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 June 30, 2015

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 July 21, 2015, the number of outstanding shares of the registrant's common stock was 44,374,509.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2015

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Unless the context indicates otherwise, the terms "AcelRx," "AcelRx Pharmaceuticals," "we," "us" and "our" refer to AcelRx Pharmaceuticals, Inc. "ACELRX" 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.

Condensed Balance Sheets
(In thousands, except share data)

	June 30, 2015 (Unaudited)	December 31, 2014[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 35,842	$ 60,038
Short-term investments	15,353	15,312
Prepaid expenses and other current assets	2,324	948
Total current assets	53,519	76,298
Property and equipment, net	9,715	9,818
Restricted cash	250	250
Other assets	76	81
Total Assets	$ 63,560	$ 86,447
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,597	$ 2,431
Accrued liabilities	2,048	3,654
Deferred revenue, current portion	152	787
Long-term debt, current portion	9,509	6,859
Total current liabilities	13,306	13,731
Deferred rent	479	529
Long-term debt, net of current portion	13,623	18,046
Deferred revenue, net of current portion	1,594	1,626
Contingent put option liability	251	282
Warrant liability	916	5,577
Total liabilities	30,169	39,791
Stockholders' Equity:		
Common stock, $0.001 par value—100,000,000 shares authorized as of June 30, 2015 and December 31, 2014; 44,374,509 and 43,712,363 shares issued and outstanding as of June 30, 2015 and December 31, 2014	44	43
Additional paid-in capital	231,074	225,423
Accumulated deficit	(197,728)	(178,806)
Accumulated other comprehensive income (loss)	1	(4)
Total stockholders' equity	33,391	46,656
Total Liabilities and Stockholders' Equity	$ 63,560	$ 86,447

(1) The condensed balance sheet as of December 31, 2014 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, 2014.

See notes to condensed financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Contract	$ 1,438	$ —	$ 1,438	$ —
Collaboration agreement	486	71	667	166
Total revenue	1,924	71	2,105	166
Operating expenses:				
Research and development	7,310	7,284	13,616	11,995
General and administrative	2,735	5,047	7,256	8,972
Restructuring costs	2	—	756	—
Total operating expenses	10,047	12,331	21,628	20,967
Loss from operations	(8,123)	(12,260)	(19,523)	(20,801)
Interest expense	(777)	(530)	(1,583)	(1,002)
Interest income and other income (expense), net	4	2,215	2,184	1,597
Net loss	(8,896)	(10,575)	(18,922)	(20,206)
Other comprehensive loss:				
Unrealized gains (losses) on available-for-sale securities	1	(2)	5	(2)
Comprehensive loss	$ (8,895)	$ (10,577)	$ (18,917)	$ (20,208)
Net loss per share of common stock, basic	$ (0.20)	$ (0.24)	$ (0.43)	$ (0.47)
Net loss per share of common stock, diluted	$ (0.20)	$ (0.30)	$ (0.47)	$ (0.50)
Shares used in computing net loss per share of common stock, basic	44,343,270	43,333,210	44,109,488	43,262,204
Shares used in computing net loss per share of common stock, diluted – see Note 9	44,343,270	44,310,166	44,397,471	43,774,033

See notes to condensed financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Six Months Ended June 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (18,922)	$ (20,206)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	997	318
Amortization of premium/discount on investments, net	47	140
Interest expense related to debt financing	472	279
Restructuring costs	(756)	—
Stock-based compensation	2,649	1,869
Revaluation of put option and PIPE warrant liabilities	(2,148)	(1,719)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,376)	(23)
Accounts payable	(834)	457
Accrued liabilities	(850)	(871)
Deferred revenue	(667)	(167)
Deferred rent	(50)	(20)
Net cash used in operating activities	(21,438)	(19,943)
Cash flows from investing activities:		
Purchase of property and equipment	(894)	(1,959)
Purchase of investments	(5,543)	(4,879)
Proceeds from maturity of investments	5,460	5,379
Net cash used in investing activities	(977)	(1,459)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	—	10,000
Payment of long-term debt	(2,240)	—
Net proceeds from issuance of common stock through equity plans and exercise of warrants	459	729
Net cash (used in) provided by financing activities	(1,781)	10,729
Net decrease in cash and cash equivalents	(24,196)	(10,673)
Cash and cash equivalents—Beginning of period	60,038	88,401
Cash and cash equivalents—End of period	$ 35,842	$ 77,728

See notes to condensed financial statements.

AcelRx Pharmaceuticals, Inc.

Notes to Condensed Financial Statements
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

AcelRx Pharmaceuticals, Inc., or the Company or AcelRx, was incorporated in Delaware on July 13, 2005 as SuRx, Inc., and in January 2006, the Company changed its name to AcelRx Pharmaceuticals, Inc. The Company's operations are based in Redwood City, California.

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. AcelRx intends to commercialize its product candidates in the United States and license the development and commercialization rights to its product candidates for sale outside of the United States through strategic partnerships and collaborations. AcelRx may also consider the option to enter into strategic partnerships for its product candidates in the United States. In March 2015, the Company began a pivotal Phase 3 study of ARX-04 (sufentanil sublingual tablet, 30 mcg), a proprietary, non-invasive, single-use tablet in a disposable, pre-filled, single-dose applicator, or SDA. This study, SAP301, is a multi-center, double-blind, placebo-controlled study that will evaluate the efficacy and safety of ARX-04 vs. placebo for the treatment of moderate-to-severe acute pain following ambulatory abdominal surgery. This study is fully enrolled and top-line data is expected early in the fourth quarter of 2015. The Company believes ARX-04 may be a candidate for use in a variety of medically supervised settings to manage moderate-to-severe acute pain, including in the emergency room, or for post-operative patients, following either short-stay or ambulatory surgery.

On July 25, 2014, the U.S. Food and Drug Administration, or FDA, issued a Complete Response Letter, or CRL, for the Company's new drug application, or NDA, for Zalviso™ (sufentanil sublingual tablet system). In March 2015, the Company received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies the Company had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. The Company has been granted a General Advice meeting with the Division of Anesthesia, Analgesia, and Addiction Products in early September 2015 to discuss the FDA's request for an additional clinical trial and the Company's planned response to the CRL. Pending the outcome of that meeting, the Company intends to finalize its plans to refile the NDA for Zalviso. The proposed indication for Zalviso is for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Zalviso consists of sufentanil sublingual tablets, 15 mcg, delivered by the Zalviso System, a needle-free, handheld, patient-administered, pain management system (together, "Zalviso").

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception and expects to continue to incur negative cash flows until its product candidates are approved for marketing in the United States and other countries, in which it has and intends to license its products, which may never occur.

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.

Basis of Presentation

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

Operating results for the three and six months ended June 30, 2015, are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The condensed balance sheet as of December 31, 2014, was derived from the Company's audited financial statements as of December 31, 2014, 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, 2014, which includes 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.

Significant Accounting Policies

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2014. In addition, during the six months ended June 30, 2015, the Company has updated its revenue recognition policy to include Contract revenue, as discussed below. There are no other significant changes to the Company's significant accounting policies from those previously disclosed in its Annual Report on Form 10-K.

Revenue Recognition - Contract Revenue

In May 2015, the Company entered into an award contract with the United States Army Medical Research and Materiel Command, or USAMRMC, to support the development of the Company's product candidate, ARX-04. The contract provides for the reimbursement of qualified expenses for research and development activities as defined under the terms of the contract. Revenue under the contract is recognized when the related qualified research expenses are incurred.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, to provide guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In April 2015, the FASB proposed a one-year deferral of the effective date for ASU 2014-09. Under the proposal, ASU 2014-09 is effective for the Company in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU 2014-09 can be applied retrospectively to all periods presented or only to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2014-09 on its results of operations, cash flows and financial position.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, *Interest—Imputation of Interest*, or ASU 2015-03. ASU 2015-03 will more closely align the presentation of debt issuance costs under U.S. GAAP with the presentation under comparable IFRS standards by requiring that debt issuance costs be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. This accounting guidance is effective for us beginning in the first quarter of 2016. Early adoption is permitted. Upon adoption, ASU 2015-03 should be applied retrospectively to all periods presented. The Company does not expect this updated standard to have a material impact on its financial statements and related disclosures.

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 or observable market inputs of almost identical assets, 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 June 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 35,839	$ —	$ —	$ 35,839
Money market funds	3	—	—	3
Total cash and cash equivalents	35,842	—	—	35,842
Marketable securities:				
U.S. government agency securities	15,352	1	—	$ 15,353
Total marketable securities	15,352	1	—	$ 15,353
Total cash, cash equivalents and investments	$ 51,194	$ 1	$ —	$ 51,195

	As of December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 60,005	$ —	$ —	$ 60,005
Money market funds	33	—	—	33
Total cash and cash equivalents	60,038	—	—	$ 60,038
Marketable securities:				
U.S. government agency securities	15,316	—	(4)	15,312
Total marketable securities	15,316	—	(4)	$ 15,312
Total cash, cash equivalents and investments	$ 75,354	$ —	$ (4)	$ 73,350

As of June 30, 2015 and December 31, 2014, 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 June 30, 2015 or December 31, 2014. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income to earnings during the three and six months ended June 30, 2015 and 2014.

As of June 30, 2015 and December 31, 2014, 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 June 30, 2015 and December 31, 2014, the Company held, in addition to Level I and Level II assets, a contingent put option liability associated with the Company's Amended and Restated Loan and Security Agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, which amends and restates the loan and security agreement with Hercules dated as of June 29, 2011, or the Original Loan Agreement, and which was classified as a Level III liability. See Note 5 "Long-Term Debt," for further description. The Company's estimate of fair value of the contingent put option 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. Changes to the estimated fair value of these liabilities are recorded in interest income and other income (expense), net in the condensed statements of comprehensive loss. 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 June 30, 2015 and December 31, 2014, 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 June 30, 2015			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 3	$ 3	$ —	$ —
U.S. government agency obligations	15,353	—	15,353	—
Total assets measured at fair value	$ 15,356	$ 3	$ 15,353	$ —
Liabilities				
PIPE warrants	$ 916	—	—	$ 916
Contingent put option liability	251	—	—	251
Total liabilities measured at fair value	$ 1,167	$ —	$ —	$ 1,167

	As of December 31, 2014			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 33	$ 33	$ —	$ —
U.S. government agency obligations	15,312	—	15,312	—
Total assets measured at fair value	$ 15,345	$ 33	$ 15,312	$ —
Liabilities				
PIPE warrants	$ 5,577	—	—	$ 5,577
Contingent put option liability	$ 282	—	—	$ 282
Total liabilities measured at fair value	$ 5,859	$ —	$ —	$ 5,859

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 June 30, 2015:

Market price	$	4.24
Exercise price	$	3.40
Risk-free interest rate		0.64%
Expected volatility		57.0%
Expected life (in years)		2.42
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, 2014:

Market price	$	6.73
Exercise price	$	3.40
Risk-free interest rate		1.10%
Expected volatility		61.0%
Expected life (in years)		2.92
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 and six months ended June 30, 2015 and June 30, 2014 (in thousands):

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Fair value—beginning of period	$ 1,155	$ 5,859
Change in fair value of PIPE warrants	68	(4,661)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	(56)	(31)
Fair value—end of period	$ 1,167	$ 1,167

	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Fair value—beginning of period	$ 14,091	$ 13,445
Change in fair value of PIPE warrants	(2,507)	(1,823)
Change in fair value of contingent put option associated with Original Loan Agreement with Hercules	142	104
Fair value—end of period	$ 11,726	$ 11,726

3. U.S. Department of Defense Contract

On May 11, 2015, the Company entered into an award contract supported by the United States Army Medical Research and Materiel Command, or USAMRMC, within the U.S. Department of Defense, or the DoD, in which the DoD agreed to provide up to $17.0 million to the Company in order to support the development of the Company's product candidate, ARX-04 (sufentanil sublingual tablet, 30 mcg), a proprietary, non-invasive, single-use tablet in a disposable, pre-filled SDA, for the treatment of moderate-to-severe acute pain. The DoD contract supports development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse the Company for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

Revenue is recognized based on expenses incurred by the Company in conducting research and development activities set forth in the agreement. Revenue attributable to the research and development performed under the DoD contract, recorded as contract revenue in the condensed statements of comprehensive loss, was $1.4 million for the three and six months ended June 30, 2015. There was no such revenue recognized for the three and six months ended June 30, 2014.

4. Collaboration Agreement

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. The License Agreement grants Grünenthal rights to commercialize Zalviso, the Company's novel sublingual patient-controlled analgesia, or PCA, system, or the Product, in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within or dispensed by hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. The Company retains rights with respect to the Product in countries outside the Territory, including the United States, Asia and Latin America. Under the MSA, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory. The Agreements were amended on July 22, 2015, effective as of July 17, 2015. See Note 11 "Subsequent Events," for further description.

License Agreement

Under the terms of the License Agreement, Grünenthal has the exclusive right to commercialize the Product in the Field in the Territory. The Company retains control of clinical development, while Grünenthal and the Company will be responsible for certain development activities pursuant to a development plan as agreed between the parties. The Company will not receive separate payment for such development activities. Grünenthal is exclusively responsible for marketing approval applications and other regulatory filings relating to the sufentanil sublingual tablet drug cartridge for the Product in the Field in the Territory, while the Company is responsible for the CE Mark and other regulatory filings relating to device portions of the Product. A CE Mark (#611742) for Zalviso was obtained in the fourth quarter 2014 which specifies AcelRx as the device design authority and manufacturer.

The Company received an upfront non-refundable cash payment of $30.0 million in December 2013, and a milestone payment of $5.0 million related to the MAA submission in the third quarter of 2014. The Company is eligible to receive an additional $15.0 million milestone payment upon the approval of the MAA. If the MAA is approved, the Company was initially eligible to receive approximately $200.0 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements (initially $171.5 million). As mentioned above, the Agreements were amended on July 22, 2015, effective as of July 17, 2015. See Note 11 "Subsequent Events," for further description. Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range on net sales of Zalviso.

Unless earlier terminated, the License Agreement continues in effect until the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments, which supply and trademark fee continues for so long as the Company continues to supply the Product to Grünenthal. The License Agreement is subject to earlier termination in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party, upon the bankruptcy or insolvency of either party, or by Grünenthal for convenience.

MSA

Under the terms of the MSA, the Company will manufacture and supply the Product for use in the Field for the Territory exclusively for Grünenthal. Grünenthal shall purchase from AcelRx, during the first five years after the effective date of the MSA, 100% and thereafter 80% of Grünenthal's and its sublicensees' and distributors' requirements of Product for use in the Field for the Territory. The Product will be supplied at the Company's fully burdened manufacturing cost, subject to certain caps (as defined in the MSA). The MSA requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and under certain specified conditions permits Grünenthal to use a third party back-up manufacturer to manufacture the Product for Grünenthal's commercial sale in the Territory.

Unless earlier terminated, the MSA continues in effect until the later of the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments or the end of any transition period for manufacturing obligations due to the expiration or termination of the License Agreement. The MSA is subject to earlier termination in connection with certain termination events in the License Agreement, in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

The Company identified the following four significant non-contingent performance deliverables under the agreements: 1) intellectual property (license), 2) the obligation to provide research and development services, 3) the significant and incremental discount on the manufacturing of Zalviso for commercial purposes, and 4) the obligation to participate on the joint steering committee.

The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value and thus should be treated as separate units of accounting. Company's management determined that the license has standalone value and represents a separate unit of accounting because the rights conveyed permit Grünenthal to perform all efforts necessary to commercialize and begin selling the product upon regulatory approval. In addition, Grünenthal has the appropriate development, regulatory and commercial expertise with products similar to the product licensed under the agreement and has the ability to engage third parties to manufacture the product allowing Grünenthal to realize the value of the license without receiving any of the remaining deliverables. Grünenthal can also sublicense its license rights to third parties. Also, the Company's management determined that the research services, committee participation and implied discount associated with the manufacturing services each represent individual units of accounting as Grünenthal could perform such services and/or could acquire these on a separate basis.

The Company developed best estimates of selling prices for each deliverable in order to allocate the noncontingent arrangement consideration to the four units of accounting.

The Company's management determined the best estimate of selling price for the license based on Grünenthal's estimated future cash flows arising from the arrangement. Embedded in the estimate were significant assumptions regarding regulatory expenses, revenue, including potential customer market for the product and product price, costs to manufacture the product and the discount rate. The Company's management determined the best estimate of selling price of the research and development services and committee participation based on the nature and timing of the services to be performed and in consideration of personnel and other costs incurred in the delivery of the services. For the discount on manufacturing services, Company's management estimated the selling price based on the market level of contract manufacturing margin it could have received if it were engaged to supply products to a customer in a separate transaction.

The Agreements entitle the Company to receive additional payments upon the achievement of certain development and sales milestones. Based on ASC Topic 605-28, *Revenue Recognition — Milestone Method*, the Company evaluates contingent milestones at inception of the agreement, and recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is considered substantive in its entirety. Milestones are events which have the following characteristics: (i) they can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) there was substantive uncertainty at the date the agreement was entered into that the event would be achieved and, (iii) they would result in additional payments due to the Company. A milestone is considered substantive if the following criteria are met: (i) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item (s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (ii) the consideration relates solely to past performance and, (iii) the consideration is reasonable relative to all of the other deliverables and payment terms, including other potential milestone consideration, within the arrangement.

The substantive milestone payments will be recognized as revenue in their entirety upon the achievement of each substantive milestone. Based on the criteria noted above, the identified substantive milestones in the agreement pertain to post approval product enhancements, expanded market opportunities and manufacturing efficiencies for Zalviso. Each of these potential achievements is based primarily on the Company's performance and involves substantive uncertainty as achievement of these milestones requires future research, development and regulatory activities, which are inherently uncertain in nature. The Company determined that the consideration for each milestone was commensurate with the Company's performance to achieve the milestone, including future research, development, manufacturing and regulatory activities and that the consideration is reasonable relative to all of the other deliverables and payments within the arrangement. Aggregate potential payments for these milestones total $28.5 million.

In addition to substantive milestones, two milestones associated with the Agreements were deemed not to be substantive. These milestones pertain to regulatory developments for Zalviso in Europe, which Company's management deemed to be not substantive due to the level of performance associated with future achievement of these milestones. Aggregate potential payments for these milestones total $20.0 million. In July 2014, Grünenthal submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. Under the terms of the License Agreement with Grünenthal, the Company received a cash payment of $5.0 million for the MAA submission in the third quarter of 2014. The Company is eligible to receive an additional $15.0 million milestone payment upon the approval of the MAA. This $15.0 million non-substantive milestone payment will be allocated across the four significant non-contingent performance deliverables identified in the Agreements, based on the relative estimated selling price method, upon approval of the MAA, if approved.

The Agreements also include milestone payments related to specified net sales targets, initially totaling $171.5 million. As mentioned above, the Agreements were amended on July 22, 2015, effective as of July 17, 2015. See Note 11 "Subsequent Events," for further description. The sales-based milestones do not meet the definition of a milestone under ASU 2010-17 because the achievement of these milestones is solely dependent on counter-party performance and not on any performance obligations of the Company.

The Company recognized $486,000 and $667,000 of previously deferred revenue related to research and development services under the collaboration agreement during the three and six months ended June 30, 2015, respectively, and $71,000 and $166,000, of previously deferred revenue related to research and development services under the collaboration agreement during the three and six months ended June 30, 2014, respectively. As of June 30, 2015, the Company had a deferred revenue balance of $1.7 million. There were no milestone payments received or recognized under these Agreements during the three and six months ended June 30, 2015.

5. Long-Term Debt

Hercules Loan and Security Agreements

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 agreement with Pinnacle Ventures is described further below. The interest rate for each tranche was 8.50%. In connection with the loan, the Company issued Hercules seven-year warrants to purchase an aggregate of 274,508 shares of common stock at a price of $3.06 per share. See Note 6 "Warrants," for further description.

On December 16, 2013, AcelRx entered into an Amended and Restated Loan and Security Agreement, or the Loan Agreement with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., together, the Lenders, under which the Company may borrow up to $40.0 million in three tranches. The loans are represented by secured convertible term promissory notes, collectively, the Notes. The Loan Agreement amends and restates the Loan and Security Agreement between the Company and the Lenders dated as of June 29, 2011, or the Original Loan Agreement, as noted above. The Company borrowed the first tranche of $15.0 million upon closing of the transaction on December 16, 2013, and the second tranche of $10.0 million on June 16, 2014. The Company used approximately $8.6 million of the proceeds from the first tranche to repay its obligations under the Original Loan Agreement. The Company recorded the new debt at an estimated fair value of $24.9 million as of December 31, 2014.

On September 24, 2014, the Company entered into an amendment, or the Amendment, to the Loan Agreement with Hercules. The Amendment extends the time period under which the Company can draw down the third tranche, of up to $15.0 million, from March 15, 2015 to August 1, 2015, subject to the Company obtaining approval for Zalviso from the FDA. The Company did not receive FDA approval of Zalviso by August 1, 2015 and as such, did not have access to the third tranche under the Loan Agreement, as amended, or the Amended Loan Agreement.

The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 9.10% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.10%. Payments under the Amended Loan Agreement are interest only until April 1, 2015, followed by equal monthly payments of principal and interest through the scheduled maturity date on October 1, 2017, or the Loan Maturity Date. In addition, a final payment equal to $1.7 million will be due on the Loan Maturity Date, or such earlier date specified in the Amended Loan Agreement. The Company's obligations under the Amended Loan Agreement are secured by a security interest in substantially all of its assets, other than its intellectual property.

If the Company prepays the Amended Loan Agreement prior to maturity, it will pay Hercules a prepayment charge, based on a percentage of the then outstanding principal balance, 2% if the prepayment occurs after December 16, 2014, but prior to December 16, 2015, or 1% if the prepayment occurs after December 16, 2015.

Subject to certain conditions and limitations set forth in the Amended Loan Agreement, the Company has the right to convert up to $5.0 million of scheduled principal installments under the Notes into freely tradeable shares of the Company's common stock, or Common Stock. The number of shares of Common Stock that would be issued upon conversion of the Amended Notes would be equal to the number determined by dividing (x) the product of (A) the principal amount to be paid in shares of Common Stock and (B) 103%, by (y) $9.30 (subject to certain proportional adjustments as provided for in the Amended Loan Agreement).

The Amended Loan Agreement includes customary affirmative and restrictive covenants, but does not include any financial maintenance covenants, and also includes standard events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Hercules' security interest or in the value of the collateral, and events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Amended Loan Agreement.

In connection with the Amended Loan Agreement, the Company issued a warrant to each Lender which, collectively, are exercisable for an aggregate of 176,730 shares of common stock and each carry an exercise price of $6.79 per share. See Note 6 "Warrants," for further description.

Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the Amended Loan Agreement, 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 $1.7 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 the amendment of the loan agreement was considered an extinguishment, the contingent put option liability associated with the Original Loan Agreement, which had an estimated fair value of $32,000 at the time of the amendment, was written off as a part of the loss on extinguishment, and a new contingent put option liability was established. As of June 30, 2015 and December 31, 2014, the estimated fair value of the contingent put option liability was $251,000 and $282,000, respectively, which was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default, and discounting such cash flows back to the reporting date using a risk-free rate. The contingent put option liability was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The contingent put option liability is revalued at the end of each reporting period and any change in the fair value is recognized in interest income and other income (expense), net in the statements of comprehensive loss.

As of June 30, 2015, the Company had outstanding borrowings under the Amended Loan Agreement of $23.1 million. Interest expense related to the Amended Loan Agreement was $0.8 million and $1.6 million for the three and six months June 30, 2015, respectively.

6. Warrants

Series A Warrants

As of June 30, 2015, warrants to purchase 3,425 shares of common stock had not been exercised and were still outstanding. These warrants expire in March 2017.

Hercules Warrants

In connection with the Amended Loan Agreement, executed in December 2013, the Company issued warrants to Hercules which are exercisable for an aggregate of 176,730 shares of common stock with an exercise price of $6.79 per share (the "Warrants"). Each Warrant 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 five years from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the Warrants. The number of shares for which the Warrants are exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in the Warrants. The Company estimated the fair value of these warrants as of the issuance date to be $1.1 million, which was used in the estimating the fair value of the amended debt instrument and was recorded as equity. The fair value of the warrants was calculated using the Black-Scholes option-valuation model, and was based on the strike price of $6.79, the stock price at issuance of $9.67, the five-year contractual term of the warrants, a risk-free interest rate of 1.55%, expected volatility of 71% and 0% expected dividend yield.

As of June 30, 2015, warrants to purchase 176,730 shares of common stock issued to Hercules had not been exercised and were still outstanding. These warrants expire in December 2018.

In connection with the original loan and security agreement with Hercules, executed in June 2011, 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, which were net exercised for 183,404 shares of common stock during the year ended December 31, 2013.

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 Statements of Comprehensive Loss in interest income and other income (expense), net. The Black-Scholes assumptions used to value the PIPE warrants are disclosed in Note 2 "Investments and Fair Value Measurement."

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 June 30, 2015, the fair value of the PIPE warrants was estimated to be $0.9 million. The change in fair value for the three months ended June 30, 2015 was $0.1 million, which was recorded as other expense, and the change in fair value for the six months ended June 30, 2015 was $2.1 million, which was recorded as other income.

In March 2015, PIPE warrants to purchase 847,058 shares were net exercised for 527,101 shares of common stock. As of June 30, 2015, PIPE warrants to purchase 512,456 shares of common stock issued in connection with the Private Placement had not been exercised and were outstanding. These warrants expire in November 2017.

7. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Expenses:				
Research and development	$ 629	$ 560	$ 1,331	$ 1,039
General and administrative	482	334	1,318	830
Total stock-based compensation expense	$ 1,111	$ 894	$ 2,649	$ 1,869

As of June 30, 2015 there were 2,377,921 shares available for grant, 5,766,994 options outstanding and no restricted stock units outstanding under the Company's 2011 Equity Incentive Plan.

8. Restructuring Costs

On March 19, 2015, the Board of Directors of the Company, in connection with its efforts to reduce operating costs, conserve capital, focus the Company's financial and development resources on working with the FDA to seek marketing approval for Zalviso, and continuing development of ARX-04, implemented a cost reduction plan. The cost reduction plan reduced the Company's workforce by 19 employees, approximately 36% of total headcount, in the first quarter of 2015. Employee termination benefits related to this restructuring, are charged to restructuring costs in the Statements of Comprehensive Loss.

Restructuring costs for the three and six months ended June 30, 2015 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Employee termination benefits	$ 2	$ —	$ 756	$ —
Total restructuring costs	$ 2	$ —	$ 756	$ —

The following table presents activities related to a cost reduction plan during the three and six months ended June 30, 2015 (in thousands):

	Employee severance and related costs
Balance of restructuring liability at December 31, 2014	$ —
Charges	754
Payments	—
Balance of restructuring liability at March 31, 2015	754
Charges	2
Payments	(753)
Balance of restructuring liability at June 30, 2015	$ 3

The Company anticipates the restructuring liability will be fully disbursed by December 31, 2015.

9. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock and warrants to purchase common stock were considered to be common stock equivalents. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive.

During the six months ended June 30, 2015, the PIPE warrants had a dilutive impact to net loss per share due to a lower share price at June 30, 2015, compared to the closing share price on December 31, 2014. Similarly, during the three and six months ended June 30, 2014, the PIPE warrants had a dilutive impact to net loss per share due to a lower share price at June 30, 2014, compared to the closing share price on March 31, 2014 and December 31, 2013. The decrease in share price created a lower Black-Scholes value and lower liability for the PIPE warrants, which resulted in other income during the six months ended June 30, 2015 and the three and six months ended June 30, 2014. There was no such dilutive impact for the PIPE warrants during the three months ended June 30, 2015, as the share price increased as compared to the closing share price on March 31, 2015. The calculation of diluted net loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the PIPE warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the PIPE warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

The following table sets forth the computation of the Company's basic and diluted net loss per share of common stock during the three and six months ended June 30, 2015 and 2014 (in thousands, except for share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands, except share and per share amounts)			
Numerator				
Net loss used to compute net loss per share:				
Basic	$ (8,896)	$ (10,575)	$ (18,922)	$ (20,206)
Adjustments for change in fair value of warrant liability	—	(2,507)	(2,117)	(1,823)
Diluted	$ (8,896)	$ (13,082)	$ (21,039)	$ (22,029)
Denominator				
Weighted average shares outstanding used to compute net loss per share:				
Basic	44,343,270	43,333,210	44,109,488	43,262,204
Dilutive effect of warrants	—	976,956	287,983	511,829
Diluted	44,343,270	44,310,166	44,397,471	43,774,033
Net loss per share — basic	$ (0.20)	$ (0.24)	$ (0.43)	$ (0.47)
Net loss per share — diluted	$ (0.20)	$ (0.30)	$ (0.47)	$ (0.50)

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

	June 30,	
	2015	2014
Stock options to purchase common stock	5,766,994	5,160,416
Restricted stock units	—	—
Common stock warrants	692,611	1,674,669

10. Manufacturing Agreements

Patheon

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 tablets, or the Product, for use with the Company's Zalviso drug product.

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. Under the terms of the Capital Agreement, as amended in January 2014, or the Amended Capital Agreement, the Company has made and has the option to make certain future modifications to Patheon's Cincinnati facility 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.

Expenditures associated with the aforementioned agreements are primarily driven by the potential commercial requirements and demand for the Company's products, none of which have been approved for commercialization; accordingly, the amounts and timing of such future expenditures cannot be determined at this time.

Grünenthal

On December 16, 2013, the Company and Grünenthal entered into a License Agreement and MSA, or the Agreements. The License Agreement grants Grünenthal rights to commercialize Zalviso, the Company's Product in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within or dispensed by hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. The Agreements were amended on July 22, 2015, effective as of July 17, 2015. See Note 11 "Subsequent Events," for further description.

Under the terms of the MSA, the Company will manufacture and supply the Product for use in the Field for the Territory exclusively for Grünenthal. Grünenthal shall purchase from AcelRx, during the first five years after the effective date of the MSA, 100% and thereafter 80% of Grünenthal's and its sublicensees' and distributors' requirements of Product for use in the Field for the Territory. The Product will be supplied at the Company's fully burdened manufacturing cost (as defined in the MSA). The MSA requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and under certain specified conditions permits Grünenthal to use a third party back-up manufacturer to manufacture the Product for Grünenthal's commercial sale in the Territory.

Unless earlier terminated, the MSA continues in effect until the later of the expiration of the obligation of Grünenthal to make royalty and supply and trademark fee payments or the end of any transition period for manufacturing obligations due to the expiration or termination of the License Agreement. The MSA is subject to earlier termination in connection with certain termination events in the License Agreement, in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

Under the MSA, the Company will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory.

Expenditures associated with the aforementioned agreements are primarily driven by the potential commercial requirements and demand for the Company's products, none of which are currently approved for commercial use; accordingly, the amounts and timing of such future expenditures cannot be determined at this time.

11. Subsequent Events

On July 22, 2015, the Company entered into amendments to the License Agreement, or the License Amendment, and the MSA, or the MSA Amendment, between the Company and Grünenthal, each effective as of July 17, 2015, and together with the License Agreement and the MSA, the Amended Agreements.

In the MSA Amendment and the License Amendment, the parties amended the Product supply configurations and packaging of Product components and accessories, and associated pricing therefor, which the Company will manufacture and supply to Grünenthal for the Territory. As consideration for an increase in the pricing of the Product components and accessories as part of the agreed packaging configurations, the total milestone payments from Grünenthal contingent upon achieving specified net sales target milestones were reduced from a total of $171.5 million to $166.0 million. The parties also updated the development plan for the Product in the Territory, providing for additional near-term development costs to be paid by Grünenthal.

On July 23, 2015, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, adopted a positive opinion for Zalviso. The opinion, while not binding, recommends marketing authorization for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients in a hospital setting. A decision by the European Commission on the approval of Zalviso is anticipated in late September or early October.

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 process and timing of anticipated future development of AcelRx's product candidates, including Zalviso (sufentanil sublingual tablet system) and ARX-04 (sufentanil sublingual tablet, 30 mcg), including the upcoming General Advice meeting with the U.S. Food and Drug Administration, or FDA, for Zalviso scheduled in early September 2015; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S., including potential additional clinical studies, additional Human Factors studies, or through the dispute resolution process provided for by the FDA; our belief that an additional clinical study should not be required to demonstrate the safety and efficacy of Zalviso beyond what has already been established in the Phase 3 clinical studies, as well as the bench testing and Human Factors studies; our ability to finalize the pathway towards resubmission of the Zalviso New Drug Application, or NDA, to the FDA; our ability to obtain and maintain regulatory approval for our product candidates, including Zalviso and ARX-04, in the United States and Europe; the anticipated timing of the European Commission's decision regarding Zalviso; potential milestones and royalty payments under the Grünenthal agreement and the timing of receipt of those payments; the timing of the receipt of top-line data from the SAP301 Phase 3 clinical study of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the additional clinical trial requested by the FDA for Zalviso and the Phase 3 ARX-04 clinical development program; our ability to obtain sufficient financing to receive regulatory approval for and commercialize Zalviso, and complete clinical development of ARX-04, including potential filing of an NDA; our future losses; the sufficiency of our cash resources; the market potential for our product candidates, including Zalviso and ARX-04, in the United States and Europe; and our estimates regarding expenses, capital requirements and needs for financing. 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, 2014.

About AcelRx Pharmaceuticals

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. We intend to commercialize our product candidates in the United States and license the development and commercialization rights to our product candidates for sale outside of the United States through strategic partnerships and collaborations. We may also consider the option to enter into strategic partnerships for our product candidates in the United States. Our product candidate, Zalviso™, is intended for the management of moderate-to-severe acute pain in hospitalized adult patients. Zalviso consists of sufentanil sublingual tablets, 15 mcg, delivered by the Zalviso System, a needle-free, handheld, patient-administered, pain management system (together, "Zalviso").

On July 25, 2014, the U.S. Food and Drug Administration, or FDA, issued a Complete Response Letter, or CRL, for our New Drug Application, or NDA, for Zalviso. The CRL contains requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of optical system errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. There were no requests for additional clinical studies in the CRL. In the third quarter of 2014, we held a Type A meeting with the FDA to discuss the Zalviso CRL received in July. During the meeting we discussed the resubmission of the Zalviso NDA and the steps necessary for the resubmission. In advance of resubmitting our Zalviso NDA, we agreed with the FDA to submit protocols for the bench testing and Human Factors, or HF, studies for their review and comment. In addition, the FDA requested in the minutes of the meeting that we provide a risk assessment that analyzes the risks associated with inadvertent dosing and the rationale that bench testing and HF studies are sufficient to address the specific items included in the CRL. We submitted the protocols and this rationale in the fourth quarter of 2014. In January 2015, we received feedback from the FDA on the protocol and the planned analysis of the results of the bench test. No modifications to the conduct of the bench test were necessary; however, in response to the FDA's request, we refined the planned analysis of the bench test results. In February 2015, we received feedback from the FDA on the HF protocols. In this feedback, the FDA confirmed that the HF studies as proposed were acceptable to evaluate the design changes related to inadvertent dispensing of tablets. In March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two HF studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. The FDA has precleared certain aspects of our proposed Risk Evaluation and Mitigation Strategy, or REMS, and indicated that they will continue discussion of our proposed REMS after the Zalviso NDA has been resubmitted.

In July 2014, Grünenthal GmbH, or Grünenthal, filed a Marketing Authorization Application, or MAA, with European Medicines Agency, or EMA, under the centralized procedure in the European Union, or EU, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. In July 2015, the Committee for Medicinal Products for Human Use, or CHMP, met to discuss the MAA for Zalviso. On July 23, 2015, the CHMP adopted a positive opinion for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients in a hospital setting. This opinion has been transmitted to the European Commission, or EC, which has the ultimate authority for granting marketing authorizations in the EU. A decision by the EC on the approval of Zalviso is anticipated in late September or early October. For additional information on the collaboration agreement with Grünenthal, see Note 4 "Collaboration Agreement" in the accompanying notes to condensed financial statements.

Zalviso

Zalviso is an investigational, pre-programmed, non-invasive, system to allow hospital patients with moderate-to-severe acute pain to self-dose with sufentanil sublingual tablets, 15 mcg, to manage their pain. Zalviso is designed to help address certain problems associated with post-operative intravenous patient-controlled analgesia, by offering:

- **A high therapeutic index opioid:** Zalviso uses sufentanil, an opioid that has a high therapeutic index. The therapeutic index is the ratio of the effective dose versus the lethal dose. In animal studies, the therapeutic index for sufentanil was approximately 100 times larger than fentanyl and 300 times larger than morphine.

- **A non-invasive route of delivery:** Zalviso utilizes a sufentanil tablet which allows for a sublingual (under the tongue) route of delivery. Sufentanil is highly lipophilic which provides for rapid absorption in the fatty cells (or mucosal tissue) found under the tongue, and for rapid transit across the blood-brain barrier to reach the mu-opioid receptors in the brain. The sublingual delivery used by Zalviso provides rapid onset of analgesia. The sublingual delivery system also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients do not require direct connection to an IV patient-controlled analgesia, or PCA, infusion pump through IV tubing, Zalviso allows for ease of patient mobility.

- **A simple, pre-programmed PCA solution:** Zalviso allows patients to self-dose sufentanil sublingual tablets via a pre-programmed, secure system designed to eliminate the risk of programming errors.

We submitted an NDA for Zalviso in September 2013 and, in December 2013, we announced that the FDA accepted for filing the Zalviso NDA. As mentioned above, the FDA issued a CRL for Zalviso on July 25, 2014, and in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two HF studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. We believe that an additional clinical study should not be required to demonstrate the safety and efficacy of the Zalviso System beyond what has already been established in the Phase 3 clinical studies, as well as the bench testing and Human Factors studies.

ARX-04

We are also developing ARX-04 (sufentanil sublingual tablet, 30 mcg), a proprietary, non-invasive, single-use tablet in a disposable, pre-filled, single-dose applicator, or SDA, for the treatment of moderate-to-severe acute pain to be administered by a healthcare professional to a patient in medically supervised settings of acute pain. If approved, potential examples include: emergency room patients; post-operative patients who are transitioning from the operating room to the recovery floor; patients who are recovering from either short-stay or ambulatory surgery and do not require more long-term patient-controlled analgesia; treatment of battlefield casualties; and patients being transported by paramedics. In December 2013, we completed an End-of-Phase 2 Meeting with the FDA to identify a Phase 3 program pathway forward for evaluation of ARX-04. We reported dosing of the first patient in SAP301, a pivotal Phase 3 study of ARX-04, in March 2015. This trial is fully enrolled and we anticipate top-line data from this study early in the fourth quarter of 2015.

On May 11, 2015, we entered into an award contract supported by the United States Army Medical Research and Materiel Command, or USAMRMC, within the U.S. Department of Defense, or the DoD, in which the DoD agreed to provide up to $17.0 million to support the development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse us for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

In the third quarter of 2015, we plan to initiate an additional Phase 3 clinical trial, an open-label safety study of patients who present to the emergency room with moderate-to-severe acute pain due to trauma or injury.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue our research and development activities and pre-commercialization activities. As we pursue development of our product candidates, including regulatory review and potential commercial development, subject to FDA approval, of our product candidates, we expect the business aspects of our company to become more complex. In the future, we plan to add personnel and incur additional costs related to the maturation of our business and the potential commercialization of Zalviso. In addition, we believe that continued investment in research and development is critical to attaining our strategic objectives. In order to develop our product candidates as commercially viable therapeutics, we expect to expend significant resources for expertise in manufacturing, regulatory affairs, clinical research and other aspects of pharmaceutical development.

To date, we have funded our operations primarily through the issuance of equity securities, borrowings, payments from our corporate collaboration and our DoD contracts.

Our revenues since inception have consisted primarily of revenues from our collaboration with Grünenthal and our research contracts with the USAMRMC within the DoD. As mentioned above, in May 2015, the DoD agreed to provide us up to $17.0 million to support the development of ARX-04. The DoD contract will support development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA.

There can be no assurance that we will enter into other collaborative agreements or receive research-related contract awards in the future. We expect revenues to continue to fluctuate from period-to-period. There can be no assurance that our existing collaboration with Grünenthal will continue beyond the initial term, or that we will be able to meet the milestones specified in this agreement, or that the DoD contract will result in an NDA submission for ARX-04, or that we will obtain marketing approval for our product candidates and subsequently generate revenue from those product candidates in excess of our operating expenses.

Our net loss for the three months and six months ended June 30, 2015 was $8.9 million and $18.9 million, respectively. As of June 30, 2015, we had an accumulated deficit of $197.7 million. As of June 30, 2015, we had cash, cash equivalents and investments totaling $51.2 million compared to $75.4 million as of December 31, 2014.

In December 2013, we entered into an Amended and Restated Loan and Security Agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we may borrow up to $40.0 million in three tranches, represented by secured convertible promissory notes. The Loan Agreement amends and restates the loan and security agreement with Hercules dated as of June 29, 2011, or the Original Loan Agreement. We borrowed the first tranche of $15.0 million upon closing of the transaction on December 16, 2013 and used approximately $8.6 million of the proceeds from the first tranche to repay our obligations under the Original Loan Agreement with Hercules. On June 16, 2014, we borrowed the second tranche of $10.0 million. On September 24, 2014, we entered into an amendment, or the Amendment, to the Loan Agreement with Hercules. The Amendment extended the time period under which we can draw down the third tranche, of up to $15.0 million, from March 15, 2015 to August 1, 2015, subject to our obtaining approval for Zalviso from the FDA. We did not receive FDA approval of Zalviso by August 1, 2015 and as such, did not have access to the third tranche under the Loan Agreement, as amended, or the Amended Loan Agreement. The interest rate for each tranche will be calculated at a rate equal to the greater of either (i) 9.10% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.10%. Payments under the Amended Loan Agreement are interest only until April 1, 2015 followed by equal monthly payments of principal and interest through the scheduled maturity date on October 1, 2017, or the Loan Maturity Date. In addition, a final payment equal to $1.7 million will be due on the Loan Maturity Date, or such earlier date specified in the Amended Loan Agreement. Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property.

As of June 30, 2015, the outstanding principal owed to Hercules was $23.1 million.

On December 16, 2013, AcelRx and Grünenthal GmbH, or Grünenthal, entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. The License Agreement grants Grünenthal rights to commercialize Zalviso, or the Product, in the countries of the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within or dispensed by hospitals, hospices, nursing homes and other medically-supervised settings, or the Field. AcelRx retains rights with respect to the Product in countries outside the Territory, including the United States, Asia and Latin America. Under the MSA, AcelRx will exclusively manufacture and supply the Product to Grünenthal for the Field in the Territory.

On July 22, 2015, we entered into amendments to the License Agreement, or the License Amendment, and the MSA, or the MSA Amendment, between AcelRx and Grünenthal, each effective as of July 17, 2015, and together with the License Agreement, and the MSA, the Amended Agreements.

In the MSA Amendment and the License Amendment, the parties amended the Product supply configurations and packaging of Product components and accessories, and associated pricing therefor, which AcelRx will manufacture and supply to Grünenthal for the Territory. As consideration for an increase in the pricing of the Product components and accessories as part of the agreed packaging configurations, the total milestone payments from Grünenthal contingent upon achieving specified net sales target milestones were reduced from a total of $171.5 million to $166.0 million. The parties also updated the development plan for the Product in the Territory, providing for additional near-term development costs to be paid by Grünenthal.

Under the terms of the Amended Agreements with Grünenthal, we received an upfront cash payment of $30.0 million in December 2013, and in the third quarter of 2014, we received a milestone payment of $5.0 million related to the MAA submission to EMA. We are eligible to receive an additional $15.0 million milestone payment upon the approval of the MAA. If approved, under the terms of the Amended Agreements, we are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales of Zalviso in the Grünenthal territory.

Grünenthal will be responsible for all commercial activities for Zalviso, including obtaining and maintaining pharmaceutical product regulatory approval in the Grünenthal territory. We will be responsible for obtaining and maintaining device regulatory approval in the Grünenthal territory and manufacturing and supply of Zalviso to Grünenthal for commercial sales.

As mentioned above, in July 2014, Grünenthal filed an MAA with EMA under the centralized procedure in the EU for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. On July 23, 2015, the CHMP adopted a positive opinion for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients in a hospital setting. A decision by the EC on the approval of Zalviso is anticipated in late September or early October.

In association with potential commercialization of Zalviso in the European Union, we underwent a Conformite Europeenne approval process for the Zalviso device, more commonly known as a CE Mark approval process. We received CE Mark approval in December 2014, which permits the commercial sale of the Zalviso device in the European Union. However, as a drug-device combination product, Zalviso will not be utilized commercially unless and until EMA approves the Zalviso MAA. In connection with the CE Mark approval, we were also granted International Standards Organization, or ISO, 13485:2003 certification of our quality management system in November 2014. This is an internationally recognized quality standard for medical devices. Certification of our quality management system was issued by the British Standards Institution, or BSI, a Notified Body.

ISO 13485:2003 certification recognizes that consistent quality policies and procedures are in place for the development, design and manufacturing of medical devices. The certification indicates that we have successfully implemented a quality system that conforms to ISO 13485 standards for medical devices. Certification to this standard is one of the key regulatory requirements for a CE Mark in the European Union as well as to meet equivalent requirements in other international markets. The certification applies to the Redwood City, California location which designs, manufactures and distributes finished medical devices, and includes critical suppliers.

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, 2014. In addition, during the six months ended June 30, 2015, we have updated our revenue recognition policy to include contract revenue, as discussed below. There are no other significant changes to our critical accounting policies and estimates from those previously disclosed in our Annual Report on Form 10-K.

Revenue Recognition - Contract Revenue

In May 2015, we entered into an award contract with the USAMRMC to support the development of our product candidate, ARX-04. The contract provides for the reimbursement of qualified expenses for research and development activities as defined under the terms of the contract. Revenue under the contract is recognized when the related qualified research expenses are incurred.

Results of Operations

Three and Six Months Ended June 30, 2015 and 2014

Revenue

To date, we have not generated any commercial product revenue. We do not expect to receive any commercial sales revenue from any product candidates that we develop until we, or our collaborators, obtain regulatory approval and commercialize our products.

Revenue for the three and six months ended June 30, 2015, was $1.9 million and $2.1 million, respectively, the majority of which was generated from our contract for ARX-04 with the DoD. In the three and six months ended June 30, 2015, $1.4 million in revenue was generated under our DoD contract, while $486,000 and $667,000, respectively, related to development work associated with our collaboration agreement with Grünenthal. Revenue for the three and six months ended June 30, 2014, was $71,000 and $166,000, respectively, all of which related to development work associated with our collaboration agreement with Grünenthal.

Contract Revenue

On May 11, 2015, we entered into an award contract supported by the USAMRMC within the DoD, in which the DoD agreed to provide up to $17.0 million to support the development of our product candidate ARX-04, a proprietary, non-invasive, single-use tablet in a disposable, pre-filled, single-dose applicator for the treatment of moderate-to-severe acute pain. The DoD contract will support development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse us for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. In addition, if ARX-04 is approved by the FDA, the DoD has the option to purchase a certain number of units of commercial product pursuant to the terms of the contract.

Collaboration Agreement Revenue

As mentioned above, under the terms of the Agreements with Grünenthal, we received an upfront cash payment of $30.0 million, and a milestone payment of $5.0 million related to the MAA submission, which occurred in July 2014. We are eligible to receive an additional $15.0 million milestone payment upon the approval of the MAA. This $15.0 million non-substantive milestone payment will be allocated across the four significant non-contingent performance deliverables identified in the Agreements, based on the relative estimated selling price method, upon approval of the MAA, if approved. In addition, if the MAA is approved, under the terms of the Amended Agreements, we are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts and net sales target achievements. Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales of Zalviso in the Grünenthal territory.

Research and Development Expenses

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

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

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 will incur substantial future expenditures as we seek to continue development of Zalviso, including activities to address issues raised by the FDA during their regulatory review process, as well as activities associated with potential preparation for commercialization of Zalviso, should we receive approval from the FDA. In addition, we plan to continue to incur significant research and development expenses, including the expenses associated with the continued development of ARX-04. We do not plan to continue development of ARX-02 and ARX-03, unless additional funding or corporate partnership resources are available to support these programs.

We track external development expenses on a program-by-program basis. Our development resources are shared among all of our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead. Below is a summary of our research and development expenses during the three and six months ended June 30, 2015 and 2014 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
Drug Indication/Description	**2015**	**2014**	**2015 vs. 2014 Increase/ (Decrease)**	**2015**	**2014**	**2015 vs. 2014 Increase/ (Decrease)**
			(In thousands, except percentages)			
Zalviso	$ 1,082	$ 3,578	(70)%	$ 2,752	$ 5,300	(48)%
ARX-04	2,996	994	201%	4,157	1,700	145%
Overhead	3,232	2,712	19%	6,707	4,995	34%
Total research and development expenses	$ 7,310	$ 7,284	0%	$ 13,616	$ 11,995	14%

Due to the inherently unpredictable nature of product development, development timelines and the probability of success, development costs can differ materially from expectations. While we are currently focused on advancing Zalviso and the continued development of ARX-04, our future research and development expenses will depend on the clinical success of each product candidate as well as ongoing assessments of the commercial potential of our

product candidates. In addition, we cannot predict which product candidates may be subject to future collaborations, when these arrangements will be secured, if at all, and to what degree these arrangements would affect our development plans and capital requirements.

Total research and development expenses for the three and six months ended June 30, 2015 and 2014 were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change	%	2015	2014	Change	%
	(In thousands, except percentages)							
Research and development expenses	$ 7,310	$ 7,284	$ 26	0%	$ 13,616	$ 11,995	$ 1,621	14%

Research and development expenses during the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, included a decrease of $2.5 million related to our Zalviso development program, partially offset by a $2.0 million increase related to the initiation of our ARX-04 Phase 3 clinical trial, and a $0.5 million increase in research and development overhead expenses, including a $0.4 million increase in facilities expense, primarily related to the amortization of the tenant improvements at our contract manufacturer's facility and depreciation of manufacturing equipment.

The $1.6 million increase in research and development expenses during the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily attributable to an increase of $2.5 million related to our ARX-04 development program, an increase of $0.8 million in manufacturing facilities expense, and an increase of $0.9 million in personnel-related expenses, including stock-based compensation, partially offset by a $2.5 million decrease related to our Zalviso Phase 3 clinical program.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel in administration, finance, marketing and business development activities. Other significant expenses included legal expenses related to litigation and 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 continue to decrease in the next quarter as a result of the cost reduction plan and then remain flat as we focus our efforts on seeking marketing approval for Zalviso, and the continued development of ARX-04.

Total general and administrative expenses for the three and six months ended June 30, 2015 and 2014 were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change	%	2015	2014	Change	%
	(In thousands, except percentages)							
General and administrative expenses	$ 2,735	$ 5,047	$ (2,312)	(46)%	$ 7,256	$ 8,972	$ (1,716)	(19)%

General and administrative expenses decreased over both comparative periods primarily due to a cost reduction plan implemented by our Board of Directors on March 19, 2015. See "Restructuring Costs" below for additional information.

The $2.3 million decrease in general and administrative expenses during the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was primarily due to a $2.3 million decrease in market research expenses and a significant reduction in pre-commercialization activities related to Zalviso.

The $1.7 million decrease in general and administrative expenses during the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to a decrease in market research and outside services of $3.0 million, primarily related to market research activities for Zalviso, partially offset by an increase of $1.3 million, primarily due to a $1.2 million increase in headcount-related expenses, including a $0.5 million increase in stock-based compensation, due to the timing of new hires added in mid-2014 who were unaffected by the March 2015 cost reduction plan.

Restructuring Costs

In March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On March 19, 2015, our Board of Directors, in connection with our efforts to reduce operating costs, conserve capital, focus the Company's financial and development resources on working with the FDA to seek marketing approval for Zalviso, and continuing development of ARX-04, implemented a cost reduction plan. The cost reduction plan reduced our workforce by 19 employees, approximately 36% of total headcount, in the first quarter of 2015.

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change	%	2015	2014	Change	%
	(In thousands, except percentages)							
Restructuring costs	$ 2	$ —	$ 2	—%	$ 756	$ —	$ 756	—%

Restructuring costs in the three and six months ended June 30, 2015 consist of employee termination benefit costs of $0 and $0.8 million, respectively.

Interest Expense

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Total interest expense for the three and six months ended June 30, 2015 and 2014, was as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	2014	Change	%	2015	2014	Change	%
Interest expense	$ 777	$ 530	$ 247	47%	$ 1,583	$ 1,002	$ 581	58%

Interest expense for both periods pertains to interest on our loan and security agreement with Hercules. In December 2013, we entered into the Amended Loan Agreement with Hercules, which amends and restates the Original Loan Agreement. The overall debt facility was increased to $40.0 million, $23.1 million of which was outstanding as of June 30, 2015, and the maturity was extended to October 1, 2017. On June 16, 2014, we borrowed the second tranche of $10.0 million. As a result, the amount of interest expense incurred during the three and six months ended June 30, 2015, increased as compared to the three and six months ended June 30, 2014.

Interest Income and Other Income (Expense), net

Interest income and other income (expense), net, during the three and six months ended June 30, 2015 and 2014, 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.

Total interest income and other income (expense), net for the three and six months ended June 30, 2014 and 2014 was as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2015	2014	Change	2015	2014	Change
Interest income and other income (expense), net	$ 4	$ 2,215	$ (2,211)	$ 2,184	$ 1,597	$ 587

The decrease in interest income and other income (expense), net, during the three months ended June 30, 2015 as compared to the three months ended June 30, 2014, of $2.2 million was primarily attributable to fewer PIPE warrants outstanding at June 30, 2015, as compared to June 30, 2014, in addition to an increase in the liability, as the stock price increased in the quarter ended June 30, 2015, whereas the liability decreased in the quarter ended June 30, 2014 due to a decrease in the stock price in that period. The increase in interest income and other income (expense), net, during the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, of $0.6 million was primarily attributable to fewer PIPE warrants outstanding at June 30, 2015, compared to June 30, 2014, and a larger decrease in our stock price during the first half of 2015 as compared to the first half of 2014, which is the primary driver in the Black-Scholes valuation model used to estimate the fair value of the PIPE warrants.

Liquidity and Capital Resources

Liquidity

We have incurred losses and generated negative cash flows from operations since inception. We expect to continue to incur significant losses and negative cash flows in 2015 and may 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, and through our collaboration agreement with Grünenthal, which we entered into in December 2013.

As of June 30, 2015, we had cash, cash equivalents and investments totaling $51.2 million compared to $75.4 million as of December 31, 2014. The decrease was primarily attributable to cash required to fund our continuing operations, as we continue our research and development activities. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the first half of 2016, excluding any potential proceeds from sales or milestones associated with our collaboration with Grünenthal, additional financings or other corporate partnerships. While we believe we have sufficient capital to meet our operational requirements through at least the first half of 2016, our expectations may change depending on a number of factors. For example, based on potential future discussion with the FDA regarding their request for a clinical trial for Zalviso, the FDA may indicate a scope or design of clinical trial that is beyond what our current and estimated future capital resources can support. If we were to decide to proceed with a large scale clinical trial, we would need to raise additional capital. We believe that together with the support from the DoD contract, we have sufficient resources to complete the Phase 3 development program for ARX-04 through submission of the NDA to the FDA. However, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations.

In December 2013, we announced a commercial collaboration with Grünenthal, covering the territory of the European Union, certain other European countries and Australia for Zalviso for potential use in pain treatment within or dispensed by a hospital, hospice, nursing home or other medically supervised setting. We retain all rights in remaining countries, including the United States, Asia and Latin America. Under the terms of the Amended Agreements, we received an upfront cash payment of $30.0 million, and a milestone payment of $5.0 million related to the MAA submission. We are eligible to receive an additional $15.0 million milestone payment upon the approval of the MAA. If approved, under the terms of the Amended Agreements, we are eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts and net sales target achievements. Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, on net sales of Zalviso in the Grünenthal territory.

In December 2013, we entered into an amended loan and security agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we may borrow up to $40.0 million in three tranches, represented by secured convertible promissory notes. The agreement amends and restates the loan and security agreement with Hercules dated as of June 29, 2011, or the Original Loan Agreement. We borrowed the first tranche of $15.0 million upon closing of the transaction on December 16, 2013 and used approximately $8.6 million of the proceeds from the first tranche to repay our obligations under the Original Loan Agreement with Hercules. On June 16, 2014, we borrowed the second tranche of $10.0 million, which we plan to provide additional funding for the commercialization of Zalviso, as a potential source of funding for clinical trials for other development programs in our pipeline and for general corporate purposes. On September 24, 2014, we entered into an amendment, or the Amendment, to the Amended Loan Agreement with Hercules. The Amendment extended the time period under which we can draw down the third tranche, of up to $15.0 million, from March 15, 2015 to August 1, 2015, subject to obtaining approval for Zalviso from the FDA. We did not receive FDA approval of Zalviso by August 1, 2015 and as such, did not have access to the third tranche under the Amended Loan Agreement.

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):

	Six Months Ended June 30,	
	2015	2014
Net cash used in operating activities	$ (21,438)	$ (19,943)
Net cash used in investing activities	(977)	(1,459)
Net cash (used in) provided by financing activities	(1,781)	10,729

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, including commercial readiness activities for our product candidate, Zalviso. Our cash used for operating activities also reflected changes in our working capital, net of 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 and the contingent put option liability.

Cash used in operating activities of $21.4 million during the six months ended June 30, 2015, reflected a net loss of $18.9 million, partially offset by aggregate non-cash charges of $1.3 million, and a net change of $3.8 million in our net operating assets and liabilities. Non-cash charges included $2.6 million for stock-based compensation, and $1.0 million for depreciation and amortization of our fixed assets, partially offset by $2.1 million for the change in fair value of our PIPE warrant liability and contingent put liability. The net change in our operating assets and liabilities included a $1.4 million increase in prepaid expenses and other assets, primarily due to the timing of payments, and a decrease in accrued liabilities of $0.9 million, largely due to payment of compensation-related expenses.

Cash used in operating activities of $19.9 million during the six months ended June 30, 2014, reflected a net loss of $20.2 million, partially offset by aggregate non-cash charges of $887,000, and a net change of $623,000 in our net operating assets and liabilities. Non-cash charges included $1.9 million for stock-based compensation, partially offset by $1.7 million for the change in fair value of our PIPE warrant liability and contingent put liability.

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 six months ended June 30, 2015, cash used in investing activities of $1.0 million was primarily as a result of $5.5 million for purchases of investments and $0.9 million for purchases of property and equipment, partially offset by $5.4 million in proceeds from maturity of investments.

During the six months ended June 30, 2014, cash used in investing activities of $1.5 million was primarily as a result of $4.9 million for purchases of investments and $2.0 million for purchases of property and equipment, partially offset by $5.4 million in proceeds from maturity 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 June 30, 2015, we had outstanding debt of $23.1 million.

During the six months ended June 30, 2015, cash used in financing activities of $1.8 million was primarily due to payments on our loan and security agreement with Hercules.

During the six months ended June 30, 2014, cash provided by financing activities of $10.1 million was primarily due to the drawdown of the second tranche of the Hercules debt of $10.0 million.

Operating Capital and Capital Expenditure Requirements

We expect our rate of cash usage to increase in the future, in particular to support our product development activities, including continued development of Zalviso, ARX-04 and the potential commercialization of our product candidates, if approved. Our future cash needs are highly dependent on the receipt of the $15.0 million milestone from Grünenthal for approval of the MAA and receipt of reimbursement of approximately $7.0 million in 2015 under the contract with the DoD. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the first half of 2016. Our current operating plan includes the continued development of ARX-04, specifically the filing of the NDA in 2016. Our operating plan does not include any significant spending for continued development of Zalviso. These assumptions may change as a result of many factors. For example, the FDA has informed us that a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. We have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. The pathway forward for Zalviso could have a material impact to our operating spend. 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 on 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 product candidates would be harmed.

Our future capital requirements may vary materially from our expectations based on numerous forward looking factors, including but not limited to the following:

- the outcome, timing and cost of regulatory approvals;
- expenditures related to the activities required in support of our resubmission of the Zalviso NDA, including an additional clinical trial for Zalviso, as requested by the FDA;
- expenditures related to our commercialization preparation of Zalviso;
- future manufacturing, selling and marketing costs related to Zalviso, if the product candidate is approved for marketing, including our contractual obligations to Grünenthal;
- the initiation, progress, timing and completion of clinical trials for our product candidates, including ARX-04;
- changes in the focus and direction of our business strategy and/or research and development programs;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the 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 expenses associated with the pending securities lawsuit, as well as any other litigation.

We will need substantial funds to:

- commercialize any products we market, including Zalviso, if approved;
- manufacture and market our product candidates;
- conduct preclinical and clinical testing of our product candidates; and
- conduct research and development programs.

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities, monetization of current and future assets, issuance of debt or debt-like securities or from development and licensing arrangements to continue our development programs. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

- significantly curtail or put on hold commercialization or development efforts of our product candidates or other operations;
- obtain funds through entering into collaboration agreements on unattractive terms; and/or
- delay, postpone or terminate planned clinical trials.

Contractual Obligations

During the six months ended June 30, 2015, there were no material changes to our contractual obligations, other than the fulfillment of existing obligations in the ordinary course of business, described under Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for our fiscal year ended December 31, 2014.

Off-Balance Sheet Arrangements

Through June 30, 2015, 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

Our cash, cash equivalents and short-term investments as of June 30, 2015, consisted primarily of primarily of money market funds and U.S. government agency securities. We do not have any auction rate securities on our balance sheet, as they are not permitted by our investment policy. Our cash is invested in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. We do not believe our cash, cash equivalents and short-term investments have significant risk of default or illiquidity.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. In an attempt to limit interest rate risk, we follow guidelines to limit the average and longest single maturity dates, place our investments with high quality issuers and follow internally developed guidelines to limit the amount of credit exposure to any one issuer. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. If a 10 percent change in interest rates were to have occurred on June 30, 2015, this change would not have had a material effect on the fair value of our investment portfolio as of that date. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

In addition, domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

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

On October 1, 2014, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against AcelRx and certain of our current and former officers. On April 17, 2015, lead plaintiff filed an amended complaint. The amended complaint alleges that between September 30, 2013 and July 25, 2014, AcelRx and certain of our current and former officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 in connection with statements related to our drug candidate, Zalviso. The amended complaint seeks unspecified damages, interest, attorneys' fees, and other costs. In response, the Company filed a Motion to Dismiss on June 1, 2015. Plaintiffs' opposition was filed July 30, 2015 and a hearing date on the Motion to Dismiss has been scheduled for October 22, 2015. We believe that we have meritorious defenses and intend to defend against this lawsuit vigorously.

This lawsuit and any future related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. Securities-related class action litigation often is expensive and diverts management's attention and our financial resources, which could adversely affect our business. Further, any negative outcome from such lawsuit could result in payments of monetary damages, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in this case or any subsequent related case. Defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

From time to time we may be involved in additional legal proceedings arising in the ordinary course of business.

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, 2014.

Risks Related to Clinical Development and Regulatory Approval

We depend substantially on the success of Zalviso, which may not receive regulatory approval or be successfully commercialized.*

Since our inception in 2005, we have focused primarily on development of our product candidate, Zalviso™. Zalviso consists of sufentanil sublingual tablets, 15 mcg, delivered by the Zalviso System, a needle-free, handheld, patient-administered, pain management system (together, "Zalviso"). The success of our business depends primarily upon our ability to develop, receive regulatory approval for and commercialize Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting. We have not marketed, distributed or sold any products to date.

Our Phase 3 program for Zalviso consisted of three Phase 3 clinical trials. We reported positive top-line data from each of these trials and submitted a New Drug Application, or NDA, for Zalviso to the U.S. Food and Drug Administration, or FDA, on September 27, 2013, which the FDA then accepted for filing in December 2013. On July 25, 2014, the FDA issued a Complete Response Letter, or CRL, for our NDA for Zalviso. The CRL contains requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of optical system errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. In September 2014, we held a Type A meeting via a teleconference with representatives from the FDA to review our proposed response to the Zalviso CRL. We submitted a Briefing Document to the FDA ahead of the teleconference and received preliminary comments from the FDA on the Briefing Document. During the meeting, we discussed the resubmission of the Zalviso NDA and the steps necessary for the resubmission, including submission of protocols for the bench testing and Human Factors, or HF, studies for their review and comment. In addition, the FDA requested in the minutes of the meeting, that we provide a risk assessment that analyzes the risks associated with inadvertent dosing and the rationale that bench testing and HF studies are sufficient to address the specific items included in the CRL. We submitted the protocols and this rationale in the fourth quarter of 2014. In January 2015, we received feedback from the FDA on the protocol and planned analysis of the results of the bench test. Based on the FDA feedback, no modifications to the conduct of the bench test were necessary; however, in response to the FDA's request, we refined the planned analysis of the bench test results. In February 2015, we received feedback from the FDA on the HF protocols. In this feedback, the FDA confirmed that the HF studies as proposed were acceptable to evaluate the design changes related to inadvertent dispensing of tablets. In March 2015, we received additional correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss their request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. Based on clinical studies to date, we believe that Zalviso has been shown to be safe and effective in the management of moderate-to-severe acute pain in the hospital setting and therefore additional human clinical trials should not be needed. However, we cannot predict what the FDA will ultimately conclude as a result of the General Advice meeting and their review of the briefing materials. We intend to continue to work with the FDA to determine a regulatory path forward to refile the NDA for Zalviso.

Our proposed trade name of Zalviso has been approved by the FDA, which must approve all drug trade names to avoid medication errors and misbranding. However, the FDA may withdraw this approval in which case any brand recognition or goodwill that we establish with the name Zalviso prior to commercialization may be worthless.

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

On December 16, 2013, we entered into a Collaboration and License Agreement, or the License Agreement, and related Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements, with Grünenthal GmbH, or Grünenthal. On July 22, 2015, we entered into amendments to the License Agreement, or the License Amendment, and the MSA, or the MSA Amendment, with Grünenthal, each effective as of July 17, 2015, and together with the License Agreement, and the MSA, the Amended Agreements. The Amended Agreements with Grünenthal grants them rights to commercialize Zalviso, in the European Union, or EU, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, for human use in pain treatment within or dispensed by hospitals, hospices, nursing homes and other medically-supervised settings. Although the Committee for Medicinal Products for Human Use, or CHMP, has adopted a positive opinion for Zalviso and we have received CE Mark approval permitting the commercial use of the Zalviso device in the EU, Grünenthal may never achieve regulatory approval for Zalviso in their licensed territories, in which case, we would not receive development or sales milestones, or product royalties, which could have a material adverse effect on our business.

We may decide to enter into the dispute resolution process through the FDA prescribed pathway.*

As noted above, on May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. We will be considering all options to determine a pathway forward for Zalviso, including the possibility of dispute resolution through the FDA prescribed pathway, as well as conducting additional clinical and Human Factors studies. Even if we determine a pathway forward for Zalviso that includes additional clinical and Human Factors studies, there is no guarantee that we will be able to define the nature and scope of any additional clinical trials and Human Factor studies to meet their request. We may choose to enter into the formal dispute resolution process with the FDA. Under FDA guidance, the formal dispute resolution process is a request for review above the FDA division level. There is no guarantee that the dispute resolution process, nor any additional work we perform related to Zalviso, including an additional human clinical trial, would be supportive of, or guarantee, an NDA resubmission, or result in our successfully obtaining FDA approval of Zalviso in a timely fashion, if at all. At any future point in time, the FDA could require us to complete further clinical, Human Factors, pharmaceutical, reprocessing or other studies, which could delay or preclude any approval of the NDA and could require us to obtain significant additional funding. There is no guarantee such funding would be available to us on favorable terms, if at all.

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

We have reported positive top-line data from each of our three Zalviso Phase 3 clinical trials, as well as our Phase 2 clinical trial, which will be considered a pivotal study, for ARX-04 (sufentanil sublingual tablet, 30 mcg). However, even if we believe that the data from clinical trials is positive, the FDA could analyze our data using alternative strategies and determine that the data from our trials was negative or inconclusive. Negative or inconclusive results of a clinical trial could cause the FDA to require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results. Any such determination by the FDA would delay the timing of our commercialization plan for Zalviso, or further development of our other product candidates, and adversely affect our business operations. For example, although we had achieved the primary endpoints in each of our three Phase 3 clinical trials for Zalviso, which were included in our NDA filed in 2013, in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures.

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 pre-commercial trials for Zalviso, and the Phase 2 clinical trial for ARX-04, current and 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. For example, in June 2014, we completed a pharmacokinetic study in support of the ARX-04 development program. In this study of healthy volunteers, it was shown that two sublingual administrations of a Zalviso sufentanil sublingual tablet, 15 mcg, dosed 20 minutes apart were equivalent to one sublingual administration of an ARX-04 sufentanil sublingual tablet, 30 mcg. Based on the results of this study, we have proposed the inclusion of approximately 300 patients from the Zalviso clinical program in the ARX-04 safety database to the FDA and we have designed the two Phase 3 ARX-04 trials accordingly. The ARX-04 safety database required by the FDA is 500 patients. We have confirmation from the FDA that some of the Zalviso patients can be included in the overall ARX-04 safety database; however, further discussion is ongoing to determine the exact number of such patients that can be used towards achieving the 500 patient minimum total safety exposure number required for ARX-04. Based on the outcome of these discussions, we may need to increase enrollment in our planned Phase 3 clinical program to meet the FDA's requested exposure requirements to ARX-04, which could delay completion of the Phase 3 clinical program and increase our clinical trial expenses.

Our clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the device components of our product candidates;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment or being delayed in entering data to allow for clinical trial database closure;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If any future clinical trials are delayed for any of the above reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

We have not yet responded to the Zalviso Complete Response Letter nor resubmitted the Zalviso NDA. Activities that we undertake to address issues raised in the CRL may be deemed insufficient by the FDA.*

We completed bench testing and additional Human Factors studies that we believed addressed certain items contained in the CRL. However, before the results from these studies were submitted as a part of the proposed NDA resubmission, the FDA, in March 2015, notified us of the need for a clinical trial prior to the resubmission of the Zalviso NDA.

In March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. We will be considering all options to determine a pathway forward for Zalviso, including the possibility of dispute resolution through the FDA prescribed pathway, as well as conducting additional clinical and Human Factors studies. As a result of this most recent correspondence, we may require additional funding. Even if we have appropriate resources to conduct an additional clinical trial, there is no guarantee that the trial results would address the issues raised by the FDA. We may be unable to obtain additional funding on favorable terms, if at all. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing Zalviso in the United States, generating revenues and achieving profitability. If any of these events occur, we may be forced to delay or abandon our development and commercialization efforts for Zalviso, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If we are able to resubmit an NDA for Zalviso with new clinical data, there is no guarantee that such data will be deemed sufficient by the FDA. In addition, the FDA may evaluate the HF studies and bench testing we completed in support of our anticipated response to the CRL and may have concerns or issues with those protocols and/or their results. While we designed the protocols for bench testing and the Human Factors studies to address the issues raised in the CRL, there is no guarantee that the FDA will deem such protocols and results sufficient to address those issues when they are formally reviewed as a part of an NDA resubmission.

Lastly, even if we believe that the test results from our bench testing and Human Factors studies are positive, and we are able to conduct and achieve positive results from the additional clinical trial the FDA has requested, the FDA may hold a different opinion and deem the results insufficient. The FDA may provide review commentary at any time during the resubmission and review process which could adversely affect or even prevent the approval of Zalviso, which would adversely affect our business. We may not be able to identify appropriate remediations to issues that the FDA may raise, and we may not have sufficient time nor financial resources to conduct future activities to remediate raised issues.

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

Adverse events, or AEs, caused by our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. In our Phase 3 active comparator clinical trial (IAP309), 7.9% of Zalviso-treated patients dropped out of the trial prematurely due to an AE, and we observed one serious adverse event, or SAE, that was assessed as possibly or probably related to Zalviso. In our Phase 3, double-blind, placebo-controlled, abdominal surgery trial (IAP310), 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 sublingual tablet group, experienced an SAE, which was determined to be unrelated to the trial drug. In our Phase 3, double-blind, placebo-controlled, orthopedic surgery trial (IAP311), treatment-emergent adverse events were generally mild-to-moderate in nature and similar for the majority of adverse events between sufentanil sublingual tablet- and placebo-treated patients. Two patients (one each in the sufentanil sublingual tablet group and placebo group) experienced a serious adverse event considered possibly or probably related to the trial drug by the investigator.

In our Phase 2 ARX-04 trial, two serious adverse events (SAEs), both in the 20 mcg-dose group, occurred one week after the study (surgical infections) and were deemed unrelated to study drug. All but two adverse events reported in the study were mild-to-moderate in nature with 58 patients (58%) reporting a total of 135 adverse events. The most frequently reported adverse events for all patients were nausea (30%), vomiting (17%), dizziness (14%) and somnolence (11%). Two patients discontinued treatment, one unrelated to study drug (anxiety/chest pain) and the other probably related to study drug (somnolence/respiratory depression); however, both patients recovered without medical intervention.

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

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

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

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

Additional time may be required to obtain regulatory approval for Zalviso because it is a drug/device combination.*

Zalviso is a combination product candidate with both drug and device components. Zalviso is viewed as a combination product by the FDA, and both drug and device components were required for review as part of our NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as Zalviso. As a result, we have in the past, and may in the future, experience delays in the development and commercialization of Zalviso due to regulatory uncertainties in the product development and approval process, in particular as it relates to a drug/device combination product approval under an NDA. For example, the Zalviso CRL received from the FDA in July 2014 contains requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of optical system errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. Furthermore, in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. We will be considering all options to determine a pathway forward for Zalviso, including the possibility of dispute resolution through the FDA prescribed pathway, as well as conducting additional clinical and Human Factors studies. We may be unable to come to an agreement with the FDA on the need, design or objectives of the requested clinical trial. Even if we come to an agreement on the design and objectives of the clinical trial and are able to complete the clinical trial, the FDA may deem the results of the clinical trial, as well as bench testing and/or the Human Factors studies inadequate, which could delay or preclude any approval of Zalviso.

We cannot predict when we will obtain regulatory approval to commercialize any of our product candidates, if at all, and we cannot, therefore, predict the timing of any future revenue.*

We cannot commercialize any of our product candidates, including Zalviso, until the appropriate regulatory authorities, such as the FDA or the European Medicines Agency, or EMA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may be unable to obtain regulatory approval for our product candidates. We received a CRL for Zalviso on July 25, 2014, which contains requests for additional information on the Zalviso System. In the CRL, the FDA acknowledged that it had not reviewed several of the amendments to the NDA we submitted to the FDA before the CRL was issued. In addition, in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products, or the Division, of the FDA for a Type B meeting. On May 1, 2015, the Division notified us that the request for a meeting was denied and restated the Division's view that a clinical study is required. Subsequently, we have been granted a General Advice meeting with the Division in early September 2015 to discuss the FDA's request for an additional clinical trial and our planned response to the CRL. Pending the outcome of that meeting, we intend to determine what additional work, if any, is required and finalize our plans to refile the NDA for Zalviso. We will then evaluate next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S. We will be considering all options to determine a pathway forward for Zalviso, including the possibility of dispute resolution through the FDA prescribed pathway, as well as conducting additional clinical and Human Factors studies. Additional delays may result if any of our product candidates 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 FDA and other foreign regulatory agencies, such as 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. In June 2014, the FDA completed an inspection at our corporate offices. We received a single observation on a Form 483 as a result of the inspection. In addition, in January 2015, EMA conducted a pre-approval inspection of our Zalviso contract manufacturer's manufacturing and packaging site, and provided its observations. Although we believe we have adequately addressed these observations in revised standard operating procedures, we, our contract manufacturers, and their vendors, are all subject to preapproval inspections at any time. The results of these inspections could impact our ability to obtain FDA or EMA approval for Zalviso, and, if approved, our ability to launch and successfully commercialize Zalviso.

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 EMA, or their advisors, may disagree with our trial design and our interpretations of data from preclinical studies 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 the Quality Systems Regulation, or QSR, which sets forth the FDA's current good manufacturing practice, or cGMP, requirements for medical devices, and other applicable government regulations and corresponding foreign standards for drug cGMPs. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

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

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 any of the clinical work submitted, including the clinical trials, Human Factors studies and bench testing submitted for a product candidate in support of an NDA were not conducted in full compliance with the applicable protocols for these trials, studies and testing as well as with applicable regulations and standards, or if the FDA does not agree with our interpretation of the results of such trials, studies and testing, the FDA may reject the data and results. The FDA may audit some of our clinical trial sites to determine the integrity of our clinical data. The FDA may audit some of our Human Factors study sites to determine the integrity of our data and may audit the data and results of bench testing. Any rejection of any of our data would negatively impact our ability to obtain marketing authorization for a product candidate and would have a material adverse effect on our business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of such an NDA. Any significant delay in the acceptance, review or approval of an NDA that we have submitted would have a material adverse effect on our business and financial condition and would require us to obtain significant additional funding.

Even if we obtain regulatory approval for Zalviso and our other product candidates in the United States, we and our collaborators 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 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. Additionally, the labeling ultimately approved for Zalviso and our other product candidates, if approved, will likely include restrictions on use due to the opioid nature of sufentanil.

Zalviso and our other product candidates, if approved in the future, 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.

We must also register and obtain various state prescription drug distribution licenses and controlled substance permits, and any delay or failure to obtain or maintain these licenses or permits may limit our market and materially impact our business. 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 cGMPs 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 facilities where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facilities, 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 candidates, 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 any future approved products and generate revenues.

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

In order to market any products outside of the United States, we or our collaborators, including Grünenthal in Europe, must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. For example, in October 2012, we received notice from EMA that Zalviso was eligible for centralized European review, and in July 2014, Grünenthal filed a Marketing Authorization Application, or MAA, for Zalviso under the centralized procedure in the EU. On July 23, 2015, the CHMP of EMA adopted a positive opinion for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients in a hospital setting. The opinion, while not binding, recommends marketing authorization for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. This opinion has been transmitted to the European Commission, which has the ultimate authority for granting marketing authorizations in the EU.

As noted elsewhere, in March 2015, we received correspondence from the FDA stating that a clinical trial is needed for Zalviso in order to assess the risk of inadvertent dispensing and overall risk of dispensing failures. We do not know what impact, if any, this may have on EMA's regulatory review process of the Zalviso MAA. EMA may at any time during its review process find issues with the MAA, and may require additional activities and data, including additional clinical trials, in order to support its review of the Zalviso MAA. 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. Our current clinical trial data may not be sufficient to support marketing approval in all territories. In addition, we lack the personnel, expertise and capabilities to gain regulatory approval of our product candidates on a global basis without a collaboration partner. If Zalviso is approved for sale in Europe, we will rely on Grünenthal to commercialize it. While Grünenthal does have products approved in international markets, we do not have any product candidates approved for sales in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. Grünenthal's experience in international markets does not guarantee regulatory approval or compliance with regulatory requirements in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Zalviso and our other product candidates will require Risk Evaluation and Mitigation Strategies.

The FDA Amendments Act of 2007 implemented safety-related changes to product labeling and requires the adoption of REMS. Our product candidates, if approved, 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 pre-clearance from the FDA regarding certain aspects of the proposed required REMS for Zalviso, we cannot predict the final REMS to be required as part of any FDA approval of Zalviso. Depending on the extent of the REMS requirements, the launch may be delayed, the costs to commercialize Zalviso may increase substantially and the potential commercial market could be restricted. 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 future product candidates, if approved, may also prevent or delay their approval for commercialization.

Existing and future legislation may increase the difficulty and cost for us to commercialize Zalviso and any of our product candidates that may obtain commercial approval in the future, and affect the prices we may obtain.

In the United States and some foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval of our product candidates, including Zalviso, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

In the United States, the Health Care Reform Law (as defined below) was enacted in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, impose new taxes and fees on the health industry and impose additional health policy reforms. Aspects of the Health Care Reform Law that may impact our business include:

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a deductible 2.3% excise tax, with limited exceptions, on the sale of certain medical devices by the manufacturer of the device;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- creation of the Independent Payment Advisory Board which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

The Health Care Reform Law has the potential to substantially change health care financing and delivery by both governmental and private insurers, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Tax Payer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

Moreover, the Drug Supply Chain Security Act of 2013, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product.

Legislative and regulatory proposals have been made to expand post-approval requirements and further restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could negatively impact our business. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception, anticipate that we will continue to incur significant losses in 2015 and may continue to incur losses for the foreseeable future.*

Since our inception in 2005, we have focused primarily on development of our product candidate, Zalviso. In March 2015, we began a pivotal Phase 3 study of ARX-04. We have two additional product candidates that have completed Phase 2 development: the sufentanil sublingual tablet BTP management system, or ARX-02, the sufentanil/triazolam sublingual tablet, or ARX-03, and We have incurred significant net losses in each year since our inception in July 2005, and as of June 30, 2015, we had an accumulated deficit of $197.7 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, debt, government contract funding and proceeds from our collaboration with Grünenthal. 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 continue our research and development activities for our product candidates, including addressing issues raised by the FDA related to regulatory review of Zalviso, as well as to support manufacturing and supply for potential approval of Zalviso in Europe, in connection with our collaboration with Grünenthal. To date, none of our product candidates have been commercialized, and if Zalviso or our other 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. Our success is also dependent on obtaining regulatory approval to market our product candidates outside of the United States through current and future collaborations which may not materialize or prove to be successful.

We have never generated product 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. We may never generate revenues from sales of Zalviso or our other product candidates in the United States. While we have a collaboration with Grünenthal for potential commercialization of Zalviso in Europe and Australia, we may never achieve the development milestones associated with the collaboration, and Grünenthal may never achieve regulatory approval or recognize commercial sales of Zalviso, for which we would receive sales milestone payments and product royalties. In addition, we do not anticipate generating revenues from our other product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- obtaining and maintaining regulatory approval for Zalviso in the United States and/or in Europe;
- launching and commercializing Zalviso, including building internally or through entering a collaboration, a hospital-directed sales force in the United States and with third parties internationally, including Grünenthal, which may require additional funding; and
- completing the clinical development of, obtaining regulatory approval for, and launching and commercializing ARX-04, which may require additional funding or corporate partnership resources.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and the regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are delayed in receiving regulatory approval, or in launching Zalviso, or if we are required by the FDA to complete activities in addition to those we currently anticipate or have already completed.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenues from the sale of any future approved 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 pharmaceutical development and clinical trials for our product candidates, understanding the market potential for our product candidates and preparing for the potential commercialization of Zalviso. We have not yet obtained regulatory approval of any of our product candidates, including Zalviso. Consequently, any predictions that are made about our future success, or viability, or evaluation of our business and prospects, may not be accurate.

We will require 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, including conducting ARX-04 Phase 3 clinical trials, development activities associated with Zalviso to respond to issues raised by the FDA and other research and development activities to advance our product candidates. While we believe we have sufficient capital resources to continue planned operations through at least the first half of 2016, we may need additional capital to continue development and commercialization of Zalviso, ARX-04, and our other product candidates and will need additional capital to potentially pursue commercialization of any of our product candidates.

Future events and circumstances, including those beyond our control, may cause us to consume capital more rapidly than we currently anticipate. For example, in March 2015, we received correspondence from the FDA stating that we needed to complete a clinical trial. This request, and the time needed to meet with the FDA to better understand the request, and any further development activities can be time consuming and costly. Even if we have sufficient resources to complete an additional clinical trial for Zalviso, and we may not depending on the size, scope and potential outcome of the trial, regulatory review for Zalviso, and a potential launch of a commercial product is expensive. In addition, commercialization costs for Zalviso in the United States may be significantly higher than estimated. We may experience technical difficulties in our commercialization efforts or otherwise, which could substantially increase the costs of commercialization. Revenues may be lower than expected and accordingly costs to produce such revenues may exceed those revenues. We will need to seek additional capital to continue operations. Such capital demands could be substantial. To raise capital, we may seek to sell additional equity or debt securities, monetize certain assets including future royalty streams and milestones, 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. Such arrangements may not be available on favorable terms, if at all. Furthermore, any product development, licensing, distribution or sale agreements that we enter into may require us to relinquish valuable rights. We may not be able to obtain sufficient additional funding or enter into a strategic transaction in a timely manner. If adequate funds are not available, we would be required to reduce our workforce, delay, reduce the scope of, or eliminate, one or more of our research and development programs in advance of the date on which we exhaust our cash resources to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value.

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

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek additional corporate partners for Zalviso on terms that might be less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

In order to raise additional funds to support our operations, we may sell additional equity or debt securities which would result in dilution to 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, such as minimum cash balances, 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 December 2013, we entered into an amended loan and security agreement, or the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology Growth Capital, Inc., collectively referred to as Hercules, under which we may borrow up to $40.0 million in three tranches, represented by secured convertible promissory notes. We drew the first tranche of $15.0 million at the closing of the new credit facility and the second tranche of $10.0 million on June 16, 2014. We will not have access to the third tranche of up to $15.0 million under the current agreement, as it was conditioned upon FDA approval to market Zalviso in the United States by August 1, 2015, which we did not obtain. We began making principal payments in April 2015. The scheduled maturity date is October 1, 2017.

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 it is licensed or sold.

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

We may not receive all of the funding from the Department of Defense for the advancement of ARX-04.*

On May 11, 2015, we entered into an award contract supported by the United States Army Medical Research and Materiel Command, or USAMRMC, within the U.S. Department of Defense, or the DoD, in which the DoD agreed to provide up to $17.0 million to support the development of ARX-04. The DoD contract will support development of ARX-04 to perform Phase 3 clinical trials and manufacturing activities in order to submit an NDA to the FDA. Under the terms of the contract, the DoD will reimburse us for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. The period of performance under the contract begins on May 11, 2015 and ends on November 10, 2016. The contract gives the DoD the option to extend the term of the contract and provide additional funding for the research. Funding under this contract will be subject to audit by the DoD to ensure adherence to specific guidance, policies and procedures. The DoD may find deficiencies during the course of an audit which could jeopardize, or even eliminate, continued funding from the DoD, as well as require repayment of any funds they had provided us since inception of the contract. The lack of ARX-04 supportive funding, may adversely affect our ability to continue to advance the development of ARX-04.

Risks Related to Our Reliance on Third Parties

We rely on third party manufacturers to produce our preclinical and clinical drug supplies and 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 stock outs, inability to successfully commercialize our products, clinical trial delays, or failure to obtain regulatory approval. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

As mentioned above, we have entered into the Amended Agreements with Grünenthal under which we are obligated to manufacture and supply Zalviso for use in the EU and their other licensed territories. If we are unable to establish a reliable commercial supply of Zalviso, if approved in Grünenthal's licensed territories, we may be unable to satisfy our obligations under the Amended Agreements in a timely manner or at all, and we may, as a result, be in breach of this agreement.

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 tablets. We only have one supplier qualified for our manufacture of Zalviso. 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.

Manufacture of sufentanil sublingual tablets requires specialized equipment and expertise.

Ethanol, which is used in the manufacturing process for our sufentanil sublingual tablets, 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 sublingual tablets. 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 sublingual tablets and have not identified a back-up commercial facility to date. Any problems with our existing facility or equipment, including ongoing expansion, may delay or impair our ability to complete our clinical trials or commercialize our product candidates and increase our cost.

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

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

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

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

If Patheon cannot provide us with an adequate supply of sufentanil sublingual tablets, we may be required to pursue alternative sources of manufacturing capacity. Switching or adding commercial manufacturing capability can involve substantial cost and require extensive management time and focus, as well as additional regulatory filings. In addition, there is a natural transition period when a new manufacturing facility commences work. As a result, delays may occur, which can materially impact our ability to meet our desired commercial timelines, thereby increasing our costs and reducing our ability to generate revenue.

The facilities of any of our future manufacturers of sufentanil-containing sublingual tablets must be approved by the FDA or the relevant foreign regulatory agency, such as EMA, before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process of sufentanil sublingual tablets and are completely dependent on these third party manufacturing partners for compliance with the FDA or other foreign regulatory agency'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 or other foreign regulatory agency's strict regulatory requirements, they will not be able to secure FDA or other foreign regulatory agency approval for their manufacturing facilities. If the FDA or the relevant foreign regulatory agency does not approve these facilities for the commercial manufacture of sufentanil sublingual tablets, we will need to find alternative suppliers, which would result in significant delays in obtaining FDA or other foreign regulatory agency approval for Zalviso. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

Related to the Zalviso device, we have conducted multiple Design Validation, Software Verification and Validation, Reprocessing and Human Factors studies, and have manufactured for and completed Phase 3 clinical trials using the intended commercial device. As mentioned above, the CRL from the FDA contains a request for additional information on the Zalviso System to ensure proper use of the device. In March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the CRL, a clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. We have made modifications to the design of the Zalviso device subsequent to the original submission of the Zalviso NDA, which we plan to include as a part of any resubmitted NDA. If we are required to further modify the Zalviso device, we may incur higher costs and experience delays in the approval and ultimate commercialization of Zalviso. Furthermore, if the identified changes to the device are substantial, the FDA may require us to perform further clinical trials or studies in order to approve the device for commercial use.

We have manufactured Zalviso devices and supplies on a small scale, including those needed for our Phase 3 clinical trials, and process validation for some of the device components has been completed. We, however, have not yet manufactured Zalviso devices and supplies on a large scale, for commercial purposes. We will not begin commercial scale production of the device until after approval by EMA or FDA. We will continue to rely on contract manufacturers, component fabricators and third party service providers to produce the necessary Zalviso devices for the commercial marketplace. We currently outsource manufacturing and packaging of the controller, dispenser and cartridge components of the Zalviso device to third parties and intend to continue to do so. These purchases and components were made and will continue to be made utilizing short-term purchase agreements and we may not be able to enter into long-term agreements for commercial supply of Zalviso devices with third party manufacturers, or may be unable to do so on acceptable terms. In addition, we may encounter production issues with our current or future contract manufacturers and other third party service providers, including the quality of the components produced, their inability to meet demand or other unanticipated delays including the scale-up and automation process, which would adversely impact our ability to supply our customers with Zalviso, if approved.

We may not be able to establish additional sources of supply for sufentanil-containing sublingual tablets or device manufacture. Such suppliers are subject to FDA and other foreign regulatory agency's regulations requiring that materials be produced under cGMPs or Quality System Regulations, or QSR, or in ISO 13485 accredited manufacturers, 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. In addition, if we are unable to establish a reliable commercial supply of Zalviso, if approved in Grünenthal's licensed territories, we may be unable to satisfy our obligations under the Amended Agreements in a timely manner or at all, and we may, as a result, be in breach of this agreement.

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

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

We utilized contract research organizations, or CROs, for the conduct of our Phase 3 clinical trials of Zalviso, the Phase 2 clinical trial of ARX-04, and our ongoing Phase 3 clinical program for ARX-04. We rely on CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our clinical programs for Zalviso, ARX-04 and our other product candidates, as well as the execution of nonclinical and clinical 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 clinical trials do not comply with cGCPs. Accordingly, if our CROs or clinical trial sites fail to comply with these regulations, we may be required to repeat clinical trials, which would delay the regulatory 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 Zalviso, or our other product candidates. As a result, our financial results and the commercial prospects for Zalviso and any future product candidates for which we may obtain approval would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of Zalviso and our other product candidates, if approved, 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 Zalviso and our other product candidates, if approved, 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 use of Zalviso for the management of moderate-to-severe acute pain in the hospital setting for patient types that were not specifically studied in our Phase 3 trials;
- the prevalence and severity of any AEs or SAEs;
- overcoming the perception of sufentanil as a potentially unsafe drug due to its high potency;
- limitations or warnings contained in the FDA-approved label for Zalviso;
- restrictions or limitations placed on Zalviso due to the REMS;
- 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.

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

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.*

In order to commercialize any products that may be approved, including Zalviso, we must build our internal sales, marketing, distribution, managerial and other capabilities or make arrangements with third parties to perform these services. In addition, we plan to enter into agreements with third parties for the distribution of approved product candidates, including Zalviso; however, if there are delays in establishing such relationships or those third parties do not perform as expected, our ability to effectively distribute products would suffer.

As a result of delays in the resubmission of the Zalviso NDA and obtaining FDA approval, our Board of Directors implemented a cost reduction plan that reduced our workforce by 19 employees, approximately 36% of total headcount, in the first quarter of 2015. As a result, the build out of our commercial capabilities, including internal sales, marketing, supply chain and medical affairs departments is currently on hold. This delay in recruiting and hiring the appropriate individuals could adversely affect the potential success of any future approved product candidates, including Zalviso.

We have entered into a collaboration with Grünenthal for the commercialization of Zalviso in Europe and Australia and intend to enter into additional strategic partnerships with third parties to commercialize our product candidates outside of the United States. We may also consider the option to enter into strategic partnerships for our product candidates in the United States. 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 future 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 current or future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of Zalviso or our other product candidates, if approved, 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 Zalviso or our product candidates, if approved, 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, if approved, 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.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our product candidates, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish and maintain successful collaborative relationships to obtain international sales, marketing and distribution capabilities for our product candidates. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully and timely transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

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

If any of our product candidates, including Zalviso, are approved for commercialization, we intend to enter into agreements with third parties to market our product candidates outside the United States, which may require us to supply products to the third party such as our existing collaboration with Grünenthal for marketing Zalviso in European countries and Australia. We may 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 current and potential partners, are unable to compete effectively, our product candidates may not reach their commercial potential.*

The market for Zalviso and our other product candidates is characterized by intense competition and cost pressure. If our product candidates obtain FDA approval, they will compete with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We or our current and potential partners will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies.

We believe that Zalviso would compete with a number of opioid-based and non-opioid based treatment options that are currently available, as well as some products that are in development. The hospital market for opioids for moderate-to-severe acute pain is large and competitive. The primary competition for Zalviso is the IV PCA pump, which is widely used in the moderate-to-severe acute pain in the hospital setting. Leading manufacturers of IV PCA pumps include Hospira Inc. (acquired by Pfizer), CareFusion Corporation (purchased by Becton Dickinson & Co.), Baxter International Inc., Curlin Medical, Inc. and Smiths Medical. The most common opioids used to treat moderate-to-severe acute pain are morphine, hydromorphone and fentanyl, all of which are available as generics both from generic product manufacturers as well as from compounding pharmacies. In addition, branded manufacturers (e.g., Hospira, Inc.) sell pre-filled glass syringes of morphine to fit their IV PCA pump systems.

Also available on the market is the Avancen Medication on Demand, or MOD, Oral PCA Device developed by Avancen MOD Corporation. Oral opioids and other agents can be used in this system. In addition, oral and parenteral opioids administered by the nurse are used to manage moderate-to-severe acute pain in the hospital, available both as branded and generic products. These oral opioids, as well as IV PCA opioids, are often used as part of a multi-modal analgesia approach, which might include, in addition to the opioid, NSAIDs, acetaminophen, gabapentanoids and other pain management modalities, as well as local anesthetic blocks to provide temporary blockage of the pain signal, either as a wound infiltration agent or as a nerve block. These local anesthetic agents such as bupivacaine can also utilize controlled-release formulations such as Pacira's Exparel. In addition, Halyard Health, Inc. has developed a medical device, the ON-Q* Pain Relief System, which is a non-narcotic elastomeric pump that automatically and continuously delivers a regulated flow of local anesthetic to a patient's surgical site or in close proximity to nerves, providing targeted pain relief for up to five days. Additional potential competitors for Zalviso include the fentanyl iontophoretic transdermal system, Ionsys, originally developed by Alza Corporation and Ortho-McNeil Pharmaceutical, Inc., both Johnson & Johnson subsidiaries, and most recently by The Medicines Company. On April 30, 2015, IONSYS was approved for marketing in the U.S. by the FDA. The Medicines Company expects Ionsys to be available in the U.S. in the third quarter of 2015, providing a potential first-to-market advantage for Ionsys. Cara Therapeutics is developing a kappa opioid agonist, CR845, as an IV agent for the management of post-operative moderate-to-severe pain. Trevena is developing TRV130, an intravenous G protein biased ligand that targets the mu opioid receptor for the treatment of moderate-to-severe acute pain where intravenous therapy is preferred, with a clinical development focus in acute postoperative pain. In January 2015, Trevena initiated a Phase 2b clinical study of TRV130. Recro Pharma is developing an intranasal form of dexmedetomidine as a potential agent for the management of post-operative pain. Finally, Innocoll is developing Xaracoll a controlled-release resorbable implant containing bupivacaine, and Durect has been developing Posidur, a controlled-release bupivacaine product candidate utilizing Durect's Saber technology.

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 Depomed, Inc.; Subsys, currently manufactured by Insys Therapeutics, Inc., as well as products approved in Europe, including Instanyl, currently manufactured by Takeda Pharmaceuticals International GmbH. The active ingredient in all approved products for cancer breakthrough pain is fentanyl. Additional potential competitors for ARX-02 include products in late stage development for cancer breakthrough pain, such as: Fentanyl Taifun, currently manufactured by Akela Pharma, Inc.

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

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. More specifically, competitors for ARX-04 in the emergency department are likely to include generic injectable intravenous opioids such as morphine, hydromorphone and fentanyl. In this environment, ARX-04 may also compete with other branded non-invasive products such as Eagalet's Sprix, Hospira's Dyloject, Pfizer's Oxecta, Depomed's Nucynta, BMS's Combunox, Purdue's Oxyfast, Endo's Opana, or generic oral opioids which have moderate-to-severe acute pain labeling. In the short-stay or ambulatory surgery segment, ARX-04 will likely compete with these products in addition to generic injectable local anesthetics such as bupivacaine, or branded formulations thereof, including Pacira's Exparel. Within the military environment, and in certain civilian settings, ARX-04 competitors may also include intramuscular morphine injections which are marketed by a variety of generic manufacturers.

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 moderate-to-severe acute pain (Zalviso and ARX-04) or breakthrough pain (ARX-02) could render our products non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

Hospital formulary approval may not be available, or could be subject to certain restrictions for Zalviso and our other product candidates, which could make it difficult for us to sell our products profitably.

Obtaining formulary approval can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell our products into our target markets. Failure to obtain timely formulary approval will limit our commercial success. If we are successful in obtaining formulary approval, we may need to complete evaluation programs whereby Zalviso is used on a limited basis for certain patient types. Hospitals may seek to obtain Zalviso devices at little or no cost during this evaluation period. Revenue generated from these hospitals during the evaluation period would be minimal. The evaluation period may last several months and there can be no assurance that use during the evaluation period will lead to formulary approval of Zalviso. Further, even successful formulary approval may be subject to certain restrictions based on patient type or hospital protocol. Failure to obtain timely formulary approval for Zalviso would materially adversely affect our ability to attain or sustain profitable operations.

Coverage and adequate reimbursement may not be available for Zalviso and our other product candidates, if approved, which could make it difficult for us, or our partners, to sell our products profitably.

Our ability to commercialize Zalviso or any of our other drug candidates, if approved, successfully will depend, in part, on the extent to which coverage and adequate reimbursement will be available from government payor programs at the federal and state levels authorities, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payors.

No uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from third party payors could significantly harm our operating results, our ability to raise capital needed to commercialize any future approved drugs and our overall financial condition.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell our products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for Zalviso or any of our other product candidates, if approved. 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 the sale of Zalviso and any of our other product candidates, if approved, 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.

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

Additionally, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in Zalviso and/or our other drug candidates, even if those drug candidates obtain marketing approval.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our product candidates, including Zalviso, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, including Zalviso, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Guidelines and recommendations published by government agencies can reduce the use of our product candidates, including Zalviso, if approved.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include the product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include the product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates, or negatively impact our ability to gain market acceptance and market share.

If we are unable to establish relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.

Many end-users of pharmaceutical products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We expect to derive revenue from end-user customers that are members of GPOs, if Zalviso is approved by the FDA. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to establish or maintain our GPO relationships, sales of our products and revenue could be negatively impacted.

We intend to rely on a limited number of pharmaceutical wholesalers to distribute our product candidates, including Zalviso, if approved.

We intend to rely upon pharmaceutical wholesalers in connection with the distribution of our product candidates, including Zalviso, if approved. If we are unable to establish or maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

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 a high 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 and also by comparable state agencies. 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. 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 in the future, including Zalviso. 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 of any of our product candidates or the commercial sale of any approved products. This, in turn, could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our relationships with investigators, health care professionals, consultants, commercial partners, third-party payors, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to penalties.*

Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any products for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, commercial partners, hospitals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute the products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws, include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties, including civil whistleblower or qui tam actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Health Care Reform Law), and its implementing regulations, requires certain manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state laws that may apply to our business practices, including but not limited to, state laws that require pharmaceutical companies to implement compliance programs and/or comply with the pharmaceutical industry's voluntary compliance guidelines; state laws that impose restrictions on pharmaceutical companies' marketing practices and require manufacturers to track and file reports relating to pricing and marketing information, which requires tracking and reporting gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities.

- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these or any other healthcare regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of our operations any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business.

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, or delays in the regulatory approval process, 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. On November 5, 2014, we announced that the Board of Directors has initiated a search to replace Richard King, our President and Chief Executive Officer. On March 31, 2015, Mr. King's employment with AcelRx terminated. On March 19, 2015, the Board of Directors of AcelRx appointed Howard B. Rosen, a member of AcelRx's Board of Directors, as interim Chief Executive Officer effective April 1, 2015. While Mr. Rosen has agreed to serve as our Chief Executive Officer and principal executive officer on an interim basis, there can be no assurance that a permanent replacement will be found on a timely basis, or at all. Our inability to find a suitable permanent replacement may have a detrimental impact on the organization and impede the progress of our research, development and commercialization objectives, as well as our ability to raise additional capital as needed.

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

As of June 30, 2015, we had 33 full-time employees. On March 19, 2015, our Board of Directors, in connection with our efforts to reduce operating costs, conserve capital, focus the Company's financial and development resources on working with the FDA to seek marketing approval for Zalviso, and continuing development of ARX-04, implemented a cost reduction plan. The cost reduction plan reduced our workforce by 19 employees, approximately 36% of total headcount, in the first quarter of 2015. As our product candidates mature and approach potential commercialization, we plan to expand our employee base to increase our managerial, sales, marketing, operational, quality, engineering, financial and other resources and to hire more consultants and contractors. Future growth will impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize Zalviso and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 June 30, 2015, we are the owner of record of 42 issued patents worldwide. These issued patents cover AcelRx's sufentanil sublingual tablet, medication delivery devices and platform technology. These issued patents are expected to provide coverage through 2027 – 2030.

In addition, we are pursuing a number of U.S. non-provisional patent applications and foreign national applications directed to our product candidates. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents.

Our commercial success will depend in part on successfully defending our current patents against third party challenges and expanding our existing patent portfolio to provide additional layers of patent protection, as well as extending patent protection. 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 additional issued patents.

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

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

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 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 patent 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 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 the mark ACCELERATE. INNOVATE. ALLEVIATE. in the United States. We have additionally applied for registration of our ZALVISO mark in the United States on an intent-to-use basis and that application has been allowed. In early 2014, the FDA accepted the ZALVISO mark as part of the NDA review process. 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.*

Since our initial public offering, or IPO, in February 2011, the trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. For example, our stock price declined by more than 40% on July 28, 2014, the first trading day following the announcement of the receipt of the CRL from the FDA. In addition, our stock price dropped by 37% on March 9, 2015, the day we announced the correspondence we received from the FDA requesting a clinical trial to assess the risk of inadvertent dispensing and overall risk of dispensing failures for Zalviso. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in resubmitting the NDA for Zalviso, submitting an NDA for any of our other product candidates and any adverse development or perceived adverse development with respect to the FDA's review of any NDA;
- any adverse development or perceived adverse development with respect to the FDA's regulatory review of Zalviso;
- adverse results or delays in current or future clinical trials, including the Phase 3 clinical development program for ARX-04;
- inability to obtain additional funding, including funding necessary for the planned potential commercialization and manufacturing of Zalviso in the United States and advancement of clinical trials for other product candidates;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

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

Historically, we have not had a high 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 six months ended June 30, 2015 and 2014 was approximately 640,000 and 600,000 shares per day, respectively. A more active market for our stock has only recently developed and may not be sustained. Our stockholders may be unable to sell their common stock at or near their asking prices, which may result in substantial losses to our investors.

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

on its share price.

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

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

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

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or Dodd-Frank Act, as well as the information and reporting requirements of the Exchange Act and other federal securities laws, and rules subsequently implemented by the SEC and NASDAQ, have imposed various requirements on public companies. The costs of compliance with the Sarbanes-Oxley Act and of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC, the Dodd-Frank Act, and regulations promulgated under these statutes, are significant. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

We have been and will continue to be involved in a substantial effort to implement appropriate processes, document the system of internal control over key processes, assess their design, remediate any deficiencies identified and test their operation. 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. All of our shares of common stock outstanding are 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. We registered for resale 3,070,000 shares of our common stock held by certain selling stockholders on a shelf registration statement that became effective on June 12, 2014. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

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

Pursuant to 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.

Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.*

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In addition, the market price of our common stock may vary significantly based on AcelRx specific events, such as receipt of a CRL, negative clinical results, or other negative feedback from the FDA or other regulatory agencies. In the past, securities-related 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 biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs and the FDA's review of their NDAs.

On October 1, 2014, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against AcelRx and certain of our current and former officers. On April 17, 2015, lead plaintiff filed an amended complaint. The amended complaint alleges that between September 30, 2013 and July 25, 2014, AcelRx and certain of our current and former officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 in connection with statements related to our lead drug candidate, Zalviso. The amended complaint seeks unspecified damages, interest, attorneys' fees, and other costs. In response, the Company filed a Motion to Dismiss on June 1, 2015. Plaintiffs' opposition was filed July 30, 2015 and a hearing date on the Motion to Dismiss has been scheduled for October 22, 2015. This lawsuit and any future related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. Securities-related class action litigation often is expensive and diverts management's attention and our financial resources, which could adversely affect our business. Further, any negative outcome from such lawsuit could result in payments of monetary damages, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in this case or any subsequent related case. Defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The completion of the July 2013 public equity offering, together with our public equity offering in December 2012, our initial public offering, private placements and other transactions that have occurred, have triggered 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 Amended Loan Agreement with Hercules. Regardless of the restrictions in our Amended Loan 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;
- 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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

		Incorporation By Reference			
Exhibit Number	**Exhibit Description**	**Form**	**SEC File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.	8-K	001-35068	3.1	2/28/2011
3.2	Amended and Restated Bylaws of the Registrant, currently in effect.	S-1	333-170594	3.4	1/7/2011
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Specimen Common Stock Certificate of the Registrant.	S-1	333-170594	4.2	1/31/2011

4.3	Second Amended and Restated Investors' Rights Agreement, among the Registrant and certain of its security holders, dated as of November 23, 2009.	S-1	333-170594	4.3	11/12/2010
4.4	Warrant to Purchase Common Stock of the Registrant, issued to Hercules Technology II, L.P., dated as of December 16, 2013.	10-K	001-35068	4.4	3/17/2014
4.5	Warrant to Purchase Common Stock of the Registrant, issued to Hercules Technology Growth Capital, Inc. dated as of December 16, 2013.	10-K	001-35068	4.5	3/17/2014
4.6	Form of Warrant issued to certain purchasers pursuant to the Securities Purchase Agreement dated May 29, 2012, between the Registrant and the purchasers identified therein.	8-K	001-35068	4.8	5/30/2012
10.1+	Offer letter, effective as of April 1, 2015, by and among the Registrant and Howard B. Rosen.	8-K	001-35068	10.1	4/3/2015
10.2#	Award/Contract with the U.S. Army Medical Research and Material Command, dated May 11, 2015.				
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 Linkbase 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.

* 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.

SIGNATURES

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

Date: August 3, 2015

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Timothy E. Morris

Timothy E. Morris
Chief Financial Officer and Head of Business Development
(Duly Authorized and Principal Financial and Accounting Officer)

EXHIBIT INDEX

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Exhibit 10.2

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 78
2. CONTRACT (Proc. Inst. Ident.) NO. W81XWH-15-C-0046	3. EFFECTIVE DATE 11 May 2015	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0010622456-0001	

5. ISSUED BY	CODE W81XWH	6. ADMINISTERED BY (If other than Item 5)	CODE
USAMED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014		See Item 5	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY [ ] FOB ORIGIN [X] OTHER (See below)
ACELRX PHARMACEUTICALS, INC. 351 GALVESTON DR REDWOOD CITY CA 94063-0000	9. DISCOUNT FOR PROMPT PAYMENT
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: — ITEM: Section G
CODE 5ZVQ4 — FACILITY CODE	

11. SHIP TO/MARK FOR	CODE W806YH	12. PAYMENT WILL BE MADE BY	CODE HQ0490
FORT DETRICK-USAMMDA FORT DETRICK-USAMMDA 1430 FORT DETRICK FREDERICK MD 21702		DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [X] 10 U.S.C. 2304(c)(1) [ ] 41 U.S.C. 253(c)( )	14. ACCOUNTING AND APPROPRIATION DATA See Schedule

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				
				15G. TOTAL AMOUNT OF CONTRACT	$17,012,744.49

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				**PART II - CONTRACT CLAUSES**	
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X	C	DESCRIPTION/ SPECS./ WORK STATEMENT	6 - 19	X	J	LIST OF ATTACHMENTS	78
	D	PACKAGING AND MARKING				**PART IV - REPRESENTATIONS AND INSTRUCTIONS**	
X	E	INSPECTION AND ACCEPTANCE	20		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	21 - 28				
X	G	CONTRACT ADMINISTRATION DATA	29 - 32		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	33 - 34		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)	18. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
/s/ Timothy E. Morris CFO	BARRY G. SAYER / CONTRACTING OFFICER TEL: (301) 619-2375 EMAIL: barry.g.sayer.civ@mail.mil

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ (Signature of person authorized to sign)	5-8-15	BY _____ (Signature of Contracting Officer)	11-May-2015

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STANDARD FORM 26 (REV. 5/2011)
Prescribed by GSA – FAR (48 CFR) 53.214(a)

Section A - Solicitation/Contract Form

ADDITIONAL INFORMATION
The Contractor's final proposal dated 13 February 2015 is herein incorporated by reference.
The Contractor's final proposal (for [*] option) dated 16 April 2015 is herein incorporated by reference.

Government Property:
No Government-furnished property will be used in the performance of this contract.
No Contractor-acquired, Government-owned property will be purchased for this contract.
All equipment used in the performance of this contract (except where subcontractors are utilized) will be purchased by AcelRx using their own funds.

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

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Job		$17,012,744.49
	Sufentanil NanoTab™ Development COST Continued development of the Sufentanil NanoTab™. FOB: Destination				
				ESTIMATED COST	$17,012,744.49

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00
	CLIN 0001 Funding FFP Funding for CLIN 0001 on PR 0010622458-0001. Amount: $993,000.00. Total funded: $993,000.00. Remainder to be funded: $16,019,744.49. FOB: Destination PURCHASE REQUEST NUMBER: 0010622458-0001				
				NET AMT	$0.00
	ACRN AA CIN: GFEBS001062245800003				$993,000.00

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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$0.00
	CLIN 0001 Funding FFP Funding for CLIN 0001 on PR 0010622458-0001. Amount: $6,500,000.00. Total funded: $7,493,000.00. Remainder to be funded: $9,519,744.49. FOB: Destination PURCHASE REQUEST NUMBER: 0010622458-0001				
				NET AMT	$0.00
	ACRN AB CIN: GFEBS001062245800004				$6,500,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103					$0.00
	CLIN 0001 Funding FFP Funding for CLIN 0001 on PR 0010622458-0001. Amount: $3,490,000.00. Total funded: $10,983,000.00. Remainder to be funded: $6,029,744.49. FOB: Destination PURCHASE REQUEST NUMBER: 0010622458-0001				
				NET AMT	$0.00
	ACRN AC CIN: GFEBS001062245800005				$3,490,000.00

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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		[*]	Unit	$[*]	$2,240,000.00
OPTION	Sufentanil NanoTab™ [*] FFP [*] initial production [*] of [*] sufentanil units. $[*] per dose/unit. 10 doses/units per box. Delivery shall be completed no later than nine months after exercising this option. Option will be exercised in accordance with FAR 52.217-7. FOB: Destination				
				NET AMT	$2,240,000.00

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

STATEMENT OF OBJECTIVES (SOO)

Statement of Objectives (SOO)
United States Army Medical Materiel Development Activity (USAMMDA)

Development, Manufacture, and Clinical Testing of a Sublingual Sufentanil Battlefield Pain Management Product in Order to Obtain US Food and Drug Administration (FDA) Approval

C.1.0. OVERALL OBJECTIVE

C.1.1. General

In support of a continuing effort by the US Army Medical Materiel Development Activity (USAMMDA) to develop a fast-acting, easily dispensed sufentanil-based sublingual battlefield pain management product, the Government is seeking to perform Phase 3 clinical trials and Phase 3 manufacturing activities in order to submit a New Drug Application (NDA) to the FDA.

C.1.2. Background

The Battlefield Pain Management Development Program is focused on developing improved treatment strategies that enable significant advances over the current standard of care in the treatment of pain experienced by Service men and women on the battlefield. The current standard treatment is intramuscular (IM) morphine via a morphine sulfate auto injector. Morphine, while fast acting, has multiple negative side effects associated with use on wounded soldiers who may be experiencing shock due to trauma. Due to morphine's opioid nature and the depressive effect it has on the respiratory and cardiovascular systems, it has the potential to exacerbate conditions of hypotension. In addition, the delivery method required for the use of morphine, i.e., the intramuscular auto injector, presents the potential for the pooling of morphine in poorly perfused muscles, minimizing the drug's analgesic effect until such time as the circulation of blood throughout the body is improved. The delay in analgesia may lead to multiple dosing of the patient, ultimately having the effect of a single massive dose of morphine upon bleeding correction and circulatory improvement.

USAMMDA has identified a sublingual, sufentanil-based (opioid) pain management that provides rapid onset of analgesia. Sufentanil NanoTabs™, under development by AcelRX Pharmaceuticals, are small, sublingual tablets dispensed from a disposable applicator for the treatment of moderate to severe acute pain in a medically supervised setting and administered by a Health Care Professional. Sufentanil has advantages over other opioids, such as high therapeutic index, no active metabolites, and appropriate duration of action. USAMMDA is seeking to continue efforts started under Grant W81XWH-11-1-0361 in accordance with established production methods and all applicable regulatory guidelines.

C.2.0. PERFORMANCE OBJECTIVES

The US Army's goal is to obtain a FDA licensed product that can be procured in the Contiguous United States (CONUS) and deployed to theaters of operation at Role of Care (ROC) 1 (i.e., combat medics at point of injury). In order to achieve this, the US Army has developed the following draft performance thresholds (minimum acceptable value) and objectives (desired value). The draft product performance requirements are shown in Table 1 below. All manufacturing and development efforts shall be executed in pursuit of achieving these performance characteristics.

Table 1.

Attribute	Production Threshold (T)*	Production Objective (O)**
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

*Threshold is the required minimum acceptable value.
**Objective is the desired performance value.

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

C.3.0. TECHNICAL TASKS

C.3.1. In compliance with current FDA regulations and guidelines, the Contractor shall undertake efforts to develop, manufacture, and clinically test a sufentanil-based sublingual tablet for the purposes of achieving FDA approval. The Contractor shall develop a product that, at minimum, meets the production threshold values delineated in Table 1 above. The contractor's facility (or that of its contract manufacturer) and quality management system shall be compliant with the applicable FDA regulations and guidelines. Keeping with the goal of achieving a cGMP, FDA licensed product, associated tasks shall include, **but are not limited to**, the following:

C.3.1.1 The Contractor shall complete all chemistry, manufacturing, and control (CMC) work necessary to produce a sufentanil-based sublingual tablet and provide CMC information suitable for supporting an eventual NDA application for FDA licensure. The Contractor shall manufacture the candidate product in sufficient quantity to support clinical trials and any necessary Registration Stability Lots (RSLs).

C.3.1.2 The Contractor shall complete human factors and usability studies in order to validate the planned design of the product delivery device relative to real-world and likely battlefield conditions. Additionally, the Contractor shall conduct shipping and temperature studies for the purpose of logistics support validation studies.

C.3.1.3 In compliance with GCP guidelines, human use regulations, and applicable sections of 21 CFR parts 11, 21, 50, 600, 601, 610, 640, and 820, the Contractor shall complete necessary Good Clinical Practices (GCP) compliant Phase 3 clinical trials. The Contractor shall select the clinical sites and ensure both Institutional Review Boards (IRB) and US Army Human Research Protection Office (HRPO) approvals are achieved. The contractor shall furnish all services, qualified personnel, facilities, equipment, and supplies and materials. The contractor shall complete all elements of testing, analysis, and reporting necessary for FDA compliance. The Contractor shall provide all necessary clinical trial support.

C.3.1.4 In compliance with Good Laboratory Practices and GCP guidelines, human use regulations, and applicable sections of 21 CFR parts 11, 21, 50, 600, 601, 610, 640, and 820, the Contractor shall complete necessary pharmacokinetic studies in order to leverage pre-existing safety data for use towards the moderate-to-severe acute pain (ARX-04) indication. The Contractor shall select the clinical site and ensure both IRB and US Army HRPO approvals are achieved. The contractor shall furnish all services, qualified personnel, facilities, equipment, and supplies and materials. The contractor shall complete all elements of testing, analysis, and reporting necessary for FDA compliance. The Contractor shall provide all necessary clinical trial support.

C.3.1.5 The contractor shall maintain the ARX-04 Investigational New Drug (IND) application with the FDA, to include submitting IND annual reports. The Contractor shall prepare a New Drug Application (NDA) for submission to the FDA.

C.3.1.6 The contractor shall submit the NDA to the Food and Drug Administration for product approval.

C.3.1.7 Option: The contractor shall provide up to [*] units of FDA approved product to meet Initial Operational Capability and deliver it to the Government. The Contracting Officer may exercise the option by written notice to the contractor within 60 calendar days of achievement of FDA approval of the product. Delivery shall be completed no later than nine months after exercising this option.

C.4.0. PROGRAM MANAGEMENT TASKS

C.4.1. The Government will utilize a Quality Assurance Surveillance Plan (QASP) that serves to monitor performance and to assure that the Government is receiving the services specified in the contract and that the services meet the performance standards specified in the contract. By employing a fully developed QASP, the Government and the contractor achieve an understanding of performance expectations and how performance will be measured against those expectations. The QASP may be negotiated between the Government and the contractor prior to final contract award.

C.4.2. The contractor shall develop and maintain an Integrated Master Schedule (IMS) and Contract Work Breakdown Structure (CWBS) by logically networking detailed program activities. The IMS shall contain the planned events and milestones, accomplishments and activities from contract award through the completion of contract. The IMS shall be updated every six (6) months to show task progress, percent completion, and schedule slippage. Prior Government approval is required for any major changes. The CWBS elements shall be extended to define the complete contract scope and shall be detailed to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of Level 4. The CWBS shall be updated annually.

C.4.3. The Contractor shall provide qualified representatives as needed for participation in Integrated Product Team (IPT) meetings for management and oversight of the product development effort. IPT meetings will be conducted telephonically at least monthly. Ad hoc meetings of the IPT or IPT working groups will be required on an intermittent basis, with frequency and times to be determined by the Government product manager and the Contractor's lead IPT representative as dictated by project management needs.

C.4.4. The Contractor shall provide monthly Contractor's Progress, Status, and Management Reports that describe the progress made within the period, summarize projected versus actual progress, reports costs incurred, reports planned monthly costs (spend plan), and informs the Government of existing or potential problem areas. Include copies of the invoices submitted during the reporting period.

C.4.5. The following items shall be submitted as separate documents as part of the Contractor's proposal:
C.4.5.1. Performance Work Statement (PWS)
C.4.5.2. Integrated Master Schedule (IMS)
C.4.5.3. Contract Work Breakdown Structure (CWBS)

C.4.6. The following list of contract data items will be incorporated into the contract in Contract Data Requirements List (CDRL) (DD1423) format:
C.4.6.1. Monthly progress reports
C.4.6.2. Semi-annual IMS update
C.4.6.3. Annual CWBS update

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C.5.0. ADMINISTRATIVE TASKS

The Contractor shall:

C.5.1. Provide all resources necessary (such as qualified personnel, facilities, equipment, supplies, services, and subcontractors, and related administrative and information technology support) to accomplish the objectives.

C.5.2. Allow the Government or its designee, to audit the contractor and/or its subcontractor(s) for regulatory compliance and quality assurance purposes.

C.5.3. Allow access to records, files, and other data derived from this work for the purposes of audit by the FDA and/or other Government entities.

C.5.4. Provide copies of draft and/or final reports, protocols, records, methods, CofAs, procedures, and/or SOPs within two weeks of the Government's request.

C.5.5. Participate in appropriate Quality Assurance audits, provide responses to audit findings to the Government, and provide support during U.S. Army Quality oversight visits.

C.5.6. Provide an Issue Summary Report within three (3) working days, of events that will cause more than a one (1) month delay in schedule or an increase in cost Estimate at Completion. The report should include an updated timeline or estimate at completion as a result of the event.

C.6.0. CONSIDERATIONS

C.6.1. The Contractor shall follow all controlling and/or applicable rules, regulations, and statutes as they relate to pharmaceutical development.

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Quality Assurance Surveillance Plan (QASP)
United States Army Medical Materiel Development Activity (USAMMDA)

Development, Manufacture, and Clinical Testing of a Sublingual Sufentanil Battlefield Pain Management Product in Order to Obtain US Food and Drug Administration (FDA) Approval

	Deliverable	Performance Standards	Acceptable Quality Level	Methods Used and Frequency	Compliance Level Data
1	Kickoff meeting	Participate in a meeting with Product Manager, IPT Staff and Government Representatives to review and document project requirements	All project requirements identified	Meeting completed upon documentation of identified requirements	Within one (1) month or less of contract award
2	IMS (CDRL A002)	Contractor will develop and maintain an IMS by logically networking detailed program activities.	Detailed IMS depicting logical network of program activities	Contracting Officer's Representative (COR) reviews documents as provided	Ten (10) days after contract award and semi-annually
3	CWBS (CDRL A003)	Contractor will develop and maintain a CWBS. The CWBS elements shall be extended to define the complete contract scope and shall be detailed to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of Level 4	CWBS defines entire contract scope and extends to at least Level 4	COR reviews documents as provided	Ten (10) days after contract award and at a minimum annually
4	IPT Teleconferences	Contractor will participate in IPT or IPT working groups meetings. Frequency and times of such meetings will be determined by the Government Product Manager and the Contractor's lead IPT representative, as dictated by project management needs.	Contractor participation at IPT meetings, as required	Participation at IPT meetings	Contractor participation at IPT meetings, as required
5	Monthly Progress Reports (CDRL A001)	Contractor's Progress, Status and Management Reports that describe progress made within the period, report costs, and inform the Government of existing or potential issues and problem areas	Report details progress made, costs incurred, and existing or potential issues/problem areas during the period	COR reviews documents as provided	On the 15th day of the month
6	Issue Summary Reports (CDRL A004)	Issue summary report that details the event that will cause more than a one (1) month delay in schedule or an increase in cost Estimate at Completion	Report details the event that will cause more than a one (1) month delay in schedule or an increase in cost Estimate at Completion	COR reviews documents as provided	As required
7	Various Clinical Trial, Manufacturing and Regulatory Documents	Contractor provides copies of draft and/or final clinical trial and regulatory documents, such as reports, protocols, records, methods, procedures, standard operating procedures, CMC documents, or IND/BLA documents within seven (7) business days of Government request.	Contractor provides reports within seven (7) days of Government's request	COR review documents as provided	As required
8	[*] Initial Production [*] Product	Contractor produces and ships FDA approved product to US Government identified facility. Contractor provides batch production records, product shipping records and documentation of temperature monitoring during shipment.	Product with at least 18-months shelf-life at time of shipment received in accordance with licensed shipping procedures and with appropriate batch production records, product shipping records, and temperature monitoring documentation.	COR reviews shipping documentation as provided	Upon exercise of option and as required thereafter

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CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (APR 2011) (USAMRAA)

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: https://cmra.army.mil. The required information includes: (l) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The CMRA help desk can be reach at 703-695-5103 or 703-695-5058 for any technical questions. The help desk can also be contacted via email: contractormanpower@hqda.army.mil. As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

RDS (RDTE DILUTE SOLUTIONS)(DEC 2006)(USAMRAA)

(a) The Contractor shall operate in a safe environment, with properly safe equipment and procedures. This means that, at a minimum, the Contractor shall satisfy the RDS-RDTE Dilute Solutions Standard located at http://www.usamraa.army.mil (then click on “Assistance Agreements” then under “Documents” click on “RDS (RDTE Dilute Solutions) Standard (November 2000).”

(b) All RDS disposal shall be addressed prior to expiration of the contract.

(c) Requests for RDS shall be provided, in writing, to the Chief, Safety & Chemical Operations Officer at:

Commander
US Army Medical Research Institute of
Chemical Defense
3100 Ricketts Point Road
ATTN: MCMR-CDZ-S
Aberdeen Proving Ground, MD 21010-5400
(410) 436-4433 and fax: (410) 436-3004

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with a copy furnished to the Contracting Officer at:

Director
US Army Medical Research Acquisition Activity
820 Chandler Street
ATTN: MCMR-AAA-**SD**
Fort Detrick, MD 21702-5014
(301) 619-**2375**

and the Contracting Officer's Representative (COR) at:

US Army Medical Materiel Development Activity
ATTN: [*]
1430 Veterans Way
Fort Detrick, MD 21702-5059
(301) 619-6823

and shall furnish the following information:

Name of the Principal Investigator:
Name(s) and phone number(s) of custodian(s):
Shipment Address:
Contract Number:
RDS, Concentration, Amount, Diluent (if applicable),
and Specific Activity (if applicable)

SAFEGUARDING PROPRIETARY INFORMATION (MAY 1999) (USAMRAA)

a. "Proprietary information" shall mean all information, whether disclosed orally, in writings, by drawings, or otherwise relating to the work to be performed under this contract, whether proprietary to the Government or one of its collaborating partners. Proprietary information includes, but is not limited to, information regarding properties, formulae, structures, manufacturing processes, and test results. Information ceases to be proprietary when it is generally available to the public or is available from sources other than the Department of the Army. All information submitted to the contractor under this contract shall be presumed to be proprietary to the Department of the Army or one of its collaborating partners until the Department of the Army announces to the contrary.

b. The contractor shall safeguard proprietary information both during and after the term of this contract, and shall neither appropriate, nor disclose, nor make unauthorized use of the proprietary information received under this contract. The requirements of this paragraph include, but are not limited to, the following:

(1) Maintenance of a high degree of physical security over proprietary information at all times;
(2) Discussion of proprietary information only among contractor's employees whose duties and responsibilities require knowledge of that information; and,
(3) Elimination of proprietary information in open publications by the contractor and its personnel.

c. The contractor shall require all personnel who receive proprietary information to execute the statement in paragraph d below when this contract becomes effective or when first employed (if employed after the contract becomes effective). All statements executed pursuant to this paragraph shall be forwarded to the U.S. Army Medical Research Acquisition Activity when this contract terminates, when the employment ends, or upon request of the Contracting Officer.

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d. The following statement shall be executed pursuant to paragraph c above:

I hereby acknowledge that I have been informed that my duties may require that I have access to proprietary information. I understand this proprietary information which I will receive includes, but is not limited to, properties, formulae, structures, protocols, manufacturing processes, and test results.

I agree that I will neither appropriate nor disclose nor make unauthorized use of proprietary information both during and after my employment. I further agree that I will neither include nor draw upon proprietary information received under this contract in open publication. This agreement is executed with the intention that collaborating partners of the United States Government who have submitted information to the Government under non-disclosure obligations shall be third party beneficiary hereunder, and shall have the right to enforce the obligations undertaken herein.

Name: _____
Date: _____

e. The contractor shall insert the substance of paragraphs a through d above in each subcontract hereunder. Compliance with the provisions of this clause shall be the responsibility of the contractor.

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PRINCIPAL INVESTIGATOR (DEC 2006) (USAMRAA)

The Principal Investigator for this contract is **Dr. Pamela Palmer**. This individual shall be continuously responsible for the conduct of the research project. The contractor shall obtain the Contracting Officer's approval to change the Principal Investigator or to continue the research work during a continuous period in excess of three months without the participation of an approved Principal Investigator. This contract is based on the Principal Investigator devoting [*] of effort to the project over the term of the contract. The contractor shall advise the Contracting Officer if the Principal Investigator will, or plans to, revise the level of effort estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

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GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

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CURRENT GOOD MANUFACTURING PRACTICES (DEC 2006) (USAMRAA)

The drug or biological drug products required by this contract shall be developed and produced in compliance with the CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FOR FINISHED PHARMACEUTICALS regulations for parenteral products, 21 CFR, Part 211. Results of routine FDA inspections for licensed facilities as recorded on Form FDA 482 shall be supplied to the Contracting Officer's Representative and become part of the contract file.

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USE OF TECHNICAL REFERENCE FACILITY (APR 2005) (USAMRAA)

The contractor agrees to use**,** to the extent practical**,** the technical reference facilities of the Defense Technical Information Center (DTIC) for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. The DTIC headquarters office is located at 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218. Information can also be obtained via the Internet at http://www.dtic.mil or via the toll-free number for the DTIC help desk, 1-800-225-3842. To the extent practical, all other sources, whether or not Government controlled, should be consulted for the same purpose.

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INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999) (USAMRAA)

a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.

c. The contractor agrees to:
(1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
(2) Comply with its own administrative process;
(3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
(4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
(5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

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d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:
(1) An immediate health hazard is involved;
(2) There is an immediate need to protect Federal funds or equipment;
(3) A probability exists that the alleged incident will be reported publicly; or
(4) There is a reasonable indication of possible criminal violation.

52.035-4030 CONTRACTOR SAFETY AND REPORTING (NON-BDRP) (DEC 2006) (USAMRAA)

a. The contractor shall operate under established safety programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. The safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.

b. The contractor shall conduct this contract work under established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.

c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.

1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Government designated Biosafety Officer
Quarterly	Contractor safety personnel
Weekly	First line supervisor

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

4. Copies of all biosafety inspection reports will be distributed as follows:

Original: In the contractor's records

One copy to the following:

a. US Army Medical Research and Materiel Command
ATTN: MCMR-ZC-SSE
504 Scott Street
Fort Detrick, Maryland 21702-5012

b. US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-DRI
504 Scott Street
Fort Detrick, Maryland 21702-5012

c. US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-**SD**
820 Chandler Street
Fort Detrick, Maryland 21702-5014

PROHIBITION OF HUMAN RESEARCH (JUN 2013) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information (human data), shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the contractor. Written approval from the USAMRMC ORP is also required for any subcontractor that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.
The contractor is required to adhere to the following reporting requirements:

Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP and the USAMRAA Contracting Office.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP and the USAMRAA Contracting Office.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

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52.035-4035 PROHIBITION OF USE OF LABORATORY ANIMALS (JUN 2013) (USAMRAA)

** PROHIBITION – READ FURTHER FOR DETAILS **

Notwithstanding any other terms and conditions contained in this award or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the contractor with a copy to the USAMRAA Contracting Office. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. Once approved, notification must be given immediately to USAMRAA contracting. For each fiscal year, the contractor shall maintain, and upon request from ACURO, submit animal usage information. Non-compliance with any of these terms and conditions may result in withholding of funds and/or ther terminations of the award.

52.035-4036 PROHIBITION OF USE OF HUMAN CADAVERS (JUN 2013) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS****

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers under this award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_ protections.overview). The USAMRMC Office of Research Protections (ORP) is the Action Office (hrpo@amedd.army.mil) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the Army Policy for Use of Human Cadavers. For certain activities involving cadavers, approval must also be obtained from ORP. Award contractors must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the contractor. Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

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CONTRACTOR IDENTIFICATION (DEC 2005) (USAMRAA)

When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications.

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REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (DEC 2006) (USAMRAA)

a. Contractors are encouraged to publish results of research supported by the US Army Medical Research and Materiel Command (USAMRMC) in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.

b. Manuscripts intended for publication in any media shall be submitted to the Contracting Officer and Contracting Officer's Representative (COR), simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the Contracting Officer and COR, even though publication may be subsequent to the expiration of the contract.

c. The Contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings, prior to public release. This is not intended to restrict dissemination of research information but to allow USAMRMC advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(l) "This work is supported by the US Army Medical Research and Materiel Command under Contract No. **W81XWH-15-C-0046**"

(2) "The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."

(3) As applicable, if the research involves the use of animals, the Contractor must include the following statement: "In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council."

(4) As applicable, if the research involves human use, the Contractor must include the following statement: "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects)."

(5) As applicable, if the research involves the use of recombinant DNA, the Contractor must include the following statement: "In conducting work involving the use of recombinant DNA the investigator(s) adhered to the current version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

KEY PERSONNEL (MAR 1999) (USAMRAA)

a. The Contractor agrees to utilize the following Key Personnel on this contract:

Pamela Palmer: [*] **- Chief Medical Officer (and Principal Investigator)**
[*]**, Clinical Operations**
[*]**, Clinical Operations**
[*]**, Medical Affairs**
[*] **Regulatory**
[*]**, Regulatory Affairs**
[*]**, Engineering**
[*]**, Quality**
[*]**, Pharmaceutical Development**
[*]**, Manufacturing Engineering**
[*] **Program Manager**

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b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.
c. The offerer must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation should include but not be limited to: name, curriculum vitae, type and description of experience.
d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.
e. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.
f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

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INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	Government
000102	N/A	N/A	N/A	Government
000103	N/A	N/A	N/A	Government
0002	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	AUG 2013
52.246-3	Inspection Of Supplies Cost-Reimbursement	MAY 2001
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001

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DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
0001	POP 11-MAY-2015 TO 10-NOV-2016	N/A	FORT DETRICK-USAMMDA FORT DETRICK-USAMMDA 1430 FORT DETRICK FREDERICK MD 21702 FOB: Destination	W806YH
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
000103	N/A	N/A	N/A	N/A
0002	N/A	N/A	N/A	N/A

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984

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REPORTING REQUIREMENTS (OCT 2009) (USAMRAA)

Technical reporting requirements (Programmatic Line Review, Monthly, Quarterly, and/or Annual/Final Reports) applicable to this award are annotated below:

_____ **PROGRAMMATIC LINE REVIEW (PLR)**

a. The reporting requirements for Telemedicine and Advanced Technology Research Center (TATRC) include quarterly, annual and final reports and the Principal Investigator's (PI's) participation in at least one programmatic line review (PLR) for this project each year of the project's period-of-performance.

b. The PI shall prepare for and participate in at least one PLR for this project for each year of the project's term, at the COR's request. The invitation and format for the programmatic review will be provided by TATRC at least 90 days prior to the meeting. The meetings will generally be held in the Fort Detrick, Maryland, area, but may occur elsewhere in the U.S. Participation in the PLR will be in lieu of submitting next scheduled Quarterly report required under the award.

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XX MONTHLY TECHNICAL PROGRESS REPORTS

a. The contractor shall submit a Monthly Technical Progress Report covering work accomplished during each month of contract performance. It shall be brief, factual, and informal, and shall be prepared in accordance with the following:

(l) Cover containing:

(a) Contract number and title

(b) Type of report, sequence number of report, and period of performance being reported

(c) Contractor's name, address, and telephone number

(d) Principal Investigator

(e) Date of publication

(f) Contracting Officer's Representative

(2) Section I - A brief introduction covering the purpose and scope of the research effort.

(3) Section II - A brief description of overall progress to date plus a separate description for each task or other logical segment of work on which effort was expended during the report period. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved.

(4) Section III - Problem Areas

(a) A description of current problems that may impede performance along with proposed corrective action.

(b) A description of anticipated problems that have a potential to impede progress and what corrective action is planned should the problem materialize.

(5) Section IV - A description of work to be performed during the next reporting period.

(6) Section V - Administrative Comments (Optional) - Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.

(7) Section VI - A Gantt Chart showing actual progress versus scheduled progress.

b. Monthly Technical Progress Reports shall be prepared by the seventh day following the month being reported, and shall be received within 10 days of the report month. The Monthly Technical Progress Report shall be submitted to the following addresses:

One Copy: Director
U.S. Army Medical Research Acquisition Activity (USAMRAA)
ATTN: MCMR-AAA-**SD**
820 Chandler Street
Fort Detrick, MD 21702-5014

One Copy: **US Army Medical Materiel Development Activity**
ATTN: [*]
1430 Veterans Way
Fort Detrick, MD 21702-5059

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_____ QUARTERLY REPORTS

a. Quarterly reports are the most immediate and direct contact between the Principal Investigator (PI) and the Contracting Officer's Representative (COR). The reports provide the means for keeping this Command advised of developments and problems as the contract effort proceeds. The quarterly reports also provide a measure against which decisions on release of funding and on requests for supplements are made.

b. In accordance with Section C., a Quarterly Report shall be submitted for each three-month period beginning with the effective date of the contract. This requirement includes all three-month periods of the contract.

c. Copies of each report shall be submitted in the quantities indicated to the addresses shown below within fifteen (15) days after the end of each quarter. Internal Government distribution will be made by those offices.

(1) One (l) copy of the report to:

Insert Name and Address of COR

(2) One (1) copy of the report to:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-_(Insert Applicable Office Symbol and Award Number
820 Chandler Street
Fort Detrick, MD 21702-5014

d. The Quarterly Report sample (See following Quarterly Report Format) shall serve as the format. Each item of the report format shall be completed.

QUARTERLY REPORT FORMAT

1. Contract No. _____2. Report Date _____

3. Reporting period from _____ to _____

4. PI _____ 5. Telephone No. _____

6. Institution_____

7. Project Title_____
_____
_____

8. Current staff, with percent effort of each on project.

_____ _____% _____ _____%

_____ _____% _____ _____%

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9. Contract expenditures to date (as applicable):

	This Qtr/Cumulative		This Qtr/Cumulative
Personnel	_____/_____	Travel	_____/_____
Fringe Benefits	_____/_____	Equipment	_____/_____
Supplies	_____/_____	Other	_____/_____

	This Qtr/Cumulative
Subtotal	_____/_____
Indirect Costs	_____/_____
Fee	_____/_____
Total	_____/_____

10. Comments on administrative and logistical matters.

_____

_____

_____

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

_____ **FORMAT REQUIREMENTS FOR ANNUAL/FINAL REPORTS**

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the approved Statement of Work. Journal articles can be substituted for detailed descriptions of specific aspects of the research, but the original articles must be attached to the report as an appendix and appropriately referenced in the text. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized. An annual report shall be submitted within 30 calendar days of the anniversary date of the award for the preceding 12-month period. If the award period of performance is extended by the Contracting Officer then an annual report must still be submitted within 30 calendar days of the anniversary date of the award. A final report will be due upon completion of the extended performance date that describes the entire research effort.

b. A final report summarizing the entire research effort, citing data in the annual reports and appended publications shall be submitted at the end of the award performance period. The final report will provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication must be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work. Submission of the report in electronic format (PDF or Word file only) shall be submitted to https://ers.amedd.army.mil.

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All reports shall have the following elements, in this order:

FRONT COVER: A Sample front cover is provided at https://mrmc.amedd.army.mil/rrpindex.asp. The Accession Document (AD) Number should remain blank.

STANDARD FORM 298: A Sample SF 298 is provided at https://mrmc.amedd.army.mil/rrpindex.asp. The abstract in Block 13 must state the purpose, scope, major findings and be an up-to-date report of the progress in terms of results and significance. Subject terms are keywords that may have previously assigned to the proposal abstract or are keywords that may be significant to the research. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Please count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. Page numbers should be typed: please do not hand number pages.

TABLE OF CONTENTS: Sample table of contents provided at https://mrmc.amedd.army.mil/rrpindex.asp.

INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer's Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

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REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Pages shall be consecutively numbered throughout the report. DO NOT RENUMBER PAGES IN THE APPENDICES.

Mark all pages of the report which contain proprietary or unpublished data that should be protected by the U.S. Government. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the U.S. Army Medical Research and Materiel Command when restricted limitation assigned to a document can be downgraded to Approved for Public Release. DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.

FACILITY SAFETY PLAN STATUS REPORT (DEC 2006) (USAMRAA)

1. A Facility Safety Plan Status Report must be submitted annually starting no later than 1 year after obtaining the initial approval of the institution's Facility Safety Plan. In the event that the Principal Investigator changes during the performance under this contract, the new Principal Investigator shall complete the "Newly Appointed Principal Investigator Assurance" form (see paragraph 3).

2. As a part of the annual Facility Safety Plan Status Report, the Facility Safety Director/Manager must provide the following: A brief description of any parts of the Facility Safety Plan that may have changed during the past 12 months. (Additional pages may be attached.)

During the past 12 months:
1. Have any change(s) in Research Operation Safety Procedure(s) been made?
Yes _____ No _____
If yes, briefly describe:

2. Have any modifications to the facility, equipment, and description (e.g., new equipment purchased, hood ventilation certification) been made?
Yes _____ No _____
If yes, briefly describe:

3. Hazard Analysis: Have any new hazards been identified for any of the awards supported by the USAMRMC?
Yes _____ No _____
If yes, provide a hazard analysis for each new hazard.

4. Radioactive Materials: Have any significant change(s) occurred in the use of the radioactive materials?
Yes _____ No _____
If yes, briefly describe:

a. Are there any additional radioactive materials in use?
Yes _____ No _____
If yes, list additional material(s).

b. Is the radioactive material licensure current?
Yes _____ No _____
If no, please explain.

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I certify that all of the above elements are true and correct to the best of my knowledge, and I assure that this institution provides a safe environment for its employees working in research laboratories in accordance with Federal, State, and local government regulations. This safety office provides employee safety training and periodic laboratory inspections in an effort to minimize, eliminate, or control potential hazards to the employees and the public.

I understand that the Safety Office, USAMRMC, may conduct periodic site visits in order to ensure the indicated elements are in compliance with regulatory requirements.

Name of the Institution: _____

Name of Safety Director/Manager: _____

Signature: _____ Date: _____
Safety Director/Manager

E-mail Address: _____

Phone Number: _____

Fax Number: _____

Facility Safety Plan approved by USAMRMC Safety Office: _____ Date _____

3. Newly Appointed Principal Investigator Assurance

_____ I assure that I have coordinated with the Facility Safety Director/Manager in the research, and have discussed with him/her all aspects of the research-related specific safety issues, and will help him/her prepare the annual Facility Safety Plan Status Report.

_____ I assure that I will comply with my institution's safety program and its requirements.

_____ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.

_____ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.

_____ I assure that hazards associated with my research have been identified, eliminated and/or controlled.

_____ I assure that all safety requirements are in compliance with 32 CFR 626 and 627, "Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements" (if applicable).

_____
Name of Principal Investigator (print)

_____ _____
Signature Date

Mailing Address: _____
Street

_____
City State Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____

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ACCOUNTING AND APPROPRIATION DATA

AA: 097201420150130000018N10337374255 R.0011882.5.3 6100.9000021001
COST CODE: A74FG
AMOUNT: $993,000.00
CIN GFEBS001062245800003: $993,000.00

AB: 097201420150130000183 10444441255 R.0012070.9 6100.9000021001
COST CODE: A7444
AMOUNT: $6,500,000.00
CIN GFEBS001062245800004: $6,500,000.00

AC: 097201520160130000018N10337374255 R.0014944.4.4 6100.9000021001
COST CODE: A74FG
AMOUNT: $3,490,000.00
CIN GFEBS001062245800005: $3,490,000.00

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52.004-4002 Contractor Performance Assessment Reporting System (CPARS) (USAMRAA) (September 2009)

The Contractor Performance Assessment Reporting System (CPARS) has been adopted electronically to capture assessment data and manage the evaluation process. CPARS is used to assess a contractor's performance and provide a record, both positive and negative, on a given contract during a specific period of time. The CPARS Automated Information System (AIS) collection tool and other CPARS information can be accessed at https://www.cpars.csd.disa.mil. CPARS collects contractor performance information and passes it to the Federal Past Performance Information Retrieval System (PPIRS) where it can be retrieved by Federal Government Agencies including the DoD Services. The CPARS process is designed with a series of checks and balances to facilitate the objective and consistent evaluation of contractor performance. Both government and contractor program management perspectives are captured on the CPAR form and together make a complete CPAR. The Contractor shall assign and provide to the Contracting Officer's Representative (COR), within 10 calendar days after award, the name, title, email address and phone number of the designated Contractor Representative (CR) within their firm who will be responsible for CPAR information and reviewing the Government's proposed assessment for the period of performance. A User ID and Password for the CPARS will be provided to the designated CR for this purpose of accessing the CPARS. The CR has the authority to: Receive the Government evaluation; Review/comment/return the evaluation to the Government within 30 calendar days after the Government's evaluation is completed; Request a meeting to discuss the CPAR. This meeting must be requested, in writing, no later than seven calendar days from the receipt of the CPAR and must be held during the contractor’s 30-day review period. The CR must either concur or nonconcur to each CPAR.

252.201-7000 CONTRACTING OFFICER'S REPRESENTATIVE (DEC 1991)

(a) "Definition. Contracting officer's representative" means an individual designated in accordance with subsection 201.602-2 of the Defense Federal Acquisition Regulation Supplement and authorized in writing by the contracting officer to perform specific technical or administrative functions.

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(b) If the Contracting Officer designates a contracting officer's representative (COR), the Contractor will receive a copy of the written designation. It will specify the extent of the COR's authority to act on behalf of the contracting officer. The COR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

(End of clause)

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall--

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this Web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Contractor shall use the following document type(s).

Invoice as a ‘Cost Voucher’.

(Contracting Officer: Insert applicable document type(s). Note: If a “Combo” document type is identified but not supportable by the Contractor's business systems, an “Invoice” (stand-alone) and “Receiving Report” (stand-alone) document type may be used instead.)

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(2) Inspection/acceptance location. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

W806YH

(Contracting Officer: Insert inspection and acceptance locations or "Not applicable".)

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
PayOfficialDoDAAC	[*]
Issue By DoDAAC	[*]
Admin DoDAAC	[*]
Inspect By DoDAAC	[*]
Ship To Code	[*]
Ship From Code	[*]
Mark For Code	[*]
Service Approver (DoDAAC)	[*]
Service Acceptor (DoDAAC)	[*]
Accept at Other DoDAAC	[*]
LPO DoDAAC	[*]
DCAA Auditor DoDAAC	[*]
Other DoDAAC(s)	[*]

(*Contracting Officer: Insert applicable DoDAAC information or "See schedule" if multiple ship to/acceptance locations apply, or "Not applicable.")

(4) Payment request and supporting documentation. The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in DFARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) WAWF email notifications. The Contractor shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.
[*]

(Contracting Officer: Insert applicable email addresses or "Not applicable.")

(g) WAWF point of contact. (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

N/A

(Contracting Officer: Insert applicable information or "Not applicable.")

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

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5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of **5/11/2015** to **11/10/2016** will be $**17,012,744.49**. There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $**10,983,000.00**. It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period **5/11/2015** to **6/21/2016**. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Funding Source	**Year**	**Amount**	**Timing**
DPH JWMRP	FY15	$500,000.00	Jun-2015
DHP core	FY16	$5,529,744.49	Jun-2016
TOTAL	**N/A**	**$6,029,744.49**	**N/A**

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Funds”, FAR 52.232-22.
(End Local Clause)

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RECOVERY PROVISION
REGULATORY RIGHTS IN EVENT OF PRODUCT DEVELOPMENT FAILURES

This contract includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this contract will result in the FDA clearance and commercialization of the **Sufentanil NanoTab™** battlefield pain management product. The Contractor is the sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls the research under this contract. As the sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This provision protects the return on research and development investment made by the U.S. Army Medical Research and Materiel Command (USAMRMC) in the event of certain regulatory product development failures related to the Technology.

The Contractor agrees to the following:

a. Contractor will, within three (3) business days of receipt, provide USAMRMC with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that USAMRMC representatives are given advance notice of and are invited to participate with at least two (2) representatives in any formal or informal sponsor meetings with FDA;

b. If contract is to be terminated or is about to expire prior to the time the Contractor obtains FDA approval or clearance; or the Contractor fails to commercially market the regulated technology within three (3) years after the FDA issues approval or clearance, the Contractor, upon the request of the Government:

(i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to USAMRMC or its designee;
(ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above.

c. The terms of this provision and its derivative obligations:
(i) will be included in any license, sale or transfer by the Contractor to a third party of any intellectual property covered by section (b) above.
(ii) will survive the acquisition or merger of the Contractor by or with any third party.
(iii) will be included in any subcontracts relating to the development of the Technology.
(iv) will survive the expiration of this contract.

SPECIAL INSTRUCTIONS
All information submitted by the Contractor to the Government or one of its collaborating partners under this contract that is marked or designated as "Proprietary" to the Contractor shall be treated as confidential and not disclosed publically or to any third party without the prior written consent of the Contractor.

For purposes of this contract and award, no claim, license, or rights to AcelRx intellectual property shall transfer to the Government or its collaborating partners, including but not limited to patents, trademarks, copyrights and trade secrets, that were invented, disclosed, registered or filed prior to the effective date of this agreement.

Contractor shall maintain all rights to its intellectual property and no rights, title or license shall transfer to the Government or any Government collaborating partner to any invention that was previously conceived, filed or registered by Contractor or its agents prior to the effective date of this agreement.

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CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	APR 2010
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	APR 2014
52.204-2	Security Requirements	AUG 1996
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2013
52.204-13	System for Award Management Maintenance	JUL 2013
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	JUL 2013
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	DEC 2014
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	APR 2015
52.222-35	Equal Opportunity for Veterans	JUL 2014
52.222-36	Equal Opportunity for Workers with Disabilities	JUL 2014
52.222-37	Employment Reports on Veterans	JUL 2014
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	MAR 2015
52.222-54	Employment Eligibility Verification	AUG 2013
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.225-1	Buy American--Supplies	MAY 2014
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-3	Patent Indemnity	APR 1984
52.227-10	Filing Of Patent Applications--Classified Subject Matter	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996

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52.230-2	Cost Accounting Standards	MAY 2014
52.230-3	Disclosure And Consistency Of Cost Accounting Practices	MAY 2014
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-17	Interest	MAY 2014
52.232-23	Assignment Of Claims	MAY 2014
52.232-25 Alt I	Prompt Payment (July 2013) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	JUL 2013
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-2	Production Progress Reports	APR 1991
52.242-3	Penalties for Unallowable Costs	MAY 2014
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-2 Alt V	Changes--Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.243-6	Change Order Accounting	APR 1984
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	APR 2015
52.245-9	Use And Charges	APR 2012
52.246-23	Limitation Of Liability	FEB 1997
52.246-25	Limitation Of Liability--Services	FEB 1997
52.247-68	Report of Shipment (REPSHIP)	FEB 2006
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	DEC 2012
252.204-7000	Disclosure Of Information	AUG 2013
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	System for Award Management Alternate A	FEB 2014
252.204-7005	Oral Attestation of Security Responsibilities	NOV 2001
252.204-7010	Requirement for Contractor to Notify DoD if the Contractor's Activities are Subject to Reporting Under the U.S.- International Atomic Energy Agency Additional Protocol	JAN 2009
252.204-7012	Safeguarding of Unclassified Controlled Technical Information	NOV 2013
252.204-7013	Limitations on the Use or Disclosure of Information by Litigation Support Solicitation Offerors	FEB 2014
252.204-7014	Limitations on the Use or Disclosure of Information by Litigation Support Contractors	FEB 2014
252.204-7015	Disclosure of Information to Litigation Support Contractors	FEB 2014
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Country that is a State Sponsor of Terrorism	DEC 2014

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252.211-7005	Substitutions for Military or Federal Specifications and Standards	NOV 2005
252.211-7008	Use of Government-Assigned Serial Numbers	SEP 2010
252.217-7016	Plant Protection	DEC 1991
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	OCT 2014
252.223-7004	Drug Free Work Force	SEP 1988
252.225-7004	Report of Intended Performance Outside the United States and Canada--Submission after Award	OCT 2010
252.225-7012	Preference For Certain Domestic Commodities	FEB 2013
252.225-7048	Export-Controlled Items	JUN 2013
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	JUN 2013
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	JUN 2012
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7004	Protection of Human Subjects	JUL 2009
252.235-7011	Final Scientific or Technical Report	JAN 2015
252.237-7010	Prohibition on Interrogation of Detainees by Contractor Personnel	JUN 2013
252.242-7005	Contractor Business Systems	FEB 2012
252.242-7006	Accounting System Administration	FEB 2012
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items	JUN 2013
252.244-7001	Contractor Purchasing System Administration	MAY 2014
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	APR 2012
252.245-7002	Reporting Loss of Government Property	APR 2012
252.245-7003	Contractor Property Management System Administration	APR 2012
252.245-7004	Reporting, Reutilization, and Disposal	MAR 2015
252.246-7000	Material Inspection And Receiving Report	MAR 2008
252.246-7001	Warranty Of Data	MAR 2014
252.247-7023	Transportation of Supplies by Sea	APR 2014

CLAUSES INCORPORATED BY FULL TEXT

52.216-7 ALLOWABLE COST AND PAYMENT (JUN 2013)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the **30th** (Contracting Officer insert day as prescribed by agency head; if not prescribed, insert “30th”) day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

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(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor categories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

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(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242-4, Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General organizational information and limitation on allowability of compensation for certain contractor personnel. See 31.205-6(p). Additional salary reference information is available at http://www.whitehouse.gov/omb/procurement_index_exec_comp/.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(5) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.216-11 COST CONTRACT--NO FEE (APR 1984)

(a) The Government shall not pay the Contractor a fee for performing this contract.

(b) After payment of 80 percent of the total estimated cost shown in the Schedule, the Contracting Officer may withhold further payment of allowable cost until a reserve is set aside in an amount that the Contracting Officer considers necessary to protect the Government's interest. This reserve shall not exceed one percent of the total estimated cost shown in the Schedule or $100,000, whichever is less.

(End of clause)

52.217-7 OPTION FOR INCREASED QUANTITY--SEPARATELY PRICED LINE ITEM (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor no later than 30 days after receipt of FDA approval. Delivery of added items shall continue at the same rate specified in Section B, CLIN 0002, unless the parties otherwise agree.

(End of clause)

52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within **30 DAYS**.

(End of clause)

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52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (JULY 2013)

(a) Definitions. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is ``not dominant in its field of operation'' when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ( ) is, ( ) is not a small business concern under NAICS Code **325412**- assigned to contract number **W81XWH-15-C-0046**.

(Contractor to sign and date and insert authorized signer's name and title).

_____
SIGNATURE

_____
DATE

_____
NAME

_____
TITLE

(End of clause)

52.227-11 PATENT RIGHTS--OWNERSHIP BY THE CONTRACTOR (MAY 2014)

(a) As used in this clause--

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, “This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention.”

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

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

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications.

(k) Subcontracts. (1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes statute in connection with proceedings under paragraph (h) of this clause.

(End of clause)

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52.227-16 ADDITIONAL DATA REQUIREMENTS (JUN 1987)

(a) In addition to the data (as defined in the clause at 52.227-14, Rights in Data--General clause or other equivalent included in this contract) specified elsewhere in this contract to be delivered, the Contracting Officer may, at any time during contract performance or within a period of 3 years after acceptance of all items to be delivered under this contract, order any data first produced or specifically used in the performance of this contract.

(b) The Rights in Data--General clause or other equivalent included in this contract is applicable to all data ordered under this Additional Data Requirements clause. Nothing contained in this clause shall require the Contractor to deliver any data the withholding of which is authorized by the Rights in Data--General or other equivalent clause of this contract, or data which are specifically identified in this contract as not subject to this clause.

(c) When data are to be delivered under this clause, the Contractor will be compensated for converting the data into the prescribed form, for reproduction, and for delivery.

(d) The Contracting Officer may release the Contractor from the requirements of this clause for specifically identified data items at any time during the 3-year period set forth in paragraph (a) of this clause.

(End of clause)

52.232-22 LIMITATION OF FUNDS (APR 1984)

(a) The parties estimate that performance of this contract will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Schedule specifies the amount presently available for payment by the Government and allotted to this contract, the items covered, the Government's share of the cost if this is a cost-sharing contract, and the period of performance it is estimated the allotted amount will cover. The parties contemplate that the Government will allot additional funds incrementally to the contract up to the full estimated cost to the Government specified in the Schedule, exclusive of any fee. The Contractor agrees to perform, or have performed, work on the contract up to the point at which the total amount paid and payable by the Government under the contract approximates but does not exceed the total amount actually allotted by the Government to the contract.

(c) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that the costs it expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of (1) the total amount so far allotted to the contract by the Government or, (2) if this is a cost-sharing contract, the amount then allotted to the contract by the Government plus the Contractor's corresponding share. The notice shall state the estimated amount of additional funds required to continue performance for the period specified in the Schedule.

(d) Sixty days before the end of the period specified in the Schedule, the Contractor shall notify the Contracting Officer in writing of the estimated amount of additional funds, if any, required to continue timely performance under the contract or for any further period specified in the Schedule or otherwise agreed upon, and when the funds will be required.

(e) If, after notification, additional funds are not allotted by the end of the period specified in the Schedule or another agreed-upon date, upon the Contractor's written request the Contracting Officer will terminate this contract on that date in accordance with the provisions of the Termination clause of this contract. If the Contractor estimates that the funds available will allow it to continue to discharge its obligations beyond that date, it may specify a later date in its request, and the Contracting Officer may terminate this contract on that later date.

(f) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause--

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of the total amount allotted by the Government to this contract; and

(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of (i) the amount then allotted to the contract by the Government or, (ii) if this is a cost-sharing contract, the amount then allotted by the Government to the contract plus the Contractor's corresponding share, until the Contracting Officer notifies the Contractor in writing that the amount allotted by the Government has been increased and specifies an increased amount, which shall then constitute the total amount allotted by the Government to this contract.

(g) The estimated cost shall be increased to the extent that (1) the amount allotted by the Government or, (2) if this is a cost-sharing contract, the amount then allotted by the Government to the contract plus the Contractor's corresponding share, exceeds the estimated cost specified in the Schedule. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(h) No notice, communication, or representation in any form other than that specified in subparagraph (f)(2) above, or from any person other than the Contracting Officer, shall affect the amount allotted by the Government to this contract. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the total amount allotted by the Government to this contract, whether incurred during the course of the contract or as a result of termination.

(i) When and to the extent that the amount allotted by the Government to the contract is increased, any costs the Contractor incurs before the increase that are in excess of (1) the amount previously allotted by the Government or, (2) if this is a cost-sharing contract, the amount previously allotted by the Government to the contract plus the Contractor's corresponding share, shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice and directs that the increase is solely to cover termination or other specified expenses.

(j) Change orders shall not be considered an authorization to exceed the amount allotted by the Government specified in the Schedule, unless they contain a statement increasing the amount allotted.

(k) Nothing in this clause shall affect the right of the Government to terminate this contract. If this contract is terminated, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

(l) If the Government does not allot sufficient funds to allow completion of the work, the Contractor is entitled to a percentage of the fee specified in the Schedule equalling the percentage of completion of the work contemplated by this contract.

(End of clause)

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52.243-7 NOTIFICATION OF CHANGES (APR 1984)

(a) Definitions.

"Contracting Officer," as used in this clause, does not include any representative of the Contracting Officer.

"Specifically authorized representative (SAR)," as used in this clause, means any person the Contracting Officer has so designated by written notice (a copy of which shall be provided to the Contractor) which shall refer to this subparagraph and shall be issued to the designated representative before the SAR exercises such authority.

(b) Notice. The primary purpose of this clause is to obtain prompt reporting of Government conduct that the Contractor considers to constitute a change to this contract. Except for changes identified as such in writing and signed by the Contracting Officer, the Contractor shall notify the Administrative Contracting Officer in writing, within **TEN (10)** calendar days from the date that the Contractor identifies any Government conduct (including actions, inactions, and written or oral communications) that the Contractor regards as a change to the contract terms and conditions. On the basis of the most accurate information available to the Contractor, the notice shall state--

(1) The date, nature, and circumstances of the conduct regarded as a change;

(2) The name, function, and activity of each Government individual and Contractor official or employee involved in or knowledgeable about such conduct;

(3) The identification of any documents and the substance of any oral communication involved in such conduct;

(4) In the instance of alleged acceleration of scheduled performance or delivery, the basis upon which it arose;

(5) The particular elements of contract performance for which the Contractor may seek an equitable adjustment under this clause, including--

(i) What contract line items have been or may be affected by the alleged change;

(ii) What labor or materials or both have been or may be added, deleted, or wasted by the alleged change;

(iii) To the extent practicable, what delay and disruption in the manner and sequence of performance and effect on continued performance have been or may be caused by the alleged change;

(iv) What adjustments to contract price, delivery schedule, and other provisions affected by the alleged change are estimated; and

(6) The Contractor's estimate of the time by which the Government must respond to the Contractor's notice to minimize cost, delay or disruption of performance.

(c) Continued performance. Following submission of the notice required by (b) above, the Contractor shall diligently continue performance of this contract to the maximum extent possible in accordance with its terms and conditions as construed by the Contractor, unless the notice reports a direction of the Contracting Officer or a communication from a SAR of the Contracting Officer, in either of which events the Contractor shall continue performance; provided, however, that if the Contractor regards the direction or communication as a change as described in (b) above, notice shall be given in the manner provided. All directions, communications, interpretations, orders and similar actions of the SAR shall be reduced to writing and copies furnished to the Contractor and to the Contracting Officer. The Contracting Officer shall countermand any action which exceeds the authority of the SAR.

(d) Government response. The Contracting Officer shall promptly, within **TEN (10)** calendar days after receipt of notice, respond to the notice in writing. In responding, the Contracting Officer shall either--

(1) Confirm that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance;

(2) Countermand any communication regarded as a change;

(3) Deny that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance; or

(4) In the event the Contractor's notice information is inadequate to make a decision under (1), (2), or (3) above, advise the Contractor what additional information is required, and establish the date by which it should be furnished and the date thereafter by which the Government will respond.

(e) Equitable adjustments.

(1) If the Contracting Officer confirms that Government conduct effected a change as alleged by the Contractor, and the conduct causes an increase or decrease in the Contractor's cost of, or the time required for, performance of any part of the work under this contract, whether changed or not changed by such conduct, an equitable adjustment shall be made--

(i) In the contract price or delivery schedule or both; and

(ii) In such other provisions of the contract as may be affected.

(2) The contract shall be modified in writing accordingly. In the case of drawings, designs or specifications which are defective and for which the Government is responsible, the equitable adjustment shall include the cost and time extension for delay reasonably incurred by the Contractor in attempting to comply with the defective drawings, designs or specifications before the Contractor identified, or reasonably should have identified, such defect. When the cost of property made obsolete or excess as a result of a change confirmed by the Contracting Officer under this clause is included in the equitable adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of the property. The equitable adjustment shall not include increased costs or time extensions for delay resulting from the Contractor's failure to provide notice or to continue performance as provided, respectively, in (b) and (c) above.

Note: The phrases “contract price” and “cost” wherever they appear in the clause, may be appropriately modified to apply to cost-reimbursement or incentive contracts, or to combinations thereof.

(End of clause)

52.244-2 SUBCONTRACTS (OCT 2010)

(a) Definitions. As used in this clause--

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

N/A.

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

_____
_____

(End of clause)

52.245-1 GOVERNMENT PROPERTY (APR 2012)

(a) *Definitions.* As used in this clause—

"Cannibalize" means to remove parts from Government property for use or for installation on other Government property.

"Contractor-acquired property" means property acquired, fabricated, or otherwise provided by the Contractor for performing a contract, and to which the Government has title.

"Contractor inventory" means—

(1) Any property acquired by and in the possession of a Contractor or subcontractor under a contract for which title is vested in the Government and which exceeds the amounts needed to complete full performance under the entire contract;

(2) Any property that the Government is obligated or has the option to take over under any type of contract, *e.g.*, as a result either of any changes in the specifications or plans thereunder or of the termination of the contract (or subcontract thereunder), before completion of the work, for the convenience or at the option of the Government; and

(3) Government-furnished property that exceeds the amounts needed to complete full performance under the entire contract.

"Contractor's managerial personnel" means the Contractor's directors, officers, managers, superintendents, or equivalent representatives who have supervision or direction of—

(1) All or substantially all of the Contractor's business;

(2) All or substantially all of the Contractor's operation at any one plant or separate location; or

(3) A separate and complete major industrial operation.

"Demilitarization" means rendering a product unusable for, and not restorable to, the purpose for which it was designed or is customarily used.

"Discrepancies incident to shipment" means any differences (*e.g.*, count or condition) between the items documented to have been shipped and items actually received.

"Equipment" means a tangible item that is functionally complete for its intended purpose, durable, nonexpendable, and needed for the performance of a contract. Equipment is not intended for sale, and does not ordinarily lose its identity or become a component part of another article when put into use. Equipment does not include material, real property, special test equipment or special tooling.

"Government-furnished property" means property in the possession of, or directly acquired by, the Government and subsequently furnished to the Contractor for performance of a contract. Government-furnished property includes, but is not limited to, spares and property furnished for repair, maintenance, overhaul, or modification. Government-furnished property also includes contractor-acquired property if the contractor-acquired property is a deliverable under a cost contract when accepted by the Government for continued use under the contract.

"Government property" means all property owned or leased by the Government. Government property includes both Government-furnished and Contractor-acquired property. Government property includes material, equipment, special tooling, special test equipment, and real property. Government property does not include intellectual property and software.

"Loss of Government property" means unintended, unforeseen or accidental loss, damage or destruction to Government property that reduces the Government's expected economic benefits of the property. Loss of Government property does not include purposeful destructive testing, obsolescence, normal wear and tear or manufacturing defects. Loss of Government property includes, but is not limited to—

(1) Items that cannot be found after a reasonable search;

(2) Theft;

(3) Damage resulting in unexpected harm to property requiring repair to restore the item to usable condition; or

(4) Destruction resulting from incidents that render the item useless for its intended purpose or beyond economical repair.

"Material" means property that may be consumed or expended during the performance of a contract, component parts of a higher assembly, or items that lose their individual identity through incorporation into an end item. Material does not include equipment, special tooling, special test equipment or real property.

“Nonseverable” means property that cannot be removed after construction or installation without substantial loss of value or damage to the installed property or to the premises where installed.

“Precious metals” means silver, gold, platinum, palladium, iridium, osmium, rhodium, and ruthenium.

“Production scrap” means unusable material resulting from production, engineering, operations and maintenance, repair, and research and development contract activities. Production scrap may have value when re-melted or reprocessed, *e.g.*, textile and metal clippings, borings, and faulty castings and forgings.

“Property” means all tangible property, both real and personal.

“Property Administrator” means an authorized representative of the Contracting Officer appointed in accordance with agency procedures, responsible for administering the contract requirements and obligations relating to Government property in the possession of a Contractor.

“Property records” means the records created and maintained by the contractor in support of its stewardship responsibilities for the management of Government property.

“Provide” means to furnish, as in Government-furnished property, or to acquire, as in contractor-acquired property.

“Real property” See Federal Management Regulation 102-71.20 (41 CFR 102-71.20).

“Sensitive property” means property potentially dangerous to the public safety or security if stolen, lost, or misplaced, or that shall be subject to exceptional physical security, protection, control, and accountability. Examples include weapons, ammunition, explosives, controlled substances, radioactive materials, hazardous materials or wastes, or precious metals.

“Unit acquisition cost” means—

(1) For Government-furnished property, the dollar value assigned by the Government and identified in the contract; and

(2) For contractor-acquired property, the cost derived from the Contractor’s records that reflect consistently applied generally accepted accounting principles.

(b) *Property management.*

(1) The Contractor shall have a system of internal controls to manage (control, use, preserve, protect, repair, and maintain) Government property in its possession. The system shall be adequate to satisfy the requirements of this clause. In doing so, the Contractor shall initiate and maintain the processes, systems, procedures, records, and methodologies necessary for effective and efficient control of Government property. The Contractor shall disclose any significant changes to its property management system to the Property Administrator prior to implementation of the changes. The Contractor may employ customary commercial practices, voluntary consensus standards, or industry-leading practices and standards that provide effective and efficient Government property management that are necessary and appropriate for the performance of this contract (except where inconsistent with law or regulation).

(2) The Contractor’s responsibility extends from the initial acquisition and receipt of property, through stewardship, custody, and use until formally relieved of responsibility by authorized means, including delivery, consumption, expending, sale (as surplus property), or other disposition, or via a completed investigation, evaluation, and final determination for lost property. This requirement applies to all Government property under the Contractor’s accountability, stewardship, possession or control, including its vendors or subcontractors (see paragraph (f)(1)(v) of this clause).

(3) The Contractor shall include the requirements of this clause in all subcontracts under which Government property is acquired or furnished for subcontract performance.

(4) The Contractor shall establish and maintain procedures necessary to assess its property management system effectiveness and shall perform periodic internal reviews, surveillances, self assessments, or audits. Significant findings or results of such reviews and audits pertaining to Government property shall be made available to the Property Administrator.

(c) *Use of Government property.*

(1) The Contractor shall use Government property, either furnished or acquired under this contract, only for performing this contract, unless otherwise provided for in this contract or approved by the Contracting Officer.

(2) Modifications or alterations of Government property are prohibited, unless they are—

(i) Reasonable and necessary due to the scope of work under this contract or its terms and conditions;

(ii) Required for normal maintenance; or

(iii) Otherwise authorized by the Contracting Officer.

(3) The Contractor shall not cannibalize Government property unless otherwise provided for in this contract or approved by the Contracting Officer.

(d) *Government-furnished property.*

(1) The Government shall deliver to the Contractor the Government-furnished property described in this contract. The Government shall furnish related data and information needed for the intended use of the property. The warranties of suitability of use and timely delivery of Government-furnished property do not apply to property acquired or fabricated by the Contractor as contractor-acquired property and subsequently transferred to another contract with this Contractor.

(2) The delivery and/or performance dates specified in this contract are based upon the expectation that the Government-furnished property will be suitable for contract performance and will be delivered to the Contractor by the dates stated in the contract.

(i) If the property is not delivered to the Contractor by the dates stated in the contract, the Contracting Officer shall, upon the Contractor's timely written request, consider an equitable adjustment to the contract.

(ii) In the event property is received by the Contractor, or for Government-furnished property after receipt and installation, in a condition not suitable for its intended use, the Contracting Officer shall, upon the Contractor's timely written request, advise the Contractor on a course of action to remedy the problem. Such action may include repairing, replacing, modifying, returning, or otherwise disposing of the property at the Government's expense. Upon completion of the required action(s), the Contracting Officer shall consider an equitable adjustment to the contract (see also paragraph (f)(1)(ii)(A) of this clause).

(iii) The Government may, at its option, furnish property in an "as-is" condition. The Contractor will be given the opportunity to inspect such property prior to the property being provided. In such cases, the Government makes no warranty with respect to the serviceability and/or suitability of the property for contract performance. Any repairs, replacement, and/or refurbishment shall be at the Contractor's expense.

(3)

(i) The Contracting Officer may by written notice, at any time—

(A) Increase or decrease the amount of Government-furnished property under this contract;

(B) Substitute other Government-furnished property for the property previously furnished, to be furnished, or to be acquired by the Contractor for the Government under this contract; or

(C) Withdraw authority to use property.

(ii) Upon completion of any action(s) under paragraph (d)(3)(i) of this clause, and the Contractor's timely written request, the Contracting Officer shall consider an equitable adjustment to the contract.

(e) *Title to Government property.*

(1) All Government-furnished property and all property acquired by the Contractor, title to which vests in the Government under this paragraph (collectively referred to as "Government property"), is subject to the provisions of this clause. The Government shall retain title to all Government-furnished property. Title to Government property shall not be affected by its incorporation into or attachment to any property not owned by the Government, nor shall Government property become a fixture or lose its identity as personal property by being attached to any real property.

(2) Title vests in the Government for all property acquired or fabricated by the Contractor in accordance with the financing provisions or other specific requirements for passage of title in the contract. Under fixed price type contracts, in the absence of financing provisions or other specific requirements for passage of title in the contract, the Contractor retains title to all property acquired by the Contractor for use on the contract, except for property identified as a deliverable end item. If a deliverable item is to be retained by the Contractor for use after inspection and acceptance by the Government, it shall be made accountable to the contract through a contract modification listing the item as Government-furnished property.

(3) *Title under Cost-Reimbursement or Time-and-Material Contracts or Cost-Reimbursable contract line items under Fixed-Price contracts.*

(i) Title to all property purchased by the Contractor for which the Contractor is entitled to be reimbursed as a direct item of cost under this contract shall pass to and vest in the Government upon the vendor's delivery of such property.

(ii) Title to all other property, the cost of which is reimbursable to the Contractor, shall pass to and vest in the Government upon—

(A) Issuance of the property for use in contract performance;

(B) Commencement of processing of the property for use in contract performance; or

(C) Reimbursement of the cost of the property by the Government, whichever occurs first.

(f) *Contractor plans and systems.*

(1) Contractors shall establish and implement property management plans, systems, and procedures at the contract, program, site or entity level to enable the following outcomes:

(i) *Acquisition of Property.* The Contractor shall document that all property was acquired consistent with its engineering, production planning, and property control operations.

(ii) *Receipt of Government Property*. The Contractor shall receive Government property and document the receipt, record the information necessary to meet the record requirements of paragraph (f)(1)(iii)(A)(*1*) through (*5*) of this clause, identify as Government owned in a manner appropriate to the type of property (*e.g.*, stamp, tag, mark, or other identification), and manage any discrepancies incident to shipment.

(A) *Government-furnished property*. The Contractor shall furnish a written statement to the Property Administrator containing all relevant facts, such as cause or condition and a recommended course(s) of action, if overages, shortages, or damages and/or other discrepancies are discovered upon receipt of Government-furnished property.

(B) *Contractor-acquired property*. The Contractor shall take all actions necessary to adjust for overages, shortages, damage and/or other discrepancies discovered upon receipt, in shipment of Contractor-acquired property from a vendor or supplier, so as to ensure the proper allocability and allowability of associated costs.

(iii) *Records of Government property*. The Contractor shall create and maintain records of all Government property accountable to the contract, including Government-furnished and Contractor-acquired property.

(A) Property records shall enable a complete, current, auditable record of all transactions and shall, unless otherwise approved by the Property Administrator, contain the following:

(1) The name, part number and description, National Stock Number (if needed for additional item identification tracking and/or disposition), and other data elements as necessary and required in accordance with the terms and conditions of the contract.

(2) Quantity received (or fabricated), issued, and balance-on-hand.

(3) Unit acquisition cost.

(4) Unique-item identifier or equivalent (if available and necessary for individual item tracking).

(5) Unit of measure.

(6) Accountable contract number or equivalent code designation.

(7) Location.

(8) Disposition.

(9) Posting reference and date of transaction.

(10) Date placed in service (if required in accordance with the terms and conditions of the contract).

(B) *Use of a Receipt and Issue System for Government Material*. When approved by the Property Administrator, the Contractor may maintain, in lieu of formal property records, a file of appropriately cross-referenced documents evidencing receipt, issue, and use of material that is issued for immediate consumption.

(iv) *Physical inventory*. The Contractor shall periodically perform, record, and disclose physical inventory results. A final physical inventory shall be performed upon contract completion or termination. The Property Administrator may waive this final inventory requirement, depending on the circumstances (*e.g.*, overall reliability of the Contractor's system or the property is to be transferred to a follow-on contract).

(v) *Subcontractor control*.

(A) The Contractor shall award subcontracts that clearly identify items to be provided and the extent of any restrictions or limitations on their use. The Contractor shall ensure appropriate flow down of contract terms and conditions (*e.g.*, extent of liability for loss of Government property.

(B) The Contractor shall assure its subcontracts are properly administered and reviews are periodically performed to determine the adequacy of the subcontractor's property management system.

(vi) *Reports*. The Contractor shall have a process to create and provide reports of discrepancies, loss of Government property, physical inventory results, audits and self-assessments, corrective actions, and other property-related reports as directed by the Contracting Officer.

(vii) *Relief of stewardship responsibility and liability*. The Contractor shall have a process to enable the prompt recognition, investigation, disclosure and reporting of loss of Government property, including losses that occur at subcontractor or alternate site locations.

(A) This process shall include the corrective actions necessary to prevent recurrence.

(B) Unless otherwise directed by the Property Administrator, the Contractor shall investigate and report to the Government all incidents of property loss as soon as the facts become known. Such reports shall, at a minimum, contain the following information:

(1) Date of incident (if known).

(2) The data elements required under (f)(1)(iii)(A).

(3) Quantity.

(4) Accountable contract number.

(5) A statement indicating current or future need.

(6) Unit acquisition cost, or if applicable, estimated sales proceeds, estimated repair or replacement costs.

(7) All known interests in commingled material of which includes Government material.

(8) Cause and corrective action taken or to be taken to prevent recurrence.

(9) A statement that the Government will receive compensation covering the loss of Government property, in the event the Contractor was or will be reimbursed or compensated.

(10) Copies of all supporting documentation.

(11) Last known location.

(12) A statement that the property did or did not contain sensitive, export controlled, hazardous, or toxic material, and that the appropriate agencies and authorities were notified.

(C) Unless the contract provides otherwise, the Contractor shall be relieved of stewardship responsibility and liability for property when—

(1) Such property is consumed or expended, reasonably and properly, or otherwise accounted for, in the performance of the contract, including reasonable inventory adjustments of material as determined by the Property Administrator;

(2) Property Administrator grants relief of responsibility and liability for loss of Government property;

(3) Property is delivered or shipped from the Contractor's plant, under Government instructions, except when shipment is to a subcontractor or other location of the Contractor; or

(4) Property is disposed of in accordance with paragraphs (j) and (k) of this clause.

(viii) *Utilizing Government property*.

(A) The Contractor shall utilize, consume, move, and store Government Property only as authorized under this contract. The Contractor shall promptly disclose and report Government property in its possession that is excess to contract performance.

(B) Unless otherwise authorized in this contract or by the Property Administrator the Contractor shall not commingle Government material with material not owned by the Government.

(ix) *Maintenance*. The Contractor shall properly maintain Government property. The Contractor's maintenance program shall enable the identification, disclosure, and performance of normal and routine preventative maintenance and repair. The Contractor shall disclose and report to the Property Administrator the need for replacement and/or capital rehabilitation.

(x) *Property closeout*. The Contractor shall promptly perform and report to the Property Administrator contract property closeout, to include reporting, investigating and securing closure of all loss of Government property cases; physically inventorying all property upon termination or completion of this contract; and disposing of items at the time they are determined to be excess to contractual needs.

(2) The Contractor shall establish and maintain Government accounting source data, as may be required by this contract, particularly in the areas of recognition of acquisitions, loss of Government property, and disposition of material and equipment.

(g) Systems analysis.

(1) The Government shall have access to the Contractor's premises and all Government property, at reasonable times, for the purposes of reviewing, inspecting and evaluating the Contractor's property management plan(s), systems, procedures, records, and supporting documentation that pertains to Government property. This access includes all site locations and, with the Contractor's consent, all subcontractor premises.

(2) Records of Government property shall be readily available to authorized Government personnel and shall be appropriately safeguarded.

(3) Should it be determined by the Government that the Contractor's (or subcontractor's) property management practices are inadequate or not acceptable for the effective management and control of Government property under this contract, or present an undue risk to the Government, the Contractor shall prepare a corrective action plan when requested by the Property Administer and take all necessary corrective actions as specified by the schedule within the corrective action plan.

(4) The Contractor shall ensure Government access to subcontractor premises, and all Government property located at subcontractor premises, for the purposes of reviewing, inspecting and evaluating the subcontractor's property management plan, systems, procedures, records, and supporting documentation that pertains to Government property.

(h) *Contractor Liability for Government Property.*

(1) Unless otherwise provided for in the contract, the Contractor shall not be liable for loss of Government property furnished or acquired under this contract, except when any one of the following applies—

(i) The risk is covered by insurance or the Contractor is otherwise reimbursed (to the extent of such insurance or reimbursement). The allowability of insurance costs shall be determined in accordance with 31.205-19.

(ii) Loss of Government property that is the result of willful misconduct or lack of good faith on the part of the Contractor's managerial personnel.

(iii) The Contracting Officer has, in writing, revoked the Government's assumption of risk for loss of Government property due to a determination under paragraph (g) of this clause that the Contractor's property management practices are inadequate, and/or present an undue risk to the Government, and the Contractor failed to take timely corrective action. If the Contractor can establish by clear and convincing evidence that the loss of Government property occurred while the Contractor had adequate property management practices or the loss did not result from the Contractor's failure to maintain adequate property management practices, the Contractor shall not be held liable.

(2) The Contractor shall take all reasonable actions necessary to protect the property from further loss. The Contractor shall separate the damaged and undamaged property, place all the affected property in the best possible order, and take such other action as the Property Administrator directs.

(3) The Contractor shall do nothing to prejudice the Government's rights to recover against third parties for any loss of Government property.

(4) The Contractor shall reimburse the Government for loss of Government property, to the extent that the Contractor is financially liable for such loss, as directed by the Contracting Officer.

(5) Upon the request of the Contracting Officer, the Contractor shall, at the Government's expense, furnish to the Government all reasonable assistance and cooperation, including the prosecution of suit and the execution of instruments of assignment in favor of the Government in obtaining recovery.

(i) *Equitable adjustment*. Equitable adjustments under this clause shall be made in accordance with the procedures of the Changes clause. However, the Government shall not be liable for breach of contract for the following:

(1) Any delay in delivery of Government-furnished property.

(2) Delivery of Government-furnished property in a condition not suitable for its intended use.

(3) An increase, decrease, or substitution of Government-furnished property.

(4) Failure to repair or replace Government property for which the Government is responsible. Standard Form 1428

(j) *Contractor inventory disposal*. Except as otherwise provided for in this contract, the Contractor shall not dispose of Contractor inventory until authorized to do so by the Plant Clearance Officer or authorizing official.

(1) Predisposal requirements.

(i) If the Contractor determines that the property has the potential to fulfill requirements under other contracts, the Contractor, in consultation with the Property Administrator, shall request that the Contracting Officer transfer the property to the contract in question, or provide authorization for use, as appropriate. In lieu of transferring the property, the Contracting Officer may authorize the Contractor to credit the costs of Contractor-acquired property (material only) to the losing contract, and debit the gaining contract with the corresponding cost, when such material is needed for use on another contract. Property no longer needed shall be considered contractor inventory.

(ii) For any remaining Contractor-acquired property, the Contractor may purchase the property at the unit acquisition cost if desired or make reasonable efforts to return unused property to the appropriate supplier at fair market value (less, if applicable, a reasonable restocking fee that is consistent with the supplier's customary practices.)

(2) *Inventory disposal schedules*.

(i) Absent separate contract terms and conditions for property disposition, and provided the property was not reutilized, transferred, or otherwise disposed of, the Contractor, as directed by the Plant Clearance Officer or authorizing official, shall use Standard Form 1428, Inventory Disposal Schedule or electronic equivalent, to identify and report—

(A) Government-furnished property that is no longer required for performance of this contract;

(B) Contractor-acquired property, to which the Government has obtained title under paragraph (e) of this clause, which is no longer required for performance of that contract; and

(C) Termination inventory.

(ii) The Contractor may annotate inventory disposal schedules to identify property the Contractor wishes to purchase from the Government, in the event that the property is offered for sale.

(iii) Separate inventory disposal schedules are required for aircraft in any condition, flight safety critical aircraft parts, and other items as directed by the Plant Clearance Officer.

(iv) The Contractor shall provide the information required by FAR 52.245-1(f)(1)(iii) along with the following:

(A) Any additional information that may facilitate understanding of the property's intended use.

(B) For work-in-progress, the estimated percentage of completion.

(C) For precious metals in raw or bulk form, the type of metal and estimated weight.

(D) For hazardous material or property contaminated with hazardous material, the type of hazardous material.

(E) For metals in mill product form, the form, shape, treatment, hardness, temper, specification (commercial or Government) and dimensions (thickness, width and length).

(v) Property with the same description, condition code, and reporting location may be grouped in a single line item.

(vi) Scrap should be reported by "lot" along with metal content, estimated weight and estimated value.

(3) *Submission requirements*.

(i) The Contractor shall submit inventory disposal schedules to the Plant Clearance Officer no later than—

(A) 30 days following the Contractor's determination that a property item is no longer required for performance of this contract;

(B) 60 days, or such longer period as may be approved by the Plant Clearance Officer, following completion of contract deliveries or performance; or

(C) 120 days, or such longer period as may be approved by the Termination Contracting Officer, following contract termination in whole or in part.

(ii) Unless the Plant Clearance Officer determines otherwise, the Contractor need not identify or report production scrap on inventory disposal schedules, and may process and dispose of production scrap in accordance with its own internal scrap procedures. The processing and disposal of other types of Government-owned scrap will be conducted in accordance with the terms and conditions of the contract or Plant Clearance Officer direction, as appropriate.

(4) *Corrections*. The Plant Clearance Officer may—

(i) Reject a schedule for cause (*e.g.*, contains errors, determined to be inaccurate); and

(ii) Require the Contractor to correct an inventory disposal schedule.

(5) *Postsubmission adjustments*. The Contractor shall notify the Plant Clearance Officer at least 10 working days in advance of its intent to remove an item from an approved inventory disposal schedule. Upon approval of the Plant Clearance Officer, or upon expiration of the notice period, the Contractor may make the necessary adjustments to the inventory schedule.

(6) *Storage*.

(i) The Contractor shall store the property identified on an inventory disposal schedule pending receipt of disposal instructions. The Government's failure to furnish disposal instructions within 120 days following acceptance of an inventory disposal schedule may entitle the Contractor to an equitable adjustment for costs incurred to store such property on or after the 121st day.

(ii) The Contractor shall obtain the Plant Clearance Officer's approval to remove property from the premises where the property is currently located prior to receipt of final disposition instructions. If approval is granted, any costs incurred by the Contractor to transport or store the property shall not increase the price or fee of any Government contract. The storage area shall be appropriate for assuring the property's physical safety and suitability for use. Approval does not relieve the Contractor of any liability for such property under this contract.

(7) Disposition instructions.

(i) The Contractor shall prepare for shipment, deliver f.o.b. origin, or dispose of Contractor inventory as directed by the Plant Clearance Officer. Unless otherwise directed by the Contracting Officer or by the Plant Clearance Officer, the Contractor shall remove and destroy any markings identifying the property as U.S. Government-owned property prior to its disposal.

(ii) The Contracting Officer may require the Contractor to demilitarize the property prior to shipment or disposal. In such cases, the Contractor may be entitled to an equitable adjustment under paragraph (i) of this clause.

(8) *Disposal proceeds*. As directed by the Contracting Officer, the Contractor shall credit the net proceeds from the disposal of Contractor inventory to the contract, or to the Treasury of the United States as miscellaneous receipts.

(9) *Subcontractor inventory disposal schedules*. The Contractor shall require its Subcontractors to submit inventory disposal schedules to the Contractor in accordance with the requirements of paragraph (j)(3) of this clause.

(k) *Abandonment of Government property*.

(1) The Government shall not abandon sensitive property or termination inventory without the Contractor's written consent.

(2) The Government, upon notice to the Contractor, may abandon any nonsensitive property in place, at which time all obligations of the Government regarding such property shall cease.

(3) Absent contract terms and conditions to the contrary, the Government may abandon parts removed and replaced from property as a result of normal maintenance actions, or removed from property as a result of the repair, maintenance, overhaul, or modification process.

(4) The Government has no obligation to restore or rehabilitate the Contractor's premises under any circumstances; however, if Government-furnished property is withdrawn or is unsuitable for the intended use, or if other Government property is substituted, then the equitable adjustment under paragraph (i) of this clause may properly include restoration or rehabilitation costs.

(l) *Communication*. All communications under this clause shall be in writing.

(m) *Contracts outside the United States.* If this contract is to be performed outside of the United States and its outlying areas, the words "Government" and "Government-furnished" (wherever they appear in this clause) shall be construed as "United States Government" and "United States Government-furnished," respectively.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

FAR (Federal Acquisition Regulation): http://farsite.hill.af.mil/vffara.htm

DFARS (Defense Federal Acquisition Regulation Supplement): http://farsite.hill.af.mil/vfdfara.htm

(End of clause)

52.252-4 ALTERATIONS IN CONTRACT (APR 1984)

Portions of this contract are altered as follows:

N/A.

(End of clause)

252.204-7006 BILLING INSTRUCTIONS (OCT 2005)

When submitting a request for payment, the Contractor shall--

(a) Identify the contract line item(s) on the payment request that reasonably reflect contract work performance; and

(b) Separately identify a payment amount for each contract line item included in the payment request.

(End of clause)

252.211-7007 REPORTING OF GOVERNMENT-FURNISHED PROPERTY (AUG 2012)

(a) Definitions. As used in this clause—

``Commercial and Government entity (CAGE) code'' means—

(i) A code assigned by the Defense Logistics Agency Logistics Information Service to identify a commercial or Government entity; or

(ii) A code assigned by a member of the North Atlantic Treaty Organization that the Defense Logistics Agency Logistics Information Service records and maintains in the CAGE master file. The type of code is known as an ``NCAGE code.''

``Contractor-acquired property'' has the meaning given in FAR clause 52.245-1. Upon acceptance by the Government, contractor-acquired property becomes Government-furnished property.

``Government-furnished property'' has the meaning given in FAR clause 52.245-1.

``Item unique identification (IUID)'' means a system of assigning, reporting, and marking DoD property with unique item identifiers that have machine-readable data elements to distinguish an item from all other like and unlike items.

``IUID Registry'' means the DoD data repository that receives input from both industry and Government sources and provides storage of, and access to, data that identifies and describes tangible Government personal property. The IUID Registry is—

(i) The authoritative source of Government unit acquisition cost for items with unique item identification (see DFARS 252.211-7003) that were acquired after January 1, 2004;

(ii) The master data source for Government-furnished property; and

(iii) An authoritative source for establishing the acquisition cost of end-item equipment.

``National stock number (NSN)'' means a 13-digit stock number used to identify items of supply. It consists of a four-digit Federal Supply Code and a nine-digit National Item Identification Number.

``Nomenclature'' means—

(i) The combination of a Government-assigned type designation and an approved item name;

(ii) Names assigned to kinds and groups of products; or

(iii) Formal designations assigned to products by customer or supplier (such as model number or model type, design differentiation, or specific design series or configuration).

``Part or identifying number (PIN)'' means the identifier assigned by the original design activity, or by the controlling nationally recognized standard, that uniquely identifies (relative to that design activity) a specific item.

``Reparable'' means an item, typically in unserviceable condition, furnished to the Contractor for maintenance, repair, modification, or overhaul.

``Serially managed item'' means an item designated by DoD to be uniquely tracked, controlled, or managed in maintenance, repair, and/or supply systems by means of its serial number.

``Supply condition code'' means a classification of materiel in terms of readiness for issue and use or to identify action underway to change the status of materiel (see http://www2.dla.mil/j-6/dlmso/elibrary/manuals/dlm/dlm--pubs.asp).

``Unique item identifier (UII)'' means a set of data elements permanently marked on an item that is globally unique and unambiguous and never changes, in order to provide traceability of the item throughout its total life cycle. The term includes a concatenated UII or a DoD recognized unique identification equivalent.

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

``Unit acquisition cost'' has the meaning given in FAR clause 52.245-1.

(b) Reporting Government-furnished property to the IUID Registry. Except as provided in paragraph (c) of this clause, the Contractor shall report, in accordance with paragraph (f), Government-furnished property to the IUID Registry as follows:--

(1) Up to and including December 31, 2013, report serially managed Government-furnished property with a unit-acquisition cost of $5,000 or greater.

(2) Beginning January 1, 2014, report—

(i) All serially managed Government-furnished property, regardless of unit-acquisition cost; and

(ii) Contractor receipt of non-serially managed items. Unless tracked as an individual item, the Contractor shall report non-serially managed items to the Registry in the same unit of packaging, e.g., original manufacturer's package, box, or container, as it was received.

(c) Exceptions. Paragraph (b) of this clause does not apply to—

(1) Contractor-acquired property;

(2) Property under any statutory leasing authority;

(3) Property to which the Government has acquired a lien or title solely because of partial, advance, progress, or performance-based payments;

(4) Intellectual property or software;

(5) Real property; or

(6) Property released for work in process.

(d) Data for reporting to the IUID Registry. To permit reporting of Government-furnished property to the IUID Registry, the Contractor's property management system shall enable the following data elements in addition to those required by paragraph (f)(1)(iii)(A)(1) through (3), (5), (7), (8), and (10) of the Government Property clause of this contract (FAR 52.245-1):

(1) Received/Sent (shipped) date.

(2) Status code.

(3) Accountable Government contract number.

(4) Commercial and Government Entity (CAGE) code on the accountable Government contract.

(5) Mark record.

(i) Bagged or tagged code (for items too small to individually tag or mark).

(ii) Contents (the type of information recorded on the item, e.g., item internal control number).

(iii) Effective date (date the mark is applied).

(iv) Added or removed code/flag.

(v) Marker code (designates which code is used in the marker identifier, e.g., D=CAGE, UN=DUNS, LD=DODAAC).

(vi) Marker identifier, e.g., Contractor's CAGE code or DUNS number.

(vii) Medium code; how the data is recorded, e.g., barcode, contact memory button.

(viii) Value, e.g., actual text or data string that is recorded in its human-readable form.

(ix) Set (used to group marks when multiple sets exist.

(6) Appropriate supply condition code, required only for reporting of reparables, per Appendix 2 of DoD 4000.25-2-M, Military Standard Transaction Reporting and Accounting Procedures manual (http://www2.dla.mil/j-6/dlmso/elibrary/manuals/dlm/dlm--pubs.asp).

(e) When Government-furnished property is in the possession of subcontractors, Contractors shall ensure that reporting is accomplished using the data elements required in paragraph (d) of this clause.

(f) Procedures for reporting of Government-furnished property. Except as provided in paragraph (c) of this clause, the Contractor shall establish and report to the IUID Registry the information required by FAR clause 52.245-1, paragraphs (e) and (f)(1)(iii), in accordance with the data submission procedures at http://www.acq.osd.mil/dpap/pdi/uid/data_submission_information.html.

(g) Procedures for updating the IUID Registry.

(1) Except as provided in paragraph (g)(2), the Contractor shall update the IUID Registry at https://iuid.logisticsinformationservice.dla.mil/ for changes in status, mark, custody, condition code (for reparables only), or disposition of items that are—

(i) Received by the Contractor;

(ii) Delivered or shipped from the Contractor's plant, under Government instructions, except when shipment is to a subcontractor or other location of the Contractor;

(iii) Consumed or expended, reasonably and properly, or otherwise accounted for, in the performance of the contract as determined by the Government property administrator, including reasonable inventory adjustments;

(iv) Disposed of; or

(v) Transferred to a follow-on or other contract.

(2) The Contractor need not report to the IUID Registry those transactions reported or to be reported to the following DCMA etools:

(i) Plant Clearance Automated Reutilization and Screening System (PCARSS); or

(ii) Lost, Theft, Damaged or Destroyed (LTDD) system.

(3) The contractor shall update the IUID Registry as transactions occur or as otherwise stated in the Contractor's property management procedure.

(End of clause)

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

252.227-7013 RIGHTS IN TECHNICAL DATA--NONCOMMERCIAL ITEMS (FEB 2014)

(a) Definitions. As used in this clause--

(1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

(4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(5) Covered Government support contractor means a contractor (other than a litigation support contractor covered by 252.204-7014) under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort (rather than to directly furnish an end item or service to accomplish a program or effort), provided that the contractor--

(i) Is not affiliated with the prime contractor or a first-tier subcontractor on the program or effort, or with any direct competitor of such prime contractor or any such first-tier subcontractor in furnishing end items or services of the type developed or produced on the program or effort; and

(ii) Receives access to technical data or computer software for performance of a Government contract that contains the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(6) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.

(7) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.

(8) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.

(i) Private expense determinations should be made at the lowest practicable level.

(ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.

(9) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.

(10) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

(11) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(12) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(13) Government purpose rights means the rights to--

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.

(14) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release, or disclose such data or authorize the use or reproduction of the data by persons outside the Government if--

(i) The reproduction, release, disclosure, or use is--

(A) Necessary for emergency repair and overhaul; or

(B) A release or disclosure to--

(1) A covered Government support contractor in performance of its covered Government support contract for use, modification, reproduction, performance, display, or release or disclosure to a person authorized to receive limited rights technical data; or

(2) A foreign government, of technical data other than detailed manufacturing or process data, when use of such databy the foreign government is in the interest of the Government and is required for evaluational or informational purposes;

(ii) The recipient of the technical data is subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and

(iii) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

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

(15) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(16) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

(b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):

(1) Unlimited rights.

The Government shall have unlimited rights in technical data that are--

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with--

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has expired.

(2) Government purpose rights.

(i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data--

(A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause; or

(B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.

(iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-

(A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or

(B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.

(3) Limited rights.

(i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data--

(A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or

(B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.

(iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.

(iv) The Contractor acknowledges that--

(A) Limited rights data are authorized to be released or disclosed to covered Government support contractors;

(B) The Contractor will be notified of such release or disclosure;

(C) The Contractor (or the party asserting restrictions as identified in the limited rights legend) may require each such covered Government support contractor to enter into a non-disclosure agreement directly with the Contractor (or the party asserting restrictions) regarding the covered Government support contractor's use of such data, or alternatively, that the Contractor (or party asserting restrictions) may waive in writing the requirement for a non-disclosure agreement; and

(D) Any such non-disclosure agreement shall address the restrictions on the covered Government support contractor's use of the limited rights data as set forth in the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends. The non-disclosure agreement shall not include any additional terms and conditions unless mutually agreed to by the parties to the non-disclosure agreement.

(E) The Contractor shall provide a copy of any such non-disclosure agreement or waiver to the Contracting Officer, upon request.

(4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(14) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless--

(i) The parties have agreed otherwise; or

(ii) Any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(14) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

(c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.

(d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.

(e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.

(2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.

(3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted--

Technical data to be Furnished With Restrictions \1/	Basis for Assertion \2/	Asserted Rights Category \3/	Name of Person Asserting Restrictions \4/
(LIST)	(LIST)	(LIST)	(LIST)

\1/ If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

\2/ Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

\3/ Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

\4/ Corporation, individual, or other person, as appropriate.
Date _____

Printed Name and Title _____

_____

Signature _____

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:

Government Purpose Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

_____

Expiration Date _____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:

Limited Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

_____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.

(End of legend)

(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:

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

Special License Rights

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No. _____ (Insert contract number) _____, License No. _____ (Insert license identifier) _____. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b)(5) of this clause).

(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

(g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliersthat will deliver technical data with other than unlimited rights, shall--

(1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and

(2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.

(h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.

(2) Nonconforming technical data markings. A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.

(i) Relation to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(j) Limitation on charges for rights in technical data. (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when--

(i) The Government has acquired, by any means, the same or greater rights in the data; or

(ii) The data are available to the public without restrictions.

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

(2) The limitation in paragraph (j)(1) of this clause--

(i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and

(ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.

(k) Applicability to subcontractors or suppliers. (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.

(2) Whenever any technical data for noncommercial items, or for commercial items developed in any part at Government expense, is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, including subcontracts or other contractual instruments for commercial items, and requireits subcontractors or suppliers to do so, without alteration, except to identify the parties. This clause will govern the technical data pertaining to noncommercial items or to any portion of a commercial item that was developed in any part at Government expense, and the clause at 252.227-7015 will govern the technical data pertaining to any portion of a commercial item that was developed exclusively at private expense. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

(3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.

(4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

252.235-7010 Acknowledgment of Support and Disclaimer. (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the **US Army Medical Research Acquisition Activity (USAMRAA)** under Contract No. **W81XWH-15-C-0046**.

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the **US Army Medical Research Acqisition Activity (USAMRAA)**.

(End of clause)

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

PROTECTION OF GOVERNMENT-PROVIDED COMMUNICATIONS SYSTEMS AND OTHER RESOURCES (DEC 2006)(USAMRAA)

The Contractor acknowledges its obligation to protect Government-provided communications systems, and other Government-provided resources, from misuse by its employees. Contractor employees shall not use Government communications systems, or other resources, for unauthorized purposes, such as, but not limited to, those discussed in the Joint Ethics Regulation, DoD 5500.7-R, Paragraphs 2-301a and 2-301b. Upon discovery of such misuses, the Government shall have the sole contractual right to have any such offending Contractor employee removed from the Government contract without any reduction of, or delay in, the Contractor's performance or delivery obligations.

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

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS

ATTACHMENT A001 – Contract Data Requirements List (CDRL) Monthly Progress Reports

ATTACHMENT A002 – Contract Data Requirements List (CDRL) Integrated Master Schedule (IMS)

ATTACHMENT A003 – Contract Data Requirements List (CDRL) Contract Work Breakdown Structure (CWBS)

ATTACHMENT A004 – Contract Data Requirements List (CDRL) Issue Summary Reports (ISM)

[*] = Certain confidential information contained in this document, marked by brackets, is filed 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, Howard B. Rosen, 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: August 3, 2015

/s/ Howard B. Rosen
Howard B. Rosen
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Timothy E. Morris, 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: August 3, 2015

/s/ Timothy E. Morris
Timothy E. Morris
Chief Financial Officer and Head of Business Development
(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), Howard B. Rosen, interim Chief Executive Officer of AcelRx Pharmaceuticals, Inc. (the "Company"), and Timothy E. Morris, 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 June 30, 2015, 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 3rd day of August, 2015.

/s/ Howard B. Rosen
Howard B. Rosen
Interim Chief Executive Officer

/s/ Timothy E. Morris
Timothy E. Morris
Chief Financial Officer and Head of Business Development

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.