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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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 ☒ No ☐

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

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

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

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

As of April 25, 2013, the number of outstanding shares of the registrant's common stock was 37,237,319.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2012

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.
(A Development Stage Company)

Condensed Balance Sheets
(In thousands, except share data)

	March 31, 2013 (Unaudited)	December 31, 2012[1]
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 37,079	$ 47,932
Short-term investments	11,119	11,831
Prepaid expenses and other current assets	2,136	2,003
Total current assets	50,334	61,766
Property and equipment, net	2,396	2,485
Restricted cash	250	205
Other assets	5	64
TOTAL ASSETS	$ 52,985	$ 64,520
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,941	$ 2,235
Accrued liabilities	3,379	4,653
Long-term debt, current portion	7,663	7,443
Total current liabilities	14,983	14,331
Deferred rent	283	312
Long-term debt, net of current portion	6,542	8,530
Contingent put option liability	60	82
Warrant liability	9,194	7,418
Total liabilities	31,062	30,673
STOCKHOLDERS' EQUITY:		
Common stock, $0.001 par value—100,000,000 shares authorized as of March 31, 2013 and December 31, 2012; 37,237,319 and 37,055,027 shares issued and outstanding as of March 31, 2013 and December 31, 2012	37	37
Additional paid-in capital	156,676	155,836
Deficit accumulated during the development stage	(134,789)	(122,027)
Accumulated other comprehensive income (loss)	(1)	1
Total stockholders' equity	21,923	33,847
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 52,985	$ 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.

AcelRx Pharmaceuticals, Inc.
(A Development Stage Company)

Condensed Statements of Comprehensive Loss
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,		Period from July 13, 2005 (Inception) Through March 31,
	2013	2012	2013
Research grant revenue	$ 940	$ 329	$ 4,406
Operating Expenses:			
Research and development	9,318	4,771	101,647
General and administrative	2,191	2,104	28,684
Total operating expenses	11,509	6,875	130,331
Loss from operations	(10,569)	(6,546)	(125,925)
Interest expense	(454)	(594)	(8,176)
Other income (expense), net	(1,739)	75	(688)
Net loss	(12,762)	(7,065)	(134,789)
Other comprehensive loss:			
Unrealized gains (losses) on available-for-sale securities	(2)	(2)	(2)
Comprehensive loss	$ (12,764)	$ (7,067)	$ (134,791)
Net loss per share of common stock, basic and diluted	$ (0.34)	$ (0.36)	
Shares used in computing net loss per share of common stock, basic and diluted	37,133,358	19,607,483	

See notes to condensed financial statements.

AcelRx Pharmaceuticals, Inc.
(A Development Stage Company)

Condensed Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,		Period from July 13, 2005 (Inception) Through March 31,
	2013	2012	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(12,762)	$ (7,065)	$ (134,789)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	141	164	2,824
Amortization of premium/discount on investments, net	29	137	604
Interest expense related to debt financing	133	164	3,607
Stock-based compensation	757	542	7,253
Revaluation of convertible preferred stock warrant liability, call option liability and put option liability	1,755	(61)	3,110
Other	—	—	33
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(83)	(1,140)	(637)
Restricted cash	(45)	—	(250)
Accounts payable	1,706	(395)	3,940
Accrued liabilities	(1,277)	(441)	1,630
Deferred rent	(26)	334	398
Net cash used in operating activities	(9,672)	(7,761)	(112,277)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(52)	(403)	(5,266)
Purchase of investments	(8,365)	(10,440)	(120,199)
Proceeds from sale of investments	—	—	21,815
Proceeds from maturity of investments	9,045	15,190	86,709
Net cash provided by (used in) investing activities	628	4,347	(16,941)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock in equity offerings, net of offering costs	—	—	88,105
Proceeds from the issuance of long-term debt	—	—	32,383
Payments of long-term debt	(1,893)	—	(18,769)
Proceeds from issuance of convertible promissory notes	—	—	9,000
Proceeds from issuance of common stock through equity plans	84	89	637
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	54,941
Net cash provided by (used in) financing activities	(1,809)	89	166,297
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(10,853)	(3,325)	37,079
CASH AND CASH EQUIVALENTS—Beginning of period	47,932	7,794	—
CASH AND CASH EQUIVALENTS—End of period	$ 37,079	$ 4,469	$ 37,079
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 335	$ 339	$ 4,869
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Issuance of convertible preferred stock warrants	$ —	$ —	$ 1,223
Beneficial conversion features related to convertible notes	$ —	$ —	$ 1,699
Issuance of call option related to convertible note	$ —	$ —	$ 476
Conversion of convertible promissory notes into common stock	$ —	$ —	$ 8,137
Issuance of common stock upon cashless exercise of warrants	$ —	$ —	$ 536
Reclassification of warrant liability and call option liability to equity	$ —	$ —	$ 906
Issuance of warrants for common stock	$ —	$ —	$ 6,795
Contingent put option liability	$ —	$ —	$ 232

See notes to condensed financial statements.

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 March 31, 2013. In addition, the Company had an accumulated deficit of $134.8 million and $122.0 million as of March 31, 2013 and December 31, 2012. Through March 31, 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 will be sufficient to fund the Company's current operations into the third quarter of 2014. 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 months ended March 31, 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.

Newly Adopted 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 and this adoption did not have a material effect on the Company's condensed consolidated financial statements.

2. Investments and Fair Value Measurement

Investments

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

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

	As of March 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 32,893	$ —	$ —	$ 32,893
Money market funds	2,045	—	—	2,045
U.S. government agency securities	2,141	—	—	2,141
Total cash and cash equivalents	37,079	—	—	37,079
Marketable securities:				
U.S. government agency securities	11,121	—	(2)	$ 11,119
Total marketable securities	11,121	—	(2)	$ 11,119
Total cash, cash equivalents and investments	$ 48,200	$ —	$ (2)	$ 48,198

	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

As of March 31, 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 March 31, 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 months ended March 31, 2013 and 2012.

As of March 31, 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 March 31, 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 March 31, 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 March 31, 2013			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 2,045	$ 2,045	$ —	$ —
U.S. government agency obligations	13,260	—	13,260	—
Total assets measured at fair value	$ 15,305	$ 2,045	$ 13,260	$ —
Liabilities				
PIPE warrant	$ 9,194	—	—	$ 9,194
Contingent put option liability	60	—	—	60
Total liabilities measured at fair value	$ 9,254	$ —	$ —	$ 9,254

	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 warrant	$ 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 March 31, 2013:

Risk-free interest rate	0.77%
Expected volatility	76.0%
Expected life (in years)	4.7
Expected dividend yield	0.0%

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 December 31, 2012:

Risk-free interest rate	0.72%
Expected volatility	78.0%
Expected life (in years)	4.9
Expected dividend yield	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 months ended March 31, 2013 and March 31, 2012 (in thousands):

	Three Months Ended March 31, 2013
Fair value—beginning of period	$ 7,500
Change in fair value of Level III liabilities	1,754
Fair value—end of period	$ 9,254

	Three Months Ended March 31, 2012
Fair value—beginning of period	$ 232
Change in fair value of Level III liabilities	(61)
Fair value—end of period	$ 171

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 the planned Phase 2 dose-finding trial in a study of acute moderate-to-severe pain, and to prepare to enter Phase 3 development. The 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 $940,000 and $329,000 for the three months ended March 31, 2013 and 2012, respectively.

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.

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

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

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the loan, including payment of any applicable prepayment charges, which range from 1%-3% of the outstanding loan balance and accrued interest, as

well as a final payment fee of $0.2 million. This option is considered a contingent put option liability as the holder of the loan may exercise the option in the event of default and, is considered an embedded derivative which must be valued and separately accounted for in the Company's financial statements. As of March 31, 2013 and December 31, 2012, the estimated fair value of the contingent put option liability was $60,000 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 will be revalued at the end of each reporting period and any change in the fair value will be recognized in the statement of operations.

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.

As of March 31, 2013, the Company had outstanding borrowings under the Hercules loan and security agreement of $14.2 million, net of debt discounts of $0.4 million. Amortization of the debt discounts, which were recorded as Interest Expense, was $108,000 and $134,000 for the three months ended March 31, 2013 and 2012, respectively. 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.

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, and then marked to fair value each reporting period, with changes in estimated fair value recorded through the Statement of Comprehensive Loss in other income or expense. 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 March 31, 2013, the fair value of the PIPE warrants was estimated to be $9.2 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 for the three months ended March 31, 2013, which was recorded as other expense, was $1.8 million.

As of March 31, 2013, PIPE warrants to purchase 2,630,103 shares of common stock issued in connection with the Private Placement had not been exercised and were outstanding. 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.

As of March 31, 2013, warrants to purchase 274,508 shares of common stock issued to Hercules had not been exercised and were outstanding.

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 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.

6. 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 March 31,		Period from July 13, 2005 (Inception) Through March 31,
	2013	2012	2013
Expenses:			
Research and development	$ 355	$ 251	$ 3,732
General and administrative	402	291	3,521
Total stock-based compensation expense	$ 757	$ 542	$ 7,253

As of March 31, 2013 there were 531,623 shares available for grant, 5,077,513 options outstanding and 65,765 restricted stock units outstanding under the Company's 2011 Equity Incentive Plan.

7. Net Loss per Share of Common Stock

The following table sets forth the computation of the Company's basic and diluted net loss per share of common stock during the three months ended March 31, 2013 and 2012 (in thousands, except for share and per share amounts):

	Three Months Ended March 31,	
	2013	2012
Net loss	$ (12,762)	$ (7,065)
Shares used in computing net loss per share of common stock, basic and diluted	37,133,358	19,607,483
Net loss per share of common stock, basic and diluted	$ (0.34)	$ (0.36)

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:

	March 31,	
	2013	2012
Stock options to purchase common stock	5,077,513	3,285,942
Restricted stock units	65,765	171,912
Common stock warrants	2,908,036	506,197

8. 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 Sufentanil NanoTab PCA System, or ARX-01.

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 our products, which are currently in development stage; accordingly, the amounts and timing of such future expenditures cannot be determined at this time.

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

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

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

About AcelRx Pharmaceuticals

We are a development stage specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. Our lead product candidate, the Sufentanil NanoTab PCA System, or the NanoTab System or ARX-01, is designed to improve the management of moderate-to-severe acute post-operative pain in patients in the hospital setting. Although widely used, the current standard of care for patients with post-operative pain, intravenous patient-controlled analgesia, or IV PCA, has been shown to cause harm 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.

The Sufentanil NanoTab PCA System

The Sufentanil NanoTab PCA System is an investigational pre-programmed, non-invasive, handheld system that allows post-operative patients to self-dose with sublingual sufentanil NanoTabs to manage their post-operative pain. The NanoTab System is designed to address the limitations of IV PCA by offering:

- **A high therapeutic index opioid:** The NanoTab System uses the high therapeutic index opioid sufentanil; it offers post-operative pain patients 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 the NanoTab System provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients are not tethered to IV tubing and a pump for pain relief, the NanoTab System allows for ease of patient mobility.
- **A simple, pre-programmed PCA solution:** The NanoTab System is a pre-programmed PCA system designed to eliminate the risk of pump programming errors.

NanoTab System Phase 3 Clinical Program

Summary

Our Phase 3 program for the NanoTab System consists of three Phase 3 clinical trials. We have reported top-line results from two of these three clinical trials and expect to report top-line data from the final planned Phase 3 trial in the second quarter of 2013. Prior to our Phase 3 program, we completed three successful Phase 2 clinical trials of sufentanil NanoTabs in the post-operative setting. These Phase 2 clinical trials demonstrated analgesic efficacy, a low adverse event profile and excellent device functionality. During our End of Phase 2 meeting with the FDA, the FDA stated that the demonstration of efficacy versus placebo in two Phase 3 clinical trials, with a total safety database of at least 600 patients exposed to sufentanil, should suffice to support a new drug application, or NDA. We have designed our Phase 3 clinical trials based on the feedback from the FDA.

Phase 3 Clinical Trials for the NanoTab System

Active comparator trial (IAP 309)

In November 2012, we reported top-line data showing that the NanoTab System had met its primary endpoint of non-inferiority in the Phase 3 open-label active comparator trial designed to compare the efficacy and safety of the NanoTab System (15 mcg/dose) to IV PCA with morphine (1mg/dose) for the treatment of moderate-to-severe acute post-operative pain.

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

- the NanoTab System was non-inferior ($p<0.001$) to IV PCA morphine for the primary endpoint of Patient Global Assessment, or PGA, comparison over the 48-hour study 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 the NanoTab System was statistically superior to IV PCA morphine for the PGA endpoint ($p=0.007$). Statistically superior PGA was also seen at the 24 hour and 72 hour timepoints.

Additional study results showed the NanoTab System demonstrated 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 NanoTab Systems 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 the NanoTab System 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 the NanoTab System 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, one was related to the NanoTab System and two were related to IV PCA morphine.

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

In March 2013, we reported top-line data results demonstrating that the NanoTab System met its primary endpoint in a pivotal Phase 3 trial designed to compare the efficacy and safety of the NanoTab System 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 study period compared to baseline, or Summed Pain Intensity Difference (SPID-48), in patients following major open abdominal surgery. Patients receiving sufentanil NanoTabs demonstrated a significantly greater SPID-48 (pain reduction) compared to placebo-treated patients during the study period (105.6 and 55.6, respectively; $p=0.001$).

Eighty, or 70.2%, of the sufentanil NanoTab-treated patients completed the 48-hour study period, compared to 30, or 51.7%, of placebo-treated patients. Reasons for drop-out in the sufentanil-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 sufentanil-treated patients and 67.2% of placebo-treated patients. Adverse events with an occurrence greater than 5% in either the sufentanil 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 sufentanil group, experienced a serious adverse event, which was determined to be unrelated to the study drug by the investigator.

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

In August 2012, we initiated a Phase 3 clinical trial with the NanoTab System in a double-blind, placebo-controlled trial for a minimum of 48 hours and up to 72 hours in patients who are undergoing a total hip or knee replacement. The objective is to compare the efficacy and safety of the Sufentanil NanoTab PCA System to placebo in the management of acute post-operative pain after major orthopedic surgery. Approximately 420 patients were randomly assigned to treatment with sufentanil or placebo. The primary endpoint is the sum of pain intensity difference to baseline (SPID) over 48 hours. Dosing of the final subject in this trial occurred in the first week of April 2013, and we expect to receive top-line data from this trial later in the second quarter of 2013. Key secondary endpoints include an assessment of different imputation strategies for the use of rescue opioids, pain intensity and relief scores and patient and healthcare professional Global Assessments and Ease of Care questionnaires.

ARX-04- Sufentanil Single Dose NanoTab

Summary

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 May 2011, we announced that the U.S. Army Medical Research and Materiel Command, or USAMRMC, awarded us a $5.6 million grant to support Phase 2 development and Phase 3 readiness of ARX-04 for the treatment of moderate-to-severe acute pain. The term of the grant ends on January 31, 2014.

Phase 2 Clinical Trial

In November 2012, we initiated a Phase 2 placebo-controlled, dose-finding trial, in which 101 patients were randomized following bunionectomy surgery in a 2:2:1 ratio to 30 mcg sufentanil, 20 mcg sufentanil or placebo treatment arms. In April 2013, we reported that the trial successfully met its primary endpoint. The primary endpoint evaluated pain intensity over the 12-hour study period compared to baseline, or Summed Pain Intensity Difference (SPID-12), in patients following bunionectomy surgery. Patients receiving 30 mcg sufentanil NanoTabs, which were administered by a healthcare professional, no more frequently than once per hour, had significantly greater pain reduction as measured by SPID-12 than placebo-treated patients (p=0.003). The 20 mcg sufentanil-treated patients did not achieve SPID-12 scores that differentiated from placebo, thus confirming that 30 mcg is the minimally effective dose when ARX-04 is dosed no more frequently than once per hour. Adverse events reported in the study 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 study drug. In addition, two patients dropped out of the study due to adverse events, one patient's discontinuation considered unrelated to study drug and the other considered probably related to study drug, both in the 30 mcg-treated group. AcelRx will present these top-line data to USAMRMC, and intends to hold an End of Phase 2 meeting with the FDA to define the Phase 3 program for ARX-04. The remainder of the period under the grant, which ends on January 31, 2014, will be focused primarily on package development for ARX-04 and other Phase 3 readiness activities.

ARX-02 and ARX-03

In addition to our NanoTab System 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 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.

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

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. 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 the manufacturing, regulatory affairs, clinical research and other aspects of pharmaceutical development. 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 ended March 31, 2013 was $12.8 million. 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 March 31, 2013, we had an accumulated deficit of $134.8 million. As of March 31, 2013, we had cash, cash equivalents and investments totaling $48.2 million compared to $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 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 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 March 31, 2013, we had a debt balance of $14.2 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 $4.4 million since inception of the grant, but continued funding from the USAMRMC is contingent upon their review and approval of our continued research and development activities associated with the grant. In addition, there can be no assurance that we will receive other research-related grant awards or produce other collaborative agreement revenues in the future.

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 three months ended March 31, 2013 from those previously disclosed in our Annual Report on Form 10-K.

Results of Operations

Three Months Ended March 31, 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 was $0.9 million and $0.3 million for the three months ended March 31, 2013 and 2012, respectively, and was generated from our grant with the USAMRMC. From inception of the grant through March 31, 2013, we have generated revenue of $4.4 million. We expect the remaining $1.2 million of the USAMRMC grant to be earned by January 31, 2014, the termination 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 ARX-01. Research and development expenses included the following:

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

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We anticipate that research and development expenses for the remaining quarters of 2013 will be substantially lower than the first quarter of 2013 due to lower clinical development expenses associated with our NanoTab System and ARX-04 programs, partially offset by higher expenses associated with preparatory activities to submit an NDA to the FDA and activities associated with preparing for the potential commercialization of the NanoTab System. Total operating expenses for 2013 are anticipated to be modestly higher than they were in 2012.

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 months ended March 31, 2013 and 2012 (in thousands):

	Three Months Ended March 31,	
	2013	2012
ARX-01 (NanoTab System)	$6,378	$ 3,023
ARX-04	895	169
Overhead	2,045	1,579
Total research and development expenses	$9,318	$ 4,771

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 the NanoTab System 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 months ended March 31, 2013 and 2012 were as follows (in thousands, except percentages):

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2013	2012		
Research and development expenses	$ 9,318	$ 4,771	$4,547	95%

The $4.5 million increase during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 was primarily attributable to an increase of $3.4 million related to Phase 3 clinical trial development for our NanoTab System program. In addition, there was an increase of $0.7 million related to our ARX-04 development program, and 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 the NanoTab System.

Total general and administrative expenses for the three months ended March 31, 2013 and 2012 were as follows (in thousands, except percentages):

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2013	2012		
General and administrative expenses	$ 2,191	$ 2,104	$ 87	4%

General and administrative expenses were relatively consistent over the comparative periods.

Interest Expense

Total interest expense for the three months ended March 31, 2013 and March 31, 2012 was as follows (in thousands, except percentages):

	Three Months Ended March 31,		Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2013	2012		
Interest expense	$ 454	$ 594	$ (140)	(24)%

Interest expense for both 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 $0.1 million decrease during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 was due to a lower average debt balance during the three months ended March 31, 2013 as compared to the three months ended March 31, 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, and our contingent put option liability associated with the loan and security agreement with Hercules. The account also reflects interest earned on our cash and investments balances.

Total other income (expense), net for the three months ended March 31, 2013 and March 31, 2012 was as follows (in thousands):

	Three Months Ended March 31,		Increase/ (Decrease)
	2013	2012	
Other income (expense), net	$ (1,739)	$ 75	$(1,814)

The $1.8 million decrease in other income (expense) during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 was primarily attributable to the increase in the estimated fair value of our PIPE warrants. The warrants are remeasured at the end of each reporting period utilizing the Black-Scholes option-pricing model, and the increase was primarily driven by a higher share price of AcelRx common stock on March 31, 2013, compared to the share price on December 31, 2012. The income during the three months ended March 31, 2012 primarily reflected the change 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 March 31, 2013, we have received net proceeds of $54.9 million from the sale of convertible preferred stock, $88.1 million from the sale of common stock and $41.4 million from our debt arrangements.

As of March 31, 2013, we had cash, cash equivalents and investments totaling $48.2 million compared to $59.8 million as of December 31, 2012. The decrease was primarily attributable to capital required to fund our continuing operations, including advancement of our lead product candidate, the NanoTab System, through Phase 3 clinical trials. 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):

	Three Months Ended March 31,	
	2013	2012
Net cash used in operating activities	$ (9,672)	$ (7,761)
Net cash provided by investing activities	628	4,347
Net cash provided by (used in) financing activities	(1,809)	89

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 $9.7 million during the three months ended March 31, 2013 reflected a net loss of $12.8 million, partially offset by aggregate non-cash charges of $2.8 million and a net change of $0.3 million in our net operating assets and liabilities. Non-cash charges primarily included $1.8 million for the change in fair value of our PIPE warrant and $0.8 million for stock-based compensation. The net change in our operating assets and liabilities was primarily a result of an increase in accounts payable of $1.7 million and a decrease in accrued liabilities of $1.3 primarily related to our Phase 3 clinical trials for ARX-01.

Cash used in operating activities of $7.8 million during the three months ended March 31, 2012 reflected a net loss of $7.1 million, partially offset by aggregate non-cash charges of $0.9 million and a net change of $1.6 million in our net operating assets and liabilities. Non-cash charges primarily included $0.5 million for stock-based compensation and $0.2 million for interest on our debt. The net change in our operating assets and liabilities was primarily a result of an increase in prepaid expenses and other current assets of $1.1 million, primarily due to prepayments related to our Phase 3 clinical trials for ARX-01.

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 three months ended March 31, 2013, cash provided by investing activities of $0.6 million was primarily as a result of $9.0 million in proceeds from the maturity of investments, partially offset by $8.4 million for purchases of investments.

During the three months ended March 31, 2012, cash provided by investing activities of $4.3 million was primarily as a result of $15.2 million in proceeds from the maturity of investments, partially offset by $10.4 million for purchases of investments.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities, proceeds from our debt financings and payments made on such debt financings. As of March 31, 2013, we had outstanding debt of $14.2 million.

During the three months ended March 31, 2013, cash used in financing activities of $1.8 million was primarily due to payments on our loan and security agreement with Hercules.

During the three months ended March 31, 2012, cash provided by financing activities of $0.1 million was a result of purchases made under our 2011 Employee Stock Purchase Plan.

Operating Capital and Capital Expenditure Requirements

We expect our rate of cash usage to increase in the future, in particular to support our product development activities. We believe that our available cash resources, will be sufficient to fund our operations into the third quarter of 2014, including support for our continuing development of our product candidates, clinical trials and commercial readiness activities. 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 initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

Off-Balance Sheet Arrangements

Through March 31, 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.

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

Changes in internal control over financial reporting. There 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, the Sufentanil NanoTab PCA System, or the NanoTab System or ARX-01. We have three additional product candidates, the Sufentanil NanoTab BTP Management System, or ARX-02, the Sufentanil/Triazolam NanoTab, or ARX-03, and Sufentanil Single-Dose Acute Pain NanoTab, or ARX-04. We have incurred significant net losses in each year since our inception in July 2005 and as of March 31, 2013 we had an accumulated deficit of $134.8 million.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we prepare for the potential commercialization of the NanoTab System 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 our product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing the clinical development of the NanoTab System, initially for the treatment of post-operative pain in the hospital setting;
- obtaining regulatory approval for the NanoTab System, which will require additional funding;
- launching and commercializing the NanoTab System, 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, 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 required by the United States Food and Drug Administration, or FDA, to perform trials in addition to those that we currently anticipate.

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

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

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

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 the completion of our Phase 3 clinical trials, preparation for potential commercialization of the NanoTab System and future advancement of other product candidates. As of March 31, 2013, we had working capital of $35.4 million.

We believe that our current cash, cash equivalents and investment balances will be sufficient to fund our current operations into the third quarter of 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 substantial additional funds to support our future operations, and such funding may not be available to us on acceptable terms, or at all. Additionally, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, we believe that our existing cash resources are adequate to complete our ongoing NanoTab System Phase 3 clinical trials, to submit our planned New Drug Application, or NDA, to the FDA for the NanoTab System, and to begin preparation for commercialization and manufacturing of the NanoTab System in the United States. However, our clinical trials may encounter technical or other difficulties that could increase our development costs more than we expected. Even if we are able to submit an 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 the NanoTab

System. Raising funds in the current economic environment, when the capital markets have been affected by the global recession, may present additional challenges. 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.

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 the NanoTab System 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.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will not be able to continue our planned level of operations beyond the third quarter of 2014 and will not have sufficient capital to complete the regulatory approval process for the NanoTab System in the United States, which would have a material adverse effect on our business, operating results and prospects. 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.

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 all of 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 March 31, 2013, our outstanding debt balance related to the Hercules agreement was $14.2 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. In order to continue our planned operations and satisfy our debt obligations with Hercules, we will need to raise additional capital in the future. 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 our NanoTab System, which is still under clinical development, and may not obtain regulatory approval or be successfully commercialized.*

We have not marketed, distributed or sold any products. The success of our business depends primarily upon our ability to develop and commercialize the NanoTab System for the treatment of acute post-operative pain. Our Phase 3 program consists of three Phase 3 NanoTab System clinical trials. We have reported positive top-line data from two of these trials and expect to report top-line data from the third trial in the second quarter of 2013.

Contingent upon receipt of successful data from the remaining Phase 3 clinical trial, we intend to submit an NDA for the NanoTab System to the FDA in the third quarter of 2013. There is no guarantee that the remaining Phase 3 NanoTab System clinical trial or the Human Factors studies to be included in the planned NDA, will be completed on schedule or if at all, or if completed, will be successful. Even if we are able to submit an NDA, 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.

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

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

In March 2013, we announced positive top-line data from our double-blind, placebo-controlled, Phase 3 trial for the NanoTab System in patients following abdominal surgery. In addition, in November 2012, we announced positive top-line data from our active comparator NanoTab System Phase 3 clinical trial. Subsequent analyses of clinical trial data may lead to different, including less favorable, interpretations of the results than the analyses conducted to date or may identify important implications of the trial that are not currently known, or be subject to differing interpretations by the regulatory agencies. In addition, we completed enrollment of our remaining NanoTab System Phase 3 clinical trial in April 2013, and we expect to report top-line results during the second quarter of 2013. There is no guarantee that the results of the remaining Phase 3 clinical trial will be positive, and the positive results to date from our Phase 3 clinical trials are not an indication or guarantee that the remaining Phase 3 clinical trial results will be positive.

Our product candidates are subject to the risks of failure inherent in pharmaceutical and medical device development. Before obtaining regulatory approval for the commercial sale of any product candidate, we must successfully complete all required Phase 3 clinical trials. Negative or inconclusive results of a Phase 3 clinical trial could cause the FDA to require that we repeat it or conduct additional clinical trials. Even if we believe that the data from required Phase 3 clinical trials is positive, the FDA could analyze our data using alternative imputation strategies and determine that any trial was negative or inconclusive. Furthermore, while we have completed multiple Phase 2 clinical trials for the NanoTab System, ARX-02, ARX-03 and ARX-04 and have obtained positive safety and efficacy results for our sufentanil-based product candidates during our prior clinical trials, we cannot be certain that these results will be duplicated when our product candidates are tested in a larger number of patients in our Phase 3 clinical trials, including in our ongoing Phase 3 clinical trial of the NanoTab System.

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 enrollment of our planned trials for the NanoTab System and 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 our 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 NanoTab System clinical trial, 7.9% of NanoTab System treated patients dropped out of the trial prematurely due to an adverse event, and we observed one serious adverse event, or SAE, that was assessed as possibly or probably related to the NanoTab System. In our Phase 3, double-blind, placebo-controlled, abdominal surgery trial, 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 a serious adverse event, which was determined to be unrelated to the study drug. Phase 2 clinical trials conducted by us with our NanoTab System, ARX-02, ARX-03 and ARX-04 product candidates have generated some AEs, but no SAEs, related to the trial drug.

The analysis of the data set from our remaining Phase 3 NanoTab System trial, when available, could result in identification of additional AEs or SAEs, related to the trial drug. Additional SAEs related to the trial drug observed in any of our clinical trials may adversely impact our ability to obtain regulatory approval for our product candidates.

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 our NanoTab System product candidate because it is a drug/device combination.

The NanoTab System 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 the NanoTab System is viewed

as a combination product by the FDA, and both drug and device components will be required for review as part of an NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as the NanoTab System. As a result, we have in the past and may in the future experience delays for the NanoTab System 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 the NanoTab System, 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 the NanoTab System. Additional delays may result if the NanoTab System 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.

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 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 that resulted from such trials. The rejection of data from clinical trials required to support an NDA could 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 review or approval of an NDA that we submit 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.

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

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

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

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

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 the NanoTab System 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 the NanoTab System 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.

The NanoTab System and our other product candidates will require Risk Evaluation and Mitigation Strategies, or REMS.

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 the NanoTab System, we cannot predict the specific REMS to be required as part of the FDA's approval of the NanoTab System. Depending on the extent of the REMS requirements, our costs to commercialize the NanoTab System 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.

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.

Currently, we use one supplier of triazolam for our ARX-03 NanoTabs. Switching triazolam suppliers may involve substantial cost and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacture of Sufentanil NanoTabs requires specialized equipment and expertise.

Ethanol, which is used in the manufacturing process 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 proceed with our planned clinical trials and obtain regulatory approval for commercial marketing. In the past we have identified impurities in our product candidates. In the future we may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our products.

Historically, we have manufactured the majority of our NanoTab supplies 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. The new facility 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. In addition, regulatory agencies may require that a bioequivalence study be conducted, which is designed to ensure that the Phase 3 drug lots made at Patheon, Toronto are equivalent to one of the registration drug lots made at Patheon, Cincinnati. There is risk that this bioequivalence study could fail the FDA's bioequivalence requirements which would adversely affect our clinical and commercial plans.

Our designs for the PCA device components of our NanoTab System for Phase 3 clinical trials may not be fully functional or commercially viable.*

The NanoTab System device we are using in Phase 3 clinical trials and plan to use commercially, or the Phase 3 device, has more features than the device used in Phase 2, including additional software. We have conducted multiple Design Validation, Software Verification and Validation, Reprocessing and Human Factors studies, which have informed the design of the Phase 3 device and we plan to conduct additional Human Factors studies prior to submitting the planned NDA for the NanoTab System. However, we cannot predict if the Phase 3 device will be fully functional or acceptable throughout all Phase 3 clinical trials or for commercial use. If we need to modify the Phase 3 device, we may incur higher costs and experience delay in regulatory approval and commercialization of the NanoTab System. Furthermore, if the 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 limited experience manufacturing the NanoTab System Phase 3 device on a clinical scale, no experience on a commercial scale and do not own or operate a manufacturing facility.

We have manufactured the NanoTab System devices and supplies on a small scale, including those needed for our Phase 3 clinical trials. We continue to rely on contract manufacturers, component fabricators and secondary service providers to produce the necessary NanoTab System devices for the remaining Phase 3 clinical trials and the commercial marketplace. We currently outsource

manufacturing and packaging of the controller, dispenser and cartridge components of the NanoTab System device to third parties and intend to continue to do so. These purchases of Phase 3 devices 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 the NanoTab System 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 the NanoTab System 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 have selected and executed agreements with CROs to conduct our three Phase 3 clinical trials for the NanoTab System and for the Phase 2 clinical trial for ARX-04. We rely on these CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our clinical programs for the NanoTab System 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.

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

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical 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 the NanoTab System, or our other product candidates. As a result, our financial results and the commercial prospects for the NanoTab System 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 the NanoTab System 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 the NanoTab System;
- 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 the NanoTab System 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 the NanoTab System and we may not become or remain profitable.

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

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

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 the NanoTab System, our lead product candidate, 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 our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market the NanoTab System 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 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.

We believe that the NanoTab System would compete with a number of opioid-based treatment options that are currently available. The market for opioids for post-operative pain is large and competitive. The primary competition for the NanoTab System is the IV PCA pump, which is widely used in the post-operative setting. Leading manufacturers of IV PCA pumps include Hospira Inc., CareFusion Corporation, Baxter International Inc., Curlin Medical, Inc. and Smiths Medical. The most common opioids used to treat post-operative pain are morphine, hydromorphone and fentanyl, all of which are available as generics. Also available on the market is the Avancen Medication on Demand, or MOD, Oral PCA Device developed by Avancen MOD Corporation.

Additional potential competitors for the NanoTab System 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, 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.; and SL Spray, currently manufactured by Insys Therapeutics, 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 post-operative pain or breakthrough pain could render the NanoTab System 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 the NanoTab System 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.

Furthermore, market acceptance and sales of the NanoTab System, 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 the NanoTab System, 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 the NanoTab System, 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 the NanoTab System 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 the NanoTab System 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 the NanoTab System 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 the NanoTab System 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.*

A substantial portion of our clinical trial manufacturing to date has been completed 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. The new facility 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, or otherwise, 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 Pharmaceuticals, Inc, or Patheon, for use with the NanoTab System. Under the terms of the Services Agreement, Patheon has agreed to manufacture, supply, and provide certain validation and stability services with respect to the NanoTab System for sale 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, however, 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, the aggregate cost of which is expected to be less than $3.5 million to support demand in the U.S. If equipment manufacture or modifications do not meet expected deadlines, the timing for our planned NDA submission for the NanoTab System may be delayed.

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

The facilities of any of our future manufacturers of sufentanil-containing NanoTabs must be approved by the FDA after we submit our planned NDA and before approval of the NanoTab System and our other product candidates. We do not control the manufacturing process of sufentanil NanoTabs and are completely dependent on these third party manufacturing partners for compliance with the FDA's requirements for manufacture. In addition, although our third party manufacturers are well established commercial manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their process. If our manufacturers 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 the NanoTab System. 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 March 31, 2013, we had 25 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize the NanoTab System and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

The use of our product candidates in clinical 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 March 31, 2013, we are the owner of record of one issued European patent, including national validation in ten countries, which expires in 2027, one issued European patent, including national validation in ten countries, which expires in 2029, one Mexican patent which expires in 2029, one Japanese patent, which expires in 2027, one New Zealand patent, which expires in 2029, five issued U.S. patents which provide coverage through at least 2027, and one issued U.S. patent which provides coverage through at least 2030. In addition, we are pursuing 15 U.S. non-provisional patent applications, and 58 foreign national applications, including six European Regional Phase applications directed to our product candidates. One of our issued U.S. patents, Patent Number 8,357,114, covers key features of our 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. 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 a re-examination or other post-grant review, 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.

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

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

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

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

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

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

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

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.

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

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

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

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

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

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. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications could be subject to opposition or cancellation after the marks are

registered. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols other than "ACELRX" that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

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

Prior to our initial public offering, or IPO, in February 2011, there was no public market for our common stock. An active public trading market for our common stock has not developed and may never develop or, if developed, may not be sustained. Moreover, the trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding, including funding necessary for the planned commercialization and manufacturing of the NanoTab System in the United States and advancement of clinical trials for other product candidates;
- any delay in submitting an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's filing or review of that NDA;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- 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.

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

To date, we have a low volume of daily trades in our common stock on 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. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

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.

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

Our executive officers and directors, together with the stockholders with whom our executive officers and directors are affiliated or associated, beneficially owned approximately 52% of our outstanding voting stock as of March 31, 2013. 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 plan to continue to assess our internal controls and procedures and intend to take further action as necessary or appropriate to address any other matters we identify. However, our independent registered public accounting firm is not currently required to deliver an attestation report on the effectiveness of our internal control over financial reporting as we qualify for an exemption as a non-accelerated filer under the applicable SEC rules and regulations.

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 March 31, 2013, we had 37,237,319 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.

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

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. Our public offering in December 2012, together with 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.

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 February 2013, the Company issued 58,580 shares of common stock to Pinnacle Ventures L.L.C. These shares were issued upon a net exercise of the warrant to purchase 228,264 shares of common stock that was issued 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.

Item 6. Exhibits

Exhibit Number	Description of the Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant, currently in effect. (1)
3.2	Bylaws of the Registrant, currently in effect. (2)
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2	Specimen Common Stock Certificate of the Registrant. (3)
4.3	Amended and Restated Investor's Rights Agreement, among the Registrant and certain of its security holders, dated as of November 23, 2009. (4)
4.4	Warrant to Purchase Stock of the Registrant, issued to Wells Fargo Bank, N.A., dated March 15, 2007. (5)
4.5	Warrant to Purchase Preferred Stock of the Registrant, issued to Pinnacle Ventures II Equity Holdings, L.L.C., dated September 16, 2008. (6)
4.6	Warrant to Purchase Stock issued to Hercules Technology II, L.P., dated as of June 29, 2011. (7)
4.7	Warrant to Purchase Stock issued to Hercules Technology Growth Capital, Inc., dated as of June 29, 2011. (8)
10.1#	Manufacturing Services Agreement between Registrant and Patheon Pharmaceuticals, Inc., dated as of January 18, 2013.
10.2#	Amended and Restated Capital Expenditure and Equipment Agreement between Registrant and Patheon Pharmaceuticals, Inc., dated as of January 18, 2013.
10.3+	Non-Employee Director Compensation Policy. (9)
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 **

\+ Indicates management contract or compensatory plan.

\# 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.

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(9) Incorporated by reference to the information under "Item 11. Executive Compensation—Director Compensation—Non-Employee Director Compensation" of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012 (File No. 001-35068), as filed with the SEC on March 12, 2013.

* 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.

** 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.

SIGNATURES

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

Date: May 8, 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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** 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.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.1

Manufacturing Services Agreement for ARX-01

December 12, 2012

Table of Contents

MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of December 12, 2012 (the "**Effective Date**")

B E T W E E N:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

("**Patheon**"),

- and -

ACELRX PHARMACEUTICALS, INC.,
a corporation existing under the laws of the State of Delaware

("**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", **"Active Pharmaceutical Ingredient" or "API"** means the material listed on Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth on Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.2(a);

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation.

"Annual Product Review Report" means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report**" means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the estimated volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

"**Applicable Laws**" means all applicable Laws, including the Laws of State of Ohio, being the jurisdiction where the Manufacturing Site is located, cGMPs, the United States Federal Food, Drug and Cosmetic Act, as amended, and the Laws of all jurisdictions in the Territory;

"Application for Marketing Authorization" means, with respect to Product, (a) in the United States, a New Drug Application filed with the FDA pursuant to 21 U.S.C. Section 357 and 21 C.F.R. Section 314 ("NDA"), and (b) in any country other than the United States, an application or set of applications for marketing approval comparable to an NDA necessary to market and sell Product commercially in such country.

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"Bill Back Items" means the expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, pallets, PAPR or PPE suits (where applicable), RFID tags and supporting equipment, and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"**Breach Notice**" will have the meaning specified in Section 8.2(a);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the States of Ohio or California;

"**Bulk Tablet Packaging**" means, as the context requires, either the packaging activities related to bulk sufentanil tablets or the packaging components which hold bulk sufentanil tablets following manufacture.

"**cGMPs**" means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations together with the latest FDA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"Capital Agreement" means the Amended and Restated Capital Expenditure and Equipment Agreement entered into by the parties effective December 12, 2012 and attached here to as Schedule K;

"Client Intellectual Property" means Intellectual Property made, invented, generated or derived by Client before entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client's Active Materials or Product, including Product Intellectual Property;

"**Client Property**" will have the meaning specified in Section 8.4(f);

"**Client-Supplied Components**" means those Components to be supplied by Client or that have been supplied by Client;

"**CMC**" has the meaning specified in Section 7.8(c);

"Commercially Reasonable Efforts" means, with respect to the activities conducted pursuant to this Agreement, the carrying out of obligations or tasks in a sustained manner consistent with the commercially reasonable efforts used by a reputable pharmaceutical contract manufacturing organization for drug substances of similar nature, complexity, and developmental stage. Commercially Reasonable Efforts requires that Patheon: (a) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently makes and implements decisions and allocates resources designed to advance progress with respect to such objectives.

"**Components**" means, collectively, all packaging components, raw materials, and ingredients (including labels, product inserts and other labelling for the Product) but excluding pallets, required to manufacture the Product in accordance with the Specifications, other than the Active Materials;

"**Confidentiality Agreement**" means the agreement about the non-disclosure of confidential information between Patheon and Client dated December 22, 2010;

"Confidential Information" means all confidential or proprietary information of a party that is disclosed to the other party under this Agreement, including, without limitation, research, development, manufacturing, marketing, financial, personnel, and other business and technical information, compositions, inventions, discoveries, processes, methods, formulae, procedures, protocols, techniques, data, specifications, and plans, whether disclosed in oral, written, graphic, or other electronic form. In addition, all confidential information disclosed by a party under the Confidentiality Agreement will be such party's Confidential Information for purposes of this Agreement. Notwithstanding the foregoing, all information and data that are developed or generated by or on behalf of Patheon as a result of performing the Manufacturing Services hereunder and that relate to Product including, without limitation, master production and control records, batch production and control records, Client Intellectual Property, Inventions, quality control tests and results thereof, in each case will be deemed to be Client Confidential Information and Patheon will be deemed to be the Receiving Party of such Confidential Information, regardless of whether Patheon generated and/or disclosed such information, data, Inventions, or other documents to Client.

"Dedicated Equipment" will have the meaning ascribed to it in the Capital Agreement related to this MSA;

"**Deficiency**" has the meaning specified in Section 7.8(d);

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

"**Delivery Date**" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(e);

"**Development Agreement**" has the meaning specified in Section 13.11;

"**FDA**" means the United States Food and Drug Administration;

"**Finished Product Packaging**" means, as the context requires, either (a) drug product in the primary packaging comprised of sufentanil drug tablets in a cartridge inside of an aluminum based pouch with an oxygen scavenger, and secondary packaging which is to be determined, or (b) the packaging activities related to such drug product in its primary and secondary packaging.

"**Firm Order**" has the meaning specified in Section 5.1(c);

"**First Firm Order**" has the meaning specified in Section 5.1(b);

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**Initial Manufacturing Month**" has the meaning specified in Section 5.1(b);

"**Initial Manufacturing Period**" has the meaning specified in Section 5.1(b);

"**Initial Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know-how;

"**Invention**" means any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"**Late Delivery**" has the meaning specified in Section 5.5(b);

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"**Manufacturing Requirements**" means performing the Manufacturing Services in conformance with the Specifications, cGMPs, the Quality Agreement, the Capital Agreement and Applicable Laws;

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, Bulk Tablet Packaging and Finished Product Packaging (if applicable) and related services, set forth in this Agreement, required to manufacture Product from Active Materials and Components;

"**Manufacturing Site**" means the facility owned and operated by Patheon that is located at 2110 East Galbraith Road, Cincinnati, OH 45237-1625;

"Materials" means all Components, Bill Back Items, and other materials used to manufacture the Product other than Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth on Schedule D;

"**Minimum Run Quantity**" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in Schedule B, with preferably three lots per manufacturing cycle and no more than five lots per manufacturing cycle;

"**Patheon Competitor**" means a company that is in the primary business of providing contract pharmaceutical development services or commercial manufacturing services to the pharmaceutical industry in exchange for compensation.

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, Intellectual Property developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business, in each case which Intellectual Property is not specific to, or dependent upon, Client's Active Materials or Products including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug Product, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components, certain cost items as set forth in Schedule B, and annual stability testing costs as set forth in Schedule C;

"**Product(s)**" means the product(s) listed on Schedule A;

"Product Intellectual Property" has the meaning specified in Section 13.1(b);

"**Quality Agreement**" means the agreement (the form of which is set forth in Schedule F) between the parties setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Regulatory Authority**" means the FDA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products, including the Product, in the Territory;

"RFID" means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Product or Materials to assist in inventory control, tracking, and identification;

"**Remediation Period**" has the meaning specified in Section 8.2(a);

"**Shortfall**" has the meaning specified in Section 2.2(b);

"**Specifications**" means the file for the Product, which is given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to the Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all known environmental, health and safety information for Products including material safety data sheets; and

(e) the finished Product specifications, Bulk Tablet Packaging specifications, and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.2(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means the geographic area of the United States of America, Canada and Mexico, and their respective territories, and any other geographic areas that may be added to the Territory upon agreement by the parties in accordance with Section 4.5;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Year**" means in the first year of this Agreement the period from the Effective Date up to and including December 121 of the same calendar year, and thereafter will mean a calendar year.

1.2 Currency.

Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section or Schedule of this Agreement.

1.4 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in, and form part of this Agreement:

Schedule A	-	Product List and Specifications
Schedule B	-	Minimum Run Quantity, Annual Volume, and Price
Schedule C	-	Annual Stability Testing
Schedule D	-	Active Materials, Active Materials Credit Value, and Maximum Credit Value
Schedule E	-	Technical Dispute Resolution
Schedule F	-	Commercial Quality Agreement
Schedule G	-	(Reserved)
Schedule H	-	Quarterly Active Materials Inventory Report
Schedule I	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Schedule J	-	(Reserved)
Schedule K	-	Capital Agreement

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services and supply to Client Product intended for marketing and sale in the Territory for the fees specified in Schedules B and C. The parties acknowledge that they intend to negotiate an amendment to this Agreement to add ARX-01 in Finished Product Packaging as a Product. If the parties enter into this amendment, Client will still have the right to purchase Product in Bulk Tablet Packaging from Patheon and have a third party package the Product into Finished Product Packaging for distribution or sale outside of the Territory. Schedule B sets forth a list of cost items that are included in the Price for Product; all cost items required for the manufacture of Product that are not included in this list are excluded from the Price and are subject to reasonable additional fees to be paid by the Client. All Manufacturing Services will be performed by Patheon at the Manufacturing Site. Patheon may change the Manufacturing Site for the Product only with the prior written consent of Client, this consent not to be unreasonably withheld. During the period commencing on the Effective Date up through the Initial Term, Patheon will supply 100% of the Client's requirements for Product offered for sale by Client in the Territory so long as Patheon is in material compliance with its obligations to Client under this Agreement. But if (a) Patheon fails to meet its supply obligations to Client for three consecutive Firm Orders, (b) in any consecutive six month period, 30% or more of the aggregate quantities of Product to be delivered by Patheon pursuant to Firm Orders during such six month period are not delivered by the due dates specified in the applicable Firm Orders, or (c) Patheon does not fulfill a Firm Order within 90 days after the Delivery Date specified therein then, in each case, Client may obtain up to 20% of its requirements for Product offered for sale in the Territory from an alternate supplier, regardless of whether any such occurrence is attributable to a Force Majeure Event. After the Initial Term, Client will only be required to obtain 80% of its requirements for Product offered for sale in the Territory from Patheon.

In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Product in Bulk Tablet Packaging.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures and in compliance with all Applicable Laws. Each time Patheon ships Product to Client, it will give Client a certificate of analysis and certificate

of compliance that includes a statement that the Product in such shipment have been manufactured and tested in accordance with Specifications and cGMPs and conform to the Specifications, and sets out the quality control and quality assurance test results for such Product. Client will have sole responsibility for the release of Product to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client's property and Client's Confidential Information.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon's expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Product in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C, subject to mutual written agreement of Patheon and Client. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Manufacturing Requirements. Patheon will give Client all stability test data and results at Client's request.

(e) Packaging. Patheon will complete Bulk Tablet Packaging as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed on the Product and on the shipping carton of Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Product. Those changes will be submitted by Client to all applicable governmental agencies and other third parties responsible for the approval of the Product. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name.

(f) Active Materials and Client Supplied Components Importing . At least 45 days before the scheduled production date, Client will deliver that quantity of Active Materials to the Manufacturing Site DDP (Incoterms 2010) sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If these Active Materials are not received 45 days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as reasonably agreed to by the parties. All shipments of Active Materials will be accompanied by certificate(s) of analysis from the Active Materials manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Materials specifications.

(g) Patheon Supplied Components Importing. At least 15 days before the scheduled production date, Patheon will have all Components at the Manufacturing Site and will be prepared to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If all Components are not ready for production at least 15 days before the scheduled production date, Patheon will provide written notification of the delay to Client and will use Commercially Reasonable Efforts to obtain such Components as soon as practicable.

(h) Bill Back Items. Bill Back Items will be charged to Client at Patheon's cost plus a 10% handling fee.

(i) Product Rejection for Finished Product Specification Failure. If Patheon manufactures Product in accordance with the agreed upon Specifications and the Manufacturing Requirements and a batch or portion of a batch of Product does not meet the Specifications for Bulk Tablet Packaging, Client will pay Patheon the applicable Price per unit for the non-conforming Product. The API in the non-conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

2.2 Active Materials Yield.

(a) Reporting. Patheon will give Client a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in Schedule H, which will contain the following information for the quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received for commercial manufacturing of Product and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability or test batches manufactured during the applicable period. For clarity, Quantity Dispensed includes all amounts of Active Materials that are lost, stolen, damaged, destroyed, or rendered unusable because of a failure to handle the Active Materials in accordance with cGMPs or other Applicable Laws, as well as Active Materials that are consumed in batches that are not released to Client because they do not comply with the Specifications.

Quantity Converted: The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.1 or 6.2), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within 60 days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Schedule I including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Products at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Product and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

Once the parties mutually agree that Patheon has produced three successful commercial production batches (including validation batches and samples) of Products at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the Parties will mutually agree on the target yield for the Products at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as reasonably agreed to by the parties. For clarity, the initial Target Yield, once established, will be applied retroactively for the purposes of determining the Actual Annual Yield for the first Year of the Agreement.

For [*] scale: If the Target Yield is not greater than or equal to [*], the Parties mutually agree to re-evaluate the production process.

For [*] scale: If the Target Yield is not greater than or equal to [*], the Parties mutually agree to re-evaluate the production process.

If during any calendar quarter more than 1 gram of Active Materials is lost, stolen, damaged, destroyed, or rendered unusable because of Patheon's failure to comply with cGMPs or other Applicable Laws, Patheon will report the occurrence to Client in writing within ten days of its discovery thereof.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than 3.5% below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [(Target Yield – 3.5%) – AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Credit for Shortfall. If there is a Shortfall in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than 60 days after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Schedule I. Not later than 45 days after the expiration or termination of this Agreement, any remaining credit owing under this Section 2.2(c) will be paid to Client. The Shortfall for each Year, if any, will be disclosed by Patheon on the reconciliation report form.

(d) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(e) Material Breach. Patheon agrees to use Commercially Reasonable Efforts to deliver 100% of all quantities of Products specified in each Firm Order that meet the Manufacturing Requirements, at the times and on the Delivery Dates specified. If Patheon uses Commercially Reasonable Efforts but fails to deliver the quantity of Product ordered in a Firm Order, it will not be a material breach of this Agreement if:

(i) No more than three batches of Product delivered by Patheon under the applicable Firm Order fail to contain at least 90% of the Target Yield set forth in Section 2.2(a); or

(ii) No batches of Products are delivered more than 90 days after the Delivery Date specified in the applicable Firm Order.

For clarity, if one or both of the situations set forth in clauses (i) or (ii) occur, Patheon will be in material breach of this Agreement. In addition, rejection of five or more shipments of Product in any one Year due to Patheon's failure to perform the Manufacturing Services in accordance with the Manufacturing Requirements will be a material breach of this Agreement.

Patheon will also comply with all of the terms and conditions of the Quality Agreement.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C. These prices may be subject to adjustment under other parts of this Agreement. Client will also pay Patheon for any Bill Back Items.

3.2 Active Materials and Client-Supplied Components.

Client will at its sole cost and expense, use commercially reasonable efforts to deliver those quantities of Active Materials and Client-Supplied Components to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Products and to ship Products on the Delivery Date. If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials into the United States. Client's obligation will include obtaining the proper release of the Active Materials from U.S. Customs and the FDA. Client or Client's designated broker will be the "Importer of Record" for Active Materials imported into the United States. The Active Materials and Client-Supplied Components will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials and Client-Supplied Components will at all times remain the property of Client. Any Active Materials and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services and will not be transferred to any third parties without Client's prior written consent. Patheon will store and handle Active Materials in accordance with cGMPs and requirements applicable to a DEA Schedule II controlled substance. Patheon will store and handle Client-Supplied Components in accordance with Applicable Laws. If any of the Client-Supplied Components are lost, damaged, stolen, destroyed, or otherwise rendered unusable for their intended purpose because they were not stored or handled in accordance with the storage conditions specified by Client in writing and in accordance with Applicable Laws while in Patheon's custody or control, Patheon will promptly pay to Client the actual replacement cost for these Client-Supplied Components.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The tiered Price and annual stability Price for the Product for the first Year are listed in Schedules B and C and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year of the Agreement, Patheon may, upon at least 60 days' written notice to Client, adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. Patheon may adjust the Price for inflation, based upon the preliminary number for any increase in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing (" **PPI**") published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. On or about November 1st of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs. On or about November 1st of each Year, Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Run Quantity and the Annual Volume specified in Schedule B for Phase 1 ([*]) equipment, and Phase 2 ([*]) equipment, respectively, together with price adjustments for manufacturing and the combination of Phase 1 and Phase 2 equipment, respectively. The Price is subject to change if the specified Minimum Run Quantity changes or if the Annual Volume is not ordered in a Year. For greater certainty, if Patheon and Client agree that the Minimum Run Quantity will be reduced or the Annual Volume will not be ordered in a Year, whether as a result of a decrease in estimated Annual Volume or otherwise, and, as a result of the reduction, Patheon demonstrates to Client that its costs to perform the Manufacturing Services or to acquire the Materials for the Product will increase on a per unit basis (including the amount of the increase), then Patheon may increase the Price by an amount that reflects Patheon's documented increased costs. On or about November 1st of each Year, Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases for the next Year. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(d) Tier Pricing. The pricing in Schedule B is set forth in Annual Volume tiers based upon the Client's volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the 18 month forecast provided in September of the previous Year. Within 30 days of the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within 45 days of the end of the Year or, if

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

the Agreement is terminated before the full amount of such credit is applied against amounts due by Client hereunder, Patheon will issue payment to the Client for the overpayment within 45 days of the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment within 45 days of the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within 30 days, the matter will be handled under Section 12.1.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1 st of each Year a revised Schedule B to be effective for Product delivered on or after the first day of the next Year.

4.3 Price Adjustments – Current Year Pricing.

During any Year of this Agreement, the Price set out in Schedule B will be adjusted as follows:

Extraordinary Increases in Component Costs . If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by 10% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by 5% of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review by Patheon and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment through good faith negotiations. Amendments to the Specifications required by the FDA or any other Regulatory Authority will be implemented by Patheon, and the parties will subsequently negotiate any change in the Price that is required because of such amendments. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change relating to a proposed Specifications change, the proposed change in the Specifications will be implemented, and the Price change will become effective, only for those orders of Product that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for

Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client.

4.5 Multi-Country Packaging Requirements (if applicable).

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional Component costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling 18 Month Forecast. When this Agreement is executed, Client will give Patheon a non-binding 18 month forecast of the volume of Product that Client expects to order in the first 18 months of commercial manufacture of the Product. This forecast will then be updated by Client: (i) every 6 months until an Application for Marketing Authorization for the Product is filed with the FDA; (ii) quarterly following Application for Marketing Authorization filing, and prior to the start of commercial manufacturing; and (iii) monthly after the start of commercial manufacturing, on or before the 10 th day of the relevant month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than 20%. The most recent 18 month forecast will prevail.

(b) Firm Orders for Initial Manufacturing Month. At least three months before the start of commercial manufacture of the Product, Client will update the rolling forecast for the first three months of manufacture of the Product (the " **Initial Manufacturing Period**"). The first month of this updated forecast ("**Initial Manufacturing Month**") will constitute a firm written order in the form of a purchase order or otherwise (" **First Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture the quantity of the Product set forth in the Firm Order. If manufacturing has not started, Client may cancel any batches from the First Firm Order at no cost if notice of cancellation is received by Patheon 60 days or more before the scheduled Delivery Date under the First Firm Order. If manufacturing has not started, Client may cancel any batches from the First Firm Order if notice of cancellation is received by Patheon more than 30 days but fewer than 60 days before the scheduled Delivery Date under the First Firm Order, but Client will pay Patheon $[*] for each cancelled batch. The parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above then the initial rolling 18 month forecast will also be adjusted as necessary.

(c) Firm Orders Thereafter. Before and during the Initial Manufacturing Period, and thereafter on a rolling basis during the term of this Agreement, Client will issue an updated 18 month forecast on or before the 10 th day of each month. The first four months of each updated forecast will constitute firm orders by Client to purchase and for Patheon to manufacture and supply the quantity of the Product set forth in such portion of the updated forecast. Concurrent with the 18 month forecast, Client will issue a firm written order in the form of a purchase order or otherwise (" **Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

manufacture and deliver the agreed quantity of the Product on a date not less than three months from the first day of the month immediately following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's Manufacturing Services purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Product. The quantities of Product ordered in those written orders will be firm and binding on Client and may not be reduced by Client.

(d) Three Year Forecast. On or before the 10th day of June of each Year, Client will give Patheon a written non-binding three-year forecast, broken down by quarters for the second and third years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the three-year period.

(e) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within ten Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the Parties or as set forth in Sections 2.1(f) or 5.1(b). For clarity, Patheon will be required to accept Firm Orders provided that such Firm Orders comply with the requirements set forth in Section 5.1(b) or 5.1(c), as applicable, and are consistent with the binding portion of the most recent forecast provided by Client.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), (b), and (c) in ordering the Components required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Product during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Product for the first six months contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client, which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Product manufactured for Client within six months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all reasonable costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Product subsequently manufactured for Client or in third party product manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components within 12 months of purchase or, in the case of finished Product, within three months of manufacture, Client will pay Patheon [*] thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [*]. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than three months to the Client at Client's expense on 14 days written notice to the Client.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

5.3 Minimum Orders.

Client may only order Manufacturing Services for batches of Product in multiples of the Minimum Run Quantities as set out in Schedule B.

5.4 Shipments.

Shipments of Product will be made EXW (INCOTERMS 2010) Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point, at which time risk of loss or damage will transfer to Client. Patheon will package each shipment of Product in a commercially reasonable manner and in accordance with Client's instructions. Patheon will, in accordance with Client's instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export licence or other official authorization necessary to export the Product. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Product will be transported in accordance with the Specifications.

5.5 On Time Delivery.

(a) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the Initial Manufacturing Period. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(b) If, after the Initial Manufacturing Period, Patheon is unable to deliver the quantity of Product ordered under a Firm Order within five days of the Delivery Date due to an act or omission by Patheon (a "**Late Delivery"**), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be 5% of the Price of the quantities of Product not delivered by Patheon under the Firm Order (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] * Price * 5%). The parties agree that the credits provided for under this Section 5.5(b) are considered liquidated damages for the shortage of supply of Product for commercial sale and will not be considered a penalty.

(c) A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2 except as set forth in Section 2.2(e). If Patheon has two consecutive Late Deliveries in a calendar quarter, the parties will meet as necessary to amicably resolve the reasons for the Late Deliveries. The parties will agree on a delivery improvement plan within five Business Days. If, after the delivery improvement plan is in place, Patheon has two further consecutive Late Deliveries in any calendar quarter, Client may exercise its right to terminate this Agreement for cause under Section 8.2(a) without a further opportunity to cure.

(d) For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials (provided that Patheon ordered Materials with sufficient lead time for such Materials to be delivered on a timely basis), a delay in Product release approval from Client, inaccurate Client forecasts, or receipt of non-conforming API or Client-Supplied Components.

5.6 Invoices and Payment.

Invoices will be sent on the date issued by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured

and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within 30 days of the date of invoice. The unpaid portion of accounts that are past due by more than 30 days will accrue interest at 1.5% per month which is equal to an annual rate of 18%. The Late Delivery credits set forth in Section 5.5(b) are only available to Client if all outstanding undisputed invoices have been paid in full or are not more than 45 days outstanding at the time the Late Delivery arose. Notwithstanding the foregoing, Client will have no obligation to pay invoices for that portion of a shipment of Product that has been rejected by Client in accordance with Section 6.1(a) unless and until an independent third party determines that the applicable Products should have been accepted by Client as set forth in Section 6.1(b).

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject any portion of any shipment of Product that deviates from the Manufacturing Requirements without invalidating any remainder of the shipment. Client will visually inspect the Product manufactured by Patheon upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Product that deviate from the Manufacturing Requirements or for shortages in Product delivered within 30 days after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt and visual inspection of the Product, within 30 days after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable 30 day period, then the delivery will be deemed to have been accepted by Client on the 30 th day after delivery or discovery, as applicable. Except as set out in Section 6.3 and Section 10.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable 30 day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have ten days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within ten days after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Manufacturing Requirements, then the parties will mutually select an independent third party to evaluate if the Products deviate from the Manufacturing Requirements. This evaluation will be binding on the parties. If the independent third party determines that any Products deviate from the Manufacturing Requirements, Client's rejection of those Products in the manner contemplated in Section 6.1(a) will be binding and Patheon will be responsible for the cost of the evaluation. If the independent third party does not find that any of the Products deviate from the Manufacturing Requirements, then Client will be deemed to have accepted delivery of the Products on the date on which the independent third party issues its findings, but this date will be no longer than 60 days after the delivery date, and Client will be responsible for the cost of the evaluation.

(c) Shortages or Production Deficiencies. Claims for shortages in the amount of Product shipped by Patheon that are the subject of a Deficiency Notice will be dealt with by Patheon either remedying the shortage by supplying additional Product as soon as practicable but in no event later than within 45 days of its receipt of the Deficiency Notice, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Product. A shortage of greater than 25% or Late Delivery of three consecutive Product shipments will be considered a material risk that Patheon will not be able to meet Client forecasts consistent with Section 2.1.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. " **Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any Regulatory Authorities to detain or destroy any of the Product. Recall will also include any action by either party to refrain from selling or shipping quantities of the Product to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating to the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Product. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Product.

(a) Defective Product. If Client rejects Product under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Manufacturing Requirements, Patheon will credit Client's account for Patheon's invoice price for the defective Product. If Client previously paid for the defective Product, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Product; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Product with conforming Product without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials required for the manufacture of the replacement Product. For greater certainty, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Manufacturing Requirements, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will promptly, at Client's election, either: (i) refund the invoice price for the Recalled or returned Product, (ii) offset the amount paid by Client for the Recalled or returned Product against other amounts due to Patheon hereunder; or (iii) replace the Recalled or returned Product with new Product without Client being liable for payment therefore under Section 3.1, contingent upon the receipt from Client of all Active Materials

required for the manufacture of the replacement Product. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the yield calculations under Section 2.2. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above and in Section 10.3, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it (collectively, " **Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Product or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) results from a defect in the Active Materials or Client-Supplied Components that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Manufacturing Requirements, or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, or Recalled Product for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Product to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Product for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition for any damaged, defective, returned, or Recalled Product.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all mutually agreed upon information that will enable Client to respond properly to questions or complaints about the Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Manufacturing Requirements, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3, monetary remedies that are expressly provided for in this Agreement, and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 and Section 2.2, as well as Client's right to terminate the Agreement in accordance with Section 8.2, will be Client's sole remedies for any failure by Patheon to provide the Manufacturing Services in accordance with the Manufacturing Requirements.

ARTICLE 7

CO-OPERATION

7.1 Supply Team.

Each party will forthwith upon execution of this Agreement establish a Supply Team, with each party appointing two of its employees to be members of the Supply Team. The members from each party collectively will have one (1) vote. Each party may replace any or all of its representatives on the Supply Team at any time upon written notice to the other party.

(a) Responsibilities. The Supply Team will perform the following functions:

(i) discuss and supervise all issues relating to the Manufacturing Services and supply of Product hereunder;

(ii) oversee and monitor the supply of Active Materials and Materials to meet forecasted delivery requirements;

(iii) establish written key performance indicators for the parties' activities with respect to Manufacturing hereunder, which key performance indicators may include, without limitation, timely delivery of Active Materials, on time product deliveries, percentage of lots accepted, Target Yield and Actual Annual Yield, and measure and monitor the parties' performance against such key performance indicators; and

(iv) oversee the handling of Product complaints, adverse events, Product recalls, and Product return processes in accordance with the applicable procedures specified in this Agreement and the Quality Agreement.

(b) Meetings. During the term of this Agreement, Supply Team meetings will be held quarterly, either in person or by means of telecommunication or video conference, and may be called by either party with not less than 30 days' notice to the other, unless such notice is waived. In addition to the quarterly meetings, the Supply Team may be convened, polled, or consulted with from time to time on an ad hoc basis by means of telecommunication, video conferences, electronic mail, or correspondence, as deemed necessary or appropriate to perform the responsibilities assigned to it under this Agreement. The Supply Team will hold its first meeting within 60 days after the Effective Date. Representatives of each party who are not members of the Supply Team may attend meetings of the Supply Team as required to further the activities of the parties with respect to the Manufacturing Services. All material decisions made by the Supply Team will be recorded in writing. For the avoidance of doubt, the Supply Team will not have the authority to amend or modify any term or condition of this Agreement, including, without limitation, any financial terms or obligations. These amendments or modifications may only be made in accordance with Section 13.11.

(c) Decision Making. The Supply Team will operate by consensus (e.g., all decisions and approvals will require a unanimous vote of both parties' members). If the Supply Team fails to reach a consensus on any matter within its jurisdiction within 30 days of first consideration of such matter, either party may refer such matter for resolution in accordance with the provisions of Article 12.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Product, regarding the Product if, in the opinion of that party's counsel, the communication is necessary to

comply with the terms of this Agreement or the requirements of any law, governmental order or regulation; provided, however, in the event such requirement applies to Patheon, Patheon will notify Client in writing of the requirement and such communication. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, Patheon will permit Client to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency within one Business Day of receipt thereof. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, Client will notify Patheon of any communications it has with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, that directly relate to Patheon's performance of the Manufacturing Services under this Agreement. To the extent practicable, Client will permit Patheon to take part in these communications with the agency, and will provide copies of all such written communications from the agency within one Business Day of receipt thereof.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by law or the Quality Agreement, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Product. Client is responsible for retaining samples of the Product necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours, and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 Access.

Patheon will give Client reasonable access at mutually agreeable times to its records relating to the Manufacturing Services and to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Manufacturing Requirements. But, with the exception of "for-cause" audits (including follow-up audits conducted to ensure that deficiencies noted by Client or a Regulatory Authority have been remedied), Client will be limited each Year to one cGMP-type audit, lasting no more than two days and involving no more than two auditors. Client may request additional cGMP-type audits, subject to payment to Patheon of a fee of $5,000 for each additional audit day and $1,000 per audit day for each additional auditor. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records.

7.6 Notification of Regulatory Inspections.

Patheon will notify Client within one Business Day of any inspections by any governmental agency specifically involving the Product. Patheon will also notify Client of receipt of any form 483's, warning letters or any other regulatory action or notice that questions Patheon's compliance with cGMPs relating to operations at the Manufacturing Facility that could have an adverse impact on the Product, including the regulatory status of the Product.

7.7 Reports.

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client's request, Patheon will provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 FDA Filings.

(a) Regulatory Authority. Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Product. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of the Product as quickly as reasonably possible.

(b) Verification of Data. At least 21 days prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data.

(c) Verification of CMC. At least 21 days prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("**CMC**") section related to any Application for Marketing Authorization, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Client will give Patheon copies of all FDA filings at the time of submission which contain CMC information regarding the Product.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection by a Regulatory Authority.

(e) Client Responsibility. For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any Application for Marketing Authorization. The Client is solely responsibility for the preparation and filing of the Application for Marketing Authorization, and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

ARTICLE 8

TERM AND TERMINATION

8.1 Term.

This Agreement will become effective as of the Effective Date and will continue in effect thereafter until December 121, 2017 (the " **Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically continue after the Initial Term for successive terms of two years each. Either party may terminate this Agreement at will upon 18 months written notice given to the other party, provided that the earliest date on which any such notice of termination at will under this Section 8.1 may be given is June 30, 2016, and the earliest such termination at will may be effective is December 121, 2017.

8.2 Termination for Cause.

(b) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within 60 days following receipt of a written notice (the " **Remediation Period**") of the breach that expressly states that it is a notice under this Section 8.2(a) (a " **Breach Notice**"). Notwithstanding the foregoing, a Remediation Period will not be required for any of the material breaches by Patheon expressly identified in Section 2.2(e) or in Section 5.5(c), and Client will be permitted to terminate this Agreement upon written notice to Patheon for any such material breaches. If Client terminates this Agreement under this Section 8.2(a), Patheon will, within 30 days after the date of termination, refund to Client (i) the cost of all Facility Modifications funded by Client under the Capital Agreement, (ii) the cost of all facility modifications funded by Client under the Phase II Capital Agreement (as such term is defined in Schedule B), and (iii) the amount of all Facility Fees paid by Client under this Agreement that have not been reimbursed by Patheon prior to termination of this Agreement. Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement upon 30 days' prior written notice if any Regulatory Authority takes any action, or raises any objection, that prevents the importation, exportation, purchase, use, marketing, or sale of the Product. But if this occurs, Client will still fulfill all of its obligations under Section 8.4 below.

(d) Patheon may terminate this Agreement upon six months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is a Patheon Competitor. Should Patheon decide to terminate in accordance with this Section 8.2(d), Patheon will continue to supply the assignee with Product until the earlier of (i) qualification and approval of another site to manufacture Product, and (ii) 12 months from the date of termination.

8.3 Product Discontinuation.

Client will give at least three months' advance notice if it intends to no longer order Manufacturing Services for Product due to Product's discontinuance in the market.

8.4 Obligations on Termination.

If this Agreement is completed, expires, or is terminated for any reason, then:

(a) Client will take delivery of and pay for all undelivered Product that was manufactured under a Firm Order and in accordance with the Manufacturing Requirements, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Product which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders in accordance with Section 5.2 prior to notice of termination being given;

(c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders in accordance with Section 5.2, and Patheon will transfer to Client all Components covered by such Firm Orders (with shipping and related expenses, if any, to be borne by Client);

(d) Patheon will return to Client all unused Active Materials (with shipping and related expenses, if any, to be borne by Client);

(e) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(f) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within five Business Days, all of Client's Components, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, Dedicated Equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control (" **Client Property**"). If Client fails to remove the Client Property within five Business Days following the completion, termination, or expiration of the Agreement, Client will pay Patheon $100.00 per pallet, per month, one pallet minimum ($200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances or requires refrigeration) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement. For greater certainty, termination or expiration of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 6, 10, 11 and 12 and Sections 2.2(c), 3.2, 4.2(d), 5.4, 5.5(b), 5.6, 7.3, 7.4, 7.6, 7.7, 8.2, 8.4, 13.1, 13.2, 13.3, 13.5, 13.9, 13.10, 13.11, 13.15 and 13.16, all of which survive any termination or expiration.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for the Product are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services according to the Specifications is Client's or its Affiliate's unencumbered property, and, to Client's knowledge, may be lawfully used as directed by Client;

(iii) to Client's knowledge, there are no actions or other legal proceedings concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for Product conform to all applicable cGMPs and Applicable Laws;

(ii) the Product, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Product, and (ii) will comply with the requirements of all applicable marketing approvals for the Product;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Manufacturing Requirements;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights; and

(c) the Product will, on delivery, conform to the Specifications, have been manufactured in accordance with the Manufacturing Requirements, and not be adulterated.

(d) neither it nor any of its Affiliates, personnel or contractors performing any Manufacturing Services will make any payments or gifts to foreign governments or related persons for the purpose of obtaining or retaining business for or with, or directing business to, any person in connection with the performance of Manufacturing Services. Accordingly, Patheon agrees that no portion of monies paid or payable in connection with this Agreement, nor any other item of value, will,

directly or indirectly, be paid, received, transferred, loaned, offered, promised or furnished to, or for the use of, any officer or employee of any foreign government department, agency, instrumentality or corporation thereof, or any political party or any official of such party or candidate for office, or any person acting for or on behalf of any of the foregoing, for the purpose of (i) inducing the recipient to misuse his or her official position to direct business wrongfully to Client, Patheon, or any other person, (ii) influencing any act or decision of an official in his or her official capacity, including to obtain regulatory approvals for Product, (iii) inducing an official to do or omit to do any act in violation of his or her lawful duty, (iv) obtaining any improper advantage, or (v) inducing a foreign official to use his or her influence improperly to affect or influence any act or decision.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person or entity debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the *Federal Food, Drug, and Cosmetic Act* (United States).

9.5 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times, at its sole expense, all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. NEITHER PARTY MAKES ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS WITH RESPECT TO THE PRODUCT.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except for a breach of Article 11, and without limiting the party's indemnification obligations under this Article 10, under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of

profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages. For clarity, the foregoing does not apply to limit a party's liability for monetary remedies that are expressly provided for in this Agreement, such as payments required under Section 6.3(b), regardless of whether such monetary remedies may be characterized as consequential damages.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D.

(b) Maximum Liability. Except for a breach of its obligations under Article 11 or liability arising under Section 10.3, Patheon's maximum liability to Client under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed [*].

10.3 Patheon.

Patheon agrees to defend, indemnify, and hold Client and Client's officers, employees, and agents harmless against any and all losses, damages, costs (including reasonable attorneys' fees and costs), claims, demands, judgments and liabilities to, from and in favour of third parties (other than Affiliates) resulting from, or relating to (a) any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Manufacturing Requirements, (b) any claim resulting from or relating to a breach by Patheon of its obligations, representations or warranties under this Agreement, or (c) any claim resulting from or relating to the negligence or wrongful act(s) of Patheon or Patheon's officers, employees, agents or Affiliates, except in each case to the extent that the losses, damages, costs, claims, demands, judgments, and liabilities are due to the negligence or wrongful act(s) of Client or its officers, employees, agents, or Affiliates.

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client.

Client agrees to defend, indemnify, and hold Patheon and Patheon's officers, employees, and agents harmless against any and all losses, damages, costs (including reasonable attorneys' fees and costs), claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights in the Product, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liabilities are due to (a) the negligence or wrongful act(s) of Patheon or Patheon's officers, employees, or agents, (b) Patheon's breach of this Agreement including, without limitation, any representation or warranty contained herein, or (c) infringement of any Third Party Rights in the Product, or any portion thereof, based on Patheon's use or incorporation of any processes or methods to perform the Manufacturing Services other than those specified by Client in the Specifications.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Product. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Client has developed and will hold the marketing approval for the Product, Client requires Patheon to manufacture and label the Product strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

For purposes of this Agreement, each party will be deemed to be the " **Disclosing Party"** with respect to its own Confidential Information, and a **"Receiving Party"** with respect to the Confidential Information of the other party. The Receiving Party will: (a) use the Disclosing Party's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of the Disclosing Party; (b) not disclose the Disclosing Party's Confidential Information to any third party without first obtaining the written consent of the Disclosing Party; and (c) protect the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care used to protect its own confidential and/or proprietary information from unauthorized use or disclosure, but in no event with less than reasonable care. The Receiving Party will be permitted to furnish and otherwise disclose the other party's Confidential Information to those of its Affiliates, officers, employees, and subcontractors who need to know such Confidential Information, provided that such personnel are bound by obligations of confidentiality with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 11. Client may also disclose Patheon's Confidential Information to its corporate partners, bona fide investors, potential acquirers, distributors, licensors and sublicensees as necessary so long as they are bound by obligations of confidentiality with respect to such Confidential Information. If the Receiving Party discloses the Disclosing Party's Confidential Information to a Third Party with the Disclosing Party's permission as permitted herein, the Receiving Party will ensure that all Confidential Information disclosed to such Third Party is identified as confidential at the time of disclosure.

11.2 Exceptions to Confidential Information.

The obligations of confidentiality in Section 11.1 will not apply to that part of the Disclosing Party's Confidential Information which the Receiving Party is able to demonstrate by competent documentary evidence:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) later became part of the public domain through no act or omission of the Receiving Party;

(d) was disclosed to the Receiving Party, other than under an obligation of confidentiality to a Third Party, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) was independently developed by employees or contractors of either party outside of such party's activities under this Agreement.

11.3 Disclosure Required by Law.

The Receiving Party may disclose the Disclosing Party's Confidential Information without violating the obligations of this Agreement to the extent that such disclosure is (a) required by a valid order of a court or other governmental body having jurisdiction, (b) required by applicable law or regulation, or (c) necessary for filings with Authorities including, without limitation, the U.S. Securities & Exchange Commission, in each case provided that the Receiving Party provides the Disclosing Party with reasonable prior written notice of such disclosure (to the extent permitted by applicable law to do so) and makes a reasonable effort to obtain, or to reasonably assist the Disclosing Party in obtaining, a protective order or other appropriate remedy preventing or limiting the disclosure and/or requiring that the Disclosing Party's Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, for which the order was issued, or for the applicable regulatory or governmental filing.

11.4 Destruction of Confidential Information.

At the Disclosing Party's request, the Receiving Party will destroy all or such parts of the Disclosing Party's Confidential Information as the Disclosing Party will direct, including any copies thereof made by the Receiving Party, except that the Receiving Party will not be required to destroy any computer files created during automatic system back up which are subsequently stored securely by the Receiving Party. Notwithstanding the foregoing, the Receiving Party may retain one copy of the Disclosing Party's Confidential Information for archival purposes, subject to the ongoing obligation to maintain the confidentiality of such information.

11.5 Remedy.

Each party acknowledges that disclosure or distribution of the other's Confidential Information or use of the information contrary to the terms of this Agreement may cause irreparable harm for which damages at law may not be an adequate remedy. Accordingly, the Disclosing Party hereunder may seek to enforce the provisions of this Agreement prohibiting disclosure or distribution of its Confidential Information or use thereof contrary to the provisions hereof in a court of competent jurisdiction, in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Dispute Resolution.

If any dispute arises out of this Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined in Section 12.2), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within ten Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the ten Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer of Patheon (or another officer as appropriate) and the Chief Development Officer of Client (or another officer as appropriate) who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be submitted to final and binding arbitration in the City of Chicago, Illinois in accordance with the rules and procedures of the American Arbitration Association, and judgment upon the award may be entered in any court having jurisdiction thereof. In any arbitration proceeding, the unsuccessful party will pay the successful party all costs and expenses, including reasonable attorneys' fees, incurred by the successful party in connection with the arbitration proceeding and will pay all other costs and expenses of the arbitration, including the arbitrators' fees.

Each party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 12.1 and agrees that the courts may award full faith and credit to such judgment in order to enforce such award.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 6.1(b)) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a " **Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as practicable and in any event no later than ten Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within 30 Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Schedule E. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Product for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Product is to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for the purposes of performing the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon or its contractors or Affiliates while performing the Manufacturing Services, to the extent it is specific to the development, manufacture,

use, dosage, formulation, or composition of matter of Product (**"Product Intellectual Property"**), will be the exclusive property of Client. Patheon hereby assigns to Client all of its right, title, and interest in and to the Product Intellectual Property, and agrees to take, at Client's expense, all further acts reasonably required to evidence such assignment and transfer to Client and to assist Client with applying for, securing, and maintaining patent or other proprietary protection for Product Intellectual Property. Patheon will ensure that each employee or contractor of Patheon or its Affiliates that performs any activities under this Agreement has a contractual obligation to assign all rights in the Product Intellectual Property to Patheon such that Patheon may assign and transfer such rights to Client in accordance with this Section 13.1(b).

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, worldwide, paid-up, royalty-free, sublicensable, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture or have manufactured the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Patheon will give Client written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute Product Intellectual Property, or improvements or other modifications of the Product or processes or technology owned or otherwise controlled by Client.

13.2 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than (i) $3,000,000 for each occurrence for personal injury or property damage liability; and (ii) $3,000,000 in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. Each party will provide a minimum of 30 days' written notice to the other party of any cancellation of the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, with the exception of Section 6.1.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder to a competitor of Client, or otherwise without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client. Patheon agrees that it will remain solely and fully liable for the performance of its subcontractors and their compliance with the terms of this Agreement.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement. Client agrees that it will remain fully liable for the performance of its assignee under this Agreement, including all payment obligations.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a " **Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 Additional Products.

Additional Products may be added to this Agreement and each additional Product will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, C, and D as applicable.

13.9 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by express courier service, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid, return receipt requested, to the respective addresses, facsimile numbers or electronic mail addresses set forth below:

If to Client:

AcelRx Pharmaceuticals, Inc.
351 Galveston Drive
Redwood City, CA 94063
Attention: Chief Development Officer
Fax No.: (650) 216-6500
Email address: lhamel@acelrx.com

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: Director of Legal Services
Fax No.: 513-948-6927

Email address: Frank.McCune@patheon.com

With a copy to:

Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: General Counsel
Fax No.: 919-474-2269

Email address: Michael.Lytton@Patheon.com

or to any other addresses, facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, express courier service, facsimile, or electronic mail will be deemed to have been sufficiently made or given when received.

13.10 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, together with the Quality Agreement and the Capital Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof, including the Confidentiality Agreement. But this Agreement is not intended to, and does not, supersede the Master Agreement for

Pharmaceutical Development Services entered into between the parties effective August 7, 2009 (the "Development Agreement"), as amended, pursuant to which Patheon is manufacturing clinical supplies of Product for Client. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Quality Agreement, and the Capital Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Governing Law.

This Agreement will be construed and enforced in accordance with the laws of the State of Delaware and the laws of the United States of America applicable therein. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Stuart Grant

Name: Stuart Grant

Title: Chief Financial Officer

ACELRX PHARMACEUTICALS, INC.

By: /s/ James Welch

Name: James Welch

Title: Chief Financial Officer

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

ARX-01 in Bulk Tablet Packaging

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement, Client will give Patheon the originally executed copies of the Specifications that will be submitted by Client to the FDA for approval. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B

MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRICE

Annual Volume Forecasts

Client has provided an estimated annual tablet volume forecast for Product as outlined below for informational purposes only. These estimates are subject to change.

Product	2012 Volume	2014 Volume	2015 Volume	2016 Volume
Tablets	[*]	[*]	[*]	[*]

Product	2017 Volume	2018 Volume	2019 Volume
Tablets	[*]	[*]	[*]

Manufacturing and Bulk Packaging Prices

Pricing includes the cost of labour, overhead, raw materials, bulk packaging Components and QC testing. Pricing for 2 batch sizes is being presented, [*] and [*]. The [*] batch size is proposed for the initial start-up volumes but is not economically viable for long-term commercial production. Based on the forecast provided, a long-term commercial batch size of [*] is being presented.

Bulk Pricing – [*] Batch

Product	Annual Quantity (1,000's)	(1,000's)	Price per 1,000 Tablets		
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]			
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	$[*]
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	$[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[*]

Bulk Pricing – [*] Batch

Product	Annual Quantity (1,000's)	(1,000's)	Price per 1,000 Tablets		
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]			
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	$[*]
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	
ARX-01 Sufentanil 15mcg Tablets	[*]	[*]	$[*]	**$[*]**	$[*]

[*]

The following cost items are included in the Price for the Product :

- Product manufactured and packaged in Bulk Tablet Packaging under the Agreement
- Standard certificate of analysis ("COA")
- Standard certificate of compliance ("COC")
- GMP required retention samples
- Copies of deviation reports
- Batch Production Records ("BPR")/Lot Packaging Records ("LPR") copies for validation batches, first ten commercial batches, and one commercial batch per Year thereafter
- One label copy change per Year
- BPR/LPR changes [one change per Year]
- Common HPLC/GC columns, reagents, and lab supplies
- Copy of the Annual Product Review Report
- Product Approval Inspection ("PAI") and copy of FDA Report

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- Simple, routine statistical review
- Storage of Production Test Record (“PTR”) batches and other experimental batches for three months
- Storage of registration batches and other experimental batches for two years or until Product approval, whichever comes first
- Routine sampling and analysis as part of Product manufacture and release
- Warehousing of equipment, raw materials, API, and finished goods for normal commercial supply
- Testing of raw materials
    - Testing of final product in Bulk Tablet Packaging

SCHEDULE C

ANNUAL STABILITY TESTING

$

STABILITY – COMMERCIAL SUFENTANIL TABLETS

	ACTIVITY								*PRICE*
	Number of Lots 1								
	Total Samples 12								
	Protocol Generation							Subtotal	$[*]
Pullpoint Month	T = 0	T = 1	T = 3	T = 6	T = 9	T = 12	T = 18	T = 24	T = 36
25ºC / 60% RH	X	X	X	X	X	X	X	X	X
40ºC / 75% RH		X	X	X					
Samples per pullpoint	**1**	**2**	**2**	**2**	**1**	**1**	**1**	**1**	**1**
Microbiology						***X****			
Cost per pullpoint (Milestone Price)	$[*]	[*]	$[*]	$[*]	$[*]	$ [*]	$ [*]	$ [*]	$ [*]

Note: For all required testing intervals pull two 40-count cartridges per pull point. Do not test T=0 unless lot from clearance testing is within 30 days of T initial (T=0).

* Note Microbiological testing: Pull fifty-one 40 -count cartridges (approximately 15 grams).

Total **$[*]**

STABILITY - COMMERCIAL SUFENTANIL TABLETS 30ºC / 65% RH* **USD**

	ACTIVITY								*PRICE*
	Number of Lots 1								
	Total Samples 5								
Pullpoint Month	T = 0	T = 1	T = 3	T = 6	T = 9	T = 12	T = 18	T = 24	T = 36
30ºC / 65% RH		**X**	**X**	**X**	**X**	**X**			
Samples per pullpoint		**1**	**1**	**1**	**1**	**1**			
Cost per pullpoint (Milestone Price)	$[*]	$[*]	$[*]	$[*]	$[*]	$ [*]	$ [*]	$ [*]	$ [*]

* Note: Contingency testing interval - pull and/or test samples only at written request of AcelRx.

Total **$[*]**

Stability Testing Requirements:

[*]

Product used for stability testing will be invoiced at current commercial pricing rates.

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SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Sufentanil [*]	[*]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
ARX-01	Sufentanil [*]	Client's actual cost for Active Materials not to exceed $[*] per gram.

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Agreement in a Year will not exceed[*].

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SCHEDULE E

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert**. Within ten Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the ten Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.

4. **Procedure**. Where an expert is appointed:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue

between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Product for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Product is to be released for sale or distribution.

SCHEDULE F

COMMERCIAL QUALITY AGREEMENT

SCHEDULE G (Reserved)

SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: ACELRX PHARMACEUTICALS, INC.

FROM: PATHEON PHARMACEUTICALS INC.

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Manufacturing Services Agreement dated December 12, 2012 (the "Agreement")

Reporting quarter:	_____		
Active Materials on hand at beginning of quarter:	_____	kg	(A)
Active Materials on hand at end of quarter:	_____	kg	(B)
Quantity Received during quarter:	_____	kg	(C)
Quantity Dispensed[1] during quarter: (A + C – B)	_____	kg	
Quantity Converted during quarter: (total Active Materials in Product produced and not rejected, recalled or returned)	_____	kg	

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON PHARMACEUTICALS INC. DATE: _____

Per: _____
Name:
Title:

[1] Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability or test batches manufactured during the month.

SCHEDULE I

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: ACELRX PHARMACEUTICALS, INC.

FROM: PATHEON PHARMACEUTICALS INC.

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Manufacturing Services Agreement dated December 12, 2012 (the "Agreement")

Reporting Year ending:	_____		
Active Materials on hand at beginning of Year:	_____	kg	(A)
Active Materials on hand at end of Year:	_____	kg	(B)
Quantity Received during Year:	_____	kg	(C)
Quantity Dispensed[1] during Year: (A + C – B)	_____	kg	(D)
Quantity Converted during Year: (total Active Materials in Product produced and not rejected, recalled or returned)	_____	kg	(E)
Active Materials Credit Value:	$ _____	/ kg	(F)
Target Yield:	_____	%	(G)
Actual Annual Yield: ((E/D) * 100)	_____	%	(H)
Shortfall: (((G – 3.5) - H)/100) * F * D	$ _____ (if a negative number, insert zero)		(I)

[1] Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability or test batches manufactured during the Year.

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON PHARMACEUTICALS INC.

Per: _____
Name:
Title:

SCHEDULE J (Reserved)

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Exhibit 10.2

AMENDED AND RESTATED CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT

THIS AMENDED AND RESTATED CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT (this "**Agreement**") is made as of December 12, 2012 (the "**Effective Date**") between

ACELRX PHARMACEUTICALS, INC.,
a corporation existing under the laws of the State of Delaware, located at 575 Chesapeake Drive, Redwood City, California 94063 ("**AcelRx**")

- and -

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware, located at 2110 East Galbraith Road, Cincinnati, Ohio 45237-1625 ("**Patheon**")

BACKGROUND

AcelRx and Patheon entered into a Manufacturing Services Agreement effective December 12, 2012 (the **"MSA"**) under which Patheon will perform certain commercial supply manufacturing services (the "**Services**") related to AcelRx's ARX-01 Tablets (the "**Product**"), which Product will be incorporated into products intended for commercial sale. For clarity, Patheon and AcelRx are parties to a Master Agreement for Pharmaceutical Development Services effective August 7, 2009, as amended (the **"Patheon MA"**), and Patheon's corporate affiliate, Patheon Inc. (**"Patheon Canada"**) and AcelRx are parties to a Master Agreement for Pharmaceutical Development Services effective October 28, 2009, as amended (the **"Patheon Canada MA"**), and Patheon and Patheon Canada have and/or are performing clinical trial manufacturing services related to the Product for AcelRx under these existing agreements. In order for Patheon to perform the Services, certain capital expenditures will be required for the purchase and installation of capital equipment and facility modifications at Patheon's facility located at 2110 East Galbraith Road, Cincinnati, Ohio 45237-1625 (the "**Facility**"). Other capital equipment owned by AcelRx and located at Patheon Canada's manufacturing facilities in Ontario will need to be transferred to the Facility. The parties entered into a Capital Expenditure and Equipment Agreement dated May 25, 2011, that set out the parties' understanding regarding the capital expenditures (the "**Capital Agreement**"). The parties intend that this Agreement will supersede the Capital Agreement and restate the parties' agreement and undertakings regarding these capital expenditures.

AGREEMENT

NOW, THEREFORE, in consideration of the rights conferred and the obligations assumed herein, and intending to be legally bound, the parties hereby agree as follows:

1. Definitions

"Dedicated Equipment" means the equipment listed in Schedule A, which equipment is to be used by Patheon solely to perform manufacturing services for AcelRx under the Patheon MA, the Patheon Canada MA, or the MSA, and for no other purpose.

"Facility Modifications" means the modifications to the Facility and all related engineering and Facility qualification costs that are listed in Schedule B.

"Project" means the activities to be performed under this Agreement with respect to the purchase, modification, transfer, testing, and qualification of Dedicated Equipment and the performance of Facility Modifications.

2. Performance of the Project

Patheon will perform the Project in compliance with the terms and conditions of this Agreement, AcelRx's instructions, and all applicable laws and regulations. Patheon will perform the Project in accordance with the timeline that will be established by the combined Patheon-AcelRx Project team. This timeline may be modified by mutual agreement of the parties.

With respect to the Dedicated Equipment that will be transferred from Patheon Canada's facilities to the Facility, AcelRx will be responsible for the packaging and transport of the Dedicated Equipment to the Facility. Patheon Canada will allow and support access to the Dedicated Equipment by the AcelRx packaging/transport contractor(s). AcelRx will bear the risk of loss of or damage to the Dedicated Equipment during transit to the Facility, and will obtain insurance covering such risk of loss or damage while in transit. AcelRx will be responsible for obtaining appropriate import and related documentation for the transport of the Dedicated Equipment. Once delivered to the Facility, Patheon will be responsible for the installation of the Dedicated Equipment and for any risk of damage thereof.

3. Expenditures and Payment

(a) The estimated cost for the purchase and, as applicable, transfer of the Dedicated Equipment for use to perform the Services is set forth in Schedule A. AcelRx will agree on the specific Dedicated Equipment to be purchased by Patheon and will agree on the actual purchase price for such equipment prior to Patheon purchasing such equipment. Notwithstanding any other provisions of this Agreement, and provided that AcelRx agrees on the purchase price for the applicable Dedicated Equipment, the individual amount of each item on Schedule A may be increased or decreased to reflect Patheon's actual cost, but the aggregate amount contributed by AcelRx for the Dedicated Equipment will not exceed $[*] (the **"Dedicated Equipment Cap"**) unless there are further modifications or changes in the processes or requirements for the Services or if the assumptions underlying the estimated costs change. If this occurs, the parties will agree on revised cost estimates and a revised maximum aggregate amount to be contributed by AcelRx. At AcelRx's option, AcelRx may purchase some or all of the Dedicated Equipment directly and arrange to have it delivered to the Facility rather than have Patheon purchase the Dedicated Equipment on AcelRx's behalf, in which case the applicable amounts specified in Schedule A for the purchase of such Dedicated Equipment will be deducted from the Dedicated Equipment Cap and will not be payable to Patheon. Upon completion of the project, Patheon will give AcelRx a final Schedule A with the actual costs for each item.

(b) The estimated cost for making the Facility Modifications (including related engineering and Facility qualification costs) is set forth in Schedule B. Notwithstanding any other provisions of

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this Agreement, the individual amount of each item on Schedule B may be increased or decreased to reflect Patheon's actual cost, but the aggregate amount contributed by AcelRx for the Phase I and Phase II Facility Modifications will not exceed $[*] unless there are further modifications or changes in the processes or requirements for the Services or if the assumptions underlying the estimated costs change. If this occurs, the parties will agree on revised cost estimates and a revised maximum aggregate amount to be contributed by AcelRx. Upon completion of the project, Patheon will give AcelRx a final Schedule B with the actual costs for each item. Any reimbursement to AcelRx for the cost of Facility Modifications will be discussed by the parties and, if agreed to, will be addressed in the MSA. For clarity, except as set forth in Section 8(d), nothing in this Agreement obliges Patheon to agree to reimburse AcelRx for the cost of the Facility Modifications.

(c) Subject to the limitations set forth in this Section 3, AcelRx hereby directs Patheon to incur, on its behalf, pre-approved direct out-of-pocket costs for the Dedicated Equipment and the Facility Modifications as set forth in Schedule A and Schedule B, respectively. Patheon will give AcelRx copies of third party invoices for these items (where applicable) within 30 days after Patheon's receipt thereof and will issue its invoice to AcelRx. AcelRx will pay all amounts owing to Patheon within 30 days of the date of the Patheon invoice to enable Patheon to pay all amounts owed under the third party invoices

4. Patheon Use of Facility Modifications and Dedicated Equipment

(a) Patheon may use the Facility Modifications to manufacture third party products but AcelRx Product will have priority over any third party product. Patheon will not use the Facility Modifications to manufacture OEL Category 4 drugs and will follow its internal SOPs to prevent cross-contamination and to ensure proper cleaning of the Facility Modifications after use on third party products. Patheon will pay the following fees to AcelRx for third party use of the Facilities Modifications during the term of this Agreement:

- $[*] for commercial product manufactured
- $[*] for Development work

The use fees will include all development and commercial batches manufactured by Patheon, will be calculated by Patheon as of December 121 of each Year, and will be paid to AcelRx by February 15 of the following Year. The total use fees paid during the term of the Agreement will not exceed the total investment paid by AcelRx for the Facilities Modifications ($[*]).

(b) Patheon may only use the Dedicated Equipment to manufacture the Product for AcelRx and not for the manufacture of any other products. Patheon will operate and use the Dedicated Equipment in accordance with its SOPs and the instructions set forth in the applicable equipment operation manual, if any, provided by the manufacturer of the Dedicated Equipment and delivered to Patheon.

(c) In no event shall AcelRx be liable for any use of the Facility Modifications by Patheon. Patheon agrees to indemnify and hold AcelRx and its affiliates, officers, directors, employees and agents harmless from and against all costs (including reasonable attorneys' fees), losses, liabilities,

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damages, and expenses of any kind arising from (i) the Modified Facility, or (ii) the negligence or misconduct of Patheon, Patheon's affiliates, or their respective personnel with respect to their use of the Dedicated Equipment.

5. Maintenance of Dedicated Equipment and Facility Modifications

(a) Patheon will at its expense perform routine repairs, preventive maintenance, and calibration on the Dedicated Equipment owned by AcelRx. Patheon will have an annual aggregate limit on these costs of $[*] but this limit will not apply if Patheon has been negligent in performing the repairs, maintenance and calibration. Repair, maintenance, and calibration costs, including the cost of spare part purchases or equipment upgrades requested by AcelRx that exceed this annual aggregate limit (other than the costs that result from Patheon's negligence, which costs will be borne by Patheon) will be invoiced to AcelRx at Patheon's actual cost.

(b) Patheon will, at its expense, perform routine repairs, preventive maintenance, calibration and air monitoring per Patheon's SOPs with respect to the Facility Modifications.

(c) Upon prior mutual agreement between the parties on a suitable date for an inspection, Patheon will give AcelRx reasonable access during normal working hours for the inspection of the Dedicated Equipment owned by AcelRx.

(d) Patheon will (i) keep the Dedicated Equipment free from encumbrances, liens, and interests of third parties, (ii) take all necessary care to prevent any damage, loss or theft to the Dedicated Equipment, and (iii) clearly identify all Dedicated Equipment in the Modified Facilities (e.g., by labelling such equipment) and in its books as belonging to AcelRx.

(e) Patheon will promptly notify AcelRx if any accident, loss of or damage occurs to the Dedicated Equipment and Facility Modifications but the notification will be no later than two business days after the occurrence.

6. Title and Risk of Loss of the Equipment and Facility Improvements

The Dedicated Equipment will be owned by AcelRx, which will be the sole legal and beneficial owner thereof. The Facility Modifications will be owned by Patheon, which will be the sole legal and beneficial owner thereof. Patheon will at all times keep the Dedicated Equipment and the Facility Modifications insured against loss, damage or destruction at the replacement cost with inflation adjustment, and Patheon will replace any of these items that are lost, damaged or destroyed. Patheon will name AcelRx as an additional insured on any insurance policy or endorsement that covers the Dedicated Equipment owned by AcelRx, and will provide proof of such insurance to AcelRx upon request.

7. Fees

OVERHEAD FEE

Due to the uniqueness of AcelRx's process and package, significant dedicated space is necessary at the Facility and a minimum return on this space is required. Commencing in 2013 and, in each Year

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thereafter during the term of the MSA, an annual "**Overhead Fee"** will be charged to AcelRx. The Overhead Fee will be $200,000 per Year, but will be prorated based on the aggregate revenues recorded by Patheon from AcelRx under both the Development Agreement and the MSA for all services performed by Patheon for any and all AcelRx products (such as the products referred to as ARX-02, ARX-03, and ARX-04, as well as any other future products that AcelRx may develop), including the Product (collectively, **"Patheon Revenues"**) in the prior Year, such that if Patheon recorded at least $[*] in Patheon Revenues in the prior Year, no Overhead Fee will be payable for such Year, but if Patheon recorded less than $[*] in Patheon Revenues in the prior Year, the Overhead Fee payable in such Year shall be pro-rated such that the actual Overhead Fee payable by AcelRx will be equal to $200,000 multiplied by a percentage equal to the percentage that the amount of Patheon Revenues recorded in the prior Year represents of $[*]. For example, if the Patheon Revenues recorded are greater than $[*] in 2012, no Overhead Fee will be due for the Year 2013. If Patheon Revenues recorded in 2012 are equal to $[*], then the Overhead Fee payable by AcelRx for 2013 will be equal to [*]of $200,000, or $[*].

If an Overhead Fee is payable for a particular Year, it will be divided into four equal installments, with each installment paid on the last day of each calendar quarter. For example, if the Overhead Fee for 2013 is equal to $[*], AcelRx will pay the first installment of $[*] to Patheon by March 31, 2013, and each subsequent $[*] installment by June 30, September 30, and December 121, 2013, respectively. There will be no Overhead Fee payable for any Year where the total Patheon Revenues recorded in the prior Year exceed $[*]. Patheon acknowledges and agrees that the Overhead Fee is intended to, and does, cover all dedicated space at the Facility for the Product included in the scopes of Phase I and Phase II Manufacturing as outlined on Schedule B. If Patheon is selected to perform Finished Product Packaging, an additional Overhead Fee will be considered by the parties if this packaging cannot be accomplished within the dedicated space covered above.

FACILITY FEES

A. Phase I Facility Fee

AcelRx will pay to Patheon a **"Phase I Facility Fee"** in the amount of $480,000 to offset taxes incurred and paid by Patheon for Facility Modifications made to the Facility pursuant to this Agreement shown as Phase I on Schedule B in the amount of $1,098,537. Upon execution of this Agreement, AcelRx will pay to Patheon $[*] of the Phase I Facility Fee. The remaining $[*] of the Phase I Facility Fee will be made in five equal quarterly installments of $[*] each, with the first installment payable on October 1, 2012 and the last installment payable on October 1, 2013.

Patheon will reimburse AcelRx for the Phase I Facility Fee paid by AcelRx hereunder over a three-year period, commencing in the Year in which the Application for Marketing Authorization is approved by the FDA. The Phase I Facility Fee reimbursement will be made by Patheon in [*] equal quarterly installments of $[*], with the first installment payable on the first day of the calendar quarter following the date of FDA approval of the Application for Marketing Authorization. For example, if the Application for Marketing Authorization is approved by the FDA on September 15, 2015, Patheon will pay to AcelRx $[*] on October 1, 2015 and an additional $[*] on the first day of each subsequent calendar quarter thereafter until the entire amount of the Phase I Facility Fee has been reimbursed to AcelRx.

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B. Phase II Facility Fee

The parties are currently in discussions regarding additional facility modifications that will be required to support Phase II Manufacturing. Once the parties have reached agreement regarding the scope and cost of these additional facility modifications, Schedule B and Section 3(b) of this Agreement will be modified to reflect the new capital amounts. The parties have agreed that AcelRx will pay to Patheon a **"Phase II Facility Fee"** to offset taxes owed by Patheon for these additional facility modifications. The Phase II Facility Fee will be equal to the cost of the facility modifications for Phase II multiplied by Patheon's effective tax rate, but will be prorated based on cumulative Patheon Revenues starting in 2013 as described herein, and will only be payable by AcelRx until such time as the cumulative Patheon Revenues recorded starting in 2013 have reached $[*]. The Phase II Facility Fee will be divided into eight equal quarterly installments and will be paid in arrears so that no installment of the Phase II Facility Fee will be paid until the first day of the calendar quarter commencing after the date on which all facility modifications required under the Phase II capital expenditure have been completed. For example, if all facility modifications required under the Phase II capital expenditure are completed during May 2014, AcelRx will make its first installment payment of the Phase II Facility Fee on July 1, 2014, and would make seven additional quarterly payments with the final payment due July 1, 2016, assuming that Patheon Revenues from AcelRx have not reached the $[*] threshold.

As noted above, the Phase II Facility Fee will be prorated based on cumulative Patheon Revenues of $[*] starting from January 1, 2013. The actual installment amount of the Phase II Facility Fee due for each calendar quarter will be determined based on the cumulative Patheon Revenues recorded from January 1, 2013 as a percentage of $[*]. For clarification, if the cumulative Patheon Revenues recorded up through the first Phase II Facility Fee installment payment are equal to or greater than $[*], no installment payment will be due by AcelRx. If the cumulative Patheon Revenues recorded up through the first Phase II Facility Fee installment payment are less than $[*], the first installment payment of the Phase II Facility Fee due by AcelRx will be equal to one eighth of the Phase II facility fee multiplied by the Patheon Revenues recorded after January 1, 2013 as a percentage of the $[*] per calendar quarter target.

The parties agree that Patheon will reimburse AcelRx for the full amount of the Phase II Facility Fee paid by AcelRx once the cumulative Patheon Revenues recorded on or after January 1, 2013 have reached $[*], regardless of whether at least $[*] of Patheon Revenues were recorded in each calendar quarter. Patheon will, within 30 days after the first day of the applicable calendar quarter, reimburse AcelRx for any installment amounts of the Phase II Facility Fee that have been paid by AcelRx in prior calendar quarters based on a quarterly true-up of the installment amounts of the Phase II Facility Fee paid by AcelRx to date and the total cumulative Patheon Revenues recorded on or after January 1, 2013. Patheon will reimburse to AcelRx all Phase II Facility Fee amounts paid by AcelRx that have not been previously reimbursed by Patheon within 30 days after the cumulative Patheon Revenues recorded on or after January 1, 2013 have reached $[*], even if this cumulative amount is not recorded until after December 121, 2014.

Example of Phase II Facility Fee payment calculations

Example 1:

If the Phase II Facility Fee is equal to $[*], then the portion of the Phase II Facility Fee that could be payable by AcelRx for each calendar quarter is $[*]. If all Facility Modifications required under the Phase II capital expenditure are completed by February 1, 2013, then the first installment of the Phase II Facility Fee is payable on April 1, 2013. If Patheon has recorded $[*] in Patheon Revenues for the first calendar quarter of 2013, AcelRx will owe Patheon [*] of the $[*] installment for the first calendar quarter (i.e., $[*] is [*]% of $[*], so AcelRx owes [*] of the $[*] installment for a total payment of $[*]). If the cumulative Patheon Revenues recorded for 2013 are $[*] at the end of the second calendar quarter

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

of 2013 (i.e., $[*] in Q1 2013 and $[*] in Q2 2013), AcelRx will not owe an installment of the Phase II Facility Fee on July 1, 2013, and instead, Patheon will reimburse to AcelRx the full amount of the first calendar quarter installment ($[*]) no later than 30 days after the first day of the second calendar quarter of 2013.

For further clarification, in this example if the cumulative Patheon Revenues recorded as of December 121, 2014 total $[*], AcelRx will have paid Patheon [*] of the Phase II Facility Fee (i.e., $[*] is [*] of $[*], so AcelRx will have paid [*] of $[*], for a total of $[*]) by January 1, 2015. AcelRx will not owe Patheon any further installments of the Phase II Facility Fee and, once Patheon has recorded additional Patheon Revenues of $[*] for a cumulative total of $[*], Patheon will reimburse to AcelRx the $[*] of the Phase II Facility Fee previously paid by AcelRx within 30 days after the date on which the cumulative Patheon Revenues recorded reach at least $[*].

Example 2:

Assuming the Phase II Facility Modifications are completed in May 2014 at a cost of $[*], Patheon's effective tax rate is [*], and as of June 30, 2014 Patheon Revenues from AcelRx are $[*] (starting from January 1, 2013), AcelRx would pay Patheon a Facility Fee installment of $[*] ($[*] *[*] tax rate = $[*]). If in the following quarter, Patheon recognized $[*] in revenue, no installment payment would be due, and Patheon would Reimburse AcelRx for the first $[*] installment payment subject to the previous section.

For further clarification, assuming the Phase II Facility Modifications are completed in May 2014 and Patheon Revenues are $[*] as of June 30, 2014 (starting from January 1, 2013), AcelRx would never make a Facility Fee payment, as the $[*] threshold for Patheon Revenues has been met prior to the completion of the Phase II facility.

8. Term; Termination; Effect of Termination on Future Funding

(a) **Term; Termination.** This Agreement will commence on the Effective Date and, unless earlier terminated as set forth in this Section 8, will continue in effect until the expiration or termination of the MSA, including any extensions thereof. Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its obligations under this Agreement within 60 days following receipt of a written notice of the breach that expressly states in reasonable detail the nature of the breach. This Agreement will terminate automatically if the parties have not executed the MSA by December 121, 2012 unless this date is extended by written agreement of the parties. AcelRx will have the right, upon written notice to Patheon, to terminate the portion of the Project applicable to Dedicated Equipment at any time upon written notice to Patheon, in which event the Project will no longer cover the transfer or purchase of Dedicated Equipment and the provisions of Section 8(c) below will apply.

(b) **Effect of Termination on Future Funding.** If this Agreement or the MSA is terminated, AcelRx's obligation to further fund expenditures under this Agreement will cease upon Patheon's receipt of the notice of termination of this Agreement or the MSA, except for the cost of non-cancelable commitments that are made by Patheon prior to receiving written notice of the termination, and for which AcelRx is responsible under Section 3 of this Agreement If this Agreement terminates automatically due to failure of the parties to enter into the MSA as set forth above in Section 8(a), AcelRx's obligation to fund expenditures under this Agreement will

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

cease as of the automatic termination date except for the cost of non-cancellable commitments that are made by Patheon under this Agreement prior to the automatic termination date. If this Agreement terminates, Patheon will use reasonable efforts to cancel or otherwise reduce the amount of non-cancellable commitments that have been made by Patheon under this Agreement prior to the termination date and for which AcelRx is responsible under Section 3 of this Agreement.

(c) **Return of Equipment; Option to Purchase Equipment.** If this Agreement expires or is terminated for any reason, or if AcelRx elects to terminate the portion of the Project applicable to the purchase and transfer of Dedicated Equipment in accordance with Section 8(a), AcelRx will remove, or arrange to remove, from the Facility at its expense all Dedicated Equipment that is not purchased by Patheon as provided in this Section 8(c), and will repair or arrange to repair, at its reasonable expense, any damage to the Facility resulting from this removal. AcelRx may, at its sole option, offer to Patheon the option to purchase some or all of the Dedicated Equipment at its depreciated value under a five year straight line depreciation schedule from the date of the original Capital Agreement or 10% of the original purchase price, whichever is greater. If Patheon elects to purchase some or all of the Dedicated Equipment, it will pay AcelRx for the agreed upon purchase price of this equipment within 30 days of electing to purchase the equipment and, as of the date of AcelRx's receipt of the payment, all right, title and interest in and to the purchased equipment will be vested in Patheon.

(d) **Refund of Facility Payments for Patheon Material Breach.** If AcelRx terminates this Agreement for Patheon's uncured material breach under Section 8(a), Patheon will refund to AcelRx, within 30 days after the date of such termination, the amounts paid by AcelRx to Patheon under this Agreement as set forth below. If AcelRx terminates this Agreement due to Patheon's uncured material breach at any time, Patheon will reimburse AcelRx for 100% of all outstanding amounts paid by AcelRx for Facility Fees. Further, Patheon will reimburse AcelRx for the then current value of all Facility Modifications. The current value of Facility Modifications shall be calculated based on the total cost of the Facility Modification prorated on a monthly basis over a ten year life from the time of completion. For example, if AcelRx terminates this agreement due to Patheon's uncured breach five years (60 months) after the September, 2011 completion date of the Phase I Facility Modifications and three years (36 months) after completion of the Phase II Facility Modifications, then Patheon would reimburse AcelRx for 50.0% of total Phase I cost [(120 - 60) / 120 = .500] and 70% of total Phase II cost [(120 - 36) / 120 = .700].

(e) **Survival.** Sections 4(a), 4(c), 8(b), 8(c), 8(d), 8(e), 9(b), 9(i) and 98(j) will survive the expiration or termination of this Agreement for any reason.

9. General

(a) All monetary amounts are expressed in the lawful currency of the United States of America.

(b) This Agreement will be construed and enforced in accordance with the laws of the State of Delaware (without regard to principles of conflicts of law).

(c) This Agreement contains the entire understanding of the parties about the subject matter herein and supersedes all previous agreements (oral and written), negotiations and discussions. For clarity, this Agreement is a supplement to, and does not supersede, the Patheon MA. The Confidentiality Agreement between Patheon and AcelRx effective December 22, 2010 (the

"**CDA**") will govern with respect to all disclosures of Information (as such term is defined in the CDA) made by the parties hereunder. The parties agree that the Information exchanged by the parties hereunder may be used as necessary for conducting the activities under this Agreement in addition to use for the Purpose (as such term is defined in the CDA).

(d) The parties may modify or amend the provisions hereof only by an instrument in writing duly executed by both of the parties.

(e) Patheon may not assign or otherwise transfer its rights or obligations hereunder without the prior written consent of AcelRx, this consent not to be unreasonably withheld. AcelRx may assign or otherwise transfer its rights or obligations hereunder without approval from Patheon. But AcelRx will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and AcelRx will remain liable hereunder.

(f) This Agreement may be signed by facsimile or in two counterparts, each of which when executed and delivered or transmitted, will be considered an original and both of which together will constitute one and the same instrument.

(g) The "Background" section of this document is expressly incorporated into the Agreement.

(h) The parties hereto are independent contractors, and nothing contained in this Agreement is intended, and will not be construed, to place the parties in the relationship of partners, principal and agent, employer/employee or joint venturer. Neither party will have any right, power or authority to bind or obligate the other, nor will either hold itself out as having such right, power or authority.

(i) If any one or more provisions of this Agreement will be found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired thereby, provided the surviving agreement materially comports with the parties' original intent. The parties will make a good faith effort to replace any such provision with a valid and enforceable one such that the objectives contemplated by the parties when entering this Agreement may be realized.

(j) Waiver or forbearance by either party hereto of any of its rights under this Agreement or applicable law in any one or more instances must be in writing and signed by the waiving party and will not be deemed to constitute a waiver or forbearance of any other right or a further or continuing waiver of such rights.

[Signature page to follow]

IN WITNESS WHEREOF the duly authorized representatives of the parties have executed this Agreement.

AcelRx Pharmaceuticals, Inc.

By: /s/ James Welch
Name: James Welch
Title: Chief Financial Officer

Patheon Pharmaceuticals Inc.

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer

SCHEDULE A

Dedicated Equipment	Investment	AcelRx Provided
[*]	—	X
[*]	—	X
[*]	—	X
[*]	—	X
[*]	—	X
[*]	—	X
[*]	—	X
Modifications to existing equipment and [*]	$ [*]	
[*]	$ [*]	
In process testing equipment	$ [*]	
Equipment Containment Level Verification IH Study	$ [*]	
Equipment Qualification Cost. This cost will be charged on a time and materials basis, and is estimated to be equal to [*]of the cost of all manufacturing equipment listed in this Schedule A, including equipment provided by AcelRx.	$ [*]	
[*] Design and Qualification Support (Excluding travel expenses to be billed separately)	$ [*]	
Total Dedicated Equipment	**$ [*]**	

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SCHEDULE B

Renovated space for process room and corridor with white zone finishes, Cat3B gowning, material airlock, CII Security	$[*]
Utility modifications: existing unit HVAC once thru air, THP monitoring, Compressed air piping, piped Chilled water, piped Purified water, piped city water, Portable Cat3b central vacuum, portable CAT3b dust collection, Misting shower, 230V and 110V power, bottled nitrogen	$[*]
Engineering Cost. This cost will be charged on a time and materials basis, and is estimated to be equal to [*] of the total cost of the first two line items in this table.	$[*]
Facility Qualification Cost. This cost will be charged on a time and materials basis, and is estimated to be equal to [*]of the total cost for the first two line items in this table.	$[*]
Contingency. This cost covers charges for items that have not yet been determined, and is estimated to be equal to [*] of the total cost for the first two line items in this table.	$[*]
[*] line Facility Support	$[*]
Total Phase I	**$[*]**
Phase II (estimated)	
[*] Facility Modifications	$[*]
Mfg facility - 5-2 Phase 2 *One additional process room, equipment wash, clean equipment room, Airlock modifications and security*	$[*]
Utility modifications *HVAC unit, THP, Utilities (CA, Purified water, CQ, CV, dust collection, elec, and N2)*	$[*]
Engineering Cost ([*])	$[*]
Qualification Cost ([*])	$[*]
Contingency ([*])	$[*]
Total Phase II	**$[*]**
Total Facility Modifications	**$[*]**

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATIONS

I, Richard A. King, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2013

/s/ Richard A. King

Richard A. King
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, James H. Welch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2013

/s/ James H. Welch

James H. Welch
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Richard A. King, Chief Executive Officer of AcelRx Pharmaceuticals, Inc. (the "Company"), and James H. Welch, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2013, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of May, 2013.

/s/ Richard A. King	/s/ James H. Welch
Richard A. King	James H. Welch
Chief Executive Officer	Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of AcelRx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.