ACELRX PHARMACEUTICALS INC
Form 10-Q
November 05, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

or

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

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

351 Galveston Drive

Redwood City, CA 94063

(650) 216-3500

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

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

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

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

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

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

As of October 15, 2013, the number of outstanding shares of the registrant s common stock was 43,039,269.

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ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013

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Unless the context indicates otherwise, the terms AcelRx, AcelRx Pharmaceuticals, we, us and our refer to AcelRx Pharmaceuticals, Inc. ACELRX , NANOTAB and ACCELERATE, INNOVATE, ALLEVIATE are U.S registered trademarks owned by AcelRx Pharmaceuticals, Inc. Other trademarks of AcelRx Pharmaceuticals, Inc. appearing in this report, including ZALVISO, are the property of AcelRx Pharmaceuticals, Inc. This report also contains other trademarks and trade names that are the property of their respective owners.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Balance Sheets

(In thousands, except share data)

	September 30, 2013 (Unaudited)	December 31, 2012[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 60,795	$ 47,932
Investments	15,173	11,831
Prepaid expenses and other current assets	1,031	2,003
Total current assets	76,999	61,766
Property and equipment, net	3,412	2,485
Restricted cash	250	205
Other assets		64
TOTAL ASSETS	$ 80,661	$ 64,520
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,248	$ 2,235
Accrued liabilities	3,046	4,653
Long-term debt, current portion	8,134	7,443
Total current liabilities	12,428	14,331
Deferred rent	220	312
Long-term debt, net of current portion	2,385	8,530
Contingent put option liability	32	82
Warrant liability	12,391	7,418
Total liabilities	27,456	30,673
STOCKHOLDERS EQUITY:		
Common stock, $0.001 par value 100,000,000 shares authorized as of September 30, 2013 and December 31, 2012; 43,039,269 and 37,055,027 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	43	37
Additional paid-in capital	216,380	155,836
Deficit accumulated during the development stage	(163,222)	(122,027)
Accumulated other comprehensive income (loss)	4	1
Total stockholders equity	53,205	33,847
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 80,661	$ 64,520

(1) The condensed balance sheet as of December 31, 2012 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, 2012.

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Comprehensive Loss

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2013	2012	2013	2012	2013
Research grant revenue	$ 548	$ 166	$ 1,895	$ 719	$ 5,361
Operating expenses:					
Research and development	6,548	6,948	21,974	17,113	114,303
General and administrative	2,310	1,410	6,571	5,290	33,064
Total operating expenses	8,858	8,358	28,545	22,403	147,367
Loss from operations	(8,310)	(8,192)	(26,650)	(21,684)	(142,006)
Interest expense	(348)	(573)	(1,205)	(1,765)	(8,927)
Other income (expense), net	(2,328)	183	(13,340)	608	(12,289)
Net loss	(10,986)	(8,582)	(41,195)	(22,841)	(163,222)
Other comprehensive loss:					
Unrealized gains on available for sale securities	5	4	3	1	4
Comprehensive loss	$ (10,981)	$ (8,578)	$ (41,192)	$ (22,840)	$ (163,218)
Net loss per share of common stock, basic and diluted	$ (0.26)	$ (0.38)	$ (1.07)	$ (1.09)	
Shares used to compute basic and diluted net loss per share of common stock	41,462,425	22,632,573	38,635,370	20,961,886	

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2013	2012	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (41,195)	$ (22,841)	$ (163,222)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	439	467	3,122
Amortization of premium/discount on investments, net	134	339	709
Interest expense related to debt financing	359	497	3,833
Stock-based compensation	2,435	1,633	8,931
Revaluation of convertible preferred stock warrant, PIPE warrant, call option and put option liabilities	13,612	(606)	14,967
Other		38	33
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	1,012	459	458
Restricted cash	(45)		(250)
Accounts payable	(987)	1,328	1,247
Accrued liabilities	(1,615)	(478)	1,292
Deferred rent	(84)	381	340
Net cash used in operating activities	(25,935)	(18,783)	(128,540)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,366)	(723)	(6,580)
Purchase of investments	(25,704)	(23,528)	(137,538)
Proceeds from sale of investments			21,815
Proceeds from maturity of investments	22,232	31,527	99,896
Net cash provided by (used in) investing activities	(4,838)	7,276	(22,407)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock in equity offerings, net of offering costs	47,944	9,077	136,057
Proceeds from the issuance of long-term debt			32,383
Payments of long-term debt	(5,789)	(1,806)	(22,665)
Proceeds from issuance of convertible promissory notes			9,000
Proceeds from issuance of common stock through equity plans and warrant exercises	1,481	163	2,026
Proceeds from issuance of convertible preferred stock, net of issuance costs			54,941
Net cash provided by financing activities	43,636	7,434	211,742

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,863	(4,073)	60,795
CASH AND CASH EQUIVALENTS Beginning of period	47,932	7,794	
CASH AND CASH EQUIVALENTS End of period	$ 60,795	$ 3,721	$ 60,795

See notes to condensed financial statements.

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AcelRx Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

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

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

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

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception through September 30, 2013. In addition, the Company had an accumulated deficit of $163.2 million and $122.0 million as of September 30, 2013 and December 31, 2012, respectively. Through September 30, 2013, the Company has relied primarily on the proceeds from equity offerings and loan proceeds to finance its operations. Management believes that the Company s current cash, cash equivalents and investments, including the net proceeds raised in the underwritten public offering completed in July 2013, will be sufficient to fund the Company s current operations through at least 2014. After that, the Company will need to raise additional funding or otherwise enter into collaborations to fund future operations. However, there is no assurance that additional funding will be available to the Company on acceptable terms on a timely basis, if at all, or that the Company will achieve profitable operations. If the Company is unable to raise additional capital to fund its operations, it will need to curtail planned activities to reduce costs. Doing so may affect the Company s ability to operate effectively. The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis of Presentation

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

Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. The condensed balance sheet as of December 31, 2012 was derived from the Company s audited financial statements as of December 31, 2012, included in the Company s Annual Report on Form 10-K filed with the SEC. These financial statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2012, which include a broader discussion of the Company s business and the risks inherent therein.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. Management evaluates its estimates on an ongoing basis including critical accounting policies. Estimates are based on historical experience and on various

other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

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New Accounting Pronouncements

In February 2013, Accounting Standards Codification Topic 220, Comprehensive Income was amended to require companies to report, in one place, information about reclassifications out of accumulated other comprehensive income. Accordingly, a company can present this information on the face of the financial statements, if certain requirements are met, or the information must be presented in the notes to the financial statements. The Company adopted this guidance as of January 1, 2013 on a retrospective basis. This adoption did not have a material effect on the Company s condensed consolidated financial statements.

The Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2013.11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists on July 18, 2013. The ASU concludes an unrecognized tax benefit should be presented as a reduction of a deferred tax asset when settlement in this manner is available under the law. We will adopt this amendment as of January 2014. The result of adoption may be to reclassify certain long term liabilities to long term deferred tax assets, and the adoption will not result in a change to the tax provision. Management does not believe that the impact on the balance sheet will be significant.

2. Investments and Fair Value Measurement

Investments

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

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

	As of September 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 60,668	$	$	$ 60,668
Money market funds	27			27
U.S. government agency securities	100			100
Total cash and cash equivalents	60,795			60,795
Marketable securities:				
U.S. government agency securities	15,169	4		$ 15,173
Total marketable securities	15,169	4		$ 15,173
Total cash, cash equivalents and investments	$ 75,964	$ 4	$	$ 75,968

	As of December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 44,440	$	$	$ 44,440
Money market funds	2,086			2,086
U.S. government agency securities	1,406			1,406
Total cash and cash equivalents	47,932			$ 47,932
Marketable securities:				
U.S. government agency securities	11,830	1		11,831

Total marketable securities	11,830		1		$ 11,831
Total cash, cash equivalents and investments	$ 59,762	$	1	$	$ 59,763

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As of September 30, 2013 and December 31, 2012, none of the available-for-sale securities held by the Company had material unrealized losses. There were no other-than-temporary impairments for these securities at September 30, 2013 or December 31, 2012. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income to earnings during the three and nine months ended September 30, 2013 and 2012.

As of September 30, 2013 and December 31, 2012, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company s financial instruments consist of Level I and Level II assets and Level III liabilities. Level I securities include highly liquid money market funds and are valued based on quoted market prices. For Level II instruments, the Company estimates fair value by utilizing third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. treasury and U.S. government agency obligations. As of September 30, 2013 and December 31, 2012, the Company held, in addition to Level I and Level II assets, a contingent put option liability associated with the Company s loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which was classified as a Level III liability. The value of this liability was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. As of September 30, 2013 and December 31, 2012, the Company also held a Level III liability associated with warrants, or PIPE warrants, issued in connection with the Company s private placement equity offering, completed in June 2012. The PIPE warrants are considered a liability and are valued using the Black-Scholes option-pricing model, the inputs for which include exercise price of the PIPE warrants, market price of the underlying common shares, expected term, volatility based on a group of the Company s peers and the risk-free rate corresponding to the expected term of the PIPE warrants. Changes to any of the inputs can have a significant impact to the estimated fair value of the PIPE warrants.

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

	As of September 30, 2013			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 27	$ 27	$	$
U.S. government agency obligations	15,273		15,273	
Total assets measured at fair value	$ 15,300	$ 27	$ 15,273	$
Liabilities				
PIPE warrants	$ 12,391			$ 12,391
Contingent put option liability	32			32
Total liabilities measured at fair value	$ 12,423	$	$	$ 12,423

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	As of December 31, 2012			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 2,086	$ 2,086	$	$
U.S. government agency obligations	13,237		13,237	
Total assets measured at fair value	$ 15,323	$ 2,086	$ 13,237	$
Liabilities				
PIPE warrants	$ 7,418			$ 7,418
Contingent put option liability	$ 82			$ 82
Total liabilities measured at fair value	$ 7,500	$	$	$ 7,500

The following table sets forth the assumptions used in the Black-Scholes option-pricing model to estimate the fair value of the PIPE warrants as of September 30, 2013 and December 31, 2012:

	As of September 30, 2013	As of December 31, 2012
Risk-free interest rate	1.39%	0.72%
Expected volatility	67.0%	78.0%
Expected life (in years)	4.2	4.9
Expected dividend yield	0.0%	0.0%

The following tables set forth a summary of the changes in the fair value of the Company s Level III financial liabilities for the three and nine months ended September 30, 2013 and September 30, 2012 (in thousands):

	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013
Fair value beginning of period	$ 17,889	$ 7,500
Change in fair value of Level III liabilities	(5,466)	4,923
Fair value end of period	$ 12,423	$ 12,423

	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2012
Fair value beginning of period	$ 5,623	$ 232
Addition of private placement warrant liability on June 1, 2012		5,828
Change in fair value of Level III liabilities	(169)	(606)
Fair value end of period	$ 5,454	$ 5,454

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3. Research Grant Agreement

In May 2011, AcelRx entered into an award contract with the US Army Medical Research and Materiel Command, or USAMRMC, in which the USAMRMC granted $5.6 million to the Company in order to support the development of a new product candidate, ARX-04, a Sufentanil NanoTab for the treatment of moderate-to-severe acute pain. Under the terms of the grant, the USAMRMC agreed to reimburse the Company for development, manufacturing and clinical costs necessary to prepare for and complete a Phase 2 dose-finding trial in a study of acute moderate-to-severe pain, and to prepare to enter Phase 3 development. The grant gives the USAMRMC the option to extend the term of the grant and provide additional funding for the research. The original term of the grant was through August 31, 2012; however, due to a longer than expected administrative review process by the USAMRMC, AcelRx has received no-cost extensions of the grant, whereby the term has been extended to January 31, 2014.

Revenue is recognized based on expenses incurred by AcelRx in conducting research and development activities set forth in the agreement. Revenue attributable to the research and development performed under the USAMRMC grant was $0.5 million and $0.2 million for the three months ended September 30, 2013 and 2012, respectively, and $1.9 million and $0.7 million for the nine months ended September 30, 2013 and 2012, respectively. From inception of the grant through September 30, 2013, AcelRx has generated grant revenue of $5.4 million.

4. Long-Term Debt

Hercules Loan and Security Agreement

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

The Company borrowed the first tranche of $10.0 million upon the closing of the transaction on June 29, 2011 and borrowed the second tranche of $10.0 million in December 2011. The Company used a portion of the proceeds from the first tranche to repay the remaining obligations under that certain loan and security agreement between the Company and Pinnacle Ventures, L.L.C., or Pinnacle Ventures, dated September 16, 2008. The interest rate for each tranche is 8.50%. The Company made interest only payments until June 30, 2012, followed by equal monthly payments of principal and interest, totaling $742,000, through the scheduled maturity date on December 1, 2014.

Subject to certain conditions and limitations set forth in the Hercules loan and security agreement, the Company has the right to convert up to $3.0 million of scheduled principal installments under the notes into that number of freely tradable shares of common stock equal to (x) the product of (A) the principal amount to be so converted and (B) 103%, divided by (y) $5.73 per share.

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

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the loan, including payment of any applicable prepayment charges, which range from 1%-3% of the outstanding loan balance and accrued interest, as well as a final payment fee of $0.2 million. This option is considered a contingent put option liability as the holder of the loan may exercise the option in the event of default and, is considered an embedded derivative which must be valued and separately accounted for in the Company s financial statements. As of September 30, 2013 and December 31, 2012, the estimated fair value of the contingent put option liability was $32,000 and $82,000, respectively, which was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. The contingent put option liability was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The contingent put option liability is revalued at the end of each reporting period and any change in the fair value is recognized in the statement of operations.

In connection with the loan, the Company issued Hercules seven-year warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share. See Note 5 Warrants, for further description.

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As of September 30, 2013, the Company had outstanding borrowings under the Hercules loan and security agreement of $10.5 million, net of debt discounts of $0.2 million. As of December 31, 2012, the Company had outstanding borrowings under the Hercules loan and security agreement of $16.0 million, net of debt discounts of $0.5 million.

Amortization of the debt discounts, which was recorded as interest expense, was $85,000 and $134,000 for the three months ended September 30, 2013 and 2012, respectively, and $290,000 and $406,000 for the nine months ended September 30, 2013 and 2012.

5. Warrants

2012 Private Placement Warrants

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

Upon execution of the Purchase Agreement, the fair value of the PIPE warrants was estimated to be $5.8 million, which was recorded as a liability. As of September 30, 2013, the fair value of the PIPE warrants was estimated to be $12.4 million. As of December 31, 2012, the fair value of the PIPE warrants was estimated to be $7.4 million. The change in fair value of the warrants resulted in other expense of $2.4 million for the three months ended September 30, 2013 and $13.4 million in other expense for the nine months ended September 30, 2013. The change in fair value for the three months and nine months ended September 30, 2012, which was recorded as other income, was $0.1 million and $0.4 million, respectively.

During the three months ended September 30, 2013, warrants to purchase 1,039,309 shares were net exercised for 747,225 shares of common stock. During the nine months ended September 30, 2013, warrants to purchase 1,135,589 shares were net exercised for 808,078 shares of common stock. As of September 30, 2013, PIPE warrants to purchase 1,494,514 shares of common stock issued in connection with the Private Placement had not been exercised and were outstanding. These warrants expire in November 2017.

Hercules Warrants

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

During the three months ended September 30, 2013, warrants to purchase 137,254 shares were net exercised, for 94,161 shares of common stock. During the nine months ended September 30, 2013, warrants to purchase 274,508 shares were net exercised, for 183,404 shares of common stock. As of September 30, 2013, no warrants to purchase shares of common stock issued to Hercules were outstanding.

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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 connection with the Company s Initial Public Offering, or IPO, in February 2011, the warrants issued in connection with the loan and security agreement were automatically converted into warrants to purchase 228,264 shares of common stock with an exercise price of $3.94 per share.

During the quarter ended March 31, 2013, warrants to purchase 228,264 shares, were net exercised by Pinnacle Ventures for 58,580 shares of common stock. No warrants were outstanding as of September 30, 2013.

6. Stockholders Equity

On July 23, 2013, AcelRx completed an underwritten public offering of 4,370,000 shares of common stock, at a price of $11.65 per share to the public. The total gross proceeds of this offering were $50.9 million with net proceeds to AcelRx of $47.9 million after deducting underwriting discounts and commissions and other expenses payable by AcelRx.

7. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 13, 2005 (Inception) Through September 30,
	2013	2012	2013	2012	2013
Expenses:					
Research and development	$ 427	$ 258	$ 1,193	$ 762	$ 4,570
General and administrative	449	304	1,242	871	4,361
Total stock-based compensation expense	$ 876	$ 562	$ 2,435	$ 1,633	$ 8,931

As of September 30, 2013 there were 270,373 shares available for grant, 4,923,633 options outstanding and 65,765 restricted stock units outstanding under the Company s 2011 Equity Incentive Plan. In addition, there were 470,189 shares available for grant under the Company s 2011 Employee Stock Purchase Plan.

8. Net Loss per Share of Common Stock

The following table sets forth the computation of the Company s basic and diluted net loss per share of common stock during the three and nine months ended September 30, 2013 and 2012 (in thousands, except for share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$ (10,986)	$ (8,582)	$ (41,195)	$ (22,841)
Shares used in computing net loss per share of common stock, basic and diluted	41,462,425	22,632,573	38,635,370	20,961,886
Net loss per share of common stock, basic and diluted	$ (0.26)	$ (0.38)	$ (1.07)	$ (1.09)

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive:

	September 30,	
	2013	2012
Stock options to purchase common stock	4,923,633	3,321,038
Restricted stock units	65,765	161,096
Common stock warrants	1,497,939	3,136,300

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9. Manufacturing Agreement

In January 2013, the Company and Patheon Pharmaceuticals Inc., or Patheon, entered into a Manufacturing Services Agreement, or the Services Agreement, and a related Amended and Restated Capital Expenditure and Equipment Agreement, or the Capital Agreement, relating to the manufacture of Sufentanil NanoTabs, or the Product, for use with the Company s product candidate, Zalviso, formerly known as the Sufentanil NanoTab PCA System.

Under the terms of the Services Agreement, the Company has agreed to purchase, subject to Patheon s continued material compliance with the terms of the Services Agreement, all of its Product requirements for the United States, Canada and Mexico from Patheon during the Initial Term of the Services Agreement (as defined below), and at least eighty percent (80%) of its Product requirements for such territories after the Initial Term.

The term of the Services Agreement extends until December 31, 2017, or the Initial Term, and will automatically renew thereafter for periods of two years, unless terminated by either party upon eighteen months prior written notice; provided, however, that the Services Agreement may not be terminated without cause prior to the end of the Initial Term.

The Company also entered into a Capital Expenditure and Equipment Agreement, or the Capital Agreement, with Patheon. Under the terms of the Capital Agreement, the Company has the option to make certain future modifications to Patheon s Cincinnati facility, the aggregate cost of which is expected to be less than $3.5 million and which would be the responsibility of the Company. If additional equipment and facility modifications are required to meet the Company s Product needs, the Company may be required to contribute to the cost of such additional equipment and facility modifications. The Capital Agreement also requires that the Company make payments in 2013 totaling $480,000 to Patheon to partially offset taxes incurred and paid by Patheon in connection with facility modifications already completed by Patheon. The Company can seek reimbursement from Patheon for this payment if it receives approval from the U.S. Food and Drug Administration for ARX-01. The Capital Agreement further requires that the Company pay a maximum overhead fee of $200,000 annually during the term of the Services Agreement, which amount may be reduced to $0 based on the amount of annual revenues earned by Patheon under the Services Agreement and the pre-existing development agreements.

Expenditures associated with the aforementioned agreements are primarily driven by the potential commercial requirements and demand for the Company s products, which are currently in development stage; accordingly, the amounts and timing of such future expenditures cannot be determined at this time.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, the acceptance of our NDA by the FDA, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2012.

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About AcelRx Pharmaceuticals

We are a development stage specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. Our lead product candidate, Zalviso™, formerly known as the Sufentanil NanoTab PCA System or ARX-01, is designed to improve the management of moderate-to-severe acute pain in adult patients in the hospital setting. Although widely used, the current standard of care for patients with moderate-to-severe pain in the hospital setting, intravenous patient-controlled analgesia, or IV PCA, has been shown to cause harm and inconvenience to patients following surgery because of the side effects of commonly used IV PCA opioids, the invasive IV needle route of delivery and the inherent potential for programming and delivery errors associated with the complexity of infusion pumps.

Zalviso

Zalviso is an investigational pre-programmed, non-invasive, patient-activated, handheld analgesic system that allows hospitalized patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil NanoTabs to manage their pain. Zalviso is designed to address the limitations of IV PCA by offering:

A high therapeutic index opioid: Zalviso uses the high therapeutic index opioid sufentanil; it offers hospitalized patients with moderate-to-severe acute pain the potential for effective patient-controlled analgesia with a low incidence of drug-related side effects.

A non-invasive route of delivery: The sublingual route of delivery used by Zalviso provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections in IV PCA treated patients. In addition, because patients are not tethered to IV tubing and a pump for pain relief, Zalviso allows for ease of patient mobility.

A simple, pre-programmed PCA solution: Zalviso is a pre-programmed PCA system designed to eliminate the risk of pump programming errors.

On September 27, 2013, we submitted a New Drug Application, or NDA, to the FDA, for Zalviso. Assuming the FDA files our NDA in the fourth quarter of 2013, we anticipate receiving a Prescription Drug User Fee Act, or PDUFA, review goal date in the third quarter of 2014, and assuming successful approval of our NDA by the FDA at that time, we anticipate launching the commercial sale of Zalviso in the first quarter of 2015.

The 505(b)(2) NDA submission for Zalviso is based on a development program that includes data from three Phase 3 clinical trials, including two placebo-controlled efficacy and safety trials and one open-label active comparator trial, in which Zalviso was compared to IV PCA morphine. Zalviso successfully achieved the primary efficacy endpoints for each of these trials. A summary of the Phase 3 trials and results is as follows:

Active comparator trial (IAP 309)

In November 2012, we reported top-line data demonstrating that Zalviso met its primary endpoint of non-inferiority in a Phase 3 open-label active comparator trial designed to compare the efficacy and safety of Zalviso (15 mcg/dose, 20 minute lock-out) to IV PCA with morphine (1mg/dose, 6 minute lock-out) for the treatment of moderate-to-severe acute post-operative pain immediately following major abdominal or orthopedic surgery.

Top-line primary endpoint results of this Phase 3 clinical trial demonstrate that:

Zalviso was non-inferior ($p<0.001$) to IV PCA morphine for the primary endpoint of Patient Global Assessment of method of pain control, or PGA, comparison over the 48-hour trial period as determined by the combined percentage of patients with PGA ratings of good or excellent (78.5% vs. 65.6%, respectively).

A secondary comparison of the primary endpoint, specifically a statistical analysis of superiority, demonstrated that Zalviso was statistically superior to IV PCA morphine for the PGA endpoint (p=0.007). Statistically superior and non-inferior PGA for Zalviso compared to IV PCA morphine was also seen at the 24 hour and 72 hour time points.

The trial also demonstrated that Zalviso produced a significantly faster onset of pain relief and reduction in pain intensity compared to IV PCA morphine that separated at 45 minutes and achieved statistical significance at 1, 2 and 4 hours ($p<0.01$). Furthermore, there were statistically fewer patients in the Zalviso group that experienced oxygen desaturation to a level less than 95% compared to the IV PCA morphine group (p=0.028).

Throughout the course of the trial, 7.3% of patients treated with Zalviso dropped out of the trial prematurely due to lack of efficacy compared to 8.9% of patients treated with IV PCA morphine. Additionally, 7.3% of the patients treated with Zalviso dropped out of the trial due to an adverse event compared to 10.0% of the IV PCA morphine patients. We observed 13 patients who experienced serious adverse events, or SAEs, in the trial, of whom three patients experienced serious adverse events assessed as possibly or probably related to the trial drug, with one related to Zalviso and two related to IV PCA morphine.

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Double-blind, placebo-controlled, abdominal surgery trial (IAP 310)

In March 2013, we reported top-line data demonstrating that Zalviso met its primary endpoint in a pivotal Phase 3 trial designed to compare the efficacy and safety of Zalviso to placebo in the management of acute post-operative pain after major open abdominal surgery. Adverse events reported in the trial were generally mild or moderate in nature and similar in both placebo and treatment groups. Utilizing a randomized, double-blind, placebo-controlled design, this pivotal Phase 3 trial enrolled 178 adult patients at 13 U.S. sites.

The primary endpoint evaluated pain intensity over the 48-hour trial period compared to baseline, or Summed Pain Intensity Difference (SPID-48), in patients following major open abdominal surgery. SPID-48 is the endpoint requested by FDA to demonstrate effectiveness of a pain control medicine. Patients receiving Zalviso demonstrated a significantly greater SPID-48 (pain reduction) compared to placebo treated patients during the trial period (105.6 and 55.6, respectively; p=0.001). Additionally, secondary endpoint data showed that 24 hours and 72 hours after first dose, SPID was significantly greater in Zalviso-treated patients than in the placebo-treated patients ($p<0.001$ and p=0.004 respectively).

Eighty, or 70.2%, of the Zalviso-treated patients completed the 48-hour trial period, compared to 30, or 51.7%, of placebo-treated patients. Reasons for drop-out in Zalviso-treated and placebo-treated groups were adverse events (5.3% and 6.9%, respectively), lack of efficacy (16.7% and 31.0%, respectively) and other (7.9% and 10.3%, respectively).

Treatment-emergent adverse events occurred in 64.0% of Zalviso-treated patients and 67.2% of placebo-treated patients. Adverse events with an occurrence greater than 5% in either the Zalviso group or the placebo group were nausea (30.7% and 41.4%, respectively), fever (14.9% and 8.6%, respectively), vomiting (8.8% and 6.9%, respectively), itching (8.8% and 0.0%, respectively), oxygen saturation decrease (6.1% and 1.7%, respectively), and hypertension (2.6% and 5.2%, respectively). Itching, a frequently observed side effect of opioids, was the only adverse event that was significantly different between the groups (p=0.017). All reported cases of itching in the trial were mild in nature.

Only one patient, in the Zalviso group, experienced a serious adverse event, which was determined to be unrelated to the trial drug by the investigator.

Double-blind, placebo-controlled, orthopedic surgery trial (IAP 311)

In May 2013, we reported top-line data demonstrating that Zalviso met its primary endpoint in a pivotal Phase 3 trial designed to compare the efficacy and safety of Zalviso to placebo in the management of acute post-operative pain after major orthopedic surgery. Utilizing a randomized, double-blind, placebo-controlled design, this pivotal Phase 3 trial enrolled 426 adult patients at 34 U.S. sites.

The primary endpoint evaluated pain intensity over the 48-hour trial period compared to baseline, or SPID-48, in patients following major orthopedic surgery. Patients receiving Zalviso demonstrated a significantly greater SPID-48 (pain reduction) compared to placebo-treated patients during the trial period (+76.1 vs. -11.5, $p<0.001$). Secondary endpoint data demonstrated that SPID at 24 hours and 72 hours was also significantly greater in the Zalviso-treated patients than in the placebo-treated patients ($p<0.001$ in each case).

Two hundred fifteen, or (68.3%), Zalviso-treated patients completed the 48-hour trial period, compared to 43 (41.3%) placebo-treated patients. Primary reasons for drop-out in the Zalviso- and placebo-treated groups were adverse events (7.0% and 6.7%, respectively) and lack of efficacy (14.3% and 48.1%, respectively).

Treatment-emergent adverse events were generally mild to moderate in nature and similar for the majority of adverse events between Zalviso and placebo-treated patients, despite the shorter duration of exposure in the placebo-treated patients caused by early termination due to inadequate analgesia. Adverse events of nausea (occurring in 52.7% of sufentanil-treated patients vs. 33.7% of placebo-treated patients), vomiting (12.7% vs. 5.8%, respectively), dizziness (6% vs. 1%, respectively) and itching (6% vs. 0%, respectively) were the only adverse effects that were statistically significantly greater for Zalviso-treated patients as compared to placebo-treated patients. Nausea, vomiting and itching are common in treatment of post-operative patients, and are managed with anti-emetic and anti-histamine treatment. Effective management of these symptoms is demonstrated by the low drop-out rate due to nausea (1.6% of Zalviso-treated patients vs. 2.9% of placebo-treated patients), vomiting (0.6% vs. 0%, respectively) and itching (0.3% vs. 0%, respectively) in this trial. Two patients (one each in the Zalviso group and placebo group) experienced an SAE considered possibly or probably related to the trial drug by the investigator.

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ARX-04

We are also developing a Sufentanil Single-Dose NanoTab, or ARX-04, for the treatment of moderate-to-severe acute pain on the battlefield, in the emergency room or in ambulatory care facilities. In April 2013, we reported top-line data showing that the primary endpoint was achieved in a placebo-controlled, dose-finding, Phase 2 clinical trial of ARX-04 for acute pain. This trial randomized 101 patients following bunionectomy surgery in a 2:2:1 ratio to 30 mcg sufentanil, 20 mcg sufentanil or placebo treatment arms. Ninety-one percent of patients entering the trial completed the 12-hour trial period.

Results demonstrated that patients receiving 30 mcg sufentanil NanoTab doses, administered by a healthcare professional, no more frequently than once per hour, had significantly greater pain reduction as measured by Summed Pain Intensity Difference to baseline during the 12-hour trial period (SPID-12) than placebo-treated patients (p=0.003). Adverse events reported in the trial were generally mild-to-moderate in nature, with two serious adverse events of post-surgical infection reported, both of which were determined by the investigator to be unrelated to trial drug. Two patients dropped out of the trial due to adverse events, one patient s discontinuation considered unrelated to trial drug, and the other considered probably related to trial drug, both in the 30 mcg-treated group.

Research and development of ARX-04, including the Phase 2 trial and pre-Phase 3 development, is funded by a $5.6 million grant from the U.S. Army Medical Research and Materiel Command, or USAMRMC. Future development of ARX-04 is contingent on identification of additional resources.

ARX-02 and ARX-03

In addition to Zalviso and ARX-04, our product candidate pipeline consists of two other sufentanil-based product candidates. The Sufentanil NanoTab BTP Management System, or ARX-02, is a pain management system for the potential treatment of cancer patients who suffer from breakthrough pain, or BTP. The Sufentanil/Triazolam NanoTab, or ARX-03, is a single, fixed-dose product designed to provide mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician s office. We have successfully completed Phase 2 clinical trials for ARX-02 and ARX-03. Future development of ARX-02 and ARX-03 is contingent on identification of corporate partnership resources.

Financial Overview

We are a development stage company with a limited operating history. We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue our research and development activities and costs associated with the preparation for U.S. commercialization of Zalviso. We believe that continued investment in research and development is critical to attaining our strategic objectives. In order to develop our product candidates as commercially viable therapeutics, we expect to expend significant resources for expertise in manufacturing, regulatory affairs, clinical research, medical affairs, commercialization preparative activities including marketing activities and other aspects of pharmaceutical development and eventual commercialization, assuming FDA approval. In addition, as we pursue commercial development of our product candidates, we expect the business aspects of our company to become more complex. We may be required in the future to add personnel and incur additional costs related to the maturation of our business.

Our net loss for the three months and nine months ended September 30, 2013 was $11.0 million and $41.2 million, respectively. In addition, our net losses were $33.4 million and $20.1 million during the years ended December 31, 2012 and 2011, respectively. As of September 30, 2013, we had an accumulated deficit of $163.2 million. As of September 30, 2013, we had cash, cash equivalents and investments totaling $76.0 million and $59.8 million as of December 31, 2012.

To date, we have funded our operations primarily through the sale of equity securities and the issuance of debt instruments. In July 2013, we completed an underwritten public offering, pursuant to which we sold 4,370,000 shares of our common stock at a public offering price of $11.65 per share for an aggregate offering price of $50.9 million. As a result of the July 2013 offering, we received net proceeds of $47.9 million, after underwriting discounts, commissions and other offering expenses. In December 2012, we completed an underwritten public offering, pursuant to which we sold 14,375,000 shares of our common stock at a public offering price of $3.31 per share for an aggregate offering price of $47.6 million. As a result of the December 2012 offering, we received net proceeds of $44.1 million, after underwriting discounts, commissions and offering expenses totaling $3.5 million. In June 2012, we completed a private placement of our common stock, in which we issued an aggregate of 2,922,337 shares of common stock and warrants to purchase up to 2,630,103 shares of common stock, for net proceeds of $9.1 million, after deducting costs related to the offering of $0.9 million. In June 2011, we entered into a loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we borrowed $20.0 million in two tranches of $10.0 million each, represented by secured convertible term promissory notes. The interest rate is 8.50%, with the initial 12 months of the facility requiring interest only payments. The notes issued pursuant to the loan and security agreement mature on December 1, 2014.

According to the terms of the Hercules agreement, beginning on July 1, 2012, we began repaying Hercules principal, with equal monthly payments of $742,000, consisting of both principal and interest payments, to continue until the maturity date of the loan. As of September 30, 2013, we had a debt balance of $10.5 million.

Since our inception in July 2005, we have not generated any revenue from the sale of our products and do not anticipate generating any product revenues for the foreseeable future, if at all. We have recognized revenue associated with our grant from the USAMRMC of $5.4 million since inception of the grant through September 30, 2013, but continued funding from the USAMRMC is contingent upon their review and approval of our continued research and development activities associated with the grant. In addition, there can be no assurance that we will receive other research-related grant awards or produce other collaborative agreement revenues in the future.

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Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2013 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Three and Nine Months Ended September 30, 2013 and 2012

Revenue

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

Revenue attributable to the research and development performed under the USAMRMC grant was $0.5 million and $0.2 million for the three months ended September 30, 2013 and 2012, respectively, and $1.9 million and $0.7 million for the nine months ended September 30, 2013 and 2012, respectively. From inception of the grant through September 30, 2013, we have generated grant revenue of $5.4 million.

We expect the remaining $0.2 million of the USAMRMC grant to be earned by January 31, 2014, the expiration date of the grant.

Research and Development Expenses

Conducting research and development is central to our business model. The majority of our operating expenses in 2013 and 2012 have been for research and development activities related to Zalviso. Research and development expenses included the following:

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

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We anticipate that research and development expenses

for the fourth quarter of 2013 will be lower than those incurred in the third quarter of 2013, due to lower clinical development expenses associated with Zalviso and our ARX-04 program. Research and development expenses in the third quarter of 2013 included a one-time NDA submission fee of $1.95 million for Zalviso. FDA regulations allow for the waiver of the NDA filing fee if the company is filing its first NDA and qualifies as a small business with less than 500 employees. The FDA requested the Small Business Administration, or SBA, to determine if AcelRx was a small business, and the SBA recently ruled that AcelRx could not qualify as a small business. The SBA came to this conclusion on the basis of determining that Three Arch, our largest venture investor, was an affiliate of AcelRx with an ownership of approximately 24%. As a result of this determination, the SBA assumed that Three Arch employees as well as employees of Three Arch s portfolio companies were also employees of AcelRx. Taking all of these into account, we exceeded the 500 employee threshold.

AcelRx anticipates increases in 2013 in sales, general and administrative expense due to costs associated with commercial preparations for the launch of Zalviso in the U.S. and expansion of its corporate infrastructure to support a commercial launch. Total operating expenses for 2013 are anticipated to be modestly higher than they were in 2012.

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We track external development expenses on a program-by-program basis. Our development resources are shared among all of our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead. Below is a summary of our research and development expenses during the three and nine months ended September 30, 2013 and 2012 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Zalviso	$ 4,032	$ 5,546	$ 14,170	$ 12,354
ARX-04	468	86	1,730	380
Overhead	2,048	1,316	6,074	4,379
Total research and development expenses	$ 6,548	$ 6,948	$ 21,974	$ 17,113

Due to the inherently unpredictable nature of product development, development timelines and the probability of success, development costs can differ materially from expectations. While we are currently focused on advancing Zalviso and ARX-04, and subsequently ARX-02 and ARX-03, our future research and development expenses will depend on the clinical success of each product candidate as well as ongoing assessments of the commercial potential of our product candidates. In addition, we cannot predict which product candidates may be subject to future collaborations, when these arrangements will be secured, if at all, and to what degree these arrangements would affect our development plans and capital requirements.

Total research and development expenses for the three and nine months ended September 30, 2013 and 2012 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2013	2012	Change	%	2013	2012	Change	%
Research and development expenses	$ 6,548	$ 6,948	$ (400)	(6)%	$ 21,974	$ 17,113	$ 4,861	28%

The $0.4 million decrease in research and development expenses during the three months ended September 30, 2013 as compared to the three months ended September 30, 2012 was primarily attributable to a decrease of $1.5 million related to Zalviso, due to the completion of our Phase 3 program, partially offset by a one-time $1.95 million NDA filing fee for Zalviso. There was an increase in our ARX-04 development program of $0.4 million and increases in personnel-related expenses, including stock-based compensation, of $0.7 million, which partially offset the decrease in Zalviso-related expenses.

The $4.9 million increase in research and development expenses during the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012 was primarily due to an increase of $1.8 million related to Zalviso, including a one-time NDA filing fee of $1.95 million, partially offset by an overall decrease in our Phase 3 clinical trial program expenses. In addition to the increase in Zalviso-related expenses, there was an increase of $1.4 million primarily related to Phase 2 clinical trial development for our ARX-04 program. The remaining increase was primarily related to an increase in personnel-related expenses, including stock-based compensation.

General and Administrative Expenses

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

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Total general and administrative expenses for the three and nine months ended September 30, 2013 and 2012 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2013	2012	Change	%	2013	2012	Change	%
General and administrative	$ 2,310	$ 1,410	$ 900	64%	$ 6,571	$ 5,290	$ 1,281	24%

The increase in general and administrative expenses during the three months ended September 30, 2013 as compared to the three months ended September 30, 2012 was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, of $0.4 million and $0.3 million in consulting services, primarily related to market research for Zalviso. The remaining increase related to legal services, primarily due to patent prosecution efforts for our expanding portfolio.

The increase in general and administrative expenses during the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012 was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, of $0.6 million and $0.6 million for consulting and outside services, primarily related to market research for Zalviso.

Interest Expense

Total interest expense for the three and nine months ended September 30, 2013 and 2012 was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2013	2012	Change	%	2013	2012	Change	%
Interest expense	$ 348	$ 573	$ (225)	(39)%	$ 1,205	$ 1,765	$ (560)	(32)%

Interest expense for all periods pertains to interest on our loan and security agreement with Hercules, which expires in December 2014. Effective July 2012, we began paying down the outstanding balance in equal monthly payments of $742,000, which consist of principal and interest. The decrease in each comparative period was due to a lower average debt balance during the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012.

Other income (expense), net

Other income (expense), net during the periods noted below consisted primarily of the change in the fair value of our warrants, or PIPE warrants, issued in connection with our private placement of our common stock, which was completed in June 2012. The account also reflects the contingent put option liability associated with the loan and security agreement with Hercules and interest earned on our cash and investments balances.

Total other income (expense), net for the three and nine months ended September 30, 2013 and September 30, 2012 was as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Change	2013	2012	Change
Other income (expense), net	$ (2,328)	$ 183	$ (2,511)	$ (13,340)	$ 608	$ (13,948)

The change in other income (expense) during the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012 was primarily attributable to the increase in the estimated fair value of our PIPE warrants, which is recorded as an expense. The fair value of the warrants are remeasured upon exercise and at the end of each reporting period utilizing the Black-Scholes option-pricing model, and the increase in the fair value was primarily driven by a higher share price of AcelRx common stock on September 30, 2013, compared to the share price on September 30, 2012. The share prices on September 30, 2013 and September 30, 2012 were $10.78 and $3.19, respectively.

The income during the three and nine months ended September 30, 2012 primarily reflected the decrease in fair value of the PIPE warrants, due to a lower stock price, and the decrease in fair value of the contingent put option liability associated with the loan and security agreement with Hercules.

Liquidity and Capital Resources

Liquidity

We have incurred losses and generated negative cash flows from operations since inception, and we expect to continue to incur significant losses and negative cash flows for the foreseeable future. We have funded our operations primarily through the issuance of equity securities and debt financings. From inception through September 30, 2013, we have received net proceeds of $54.9 million from the sale of convertible preferred stock, $138.1 million from the sale of common stock and $41.4 million from our debt arrangements.

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As of September 30, 2013, we had cash, cash equivalents and investments totaling $76.0 million compared to $59.8 million as of December 31, 2012. The increase is due to an underwritten public offering completed in July 2013, pursuant to which we sold 4,370,000 shares of our common stock at a public offering price of $11.65 per share for an aggregate offering price of $50.9 million. As a result of the offering, we received net proceeds of $47.9 million, after underwriting discounts, commissions and other offering expenses.

The increase in cash, cash equivalents and investments was partially offset by capital required to fund our continuing operations, including advancement of our lead product candidate, Zalviso, through Phase 3 clinical trials and the submission of the NDA for Zalviso, which occurred on September 27, 2013. Our most significant use of capital pertains to salaries and benefits for our employees and clinical trial expenses related to our development programs.

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

Cash Flows

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

	Nine Months Ended September 30,	
	2013	2012
Net cash used in operating activities	$ (25,935)	$ (18,783)
Net cash provided by (used in) investing activities	(4,838)	7,276
Net cash provided by financing activities	43,636	7,434

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund the development of our product candidates. Our cash used for operating activities also reflected changes in our working capital and adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, interest expense related to our debt financings and the revaluation of our PIPE warrant liability.

Cash used in operating activities of $25.9 million during the nine months ended September 30, 2013 reflected a net loss of $41.2 million, partially offset by aggregate non-cash charges of $17.0 million and a net change of $1.7 million in our net operating assets and liabilities. Non-cash charges primarily included $13.6 million for the increase in fair value of our PIPE warrant primarily due to a higher price of our common stock at September 30, 2013 compared to December 31, 2012, and $2.4 million for stock-based compensation. The net change in our operating assets and liabilities was primarily a result of a decrease in accrued liabilities of $1.6 million, a decrease in accounts payable of $1.0 million and a decrease in prepaid expenses of $1.0 million, all primarily related to the completion of our Phase 3 clinical trials for Zalviso.

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

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales and maturities of our available-for-sale investments.

During the nine months ended September 30, 2013, cash used in investing activities of $4.8 million was primarily as a result of $25.7 million for purchases of investments, partially offset by $22.2 million in proceeds from the maturity of investments.

During the nine months ended September 30, 2012, cash provided by investing activities of $7.3 million was primarily a result of $31.5 million in proceeds from maturity of investments, partially offset by $23.5 million for purchases of investments.

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Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities, proceeds from our debt financings and payments made on such debt financings. As of September 30, 2013, we had outstanding debt of $10.5 million.

During the nine months ended September 30, 2013, cash provided by financing activities of $43.6 million was primarily due to an underwritten public offering of our common stock, completed in July 2013, pursuant to which we issued an aggregate of 4,370,000 shares of common stock at an offering price of $11.65 per share, for net proceeds of $47.9 million. In addition, we received proceeds from the issuance of common stock through equity plans and the exercise of warrants for $1.5 million. These inflows were partially offset by payments of long-term debt of $5.8 million related to our loan and security agreement with Hercules.

During the nine months ended September 30, 2012, cash provided by financing activities of $7.4 million was primarily a result of the Private Placement, pursuant to which, on June 1, 2012, we issued an aggregate of 2,922,337 shares of common stock and PIPE warrants to purchase up to 2,630,103 shares of common stock for net proceeds of $9.1 million. These proceeds were partially offset by payments of long-term debt of $1.8 million related to our loan and security agreement with Hercules.

Operating Capital and Capital Expenditure Requirements

We expect our rate of cash usage to increase in the future, in particular to support our product development activities, including commercial preparation activities for Zalviso. We believe that our available cash resources, including proceeds from our underwritten public equity offering completed in July 2013, will be sufficient to fund our operations through at least 2014, including support for our continuing development of our product candidates and commercial readiness activities for Zalviso. Future capital requirements will be substantial and we will need to raise additional capital to fund our operations, including product candidate development activities. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Additional capital may not be available in terms acceptable to us, or at all. If adequate funds are not available, or if the terms underlying potential funding sources are unfavorable, our business and our ability to develop our technology and product candidates would be harmed.

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

- the outcome, timing and cost of regulatory approvals;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

the timing and terms of future in-licensing and out-licensing transactions;

the extent to which we acquire or invest in businesses, products or technologies; and

the possible costs of litigation.

Off-Balance Sheet Arrangements

As of September 30, 2013, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

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

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

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Changes in internal control over financial reporting. There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be involved in legal proceedings arising in the ordinary course of business. We believe there is no litigation currently pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

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

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2012.

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, Zalviso™. We have three additional product candidates, the Sufentanil NanoTab BTP Management System, or ARX-02, the Sufentanil/Triazolam NanoTab, or ARX-03, and Sufentanil Single-Dose Acute Pain NanoTab, or ARX-04. We have incurred significant net losses in each year since our inception in July 2005, and as of September 30, 2013, we had an accumulated deficit of $163.2 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. We expect to continue to incur substantial expenses as we prepare for the potential commercialization of Zalviso and continue our research and development activities for our product candidates. 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. As a result of the foregoing, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future.

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

Our ability to generate revenue from commercial sales and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. Other than the revenue received from the U.S. Army Medical Research and Materiel Command, or USAMRMC, for research and development reimbursement under the terms of the grant for ARX-04 we received from the USAMRMC, we do not anticipate generating revenues from sales of Zalviso until 2015, if ever. In addition, we do not anticipate generating revenues from our other product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

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obtaining and maintaining regulatory approval for Zalviso;

launching and commercializing Zalviso, including building or contracting out, a hospital-directed sales force in the U.S. and collaborating with third parties internationally, which will require additional funding; and

completing the clinical development of, obtaining regulatory approval for, and launching and commercializing ARX-02, ARX-03 and ARX-04, which will require additional funding or corporate partnership resources.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are delayed in obtaining approval of, or launching, Zalviso, or are required by the United States Food and Drug Administration, or FDA, to perform trials in addition to those that we have completed.

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

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

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

We will require substantial additional capital and may be unable to raise capital, which would force us to delay, reduce or eliminate our product development programs and could cause us to cease operations.*

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect to incur significant expenditures in connection with our ongoing activities, particularly preparation for the potential commercialization of Zalviso and future advancement of our other product candidates. As of September 30, 2013, we had working capital of $64.6 million. In July 2013, in an underwritten public offering of our common stock, we raised $47.9 million in net proceeds, after underwriting discounts, commissions and other estimated offering expenses.

We believe that our current cash, cash equivalents and investment balances, including the net proceeds from our equity offering in July 2013, will be sufficient to fund our current operations through at least 2014. We may be able to extend this time period to the extent that we can access additional capital through equity offerings, including our Sales Agreement with MLV. However, we will need to raise additional funds following this offering to support our future operations, and such funding may not be available to us on acceptable terms, or at all. Additionally, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, we believe that our existing cash resources, including the net proceeds from our equity offering in July 2013, based on our current estimates, are adequate to fund potential regulatory approval of Zalviso both in the United States and Europe, and to continue preparation for the potential commercial launch of Zalviso in the United States. However, our planned regulatory filings and commercialization efforts may encounter technical or other difficulties that could increase our development costs more than we expected. The FDA may not accept our Zalviso NDA for filing, and subsequent to the submission of the NDA, the FDA could require us to complete further studies, which would require additional capital before we receive our regulatory approval, if at all. In any event, we will require substantial additional capital to obtain regulatory approval for, and to commercialize, our product candidates, including Zalviso. To raise capital, we may seek to sell additional equity or debt securities, obtain a credit facility or enter into product development, license or distribution agreements with third parties or divest one or more of our product candidates. Any product development, licensing, distribution or sale agreements that we enter into may require us to relinquish valuable rights. We may not be able to obtain sufficient additional funding or enter into a strategic transaction in a timely manner. If adequate funds are not available, we would be required to reduce our workforce, delay, reduce the scope of or eliminate one or more of our research and development programs in advance of the date on which we exhaust our cash resources to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value.

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 Zalviso on terms that might be less favorable than might otherwise be available; or

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

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

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

In June 2011, we entered into a loan and security agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we borrowed $20.0 million in two tranches of $10.0 million each, represented by secured convertible term promissory notes. The interest rate is 8.50%, with the initial 12 months of the facility requiring interest only payments. The notes issued pursuant to the loan and security agreement mature on December 1, 2014. According to the terms of the Hercules agreement, beginning on July 1, 2012, we began repaying Hercules principal, with equal monthly payments of $742,000, consisting of both principal and interest payments, until the maturity date of the loan in December, 2014. As of September 30, 2013, our outstanding debt balance related to the Hercules agreement was $10.5 million. We granted Hercules a first priority security interest in substantially all of our assets, with the exception of our intellectual property, where the security interest is limited to proceeds of intellectual property.

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

Risks Related to Clinical Development and Regulatory Approval

We depend substantially on the success of Zalviso, which may not receive 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 Zalviso for the management of moderate-to-severe acute pain in patients in the hospital setting. Our Phase 3 program consisted of three Phase 3 clinical trials. We have reported positive top-line data from each of these trials and submitted an NDA for Zalviso to the FDA on September 27, 2013. There is no guarantee that the NDA will be successfully filed by the FDA. The FDA has advised us that they will conduct a preliminary review of the NDA within 60 days of receipt, but may determine that the application is not sufficiently complete to permit a substantive review, and will not file the NDA until appropriate modifications are made by us, if at all. In addition, there is no guarantee that the NDA will be successfully approved by the FDA. For example, the FDA could require us to complete further studies, which could delay or preclude any approval of the NDA and would require us to obtain significant additional funding.

Our proposed tradename of Zalviso has not received final approval from FDA, which must approve all drug tradenames to avoid medication errors and misbranding. Any brand recognition or goodwill that we establish with the name Zalviso prior to approval may be worthless if the FDA rejects this tradename.

Any delay in filing, or approval by the FDA, of the Zalviso NDA may negatively impact our stock price and harm our business operations. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing Zalviso, generating revenues and achieving profitability. If any of these events occur, we may be forced to delay or abandon our development efforts for Zalviso, which would have a material adverse effect on our business and could potentially cause us to cease operations.

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Positive clinical results obtained to date for our product candidates may be disputed in FDA review, do not guarantee regulatory approval and may not be obtained from future clinical trials. *

We have reported positive top-line data from each of our three Zalviso Phase 3 clinical trials. However, even if we believe that the data from required Phase 3 clinical trials is positive, the FDA could analyze our data using alternative strategies and determine that the data from our trials was negative or inconclusive. Negative or inconclusive results of a Phase 3 clinical trial could cause the FDA to require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results. Any such determination by the FDA would delay the timing of our commercialization plan for Zalviso and adversely affect our business operations.

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 have experienced and may in the future experience delays in clinical trials of our product candidates. While we have completed our planned trials for Zalviso and the Phase 2 clinical trial for ARX-04, and have no additional trials currently planned, potential future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in 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 contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the device components of our product candidates;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment or being delayed in entering data to allow for clinical trial database closure;

time required to add new clinical sites; or

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

If any future clinical trials are delayed 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 trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. In our Phase 3 active comparator clinical trial (IAP 309), 7.9% of Zalviso treated patients dropped out of the trial prematurely due to an AE, and we observed one serious adverse event, or SAE, that was assessed as possibly or probably related to Zalviso. In our Phase 3, double-blind, placebo-controlled, abdominal surgery trial (IAP 310), adverse events reported in the trial were generally mild or moderate in nature and similar in both placebo and treatment groups. In addition, one patient in the trial, who was in the sufentanil group, experienced an SAE, which was determined to be unrelated to the trial drug. In our Phase 3, double-blind, placebo-controlled, orthopedic surgery trial (IAP 311), treatment-emergent adverse events were generally mild to moderate in nature and similar for the majority of adverse events between sufentanil and placebo treated patients. Two patients (one each in the sufentanil group and placebo group) experienced a serious adverse event considered possibly or probably related to the trial drug by the investigator.

Phase 2 clinical trials conducted by us with our Zalviso, ARX-02, ARX-03 and ARX-04 product candidates have generated some AEs, but no SAEs, related to the trial drug.

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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 the 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 trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

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 Zalviso because it is a drug/device combination. *

Zalviso is a drug/device combination product candidate with both drug and device components submitted in the investigational new drug, or IND, application. Based on our discussions with the FDA, we believe that Zalviso is viewed as a combination product by the FDA, and both drug and device components will be required for review as part of our NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as Zalviso. As a result, we have in the past and may in the future experience delays in the development and commercialization of Zalviso due to regulatory uncertainties in the product development and approval process, in particular as it relates to a drug/device combination product approval under an NDA.

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

We cannot commercialize any of our product candidates, including Zalviso, until the appropriate regulatory authorities, such as the FDA or the European Medicines Agency, or EMA, 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 Zalviso. Additional delays may result if Zalviso 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 trials and the review process.

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The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

If the FDA determines that the clinical trials submitted for a product candidate, including Zalviso, in support of an NDA were not conducted in full compliance with the applicable protocols for these trials, as well as with applicable regulations and standards, or if the FDA does not agree with our interpretation of the results of such trials, the FDA may reject the data from such trials. Such rejection would negatively impact our ability to obtain marketing authorization for a product candidate and would have a material adverse effect on our business and financial condition.

In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, objections have been raised to the FDA s interpretation of Section 505(b)(2). If challenges to the FDA s interpretation of Section 505(b)(2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of such an NDA. Any significant delay in the acceptance, review or approval of an NDA that we have submitted would have a material adverse effect on our business and financial condition.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.*

The FDA and other foreign regulatory agencies, such as the EMA, can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- the manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Part of the regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The regulatory agency may delay, limit or deny marketing approval of our product candidates as a result of such inspections.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from generating meaningful revenues or achieving profitability.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical trials and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. To date, our product candidates are being regulated as drug products under the NDA process administered by the FDA. The FDA could in the future require additional regulation of our product candidates under the medical device provisions of the FDCA. Our systems are designed to comply with Quality Systems Regulation, or QSR, which sets forth the FDA s current good manufacturing practice, or GMP, requirements for medical devices, and other applicable government regulations and corresponding foreign standards for drug GMPs. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing trials. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For example, we have submitted our NDA seeking approval of Zalviso for the management of moderate-to-severe acute pain in patients in the hospital setting; however, our clinical trial data was generated exclusively from the post-operative segment of this population, and FDA may restrict any approval to post-operative patients only, which would reduce our commercial opportunity.

Even if we obtain regulatory approval for Zalviso 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 trials or post-market surveillance. For example, the labeling ultimately approved for Zalviso and our other product candidates will likely include restrictions on use due to the opioid nature of sufentanil. Zalviso 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.

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

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

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. In October 2012, we received notice from the EMA that Zalviso was eligible for centralized European review. Outside of Europe, 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 trials 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.

Zalviso 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 Zalviso, we cannot predict the specific REMS to be required as part of any FDA approval of Zalviso. Depending on the extent of the REMS requirements, our costs to commercialize Zalviso may be substantial. ARX-02, ARX-03 and ARX-04, if approved, will also require REMS programs that may significantly 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.

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

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

Currently, we use two established suppliers of sufentanil citrate for our NanoTabs. For each product candidate, only one of the two suppliers will be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. The alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional trials 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.

Manufacture of Sufentanil NanoTabs requires specialized equipment and expertise.

Ethanol, which is used in the manufacturing process for our Sufentanil NanoTabs, is flammable, and sufentanil is a highly potent, Schedule II compound. These factors necessitate the use of specialized equipment and facilities for manufacture of sufentanil NanoTabs. There are a limited number of facilities that can accommodate our manufacturing process and we need to use dedicated equipment throughout development and commercial manufacturing to avoid the possibility of cross-contamination. If our equipment breaks down or needs to be repaired or replaced, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Furthermore, we are using one manufacturer to produce our sufentanil NanoTabs and have not identified a back-up commercial 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 delay or increase costs related to product and regulatory approval and 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 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.

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Early stage development and manufacture of clinical supplies were conducted at Patheon in Toronto, Canada. Because the DEA requires that sufentanil be manufactured in the United States if our product candidates are marketed in the United States, we transferred our manufacturing capability in the third quarter of 2011 from Patheon in Toronto, Canada to Patheon s production facility in Cincinnati, Ohio, where we have built out a suite within their existing buildings, and where we have conducted late stage development and manufacture of Zalviso registration stability lots, which were utilized in Phase 3 clinical trials. The new facility at Patheon in Cincinnati, Ohio has been qualified; however, we have not yet produced commercial supplies out of this facility and we may encounter difficulties in production at the new facility, which may adversely affect our clinical and commercial plans.

We have limited experience manufacturing the Zalviso device on a clinical scale, no experience on a commercial scale and do not own or operate a manufacturing facility. *

Related to the Zalviso device, we have conducted multiple Design Validation, Software Verification and Validation, Reprocessing and Human Factors studies, and have manufactured for and completed Phase 3 clinical trials using the intended commercial device. If, due to regulatory request or commercial demand, we need to modify the Phase 3 device, we may incur higher costs and experience delay in regulatory approval and/or commercialization of Zalviso. Furthermore, if the identified changes to the device are substantial, we may need to conduct further clinical trials in order to have the commercial device approved by the FDA.

We have manufactured Zalviso devices and supplies on a small scale, including those needed for our Phase 3 clinical trials. We will continue to rely on contract manufacturers, component fabricators and third party service providers to produce the necessary Zalviso devices for the commercial marketplace. We currently outsource manufacturing and packaging of the controller, dispenser and cartridge components of the Zalviso device to third parties and intend to continue to do so. These purchases and components were made and will continue to be made utilizing short term purchase agreements and we may not be able to enter into long-term agreements for commercial supply of Zalviso devices with third party manufacturers, or may be unable to do so on acceptable terms. We may encounter unanticipated problems in the scale-up and automation process that will result in delays in the manufacturing of Zalviso cartridge, dispenser or controller.

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 current Good Manufacturing Practices, or 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 trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. *

We utilized CROs for the conduct of our Phase 3 clinical trials of Zalviso and for the Phase 2 clinical trial of ARX-04 and to assist us in preparing the New Drug Application, or NDA, which we submitted to the FDA in the third quarter of 2013. We rely on CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. 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 clinical programs for Zalviso and our other product candidates, as well as the execution of nonclinical trials. We control only certain aspects of our CROs activities. Nevertheless, we are responsible for ensuring that each of our trials 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.

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

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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 trials, 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 Zalviso, or our other product candidates. As a result, our financial results and the commercial prospects for Zalviso and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Pre-Phase 3 development of ARX-04 is dependent on funding from our government grant with the USAMRMC.

In May 2011, we received a grant from the USAMRMC, effective June 1, 2011, in which the USAMRMC granted $5.6 million to us in order to support the development of ARX-04. Under the terms of the grant, the USAMRMC will reimburse us for development, manufacturing and clinical costs necessary to prepare for and complete the Phase 2 dose-finding trial for the treatment of moderate-to-severe acute pain as well as Phase 3 readiness activities. The grant gives the USAMRMC the option to extend the term of the grant and provide additional funding for the research.

Pre-Phase 3 development of ARX-04 is dependent on the continued performance by the USAMRMC of its responsibilities under this agreement, including adequate continued funding of USAMRMC programs. We have no control over the resources and funding that USAMRMC may devote to this or future agreements, which may be subject to annual renewal and which generally may be terminated by USAMRMC at any time. USAMRMC may fail to perform their responsibilities under the agreement, which may result in the termination of the agreement. In addition, we may fail to perform our responsibilities under the agreement, which may also lead to the termination of this agreement. Our government agreement is subject to audits, which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful in entering, or ineligible to enter, into future government agreements.

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

Risks Related to Commercialization of Our Product Candidates

The commercial success of Zalviso and our other product candidates will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.

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 or SAEs;
- 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 Zalviso;

availability of alternative treatments;

existing capital investment by hospitals in IV PCA technology;

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 Zalviso is approved, but does not achieve an adequate level of acceptance by physicians, nurses, patients and pharmacy and therapeutics committees, or P&T Committees, we may not generate sufficient revenue from Zalviso and we may not become or remain profitable.

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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.

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 Zalviso 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 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 any of our product candidates, including Zalviso, is approved for commercialization, we intend to enter into agreements with third parties to market our product candidates 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.

If we, or potential partners, 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 or our potential partners 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.

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We believe that Zalviso would compete with a number of opioid-based treatment options that are currently available. The hospital market for opioids for moderate-to-severe acute pain is large and competitive. The primary competition for Zalviso is the IV PCA pump, which is widely used in the moderate-to-severe acute pain in the hospital 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 moderate-to-severe acute 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.

Additional potential competitors for Zalviso 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., which was acquired by The Medicines Company. Also in development is MoxDuo, an orally administered, fixed ratio combination of morphine and oxycodone being developed by QRx Pharma, an Australian company. This drug is also in development as an IV product.

Our potential competitors for ARX-02 include products approved in the United States for cancer breakthrough pain, including: ACTIQ and FENTORA, currently manufactured by Teva Pharmaceuticals; Onsolis, currently manufactured by BioDelivery Sciences International, Inc.; Abstral, currently manufactured by ProStrakan Group plc; Lazanda, currently manufactured by Archimedes Pharma Limited; Subsys, currently manufactured by Insys Therapeutics, Inc., 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 Fentanyl TAIFUN, currently manufactured by Akela Pharma, Inc.

We are not aware of any approved or development stage non-IV sedative/analgesic products that would present competition to ARX-03. In the future, there may be products developed or approved for this market which could directly compete with ARX-03.

Competitors for ARX-04 within the military environment include intramuscular morphine injections which are marketed by a variety of generic manufacturers. Within the civilian environment, there are a wide variety of approved injectable and oral opioid products to treat moderate-to-severe acute pain, including IV opioids such as morphine, fentanyl, hydromorphone and meperidine or oral opioids such as oxycodone and hydrocodone.

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 mild-to-moderate acute pain or breakthrough pain could render Zalviso 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 Zalviso and our other product candidates, which could make it difficult for us to sell our products profitably.

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

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Furthermore, market acceptance and sales of Zalviso, or any of our other product candidates, 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 Zalviso, or any of our other 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 Zalviso, or any of our other product candidates.

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 Zalviso or any of our other product candidates. The 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 any sale of Zalviso and any of our other product candidates, 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. Our contract manufacturers have applied annually for a quota on our behalf. In future years, we may need greater amounts of sufentanil to continue development of our product candidates, and we will need significantly greater amounts of sufentanil to implement our commercialization plans for any of our products that may be approved by the FDA, including Zalviso if approved by the FDA. 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 to meet anticipated increases in demand could delay or stop the clinical development or commercial sale of Zalviso or any of our other product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have not yet produced commercial supplies and we may encounter difficulties in production, which may adversely affect our clinical and commercial plans.*

Early development and clinical trial manufacturing was conducted at Patheon in Toronto, Canada. Because the DEA requires that sufentanil be manufactured in the United States if our product candidates are marketed in the United States, we transferred our manufacturing capability in the third quarter of 2011 from Patheon in Toronto, Canada to Patheon s production facility in Cincinnati, Ohio, where we have built out a suite within their existing buildings that will serve as a manufacturing facility for clinical and commercial supplies of NanoTabs. Late stage development and manufacture of registration stability lots, which were utilized in clinical trials, were manufactured at Patheon, Cincinnati. However, we have not yet produced commercial supplies at this facility and we may encounter difficulties in production at the new facility, which may adversely affect our clinical and commercial plans.

In January 2013, we entered into a Manufacturing Services Agreement, or the Services Agreement, with Patheon under which Patheon has agreed to manufacture, supply, and provide certain validation and stability services with respect to Zalviso for potential sales in the United States, Canada, Mexico and other countries, subject to agreement by the parties to any additional fees for such other countries. There is no guarantee that Patheon s services will be satisfactory or that they will continue to meet the strict regulatory guidelines of the FDA or other regulatory agencies. In addition, in January 2013, we entered into a Capital Expenditure and Equipment Agreement, or the Capital Agreement, with Patheon, relating to the manufacture of Sufentanil NanoTabs. Under the terms of the Capital Agreement, we have planned certain future modifications to Patheon s Cincinnati facility.

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If Patheon cannot provide us with an adequate supply of NanoTabs, we may be required to pursue alternative sources of manufacturing capacity. 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 before approval of Zalviso and our other product candidates for commercial distribution. We do not fully 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 do not meet 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 Zalviso. 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 trials 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.

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

As of September 30, 2013, we had 27 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, particularly in preparation for the commercial launch of Zalviso if our NDA submission is approved by the FDA. 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 Zalviso and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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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 trials 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 trial 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

***If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected. **

To protect our proprietary technology, we rely on patents as well as other intellectual property protections including trade secrets, nondisclosure agreements, and confidentiality provisions. As of October 15, 2013, we were the owner of record of 19 issued patents worldwide. These issued patents cover AcelRx s sufentanil Nanotab , medication delivery devices and platform technology, and include nine issued U.S. patents, three issued European patents with 27 national registrations and seven issued patents in other international territories including Japan and China. These issued patents are expected to provide coverage through 2027 2031.

In addition, we are pursuing a number of U.S. non-provisional patent applications and foreign national applications directed to our product candidates. One of our issued U.S. patents, Patent Number 8,357,114, covers key features of our Zalviso (ARX-01) PCA device, but we have not yet obtained any issued patents that provide protection for key features of our ARX-02, ARX-03 and ARX-04 SDAs independent of the drug composition used in them. We have received a Notice of Allowance for two of our pending U.S. applications that include claims covering key features of our ARX-02, ARX-03 and ARX-04 SDA device. 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.

Our commercial success will depend in part on successfully defending our current sufentanil formulation patents against third party challenges and expanding our existing formulation patent portfolio to provide additional layers of patent protection, as well as extending patent protection to our proprietary delivery devices. There can be no assurance that we will be successful in defending our existing and future patents against third party challenges, or that our pending patent applications will result in issued patents.

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.

There is also no assurance that any patents issued to us will not become the subject of adversarial proceedings such as opposition, inter partes review, post-grant review, reissue, re-examination or other post-issuance proceedings, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

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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.

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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.

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. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, that became effective March 16, 2013. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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.

Competitors or third parties may infringe our patents. We may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or that the third party s technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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.

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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 applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

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

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 the United States, Canada, the European Union and India. We have also registered our NANOTAB mark in the United States, Hong Kong and Singapore, and our ACCELERATE. INNOVATE. ALLEVIATE. tagline in the United States. We have additionally applied for registration of our ZALVISO mark in the United States on an intent-to-use basis and that application has been allowed. 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.

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Risks Related to Ownership of Our Common Stock

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

Since our initial public offering, or IPO, in February 2011, the trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any adverse development or perceived adverse development with respect to the FDA s filing or review of the NDA for Zalviso;
- any delay in submitting an NDA for any of our other product candidates and any adverse development or perceived adverse development with respect to the FDA s filing or review of that NDA;
- adverse results or delays in future clinical trials;
- inability to obtain additional funding, including funding necessary for the planned commercialization and manufacturing of Zalviso in the United States and advancement of clinical trials for other product candidates;
- 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;
- 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, or NASDAQ, 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.

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

Until recently, we had a low volume of daily trades in our common stock on NASDAQ. For example, the average daily trading volume in our common stock on NASDAQ during the first quarter of 2013 was approximately 275,000 shares per day. A more active market for our stock has only recently developed and may not be sustained. For example, the average daily trading volume in our common stock on NASDAQ during the third quarter of 2013 was approximately 600,000 shares per day. Our stockholders may be unable to sell their common stock at or near their asking prices, which may result in substantial losses to our investors.

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

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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 own a significant percentage of our voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders are able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and NASDAQ, 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 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 stockholders. 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 September 30, 2013, we had 43,039,269 shares of common stock outstanding, all of which is 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. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

In addition, certain holders of our securities are entitled to certain rights with respect to the registration of their shares of common stock under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction 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.

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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, including pursuant to our Sales Agreement with MLV, 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 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.

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. The completion of the July 2013 equity offering, together with our public offering in December 2012, our initial public offering, private placements and other transactions that have occurred, may trigger such an ownership change. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. 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 dividends on our capital stock, and we are prohibited from doing so under the terms of our loan and security agreement with Hercules. Regardless of the restrictions in our loan and security agreement with Hercules or the terms of any potential future indebtedness, we anticipate that we will retain all available funds and any future earnings to support our operations and finance the growth and development of our business and, therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

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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.

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

In July 2013, the Company issued 94,161 shares of common stock upon the net exercise of a warrant by Hercules Technology Growth Capital, Inc. The warrant was initially exercisable into 137,254 shares of common stock and was issued in June 2011 in connection with a debt facility in a private placement transaction not involving a public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended. The conversion of the warrants into common stock was an exempt exchange under Section 3(a)(9) of the Securities Act. The shares were issued pursuant to a cashless exercise of warrants and the Company received no proceeds.

In July 2013, the Company issued 76,765 shares of common stock upon the cash exercise of a warrant by Capital Ventures International. The warrant was initially exercisable into 76,765 shares of common stock and was issued in June 2012 in a private placement transaction not involving a public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended. The shares issued upon conversion of the warrants were issued in reliance on an exemption from registration under Section 4(a)(2) under the Securities Act.

In August 2013, the Company issued 670,460 shares of common stock upon a partial net exercise of warrants by OTA, LLC. The warrants were initially exercisable into 1,058,824 shares of common stock and were issued in June 2012 in a private placement transaction not involving a public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended. The conversion of the warrants into common stock was an exempt exchange under Section 3(a)(9) of the Securities Act. The shares were issued pursuant to a cashless exercise of warrants and the

Company received no proceeds.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit Number	Description of the Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.(1)
3.2	Bylaws of the Registrant, currently in effect.(2)
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2	Specimen Common Stock Certificate of the Registrant.(3)
4.3	Amended and Restated Investor s Rights Agreement, among the Registrant and certain of its security holders, dated as of November 23, 2009.(4)
4.4	Warrant to Purchase Stock of the Registrant, issued to Wells Fargo Bank, N.A., dated March 15, 2007.(5)
4.5	Warrant to Purchase Preferred Stock of the Registrant, issued to Pinnacle Ventures II Equity Holdings, L.L.C., dated September 16, 2008.(6)
4.6	Warrant to Purchase Stock issued to Hercules Technology II, L.P., dated as of June 29, 2011. (7)
10.1+	Supply Agreement with Mallinckrodt LLC, effective as of May 31, 2013.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document **
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document **
101.LAB	XBRL Taxonomy Extension Label Linkbase Document **
101.PRE	XBRL Taxonomy Extension Presentation Document **

\+ Material in the exhibit marked with a *** has been omitted pursuant to a request for confidential treatment filed with the SEC. Omitted portions have been filed separately with the SEC.

(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.

(7) Incorporated herein by reference to Exhibit 4.4 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on June 30, 2011.

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

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** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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SIGNATURES

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

Date: November 5, 2013

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ James H. Welch
James H. Welch
Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

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31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document **
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document **
101.LAB	XBRL Taxonomy Extension Label Linkbase Document **
101.PRE	XBRL Taxonomy Extension Presentation Document **

\+ Material in the exhibit marked with a *** has been omitted pursuant to a request for confidential treatment filed with the SEC. Omitted portions have been filed separately with the SEC.

(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.

(7) Incorporated herein by reference to Exhibit 4.4 to the Registrant s current report on Form 8-K (File No. 001-35068), as filed with the SEC on June 30, 2011.

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

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** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.