we will incur in the continued development of ARX-01, ARX-02 and ARX-03. Development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing ARX-01, 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 two of our planned ARX-01 Phase 3 clinical trials, and subject to additional funding, our third Phase 3 clinical trial required to submit an NDA to the FDA.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation for personnel in administration, finance and business development. Other significant expenses include 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 Income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments.

Interest Expense

Interest expense consists primarily of interest accrued or paid on our loan and security agreement and our then-outstanding convertible notes and amortization of debt discount.

Other Income (Expense), net

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 in February 2011, 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.

Table of Contents

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 and have not changed substantially in the three months ended March 31, 2011 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Three Months Ended March 31, 2011 and 2010

Revenue

To date, we have not generated any 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.

Research and Development Expenses (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010		
Research and development expenses	$ 1,946	$ 2,761	$ (815)	(30)%

The $0.8 million decrease during the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 was primarily attributable to a decrease of $1.4 million in development expenses related to our ARX-02 and ARX-03 development programs which were completed in early 2010, offset by an increase of $0.6 million in engineering development expenses related to our ARX-01 development program in the three months ended March 31, 2011.

General and Administrative Expenses (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010		
General and administrative expenses	$ 1,589	$ 672	$ 917	136%

The $0.9 million increase during the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 was primarily due to an increase in legal, audit and consulting fees in connection with our annual audit and newly required SEC filings.

Interest Income (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010		
Interest income	$ 8	$ 2	$ 6	300%

The $6,000 increase during the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 was due to the increase in our average cash, cash equivalent and short-term investment balances resulting from the proceeds of our IPO.

Table of Contents

Interest Expense (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010		
Interest expense	$ 1,359	$ 244	$ 1,115	457%

The $1.1 million increase during the three months ended March 31, 2011 as compared to the three months ended March 31, 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, or the 2010 notes. The $1.1 million in unamortized debt discounts was recognized as interest expense during the three months ended March 31, 2011 in connection with conversion of these notes immediately prior to the IPO.

Other Income (Expense), net (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010		
Other income (expense), net	$ 1,682	$ (6)	$ 1,688	*%

The $1.7 million change in other income (expense), net during the three months ended March 31, 2011 as compared to the three months ended March 31, 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 2010 notes upon the expiration of the call option.

Liquidity and Capital Resources

We have funded our operations to date primarily with the proceeds from the sale of our securities and the proceeds received from our debt financings. To date, we have not generated any revenue from the sale of our product candidates and do not anticipate generating any revenues for the foreseeable future. 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 March 31, 2011, our cash, cash equivalents and short-term investments totaled $36.2 million and we had working capital of $31.2 million. In February 2011, we completed our IPO selling 8,000,000 shares at $5.00 per share and received net proceeds of $35.2 million, after underwriting discounts, commissions and offering expenses totaling $4.8 million. We believe that our current cash and cash equivalents, including the net proceeds of $35.2 million from our IPO in February 2011, and the interest earned thereon, will be sufficient to fund our current operations through the second quarter of 2012. However, 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.

From inception through March 31, 2011, we have received net proceeds of $54.9 million from the sale of convertible preferred stock and $21.6 million from our debt agreements. In February 2011, we completed our IPO selling 8,000,000 shares at $5.00 per share and received net proceeds of $35.2 million. As of March 31, 2011, we had $4.0 million of debt outstanding related to our loan and security agreement.

While we believe that our current cash and cash equivalents will be sufficient to fund our current operations through the second quarter of 2012, we may raise additional funds within this period of time through collaborations, or by undertaking public or private debt or equity financings. Our existing capital resources will not be sufficient to enable us to fund our third Phase 3 trial for ARX-01 and, if we choose, to initiate clinical trials for our product candidates other than ARX-01. We will need to raise substantial additional capital to fund our operations, continue to develop our product candidates and commercialize and market our product candidates.

Table of Contents

The sale of additional equity securities could result in additional dilution to our stockholders and those securities may have rights senior to those of our common stock. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot assure you that financing will be available in the amounts we need or on terms acceptable to us, if at all. We currently have no commitments for future external financing.

Cash Flows

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

	Three Months Ended March 31,	
	2011	2010
Net cash used in operating activities	$ (1,375)	$ (3,552)
Net cash used in investing activities	(2,437)	(439)
Net cash provided by (used in) financing activities	33,963	(1,068)

Cash Flows from Operating Activities

Net cash used in operating activities amounted to $1.4 million and $3.6 million for the three months ended March 31, 2011 and 2010. The primary use of cash for our operating activities during these periods was to fund the development of our product candidates. Our cash used for operating activities also reflected changes in our working capital and adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, interest expense related to our debt financings, and the revaluation of our convertible preferred stock warrant liability.

Cash used in operating activities of $1.4 million during the three months ended March 31, 2011 reflected a net loss of $3.2 million, partially offset by a net change of $1.8 million in our net operating assets and liabilities. In addition, we had non-cash charges of $1.2 million for interest on our debt, $0.1 million of depreciation and amortization and $0.3 million in stock-based compensation which were offset by $1.7 million of non-cash benefits for the revaluation of the warrant liability and the write off of the call option liability. The net change in our operating assets and liabilities was primarily a result of a decrease in prepaid expenses of $1.3 million and an increase in accounts payable of $0.8 million.

Cash used in operating activities of $3.6 million during the three months ended March 31, 2010 reflected a net loss of $3.7 million, partially offset by aggregate non-cash charges of $0.3 million and a net change of $0.2 million in our net operating assets and liabilities. Non-cash charges primarily included $0.1 million of depreciation and amortization and $0.1 million in stock-based compensation. The net change in our operating assets and liabilities was primarily a result of an increase in accrued liabilities of $0.3 million.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales of our available-for-sale investments. To date, we have not had significant capital expenditures and we do not have any significant capital expenditures currently planned.

During the three months ended March 31, 2011, cash used in investing activities of $2.4 million was primarily as a result of $0.6 million in proceeds from sale of investments, partially offset by $3.0 million used for purchases of our investments.

During the three months ended March 31, 2010, cash used in investing activities of $0.4 million was primarily as a result of $0.4 million used for purchases of our investments.

Table of Contents

Cash Flows from Financing Activities

To date, we have financed our operations primarily with the proceeds from the sale of our securities and the proceeds received from our debt financings. As of March 31, 2011, we had outstanding debt of $4.0 million. During the three months ended March 31, 2011, and in conjunction with our IPO, the outstanding principal amount of $8.0 million and accrued interest under the 2010 notes converted into 2,034,438 shares of common stock.

During the three months ended March 31, 2011, cash provided by financing activities of $34.0 million was primarily a result of the receipt of $35.2 million in proceeds from our IPO, net of offering costs, partially offset by principal repayments on our long-term debt of $1.2 million.

During the three months ended March 31, 2010, cash used in financing activities of $1.2 million was primarily a result of principal repayments on our long-term debt of $1.2 million.

Contractual Obligations

We are obligated to make principal and interest payments on our loan and security agreement entered into in September 2008. As of March 31, 2011, our obligation to make principal, interest, and other payments on debt outstanding under the loan and security agreement total $4.1 million through November 2011 at which time the total loan and security agreement will be paid in full.

As of March 31, 2011, we had operating lease obligations totaling $0.4 million for our office and laboratory facilities in Redwood City, California, which lease expires in 2012.

Off-Balance Sheet Arrangements

Through March 31, 2011, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board, or FASB, issued an amendment to an accounting standard which requires new disclosures for fair value measurements and provides clarification for existing fair value disclosure requirements. The amendment will require an entity to disclose separately the amounts of significant transfers in and out of Levels I and II fair value measurements and to describe the reasons for the transfers; and to disclose information about purchases, sales, issuances and settlements separately in the reconciliation for fair value measurements using significant unobservable inputs, or Level III inputs. This amendment clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and require disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level II and Level III inputs. This guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level III activity disclosure requirements that are effective for reporting periods beginning after December 15, 2010. The adoption of this amendment during the three months ended March 31, 2011 did not impact our financial position or results of operation.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (including documents incorporated by reference) and other written and oral statements we make from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, but not limited to, statements related to our goals, plans, expectations and projections regarding our financial position, results of operations, cash flows, financial outlook, the cost and timing of our clinical trials, product candidate development, product approvals and other regulatory matters, and the sufficiency of our cash resources and need for additional capital. You can identify these forward-looking statements by the fact they use words such as expect, anticipate, estimate, may, intend, plan, believe and other words of similar meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. Our actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: the success, cost and timing of our product development activities and clinical trials; our ability to obtain and maintain regulatory approval of our product candidates; our ability to obtain funding for our operations; our plans to research, develop and commercialize our product candidates; our ability to attract collaborators with development, regulatory and commercialization expertise; the accuracy of our estimates regarding expenses, capital requirements and needs for financing; and other risks detailed under Part II Item 1A Risk Factors included elsewhere

in this report.

Table of Contents

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.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our outstanding debt obligations. Our cash, cash equivalents and investment accounts as of March 31, 2011 and December 31, 2010 totaled $36.2 million and $3.7 million and consisted primarily of cash, money market funds and U.S. government obligations with maturities of less than one year from the date of purchase. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or our results of operations.

As of March 31, 2011, we had debt obligations outstanding under a loan and security agreement totaling $4.0. The entire outstanding principal and accrued interest under the 2010 notes converted into common stock in connection with our IPO in February 2011. Our obligations under the loan and security agreement carry interest rates that are fixed and are not subject to fluctuations. However, to the extent in the future we enter into other long-term debt arrangements, we would be subject to fluctuations in interest rates which could have a material impact on our future financial condition and results of operations.

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, 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 U.S. Securities and Exchange Commission Rule 13a-15(b), 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. 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.

Table of Contents

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the three months ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Form 10-Q. If any of the following risks comes to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

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 two additional product candidates, the Sufentanil NanoTab BTP Management System, or ARX-02, and the Sufentanil/Triazolam NanoTab, or ARX-03. We have incurred significant net losses in each year since our inception in July 2005, including net losses of $3.2 million and $3.7 million during the three months ended March 31, 2011 and 2010. As of March 31, 2011, we had an accumulated deficit of $71.8 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 revenue and may never be profitable.

Our ability to generate revenue 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. 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;

27

Table of Contents

launching and commercializing ARX-01, including building a hospital-directed sales force and collaborating with third parties; and

completing the clinical development, obtaining regulatory approval, launching and commercializing ARX-02 and ARX-03, 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 which 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. For example, we have manufactured NanoTabs for all three Phase 3 studies and are in the process of manufacturing components for the ARX-01 device. As of March 31, 2011, we had working capital of approximately $31.2 million. Although we raised $35.2 million in net proceeds in our initial public offering, or IPO, 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.

We believe that our current cash and cash equivalents will be sufficient to fund our current operations through the second quarter of 2012. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expected. We will need to raise additional funding or otherwise enter into collaborations to complete the third ARX-01 Phase 3 clinical trial required to submit an NDA to the FDA and, if we choose, to initiate clinical trials for our product candidates other than ARX-01. 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.

Table of Contents

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, including completing the third ARX-01 Phase 3 clinical trial required to submit an NDA to the FDA, 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.

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. Contingent on our ability to secure additional funding, we plan to begin a third Phase 3 clinical trial in the second half of 2012. We intend to use these trials as a basis to submit an NDA for ARX-01. 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 an End of Phase 2 meeting for each of our three product candidates. 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.

Table of Contents

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 early 2012. 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, including the inability to secure additional funding to complete the third ARX-01 Phase 3 clinical trial required to submit an NDA;
- delays in pharmacokinetic studies required prior to Phase 3 initiation;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- 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 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 Phase 3 trials 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 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.

Table of Contents

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 ARX-01 and we cannot, therefore, predict the timing of any future revenue from ARX-01.

We cannot commercialize 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 opiate 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 discovers 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.

Table of Contents

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 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 and ARX-03, 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;

Table of Contents

- 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, Covidien plc and Johnson Matthey plc. 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 a 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 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 facility to date. 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.

33

Table of Contents

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 an additional user testing study prior to 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 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 ARX-02 and ARX-03 are still under development. We cannot be certain that the dispensing components of ARX-02 and ARX-03 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 ARX-02 and ARX-03.

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

We have relied on contract manufacturers, component fabricators and secondary service providers to produce ARX-01 devices for Phase 2 clinical trials. 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 a CRO to conduct our first two Phase 3 clinical studies. 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.

Table of Contents

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.

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;
- 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.

Table of Contents

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. In addition, without a partnership, we will bear all the risk related to the development of ARX-02 or ARX-03. 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 or ARX-03 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.

Table of Contents

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 may also be in development as an IV product for PCA administration.

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.

Table of Contents

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. 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, we purchase sufentanil in the United States and ship 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 to export drug out of the United States and import NanoTabs into the United States. 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 from or imported into 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, civil penalties or criminal prosecution and delays in conducting our clinical trials.

Table of Contents

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. However, we cannot rely on the Patheon facility located in Toronto for commercial manufacturing of sufentanil because the DEA requires that sufentanil be manufactured in the United States if our product candidates are marketed in the United States.

We have identified potential commercial manufacturers for ARX-01 in the United States. However, 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.

Table of Contents

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

As of March 31, 2011, we had 18 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.

Table of Contents

In addition, there can be no assurance that our pending patent applications will result in issued patents. As of March 31, 2011, we are the owner of record and are pursuing 15 U.S. non-provisional patent applications, three pending international Patent Cooperation Treaty applications and 39 foreign national and ten European regional counterpart patent applications 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 on April 21, 2011. To date, there has been no indication that the patent has been opposed, and we are awaiting formal notification from the European patent authority that the opposition period ended with no opposition filed. Should an opposition come to our attention, we will need to spend considerable time and resources to defend our granted claims.

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.

Table of Contents

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 to remind us to pay periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees, and we employ an outside firm, Cooley LLP, or Cooley, in Washington, DC, to pay these 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. We employ Cooley and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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.

42

Table of Contents

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 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;

Table of Contents

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 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 May 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 Securities and Exchange Commission, or 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.

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.

Table of Contents

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 May 1, 2011, we had 19,371,750 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 16,171,750 of the shares outstanding as of May 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 May 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.

Table of Contents

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.

Table of Contents

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

Unregistered Sales of Equity Securities

All shares of our convertible preferred stock that were outstanding at the time of our IPO, including 2,111,639 shares of our Series A convertible preferred stock, 1,263,635 shares of our Series B convertible preferred stock, and 3,776,528 shares of Series C convertible preferred stock, converted into a total of 8,555,713 shares of our common stock upon the completion of our IPO. Each share of Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock converted into 1.37, 1.50 and 1.00 share(s) of common stock.

All warrants to purchase shares of our convertible preferred stock that were outstanding at the time of our IPO, including warrants to purchase 2,500 shares of Series A convertible preferred stock and warrants to purchase 228,264 shares of Series C convertible preferred stock, were converted into warrants to purchase 231,678 shares of common stock. In each of these warrant conversions, each share of Series A convertible preferred stock and Series C convertible preferred stock underlying each applicable warrant converted into 1.37 and 1.00 share(s) of common stock.

In September 2010, in connection with a bridge loan financing, we granted warrants to purchase an aggregate of $2.0 million of our preferred stock to eight purchasers. In connection with our IPO, these warrants became warrants to purchase 507,245 shares of our Series C convertible preferred stock at an exercise price of approximately $3.94 per share. These warrants were net exercised for an aggregate of 107,246 shares of our Series C convertible preferred stock, which shares automatically converted into 107,246 shares of our common stock immediately prior to our IPO.

In September 2010, in connection with a bridge loan financing, we issued convertible promissory notes to eight purchasers for an aggregate principal amount of $8.0 million. Upon completion of our IPO, the outstanding principal and accrued interest under these convertible promissory notes converted into 2,034,438 shares of our common stock at a conversion price equal to $4.00 per share.

The issuances of securities described above were exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, in reliance on Section 4(2) of the Securities Act, and Regulation D promulgated thereunder, as transactions by an issuer not involving any public offering. The purchasers of the securities in these transactions represented that they were accredited investors and that they were acquiring the securities for investment only and not with a view toward the public sale or distribution thereof. Such purchasers received written disclosures that the securities had not been registered under the Securities Act, and that any resale must be made pursuant to a registration statement or an available exemption from registration. All purchasers either received adequate financial statement or non-financial statement information about us or had adequate access, through their relationship with us, to financial statement or non-financial statement information about us. The sale of these securities was made without general solicitation or advertising.

The share and per share information above gives effect to a 1-for-4 reverse stock split of our common stock and preferred stock that became effective on January 28, 2011.

Use of Proceeds

On February 10, 2011, our registration statement on Form S-1 (File No. 333-170594) was declared effective for our 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 March 31, 2011, the net offering proceeds have been invested in high credit quality U.S. government agency 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.

Table of Contents

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)
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.(7)
10.2	2011 Equity Incentive Plan.(8)
10.3	Forms of Stock Option Grant Notice, Stock Option Exercise Notice and Stock Option Agreement under 2011 Equity Incentive Plan.(9)
10.4	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2011 Equity Incentive Plan.(10)
10.5	2011 Employee Stock Purchase Plan.(11)
10.6	Note and Warrant Purchase Agreement between Registrant and the Purchasers defined therein, dated September 14, 2010, as amended on January 28, 2011.(12)
10.7	Compensatory Arrangements of Executive Officers.(13)
10.8	Non-Employee Director Compensation Policy.(14)
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.*

(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.

Table of Contents

(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.

(5) Incorporated herein by reference to Exhibit 4.4 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.

(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.

(7) Incorporated herein by reference to Exhibit 10.1 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.

(8) Incorporated herein by reference to Exhibit 99.3 to the Registrant s registration statement on Form S-8 (File No. 333-172409), as filed with the SEC on February 24, 2011.

(9) Incorporated herein by reference to Exhibit 10.5 to the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 30, 2011.

(10) Incorporated herein by reference to Exhibit 10.6 to the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 30, 2011.

(11) Incorporated herein by reference to Exhibit 99.6 to the Registrant s registration statement on Form S-8 (File No. 333-172409), as filed with the SEC on February 24, 2011.

(12) Incorporated herein by reference to Exhibit 10.10 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.

(13) Incorporated by reference to Item 5.02 of the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on March 8, 2011.

(14) Incorporated by reference to the information under Item 11. Executive Compensation Director Compensation Non-Employee Director Compensation of the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 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.

Table of Contents

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: May 16, 2011

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ James H. Welch
James H. Welch

Chief Financial Officer

(Duly Authorized and Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

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)
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.(7)
10.2	2011 Equity Incentive Plan.(8)
10.3	Forms of Stock Option Grant Notice, Stock Option Exercise Notice and Stock Option Agreement under 2011 Equity Incentive Plan.(9)
10.4	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2011 Equity Incentive Plan.(10)
10.5	2011 Employee Stock Purchase Plan.(11)
10.6	Note and Warrant Purchase Agreement between Registrant and the Purchasers defined therein, dated September 14, 2010, as amended on January 28, 2011.(12)
10.7	Compensatory Arrangements of Executive Officers.(13)
10.8	Non-Employee Director Compensation Policy.(14)
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.*

(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.

(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.

(5) Incorporated herein by reference to Exhibit 4.4 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.

(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.

51

Table of Contents

(7) Incorporated herein by reference to Exhibit 10.1 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.

(8) Incorporated herein by reference to Exhibit 99.3 to the Registrant s registration statement on Form S-8 (File No. 333-172409), as filed with the SEC on February 24, 2011.

(9) Incorporated herein by reference to Exhibit 10.5 to the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 30, 2011.

(10) Incorporated herein by reference to Exhibit 10.6 to the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 30, 2011.

(11) Incorporated herein by reference to Exhibit 99.6 to the Registrant s registration statement on Form S-8 (File No. 333-172409), as filed with the SEC on February 24, 2011.

(12) Incorporated herein by reference to Exhibit 10.10 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.

(13) Incorporated by reference to Item 5.02 of the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on March 8, 2011.

(14) Incorporated by reference to the information under Item 11. Executive Compensation Director Compensation Non-Employee Director Compensation of the Registrant s Annual Report on Form 10-K (File No. 001-35068), as filed with the SEC on March 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.