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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-33221

HERON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2875566**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
123 Saginaw Drive Redwood City, CA	**94063**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 366-2626

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.

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 Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock, par value $0.01 per share, outstanding as of July 29, 2016 was 39,050,628.

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HERON THERAPEUTICS, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2016

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PART I. FINANCIAL STATEMENTS

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — UNAUDITED

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2016 (unaudited)	December 31, 2015 (See Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,943	$ 75,180
Short-term investments	12,700	55,986
Inventory	3,312	—
Prepaid expenses and other current assets	3,175	3,585
Total current assets	81,130	134,751
Property and equipment, net	4,471	3,049
Other assets	130	45
Total assets	$ 85,731	$ 137,845
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,661	$ 3,300
Accrued clinical liabilities	9,485	5,231
Accrued payroll and employee liabilities	4,674	4,828
Other accrued liabilities	2,512	4,154
Convertible notes payable to related parties, net of discount	2,558	2,222
Total current liabilities	27,890	19,735
Stockholders' equity:		
Common stock	390	361
Additional paid-in capital	546,951	530,617
Accumulated other comprehensive loss	(1)	(40)
Accumulated deficit	(489,499)	(412,828)
Total stockholders' equity	57,841	118,110
Total liabilities and stockholders' equity	$ 85,731	$ 137,845

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 27,286	$ 16,175	$ 43,378	$ 30,679
General and administrative	4,774	4,082	10,141	7,669
Sales and marketing	11,006	2,757	22,859	5,026
Total operating expenses	43,066	23,014	76,378	43,374
Loss from operations	(43,066)	(23,014)	(76,378)	(43,374)
Interest expense, net	(160)	(93)	(293)	(303)
Net loss	(43,226)	(23,107)	(76,671)	(43,677)
Other comprehensive income (loss):				
Unrealized gains (losses) on short-term investments	(2)	—	39	—
Comprehensive loss	$(43,228)	$(23,107)	$(76,632)	$(43,677)
Basic and diluted net loss per share	$ (1.17)	$ (0.74)	$ (2.09)	$ (1.45)
Shares used in computing basic and diluted net loss per share	37,048	31,035	36,639	30,218

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net loss	$(76,671)	$ (43,677)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation expense	11,186	5,691
Depreciation and amortization	489	323
Amortization of debt discount	336	305
Amortization of premium on short-term investments	196	—
Gain on disposal of property and equipment	—	(118)
Changes in operating assets and liabilities:		
Inventory	(3,312)	—
Prepaid expenses and other assets	325	(838)
Accounts payable	5,361	438
Accrued clinical liabilities	4,254	2,531
Accrued payroll and employee-related liabilities	(154)	(447)
Other accrued liabilities	(1,471)	304
Net cash used for operating activities	(59,461)	(35,488)
Investing activities:		
Maturities of short-term investments	43,129	—
Purchases of property and equipment	(1,911)	(531)
Proceeds from sale of property and equipment	—	241
Net cash provided by (used for) investing activities	41,218	(290)
Financing activities:		
Proceeds from purchases under the Employee Stock Purchase Plan	251	118
Proceeds from stock option exercises	4,755	6,306
Net proceeds from sale of common stock	—	128,205
Net cash provided by financing activities	5,006	134,629
Net (decrease) increase in cash and cash equivalents	(13,237)	98,851
Cash and cash equivalents at beginning of period	75,180	72,675
Cash and cash equivalents at end of period	$ 61,943	$171,526

See accompanying notes.

HERON THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements
(unaudited)

In this quarterly report on Form 10-Q, all references to "Heron," the "Company," "we," "our," "us" and similar terms refer to Heron Therapeutics, Inc. Heron Therapeutics®, the Heron logo, SUSTOL® and Biochronomer® are our trademarks. All other trademarks appearing or incorporated by reference into this Quarterly Report on Form 10-Q are the property of their respective owners.

1. Business

Overview

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents.

We are developing three pharmaceutical products for patients suffering from cancer or pain. SUSTOL® (granisetron) Injection, extended release ("SUSTOL") is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting ("CINV"). HTX-019, an intravenous formulation of the neurokinin-1 ("NK_1") receptor antagonist aprepitant, is being developed for the prevention of CINV as an adjunct to other antiemetic agents. HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is being developed for the prevention of post-operative pain.

Liquidity

As of June 30, 2016, we had approximately $74,643,000 in cash, cash equivalents and short-term investments, or $124.6 million in pro-forma cash, cash equivalents and short-term investments adjusting for the first close of our loan agreement announced on August 2, 2016 for up to $100 million. We have incurred significant operating losses and negative cash flows from operations; our accumulated deficit is $489,499,000.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2016. The condensed consolidated balance sheet as of December 31, 2015 has been derived from the audited financial statements as of that date, but does not include all of the information and disclosures required by GAAP. For more complete financial information, these unaudited condensed consolidated financial statements and the notes thereto should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the Securities and Exchange Commission (the "SEC") on February 19, 2016.

3. Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Heron Therapeutics, Inc. and its wholly owned subsidiary, Heron Therapeutics, B.V., which was organized in the Netherlands in March 2015. Heron Therapeutics, B.V. has no operations and no material assets or liabilities and there have been no significant transactions related to Heron Therapeutics, B.V. since its inception.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Our critical accounting policies that involve significant judgment and estimates include accrued clinical liabilities, income taxes, stock-based compensation and pre-launch inventories. Actual results could differ materially from those estimates.

Reclassifications

Certain amounts in the 2015 financial statements have been reclassified to conform to the 2016 presentation.

Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consist of cash and highly liquid investments with original maturities from purchase date of three months or less.

Short-term investments consist of securities with maturities from purchase date of greater than three months. We have classified our short-term investments as available-for-sale securities in the accompanying condensed consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income (loss) and realized gains and losses included in interest income. The cost of securities sold is based on the specific-identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Our bank accounts have been placed under a control agreement in accordance with our Senior Secured Convertible Notes ("Convertible Notes").

Pre-Launch Inventories

We capitalize certain inventory costs prior to regulatory approval and product launch based on management's judgment of probable future commercial use and net realizable value of the inventory. We capitalize pre-launch quantities into inventories when we believe it is probable that: (i) a future economic benefit will be derived from the commercialization of the product; (ii) the U.S. Food and Drug Administration ("FDA") will approve the marketing of the product; and (iii) our process for manufacturing the product is within the specifications that we believe will be approved by the FDA for such product. In evaluating whether it is probable that we will derive future economic benefits from our pre-launch inventories and whether the pre-launch inventories are stated at the lower of cost or market, we consider, among other things, the remaining shelf life of that inventory, the current and expected market conditions, the amount of inventory on hand, and the substance of communications with the FDA during the regulatory approval process. The manufacture of pre-launch inventories involves the risk that the FDA may not approve such product(s) for marketing on a timely basis or at all, and that each approval may require additional or different testing and/or specifications than what was performed in the manufacture of such pre-launch inventory. If any of these risks were to materialize with respect to a given product or if the launch of such product is significantly postponed, we may have to write-off the pre-launch inventories, which could be material. During the first half of 2016, we capitalized approximately $3,312,000 of pre-launch inventory costs associated with SUSTOL.

Earnings per Share

Basic earnings per share ("EPS") is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of common share equivalents. Diluted EPS is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, warrants and common stock underlying Convertible Notes are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive.

Because we have incurred a net loss for all periods presented in the condensed consolidated statements of comprehensive loss, outstanding stock options, warrants and common stock underlying Convertible Notes are not included in the computation of net loss per share because their effect would be anti-dilutive.

The following table includes the number of outstanding stock options, warrants and shares of common stock underlying Convertible Notes not included in the computation as of the dates shown below (in thousands):

	As of June 30,	
	2016	2015
Stock options outstanding	8,747	6,985
Warrants outstanding	600	3,649
Common stock underlying convertible notes outstanding	7,301	6,879

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Unrealized gains and losses on available-for-sale securities are included in other comprehensive loss and represent the difference between our net loss and comprehensive loss for the three-month and six-month periods ended June 30, 2016. Our comprehensive loss for the three-month and six-month periods ended June 30, 2015 was comprised solely of our net loss, and there were no changes in equity from non-owner sources.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 addresses several aspects of the accounting for share-based payment award transactions, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We plan to adopt the provisions of ASU 2016-09 in the first quarter of 2017. We do not expect the adoption of ASU 2016-09 to have a material impact on our results of operations or financial condition.

In February 2016, FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months. In addition, ASU 2016-02 requires both lessees and lessors to disclose certain key information about lease transactions. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We plan to adopt the provisions of ASU 2016-02 in the first quarter of 2019. We do not expect the adoption of ASU 2016-02 to have a material impact on our results of operations or financial condition.

In July 2015, FASB issued ASU No. 2015-11, *Inventory (Topic 330)* ("ASU 2015-11"). ASU 2015-11 requires entities to measure inventory at the lower of cost and net realizable value. Net realizable value is estimated selling prices in the ordinary course of business, less reasonably predicable costs of completion, disposal and transportation. Subsequent measurements are unchanged for inventory measured using LIFO or the retail inventory method. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. We plan to adopt the provisions of ASU 2015-11 in 2017. We do not expect the adoption of ASU 2015-11 to have a material impact on our results of operations or financial condition.

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered

observable and the last unobservable, that may be used to measure fair value, is as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We measure the following financial assets at fair value on a recurring basis. The fair values of these financial assets at June 30, 2016 were as follows (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Balance at June 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)*	Significant Other Observable Inputs (Level 2)*	Significant Unobservable Inputs (Level 3)
Money market funds	$ 55,330	$ 55,330	$ —	$ —
United States corporate debt securities	4,904	—	4,904	—
United States commercial paper	7,796	—	7,796	—
Total	$ 68,030	$ 55,330	$ 12,700	$ —

* There were no significant transfers between level 1 and level 2 investments during the six months ended June 30, 2016.

As of June 30, 2016, short-term investments consisted of approximately $12,700,000 of available-for-sale securities with contractual maturities of one year or less. As of June 30, 2015, we did not hold any investment securities, and our cash equivalents consisted solely of money market funds.

A company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item such as debt issuance costs must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. Unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings and any changes in fair value are recognized in earnings. We have elected to not apply the fair value option to our financial assets and liabilities.

We consider the carrying amount of cash and cash equivalents, receivables, pre-launch inventory, prepaid expenses and other current assets, accounts payable and accrued liabilities to be representative of their respective fair values because of the short-term nature of those instruments.

Unrealized gains and losses associated with our investments, if any, are reported in stockholders' equity. For the three months ended June 30, 2016, we recorded approximately $2,000 in net unrealized losses associated with our short-term investments. For the six months ended June 30, 2016, we recorded approximately $39,000 in net unrealized gains associated with our short-term investments. There were no unrealized gains or losses for the three and six months ended June 30, 2015.

Realized gains and losses associated with our investments, if any, are reported in the statement of comprehensive loss. There were no realized gains or losses for the three and six months ended June 30, 2016 and 2015.

5. Convertible Notes to Related Parties

In April 2011, we entered into a securities purchase agreement for a private placement of up to $4.5 million in Convertible Notes with certain investors, including Tang Capital Partners, LP ("TCP"). TCP is controlled by Tang Capital Management, LLC ("TCM"). The manager of TCM is Kevin C. Tang, who served as a director at the time and currently serves as the Chairman of our Board of Directors. The terms of the Convertible Notes were determined by our independent directors to be no less favorable than terms that would be obtained in an arm's length financing transaction. We received a total of $4.3 million, net of issuance costs, from the issuance of these Convertible Notes.

The Convertible Notes are secured by substantially all of our assets, including placing our bank and investment accounts under a control agreement. The Convertible Notes bear interest at 6% per annum, payable quarterly in cash or in additional principal amount of Convertible Notes, at the election of the purchasers. The Convertible Notes mature on May 2, 2021; however, the holders of the Convertible Notes may require prepayment of the Convertible Notes at any time, at each holder's option.

The Convertible Notes are convertible into shares of our common stock at a rate of 1,250 shares for every $1,000 of outstanding principal due under the Convertible Notes. There is no right to convert the Convertible Notes to the extent that, after giving effect to such conversion, the holder would beneficially own in excess of 9.99% of our outstanding common stock. Each holder of the Convertible Notes can increase or decrease this beneficial ownership conversion limit by written notice to us, which will not be effective until 61 days after delivery of the notice.

As of June 30, 2016, we were in compliance with all covenants under the Convertible Notes. Upon the occurrence of an event of default under the Convertible Notes, the holders of the Convertible Notes have the right to require us to redeem all or a portion of their Convertible Notes.

In 2011, we filed a registration statement with the Securities and Exchange Commission ("SEC") to register for resale 3.5 million shares underlying the Convertible Notes. The registration statement was declared effective on July 29, 2011. The Convertible Note holders have agreed to waive their right to require us to maintain the effectiveness of the registration statement and to register the additional shares underlying the Convertible Notes until they provide notice otherwise.

The Convertible Notes contain an embedded conversion feature that was in-the-money on the issuance dates. Based on an effective fixed conversion rate of 1,250 shares for every $1,000 of principal and accrued interest due under the Convertible Notes, the total conversion benefit at issuance exceeded the loan proceeds. Therefore, a debt discount was recorded in an amount equal to the face value of the Convertible Notes on the issuance dates and we began amortizing the resultant debt discount over the respective 10-year term of the Convertible Notes. During the six months ended June 30, 2016, accrued interest of approximately $171,000 was paid-in-kind and rolled into the Convertible Note principal balance, which resulted in an additional debt discount of approximately $171,000. For the three months ended June 30, 2016 and 2015, interest expense relating to the stated rate was approximately $88,000 and $83,000, respectively, and interest expense relating to the amortization of the debt discount was approximately $170,000 and $154,000, respectively. For the six months ended June 30, 2016 and 2015, interest expense relating to the stated rate was approximately $174,000 and $164,000, respectively, and interest expense relating to the amortization of the debt discount was approximately $336,000 and $305,000, respectively.

As of June 30, 2016, the carrying value of the Convertible Notes was approximately $2,558,000, which is comprised of the $5,840,000 principal amount of the Convertible Notes outstanding, less debt discount of $3,282,000. If the $5,840,000 principal amount of Convertible Notes is converted, we would issue approximately 7,301,000 shares of our common stock.

6. Stockholders' Equity

2015 Common Stock Offering

In June 2015, we sold approximately 5,520,000 shares of our common stock at a public offering price of approximately $24.75 per share. We received total net proceeds of approximately $128,199,000 (net of approximately $8,421,000 in issuance costs) from the sale of the common stock.

Private Placement Warrants

In June 2011, we sold shares of common stock and warrants to purchase common stock in a private placement. A total of 4,000,000 warrants to purchase common stock at an exercise price of $3.60 per share were issued as part of this private placement.

During the six months ended June 30, 2016, warrant holders exercised 2,965,477 warrants under the cashless exercise provision in each such holder's warrant, which resulted in the net issuance of 2,395,700 shares of common stock and no net cash proceeds to us. During the six months ended June 30, 2015, warrant holders exercised 260,480 warrants under the cashless exercise provision in each such holder's warrant, which resulted in the net issuance of 209,607 shares of common stock and no net cash proceeds to us. As of June 30, 2016, all warrants from the June 2011 Private Placement have been exercised.

Stock Option Activity

The following table summarizes the stock option activity for the six months ended June 30, 2016:

	Shares (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance at January 1, 2016	8,435	$ 13.64	7.94
Granted	1,080	$ 20.76	
Exercised	(531)	$ 8.96	
Expired and forfeited	(237)	$ 24.81	
Balance at June 30, 2016	8,747	$ 14.50	7.91

For the six months ended June 30, 2016, 530,840 shares of common stock were issued pursuant to the exercise of stock options, resulting in proceeds to us of approximately $4,755,000. For the six months ended June 30, 2015, 713,381 shares of common stock were issued pursuant to the exercise of stock options, resulting in proceeds to us of approximately $6,306,000.

Stock-Based Compensation

The following table summarizes stock-based compensation expense related to stock-based payment awards granted pursuant to all of our equity compensation arrangements for the three and six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 2,329	$ 919	$ 4,402	$1,725
General and administrative	1,798	1,470	3,465	2,472
Sales and marketing	1,704	752	3,319	1,494
Stock-based compensation expense included in operating expenses	$ 5,831	$ 3,141	$11,186	$5,691
Impact on basic and diluted net loss per share	$ 0.16	$ 0.10	$ 0.31	$ 0.19

As of June 30, 2016, there was approximately $65,205,000 of total unrecognized compensation cost related to non-vested, stock-based payment awards granted under all of our equity compensation plans and all non-plan option grants. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We expect to recognize this compensation cost over a weighted-average period of 2.2 years.

We estimated the fair value of each option grant on the grant date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	June 30,	
	2016	2015
Risk-free interest rate	1.5%	1.7%
Dividend yield	0.0%	0.0%
Volatility	90.6%	91.0%
Expected life (years)	6	6

We estimate the fair value of each purchase right granted under our 1997 Employee Stock Purchase Plan at the beginning of each new offering period using the Black-Scholes option pricing model with the following assumptions:

	June 30,	
	2016	2015
Risk-free interest rate	0.4%	0.1%
Dividend yield	0.0%	0.0%
Volatility	85.1%	59.1%
Expected life (months)	6	6

7. Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding our ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. We continue to maintain a full valuation allowance against our deferred tax assets as of June 30, 2016.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An

uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There have been no material changes in our unrecognized tax benefits since December 31, 2015, and, as such, the disclosures included in our 2015 Annual Report on Form 10-K for the year ended December 31, 2015 continue to be relevant for the six-month period ended June 30, 2016.

8. Subsequent Events

On August 2, 2016, we entered into an agreement with Tang Capital Partners, LP ("TCP") whereby TCP will lend us up to $100 million. The loan has a two-year term and bears interest of 8% per annum. The first close of $50 million occurred on August 5, 2016. The second close of an additional $50 million is subject to the achievement of a corporate milestone. There are no fees, no warrants and no equity conversion feature associated with this transaction. The loan is secured by a second-priority lien on substantially all of our assets. TCP is controlled by Tang Capital Management, LLC ("TCM"). The manager of TCM is Kevin C. Tang, who serves as the Chairman of our Board of Directors. The terms of the loan were determined by our independent directors to be no less favorable than terms that would be obtained in an arm's length financing transaction.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission (the "SEC") on February 19, 2016.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. You can identify forward-looking statements by the use of the words "believe," "expect," "anticipate," "intend," "estimate," "project," "will," "should," "may," "plan," "assume" and other expressions that predict or indicate future events and trends and which do not relate to historical matters. You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control. These risks, uncertainties and other factors may cause our actual results, performance or achievements to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that might cause these differences include the following:

- estimates of the outcome of our New Drug Application ("NDA") resubmission to the U.S. Food and Drug Administration ("FDA") for SUSTOL® (granisetron) Injection, extended release ("SUSTOL") and potential regulatory approval for and commercial launch of SUSTOL, including the timing for potential approval and the potential scope of the product label for the approved indication;
- the possibility that the FDA might not interpret the results of our Phase 3 MAGIC study for SUSTOL for the prevention of delayed chemotherapy-induced nausea and vomiting ("CINV") associated with highly emetogenic chemotherapy regimens to be sufficient to support as broad a label indication as proposed in the NDA;
- whether the Phase 2 study results for HTX-011 are indicative of results in future studies related to HTX-011 and whether the Phase 2 data for HTX-011 will be sufficient to allow the commencement of Phase 3 registration studies for HTX-011;
- the anticipated progress of our current research and development programs for HTX-011, HTX-019 and any other research and development programs we may pursue, including the completion of ongoing clinical trials, initiation of new clinical trials and preclinical testing and the results of clinical and stability studies;

- the anticipated timing of our filing of the NDA for HTX-019;
- the potential market opportunities for SUSTOL, HTX-011 and HTX-019;
- whether safety and efficacy results of our clinical trials and other required tests for approval provide data to warrant potential regulatory approval of SUSTOL or further development of any of our other product candidates;
- if approved, the possibility that the FDA approval of SUSTOL or other future product candidates might entail post-marketing studies and our ability to meet these requirements within the mandated timelines;
- if approved, our ability to comply with standard post-marketing requirements including U.S. federal advertising and promotion laws, federal and state anti-fraud and abuse laws, healthcare information privacy and security laws, safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities for SUSTOL or other future product candidates;
- if approved, the market conditions during the commercial launch of SUSTOL or other future product candidates;
- our ability to successfully market, commercialize and achieve market acceptance for SUSTOL or other future product candidates, including our positioning relative to competing products;
- our ability to successfully develop and achieve regulatory approval for other future product candidates utilizing our proprietary Biochronomer® drug delivery technology ("Biochronomer technology");
- our ability to establish key collaborations for our products and any other future product candidates;
- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;
- unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment;
- our ability to successfully establish and maintain key vendor relationships necessary to manufacture our products;
- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;
- uncertainties associated with obtaining and enforcing patents to protect our products, and our ability to successfully defend ourselves against unforeseen third-party infringement claims;
- our estimates regarding our capital requirements; and
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities.

These forward-looking statements were based on information, plans and estimates at the date of this Quarterly Report on Form 10-Q, and we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. In addition, please see the "Risk Factors" section of this Quarterly Report on Form 10-Q. These risk factors may be updated from time to time by our future filings under the Exchange Act. You should carefully review all information therein.

Overview

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents.

We are developing three pharmaceutical products for patients suffering from cancer or pain. SUSTOL® (granisetron) Injection, extended release ("SUSTOL") is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting ("CINV"). HTX-019, an intravenous formulation of the neurokinin-1 ("NK_1") receptor antagonist aprepitant, is being developed for the prevention of CINV as an adjunct to other antiemetic agents. HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is being developed for the prevention of post-operative pain.

CINV

SUSTOL

SUSTOL, which utilizes our Biochronomer technology, is our long-acting formulation of granisetron for the prevention of CINV. Granisetron, an FDA-approved 5-hydroxytryptamine type 3 ("5-HT_3") receptor antagonist, was selected due to its broad use by physicians based on a well-established record of safety and efficacy. SUSTOL has been shown to maintain therapeutic drug levels of granisetron for 5 days with a single subcutaneous injection and is being developed for the prevention of both acute and delayed CINV associated with emetogenic chemotherapy (as defined under the 2011 CINV guidelines of the American Society of Clinical Oncology ("ASCO; 2011 ASCO CINV Guidelines")). While other 5-HT_3 receptor antagonists are indicated for the prevention of CINV, we believe SUSTOL is the first agent in the class to demonstrate efficacy in reducing the incidence of delayed CINV in patients receiving HEC (as defined under the 2011 ASCO CINV Guidelines) in a randomized Phase 3 study.

Our New Drug Application ("NDA") for SUSTOL, which was assigned a Prescription Drug User Fee Act ("PDUFA") goal date of January 17, 2016 by the FDA, is pending review. In January 2016, we announced that we were notified by the FDA that the FDA would not be taking action by the PDUFA goal date. In April 2016, we announced the FDA had indicated that no substantive deficiencies had been identified with the NDA and labeling discussions had begun.

CINV is one of the most debilitating side effects of chemotherapy, often attributed as a leading cause of premature discontinuation of cancer treatment. Most chemotherapy agents cause some degree of nausea and vomiting. However, the chemotherapy regimens that cause the worst degree of nausea and vomiting are categorized into two groups: moderately emetogenic chemotherapy ("MEC") or highly emetogenic chemotherapy ("HEC") (as defined under the 2011 ASCO CINV Guidelines). Despite advancements in the field, CINV remains a major problem for cancer patients and their caregivers.

In its 2011 guidelines for the prevention of CINV following the administration of MEC or HEC regimens (the 2011 ASCO CINV Guidelines), ASCO recommends the use of 5-HT_3 receptor antagonists, often in combination with other agents such as corticosteroids and/or NK_1 receptor antagonists to achieve optimal control of CINV symptoms.

Nausea and vomiting that occurs within the first 24 hours following the administration of chemotherapy regimens is considered acute CINV, while nausea and vomiting on days 2-5 following the administration of chemotherapy regimens is considered delayed CINV. A particular unmet medical need exists for patients suffering from CINV during the delayed phase. None of the currently available 5-HT_3 receptor antagonists have demonstrated sufficient efficacy to gain approval for the prevention of delayed CINV associated with HEC (as defined under the 2011 ASCO CINV Guidelines).

In 2015, Heron successfully completed a multi-center, placebo-controlled, Phase 3 clinical study of SUSTOL in patients receiving HEC regimens (as defined under the 2011 ASCO CINV Guidelines). This study, known as the MAGIC study, evaluated the efficacy and safety of SUSTOL as part of a three-drug regimen with the intravenous ("IV") NK_1 receptor antagonist fosaprepitant and the corticosteroid dexamethasone. The MAGIC study, which was conducted entirely in the U.S. using the 2011 ASCO CINV Guidelines for classification of emetogenic potential, is the only Phase 3 CINV prophylaxis study in a HEC (as defined under the 2011 ASCO CINV Guidelines) population performed to date to use the currently recommended, standard-of-care, three-drug regimen as a comparator: a 5-HT_3 receptor antagonist, fosaprepitant, and dexamethasone. The study's primary endpoint was achieved. Specifically, the percentage of patients who achieved a Complete Response in the delayed phase was significantly higher in the SUSTOL arm compared with the comparator arm ($p=0.014$). Adverse events reported in the study were generally mild to moderate in severity and of short duration, with the most common being injection site reactions.

SUSTOL was previously the subject of a pivotal Phase 3 clinical trial completed in 2008 that compared SUSTOL to palonosetron (ALOXI; Eisai Inc. and Helsinn Therapeutics (U.S.), Inc.). The results from this study comprised the foundation for the original SUSTOL NDA. In this study, we enrolled more than 1,300 patients and successfully demonstrated that SUSTOL's efficacy in preventing CINV was statistically non-inferior to that of palonosetron. The study was designed to demonstrate the safety and efficacy of SUSTOL in the treatment of CINV following the administration of MEC or HEC regimens (as defined under the then-prevailing Hesketh CINV guidelines) and to establish an effective dose for SUSTOL. Four primary efficacy endpoints were selected: non-inferiority to ALOXI for the prevention of acute and delayed CINV following administration of MEC regimens and acute CINV following administration of HEC regimens (as defined under the then-prevailing Hesketh CINV guidelines); and superiority for the prevention of delayed CINV following administration of HEC regimens (as defined under the then-prevailing Hesketh CINV guidelines).

SUSTOL is not currently approved by the FDA or any other regulatory authority.

HTX-019

HTX-019 is our proprietary intravenous formulation of aprepitant, an NK_1 receptor antagonist for the prevention of CINV. NK_1 receptor antagonists are used in combination with 5-HT_3 receptor antagonists. At present, the only injectable NK_1 receptor antagonist approved in the U.S., EMEND for Injection (fosaprepitant), contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions, infusion site reactions or other adverse reactions in some patients. HTX-019 is formulated without polysorbate 80, and, in a recently completed bioequivalence study in healthy volunteers, HTX-019 was shown to be well-tolerated, and the pharmacokinetic profile of HTX-019 was comparable to IV fosaprepitant in the study. The FDA has stated that achieving bioequivalence to IV fosaprepitant would be sufficient for regulatory approval of HTX-019 under the 505(b)(2) pathway. We intend to file an NDA for HTX-019 in the fourth quarter of 2016 using the 505(b)(2) development pathway.

Pain Management

HTX-011

HTX-011, which utilizes our Biochronomer technology, is our long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. By delivering sustained levels of both a potent anesthetic and an anti-inflammatory agent, HTX-011 was designed to provide extended pain relief while potentially reducing the need for systemically administered pain medications such as opioids, which carry the risk of abuse, addiction and other harmful side effects.

In August 2016, we reported preliminary, positive, top-line efficacy results from two Phase 2 clinical studies of HTX-011 in patients undergoing bunionectomy (Study 208) and inguinal hernia repair (Study 202) and safety data from our ongoing Phase 2 program.

Study 208 – Bunionectomy

Study 208 is a randomized, placebo- and active-controlled, double-blind Phase 2 clinical study in patients undergoing bunionectomy. This study is evaluating the efficacy and safety of two formulations of HTX-011 at 200 mg compared to the standard dose of bupivacaine solution and placebo. Bupivacaine solution is the standard-of-care agent for the management of post-operative pain. In addition, HTX-011 is being evaluated when administered via Mayo Block (nerve block via closed wound injection) or infiltration (open wound injection).

The primary endpoint is the difference as compared to placebo in pain intensity as measured by the Summed Pain Intensity (SPI) score in the first 24 hours post-surgery (SPI 0-24). Key secondary endpoints included comparison to bupivacaine solution, the time to first use of opioid rescue medication, total opioid consumption and difference in pain intensity compared to placebo or bupivacaine solution when administered as a Mayo Block or infiltration. The major findings for our Phase 3 formulation of HTX-011 are as follows:

- There was a 66% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to placebo ($p<0.0001$). There was a 64% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to bupivacaine solution ($p<0.0001$).
- There was a 69% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to placebo ($p<0.0001$). There was a 71% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to bupivacaine solution ($p<0.0001$).

- Significant reductions in pain were maintained through 96 hours post-surgery (SPI 0-96) for all groups: HTX-011 by infiltration versus placebo (p=0.005), HTX-011 by infiltration versus bupivacaine solution (p=0.019), HTX-011 by nerve block versus placebo (p=0.004), and HTX-011 by nerve block versus bupivacaine solution (p=0.007).
- Mean time to first opioid rescue medication was 716% longer than for placebo (p<0.0001) and 167% longer than for bupivacaine solution (p=0.037).
- Over the first 24 hours post-surgery, patients receiving HTX-011 consumed 74% less opioids than placebo patients (p<0.0001) and 67% less than bupivacaine solution patients. Over the first 96 hours post-surgery, patients receiving HTX-011 consumed 53% less opioids than placebo patients (p=0.003) and 50% less than bupivacaine solution patients (p=0.008).

Study 202 – Inguinal Hernia Repair

Study 202 is a randomized, placebo-controlled, double-blind Phase 2 clinical study in patients undergoing inguinal hernia repair. The study is evaluating the efficacy and safety of two formulations of HTX-011 at two doses (200 mg and 400 mg), compared to placebo.

In addition, two routes of administration into the wound (injection and instillation) were evaluated. Instillation into the incision site is an easier and potentially safer route of administration as it avoids multiple injections around the wound (as many as 10 or more in large operations) that carry the risk of venous puncture.

The primary endpoint was the difference as compared to placebo in pain intensity as measured by SPI 0-24. Key secondary endpoints included the time to first use of opioid rescue medication and total opioid consumption. The major findings for the 400 mg dose of our Phase 3 formulation of HTX-011 as compared to placebo are as follows:

- There was a 29% reduction in pain as measured by SPI 0-24 (p=0.008).
- HTX-011 by instillation (28.4% reduction in SPI 0-24) was equally as effective as HTX-011 by injection (29.2% reduction in SPI 0-24).
- The pain reduction was long-lasting, with a statistically significant, 25% reduction through 48 hours (SPI 0-48; p=0.038).
- Mean time to first opioid rescue medication was 110% longer (27.9 hours versus 13.3 hours).
- Mean total opioid consumption was 36% less through 96 hours post-surgery.
- The number of patients that did not take any opioid rescue medication at all through 96 hours post-surgery was approximately double (21% versus 11%).

HTX-011 has been generally well tolerated in the ongoing Phase 2 program, which has involved more than 250 administrations of HTX-011. The most frequent treatment-related adverse events reported have been nausea and vomiting, which occurred at similar rates in active and control patients.

In September 2015, we reported positive, top-line results from a randomized, placebo-controlled, double-blind, Phase 2 clinical trial of HTX-011 in patients undergoing bunionectomy (Study 201). The primary and all key secondary endpoints in this study were achieved, and HTX-011 was generally well-tolerated in the study.

HTX-011 is currently being evaluated in Phase 2 clinical trials in preparation for a broad-based and comprehensive Phase 3 development program.

Biochronomer Technology

Our proprietary Biochronomer technology can deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period of days to weeks with a single subcutaneous injection. Our Biochronomer technology consists of bioerodible polymers that have been the subject of comprehensive animal and human toxicology studies that support the safety of the polymer. When injected into subcutaneous tissue, the polymers undergo controlled hydrolysis, resulting in a controlled, sustained release of the pharmacological agent encapsulated within the Biochronomer-based composition. Furthermore, more than one pharmacological agent can be incorporated into our Biochronomer technology such that multimodal therapy can be delivered with a single injection.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make

estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to clinical trial accruals, income taxes, stock-based compensation and pre-launch inventory. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our critical accounting policies include: accrued clinical liabilities, income taxes, stock-based compensation and pre-launch inventories. There have been no material changes to the accrued clinical liabilities, income taxes or stock-based compensation disclosures included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the SEC on February 19, 2016.

Pre-Launch Inventories

Pre-launch inventories consist primarily of our product candidates prior to the date that we anticipate that such products will receive FDA final marketing approval. We will capitalize pre-launch quantities into inventories when we believe it is probable that: (i) a future economic benefit will be derived from the commercialization of the product; (ii) the FDA will approve the marketing of the product; and (iii) our process for manufacturing the product is within the specifications that we believe will be approved by the FDA for such product. In evaluating whether it is probable that we will derive future economic benefits from our pre-launch inventories and whether the pre-launch inventories are stated at the lower of cost or market, we consider, among other things, the remaining shelf life of that inventory, the current and expected market conditions, the amount of inventory on hand, and the substance of communications with the FDA during the regulatory approval process.

The manufacture of pre-launch inventories involves the risk that the FDA may not approve such product(s) for marketing on a timely basis or at all, and that each approval may require additional or different testing and/or specifications than what was performed in the manufacture of such pre-launch inventory. If any of these risks were to materialize with respect to a given product or if the launch of such product is significantly postponed, we may have to write-off the pre-launch inventories, which could be material.

Recent Accounting Pronouncements

See Note 2 of Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Six Months Ended June 30, 2016 and 2015

Research and Development Expense

Research and development expense consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
SUSTOL-related costs	$ 1,500	$ 7,693	$ 3,461	$15,649
HTX-011-related costs	12,808	2,317	16,072	4,198
HTX-019-related costs	1,473	1,304	2,183	1,802
New product development related costs	3,452	578	4,060	1,063
Personnel and related costs	4,459	2,344	10,851	4,465
Stock-based compensation expense	2,329	919	4,402	1,725
Facility-related costs	677	528	1,161	957
Other	588	492	1,188	820
Total research and development expense	$27,286	$16,175	$43,378	$30,679

For the three months ended June 30, 2016, research and development expense increased to $27.3 million from $16.2 million for the same period in 2015. The increase in research and development expense was primarily due to an increase of $10.5 million in clinical and manufacturing costs associated with our Phase 2 clinical program for HTX-011, as well as an increase in new product development costs of $2.9 million. In addition, the increase was due to an increase in salaries and related expense of $2.1 million to support our development efforts and an increase in stock-based compensation expense of $1.4 million. These increases were partially offset by a decrease of $6.2 million in SUSTOL-related costs due to the completion of our Phase 3 program in May 2015.

For the six months ended June 30, 2016, research and development expense increased to $43.4 million from $30.7 million for the same period in 2015. The increase in research and development expense was primarily due to an increase of $11.9 million in clinical and manufacturing costs associated with our Phase 2 clinical program for HTX-011, as well as an increase in new product development of $3.0 million. In addition, the increase was due to an increase in salaries and related expense of $6.4 million to support our development efforts and an increase in stock-based compensation expense of $2.7 million. These increases were partially offset by a decrease of $12.2 million in SUSTOL-related costs due to the completion of our Phase 3 program in May 2015.

General and Administrative Expense

For the three and six months ended June 30, 2016, general and administrative expense increased to $4.8 million and $10.1 million, respectively, from $4.1 million and $7.7 million, respectively, for the same periods in 2015. The increase in general and administrative expense was primarily due to an increase in stock-based compensation expense, as well as an increase in salaries and related expense and professional fees to support our increased development and pre-commercialization efforts. For the three and six months ended June 30, 2016, general and administrative expense consisted primarily of salaries and related expenses, stock-based compensation expense, professional fees, facility-related costs and insurance expense.

Sales and Marketing Expense

For the three and six months ended June 30, 2016, sales and marketing expense increased to $11.0 million and $22.9 million, respectively, from $2.8 million and $5.0 million, respectively, for the same periods in 2015. The increase in sales and marketing expense was primarily due to an increase in activities in preparation for the commercial launch of SUSTOL, including the hiring and training of a sales force, as well as an increase in stock-based compensation expense. For the three and six months ended June 30, 2016, sales and marketing expense consisted primarily of salaries and related expenses, stock-based compensation expense, professional fees and pre-commercialization costs.

Other Expense, net

For the three and six months ended June 30, 2016, other expense, net, was $0.2 million and $0.3 million, respectively, which was comparable to $0.1 million and $0.3 million, respectively, for the same periods in 2015. For the three and six months ended June 30, 2016 and 2015, other expense, net, primarily consisted of interest expense and amortization of debt discount related to our outstanding Senior Secured Convertible Notes.

Capital Resources and Liquidity

As of June 30, 2016, Heron had approximately $74.6 million in cash, cash equivalents and short-term investments, or $124.6 million in pro-forma cash, cash equivalents and short-term investments adjusting for the first close of our loan agreement announced on August 2, 2016 for up to $100 million. This compares to $131.2 million in cash, cash equivalents and short-term investments as of December 31, 2015.

Heron’s net cash used for operating activities for the three and six months ended June 30, 2016 was $27.1 million and $59.5 million, respectively, compared to net cash used for operating activities of $15.8 million and $35.5 million, respectively, for the same periods in 2015. Heron’s net loss for the three and six months ended June 30, 2016 was $43.2 million and $76.7 million, or $1.17 per share and $2.09 per share, respectively, compared to a net loss of $23.1 million and $43.7 million, or $0.74 per share and $1.45 per share, respectively, for the same periods in 2015. The increases in net cash used for operating activities and net loss in the 2016 periods as compared to the 2015 periods were primarily due to costs incurred in preparation for the commercial launch of SUSTOL, as well as clinical and manufacturing costs related to our Phase 1 and Phase 2 clinical studies for HTX-011 and costs associated with the development of HTX-019.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock and debt financings.

In August 2016, we entered into an agreement with Tang Capital Partners, LP ("TCP") whereby TCP will lend us up to $100 million. The loan has a two-year term and bears interest of 8% per annum. The first close of $50 million occurred on August 5, 2016. The second close of an additional $50 million is subject to the achievement of a corporate milestone. There are no fees, no warrants and no equity conversion feature associated with this transaction. The loan is secured by a second-priority lien on substantially all of our assets. TCP is controlled by Tang Capital Management, LLC ("TCM"). The manager of TCM is Kevin C. Tang, who serves as the Chairman of our Board of Directors. The terms of the loan were determined by our independent directors to be no less favorable than terms that would be obtained in an arm's length financing transaction.

In June 2015, we completed a public offering of common stock whereby we received approximately $128.2 million in proceeds, net of issuance costs.

Our capital requirements going forward will depend on numerous factors, including but not limited to: the scope, rate of progress, results and costs of preclinical testing and clinical trials; an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program, including the timing of clinical trials; the time, cost and outcome involved in seeking other regulatory approvals; scientific progress in our research and development programs; the magnitude and scope of our research and development programs; our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates; the cost and timing of establishing sales, marketing and distribution capabilities if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

We may not be able to raise sufficient additional capital when we need it on favorable terms, or at all. The sale of additional equity in the future may be dilutive to our stockholders. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms.

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts related to any of our product candidates will be successful, that required regulatory approvals will be obtained, or that any products, if introduced, will be successfully marketed or achieve commercial acceptance. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by our failure to achieve significant business objectives, covenants applicable to the Convertible Notes, and numerous other factors.

Contractual Obligations

Below is a summary of fixed payments related to certain contractual obligations (in thousands), consisting solely of our operating lease obligations. This table excludes amounts already recorded on our balance sheet as current liabilities as of June 30, 2016.

	Payment due by period				
	Total	1 year	Less than 1-3 years	3-5 years	More than 5 years
Operating lease obligations	$3,246	$1,298	$ 1,003	$ 945	$ —

The holders of the Senior Secured Convertible Notes may require prepayment of such notes at any time at each holder's option (see Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q). As of June 30, 2016, $5.8 million aggregate principal amount of the Senior Secured Convertible Notes were outstanding.

We also enter into agreements from time to time with clinical sites and clinical research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based in part upon the number of eligible patients enrolled and the length of their participation in the clinical trials. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. At this time, due to the variability associated with clinical site and contract research organization agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital to fund operations. Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate-sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities, such as treasury-backed money market funds, corporate debt securities and commercial paper. As a result of the generally short-term nature of our investments, a 50-basis point movement in market interest rates would not have a material impact on the fair value of our portfolio as of June 30, 2016. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statement of comprehensive loss until the investment is sold or if a reduction in fair value is determined to be a permanent impairment. Our debt obligations on our Convertible Notes carry a fixed interest rate and, as a result, we are not exposed to interest rate risk on our convertible debt. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk and reinvestment risk. We do not have any material foreign currency obligations or other derivative financial instruments.

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, filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC'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 timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during the second quarter of 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q. If any of the following events, described as risks, actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment.

Risks Related to Our Business

The review of the New Drug Application ("NDA") for SUSTOL® (granisetron) Injection, extended release ("SUSTOL") has been subject to numerous delays. Any further delays, changes in expected product label or adverse determinations on this NDA submission could negatively impact our ability to commercialize SUSTOL and harm our long-term prospects.

We resubmitted the NDA for SUSTOL in July 2015, and the U.S. Food and Drug Administration ("FDA") assigned a Prescription Drug User Fee Act goal date of January 17, 2016. Commencing in January 2016, we were notified by the FDA of delays in the review of the SUSTOL NDA, and, in April 2016, we announced that the FDA had indicated that no substantive deficiencies had been

identified with the NDA and that labeling discussions had begun. Even if SUSTOL is approved, any further delays, changes in the expected product label or adverse determinations on this NDA submission could negatively impact our ability to commercialize SUSTOL and may harm our long-term prospects.

We are substantially dependent upon the approval and success of SUSTOL.

The success of our business is dependent upon our ability to develop and commercialize our most advanced product candidate, which we intend to market as SUSTOL, subject to regulatory approval. We have invested a significant portion of our time and financial resources in the development of SUSTOL, which is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting ("CINV") associated with moderately emetogenic chemotherapy ("MEC") or highly emetogenic chemotherapy ("HEC") (as defined under the 2011 ASCO CINV Guidelines). In May 2015, we reported positive, top-line results from our Phase 3 MAGIC study, which evaluated the efficacy and safety of SUSTOL for the prevention of delayed CINV associated with HEC regimens (as defined under the 2011 ASCO CINV Guidelines). SUSTOL, when administered as part of a three-drug regimen with the intravenous neurokinin-1 ("NK_1") receptor antagonist fosaprepitant and corticosteroid dexamethasone, demonstrated a statistically significant benefit in the prevention of delayed CINV compared to the currently recommended, standard-of-care, three-drug regimen. Results from the MAGIC study were included in our NDA for SUSTOL.

We first resubmitted our SUSTOL NDA in September 2012. In March 2013, we received a Complete Response Letter ("CRL"). In the CRL, the FDA identified several remaining issues that needed to be addressed prior to approval of our NDA for SUSTOL, including issues relating to: manufacturing of SUSTOL, the administration of SUSTOL and our analysis of efficacy data for SUSTOL under more recent guidelines classifying chemotherapy regimens. We believe we have addressed these issues in our current resubmission, although there can be no assurance that the FDA will agree (see discussion of communication with the FDA in risk factor above). The FDA's review of our resubmission may not produce positive decisions as to whether:

- SUSTOL is safe and effective in its proposed use(s) and whether its benefits outweigh the risks;
- the labeling for SUSTOL can include our desired product indications covering acute and delayed CINV, for use in both MEC and HEC regimens (as defined under the 2011 ASCO CINV Guidelines); and
- the methods used in manufacturing SUSTOL and the controls used to maintain its quality are adequate to preserve chain of identity, strength, quality and purity.

Our ability to generate revenue in the next few years and our future success, in large part, depends on the approval, scope of the approved product label, requirement for post-approval studies and successful commercialization of SUSTOL. We will not be able to commercialize SUSTOL until we obtain regulatory approval in the U.S. Delays in obtaining regulatory approval for SUSTOL, or the issuance of another CRL by the FDA, would, among other consequences, delay the launch of SUSTOL and impact our ability to raise additional capital, which would have a material adverse effect on our business and financial condition.

If SUSTOL is approved, but does not attain market acceptance by healthcare professionals and patients, our business and results of operations will suffer.

If SUSTOL receives regulatory approval for commercial sale by the FDA, the revenue that we may receive from the sale of SUSTOL may be less than expected and will depend on many factors that are outside of our control. Factors that may affect revenue from SUSTOL, if approved, include:

- the scope of our approved product label;

- the perception of physicians and other members of the health care community of the safety and efficacy and cost-competitiveness relative to that of competing products;
- the cost-effectiveness of our product;
- acceptance by institutional formulary committees;
- patient and physician satisfaction with our product;
- our ability to have SUSTOL manufactured at a commercial production level successfully and on a timely basis;
- the cost and availability of raw materials;
- the size of the potential market for our product;
- our ability to obtain adequate reimbursement from government and third-party payors;
- unfavorable publicity concerning our product or similar products;
- the introduction, availability and acceptance of competing treatments;
- adverse event information relating to our product or products of the same or similar class;
- product liability litigation alleging injuries relating to our product or products of the same or similar class;
- product labeling or product insert language required by the FDA or regulatory authorities in other countries;
- our ability to access third parties to manufacture and distribute our product on acceptable terms;
- regulatory developments related to the manufacture or continued use of our product;
- any post-approval study requirements and the results thereof;
- the extent and effectiveness of sales and marketing and distribution support for our product;
- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting; and
- any other material adverse developments with respect to the potential commercialization of our product.

Our revenue will be adversely affected if, due to these or other factors, our commercialization of SUSTOL does not achieve the acceptance and demand to sustain product revenue growth. If we are unable to successfully commercialize SUSTOL, we may not be able to earn sufficient revenues to continue our business.

We have yet to receive regulatory approval for a product utilizing our proprietary drug delivery technology.

Our proprietary Biochronomer® drug delivery technology has not yet been proven through regulatory approval and successful commercial launch of a product utilizing this technology. We may not be able to substantiate the commercial viability of our drug delivery technology for a variety of reasons, including:

- the failure to receive regulatory approval of a drug utilizing the delivery technology;
- the inability to show consistent results in the quality or quantity of product manufactured utilizing this delivery technology; and
- the inability to manufacture drugs using this delivery platform at a cost-effective price.

In the event we are unable to demonstrate commercial success and viability of products utilizing this delivery technology, our prospects for success and growth would be significantly harmed.

Because the results of clinical studies are not necessarily predictive of future results, we can provide no assurances that HTX-011 or any other of our product candidates will have favorable results in future clinical studies or receive regulatory approval.

Positive results from clinical studies should not be relied upon as evidence that later or larger-scale clinical studies will succeed. Even if our product candidates achieve positive results in early-stage clinical studies, we will be required to demonstrate that these product candidates are safe and effective for use in Phase 3 clinical studies before we can seek regulatory approvals for their commercial sale. Even if our early-stage clinical studies achieve the specified endpoints, the FDA may determine that these data are not sufficient to allow the commencement of Phase 3 clinical studies. There is an extremely high historical rate of failure of product candidates proceeding through clinical studies in our industry. There is no guarantee that the efficacy of any product candidate, including HTX-011, shown in early patient studies will be replicated or maintained in future studies of longer duration and/or larger patient populations. Similarly, favorable safety and tolerability data seen in short-term studies might not be replicated in studies of longer duration and/or larger patient populations. If any product candidate demonstrates insufficient safety or efficacy in any clinical study, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product candidates, then we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

Our product platforms or product development efforts may not produce safe, efficacious or commercially viable products, and, if we are unable to develop new products, our business may suffer.

Our long-term viability and growth will depend upon the successful development of products from our research and development activities. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early-stage clinical trials does not ensure that later-stage or larger-scale clinical trials will be successful. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials and compliance with extensive current good clinical practices (“cGCP”) requirements.

In addition, because we fund the development of our product candidates, we may not be able to continue to fund all such development efforts to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals, or market any approved products. If our drug delivery technologies or product development efforts fail to result in the successful development and commercialization of product candidates, or if new products do not perform as anticipated, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

We rely on third parties to do our preclinical testing and conduct our clinical trials, and their failure to perform their obligations in a timely and competent manner may delay development and commercialization of our product candidates and our business could be substantially harmed.

We have used contract research organizations ("CROs") to oversee our clinical trials for SUSTOL, HTX-011 and HTX-019, and we expect to use the same or similar organizations for our future clinical trials and pipeline programs. There can be no assurance that these CROs will perform their obligations at all times in a competent or timely fashion, and we must rigorously oversee their activities in order to be confident in their conduct of these trials on our behalf. If the CROs fail to commit resources to our product candidates, our clinical programs related to our product candidates could be delayed, terminated or unsuccessful, and we may not be able to obtain regulatory approval for or successfully commercialize them. Different cultural and operational issues in foreign countries could cause delays or unexpected problems with patient enrollment or with the data obtained from those locations. If we experience significant delays in the progress of our clinical trials or experience doubts with respect to the quality of data derived from our clinical trials, we could face significant delays in gaining necessary product approvals.

We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices and the Animal Welfare Act requirements. We, our CROs, and other third parties are required to comply with cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCP, the clinical data generated in the clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our ongoing or future clinical trials comply with cGCP requirements. In addition, all of our clinical trials must be conducted with product produced under cGCP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs and other third parties we may engage to support our development programs are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner, or may fail to perform at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the preclinical results or clinical data they obtain is compromised due to the failure to adhere to test requirements, our clinical protocols, regulatory requirements or for 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 our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If our suppliers and contract manufacturers fail to manufacture SUSTOL in a timely manner or fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for SUSTOL.

We are dependent on third-party manufacturers for the manufacture of our product candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the approval or manufacturing of SUSTOL or any of our product candidates could be delayed, which could harm our results of operations. To date, we have relied on third parties to manufacture and perform important pre-commercialization manufacturing activities for SUSTOL. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture SUSTOL are capable of consistently producing a product that meets all applicable quality

criteria, and that the SUSTOL manufactured is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes of our third-party suppliers and manufacturers, and data supporting the stability of SUSTOL. If our third-party suppliers and manufacturers are not in compliance with current Good Manufacturing Practice ("cGMP") requirements, the approval by regulatory authorities for us to begin marketing a product may be delayed, existing product batches may be compromised, and we may experience delays in the availability of SUSTOL for commercial distribution.

For example, our most recent CRL from the FDA regarding our NDA resubmission for SUSTOL stated that the NDA could not be approved due to, among other issues, deficiencies observed during an inspection of the facilities used by our third-party suppliers and manufacturers to produce SUSTOL. If the FDA is not satisfied with our response and corrective actions taken by these third parties, we may be required to complete additional manufacturing development activities or provide other information to the FDA, which could cause substantial delays in obtaining regulatory approval for SUSTOL, increase our costs and have a material adverse effect on our business and financial condition.

If our suppliers and contract manufacturers are unable to manufacture in commercially viable quantities, we could face delays in our ability to commercialize SUSTOL, and our costs will increase.

To date, SUSTOL has been manufactured primarily in small quantities for clinical trials. If in the future, SUSTOL or any of our product candidates are approved for commercial sale, we will need to be able to consistently manufacture our products in larger quantities and be able to show equivalency for the FDA in the manufacture of product at commercial scale as compared to development batch size. The commercial success of our products will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture in a process that is validated by the FDA. If SUSTOL receives regulatory approval, we plan to scale-up manufacturing for SUSTOL in order to realize important economies of scale. These scale-up activities take time to implement, require additional capital investment, process development and validation studies and regulatory approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time, including product loss due to material failure, equipment failure, vendor error, operator error, labor shortages, inability to obtain material, equipment or transportation, physical or electronic security breaches and natural disasters. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. We may not be able to resolve any such problems in a timely manner, if at all.

We expect to depend on third-party suppliers and contract manufacturers for manufacturing SUSTOL, as well as any future products that we develop; if our contract manufacturers do not perform as expected, our business could suffer.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of any product, including SUSTOL. Our ability to progress and commercialize SUSTOL, as well as any other products or product candidates that we may develop will depend in part on our ability to arrange for other parties to manufacture our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and eventual commercialization, if approved. We currently rely on a small number of third-party manufacturers to produce compounds used in our product development activities and expect to continue to do so to meet the preclinical and clinical requirements of our potential products and for all of our commercial needs. Certain contract manufacturers are, at the present time (and are expected to be for the foreseeable future), our sole resource to manufacture certain key components of SUSTOL, as well as key components for product candidates in clinical and preclinical testing in our research and development program. Although we entered into a single-source, long-term commercial manufacturing agreement for the manufacture of

SUSTOL and have a long-term agreement for the manufacture of our bioerodible polymer, we may not be able to successfully negotiate long-term agreements with any additional third parties and thereby reduce or remove our dependence on a single supplier. We may have difficulties with these manufacturer relationships, and we may not be able to find replacement contract manufacturers on satisfactory terms or on a timely basis. Also, due to regulatory and technical requirements, we may have limited ability to shift production to a different third party should the need arise. We cannot be certain that we could reach agreement on reasonable terms, if at all, with such a manufacturer. Even if we were to reach agreement, the transition of the manufacturing process to a different third party could take a significant amount of time and money, and may not be successful.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our products and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, or fail to scale-up manufacturing processes in a timely manner, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in an enforcement action, such as product recall, or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

SUSTOL, HTX-011, HTX-019 or any of our other product candidates may be in competition with other products for access to the facilities of third parties. Consequently, SUSTOL, HTX-011, HTX-019 or any of our other product candidates may be subject to manufacturing delays if our contractors give other companies' products greater priority than our products. For this and other reasons, our third-party contract manufacturers may not be able to manufacture SUSTOL, HTX-011, HTX-019 or any of our other product candidates in a cost-effective or timely manner. If not manufactured in a timely manner, the clinical development of any of our product candidates or their submission for regulatory approval could be delayed, and our ability to deliver products to market on a timely basis could be impaired. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

Certain of the components used in the manufacture of SUSTOL, HTX-011, HTX-019 and our other product candidates are sourced from a single vendor.

Some of the critical materials and components used in manufacturing SUSTOL, HTX-011, HTX-019 and our other product candidates are sourced from single suppliers. An interruption in the supply of a key material could significantly delay commercialization of SUSTOL, if approved, our research and development process or increase our expenses for commercialization or development products. Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in the technologies in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source of a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required or if the materials traditionally have not been used in pharmaceutical products.

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

We are currently developing an internal sales organization for the sale, marketing and distribution of SUSTOL, or for any other products we may develop. In order to successfully commercialize SUSTOL or any other product, we must build our sales, marketing, distribution and other non-technical capabilities or make arrangements with third parties to perform these services. The establishment and development of a sales organization to market SUSTOL and our other product candidates has been and will continue to be expensive and time consuming and could delay product launch, and we cannot be certain that we will be able to successfully develop this capacity. 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 product revenue and may not become profitable.

If we are unable to recruit and retain skilled employees, we may not be able to achieve our objectives.

We depend on a small number of key management and technical personnel. Retaining our current employees and recruiting qualified personnel to perform future research and development and commercialization work will be critical to our success. Competition is always present for highly skilled and experienced personnel, and an inability to recruit or retain sufficient skilled personnel could result in delays in our business growth and development and adversely impact our research and development or commercial activities. If we lose key members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

Our business strategy may include acquisitions of other businesses, products or product licenses. We may not be able to successfully manage such activities.

We may engage in strategic transactions that could cause us to incur contingent liabilities, commitments, or significant expense. In the course of pursuing strategic opportunities, we may evaluate potential acquisitions or investments in strategic technologies, products, or businesses. Future acquisitions or investments could subject us to a number of risks, including, but not limited to:

- our inability to appropriately evaluate and take into consideration the potential uncertainties associated with the other party to such a transaction, including but not limited to the prospects of that party and their existing products or product candidates and regulatory approvals;
- difficulties associated with realizing the perceived potential for commercial success with respect to any acquired technology, product, or business;
- our ability to effectively integrate any new technology, product, and/or business including personnel, intellectual property or business relationships into our company;
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs and/or assumption of liabilities; and
- the distraction of our management from our existing product development programs and initiatives in pursuing an acquisition.

In connection with an acquisition, we must estimate the value of the transaction by making certain assumptions that may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Any strategic transaction we may pursue may not result in the benefits we initially anticipate, and/or result in costs that end up outweighing the benefits, and may adversely impact our financial condition and be detrimental to our future business prospects.

Our business strategy may include entry into collaborative agreements. We may not be able to enter into collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our current business strategy may include the entry into collaborative agreements for the development and commercialization of our products and product candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to our research activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators we may work with in the future, we may rely significantly on them to, among other activities:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market for or with us any commercial products that result from our collaborations.

If we do not consummate collaborative agreements, we may use our financial resources more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative relationships, our business prospects could suffer.

Risks Related to Our Financial Condition

We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

We have incurred significant operating losses and negative cash flows from operations and had an accumulated deficit of $489.5 million through June 30, 2016. Even if SUSTOL is approved, we expect to continue to generate substantial losses over at least the next several years as we:

- continue to develop our sales and marketing organization and commence commercialization of SUSTOL, if approved;
- expand product development activities with respect to our product candidates;
- conduct preclinical development and clinical trials for our product candidates;
- pursue regulatory approvals for any current or future product candidates; and
- engage in commercialization efforts for any future approved product candidates.

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, on:

- the number of product candidates we pursue;
- the progress of our research and development programs for our product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our product candidates, whether such approvals are obtained and the scope of any approved product label;
- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the costs of potential litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

To achieve and sustain profitability, we must, alone or in cooperation with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. If SUSTOL is approved for commercialization, we must successfully launch and commercialize the product. If SUSTOL is not approved, we will likely experience significant delays before we begin to recognize meaningful levels of revenue, if ever. We will incur substantial expenses in our efforts to develop and commercialize our products and we may never generate sufficient revenue to become profitable or to sustain profitability.

Additional capital may be needed in the future to enable us to implement our business plan, and we may be unable to raise capital, which would force us to limit or cease our operations and related product development programs.

As of June 30, 2016, Heron had approximately $74.6 million in cash, cash equivalents and short-term investments, or $124.6 million in pro-forma cash, cash equivalents and short-term investments adjusting for the first close of our loan agreement announced on August 2, 2016 for up to $100 million. Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock and debt financings. Our capital requirements going forward will depend on numerous factors, including but not limited to: the scope, rate of progress, results and costs of preclinical testing and clinical trials; an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program, including the timing of clinical trials; the time, cost and outcome involved in seeking other regulatory approvals; scientific progress in our research and development programs; the magnitude and scope of our research and development programs; our ability to establish and maintain strategic

collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates; the cost and timing of establishing sales, marketing and distribution capabilities if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

We may not be able to raise additional capital when needed or desired, or we may need to raise additional capital on unfavorable terms, which could result in dilution to existing stockholders.

We may not be able to raise sufficient additional capital when we need it on favorable terms, or at all. If we are unable to obtain adequate funds, we may be required to curtail significantly or cease our operations.

The timing and degree of any future capital requirements will depend on many factors, including:

- the status of regulatory approval of any pending applications with the FDA, or other regulators, as the case may be, and the costs involved with pursuing regulatory approvals;
- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of preclinical testing and clinical trials;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates;
- the cost and timing of establishing sales and marketing capabilities if we commercialize any products independently; and
- the cost of establishing supply arrangements for clinical and commercial development of our product candidates and any products that we may develop.

If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment, and such issuance may adversely affect the market price of our common stock. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. Our Senior Secured Convertible Notes (“Convertible Notes”) also include restrictions on our use of cash and financial activities and both the Convertible Notes and the Subordinated Secured Promissory Note issued in August 2016 (the “Subordinated Secured Note”) are secured by liens on substantially all of our assets. In the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products on terms that are not favorable to us or require us to enter into a collaboration arrangement that we would otherwise seek to develop and commercialize ourselves. If adequate funds are not available, we may default on our indebtedness, be required to delay, reduce the scope of, or eliminate one or more of our product development programs and reduce personnel-related and other costs, which would have a material adverse effect on our business.

Provisions contained in our debt instruments limit our ability to incur additional indebtedness.

The Convertible Notes and the Subordinated Secured Note (collectively, the “Secured Notes”) are secured by substantially all of our assets, including our bank and investment accounts, and the terms of the Secured Notes require us to seek approval from the holders of the Secured Notes before taking certain actions, including incurring certain additional indebtedness or modifying the terms of certain existing indebtedness. The Secured Notes also include events of default which include any default of our financial obligations under certain material contracts we may enter into. In addition, potential third-party lenders may be unwilling to subordinate new debt to the Secured Notes. As a result, we may not be able to raise funds through the issuance of debt in the future, which could impair our ability to finance our business obligations or pursue business expansion initiatives.

We could be exposed to significant product liability claims that could be time-consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our product candidates and products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug reactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time.

Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our products, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could also significantly harm our reputation and delay market acceptance of our products.

The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.

Our investments of cash, cash equivalents and short-term investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

Risks Related to Our Industry

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we have incurred significant expenses in developing SUSTOL and, even if approved and depending on the scope of the approved product label, it may not result in a commercially viable product. Before obtaining regulatory approvals for the commercial sale of any products, we, or our potential partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and will continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials.

The outcome of clinical testing is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later stage clinical trials. In addition, regulations are not static, and regulatory agencies, including the FDA, alter their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfying FDA, and other regulatory agencies', requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product candidate. Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials.

Factors that could impede our ability to generate commercially viable products through the conduct of clinical trials include:

- insufficient funds to conduct clinical trials;
- the inability to find partners, if necessary, for support including research, development, manufacturing or clinical needs;
- the failure of tests or studies necessary to submit an NDA, such as clinical studies, bioequivalence studies in support of a 505(b)(2) regulatory filing, or stability studies, to meet the required standards;
- the failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- the failure by us or third-party investigators, CROs, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- the failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- any delay in completion of clinical trials, resulting in increased costs; and
- the inability to obtain regulatory approval of our product candidates following completion of clinical trials, or delays in obtaining such approvals.

There can be no assurance that if our clinical trials are successfully initiated and completed we will be able to obtain approval by the FDA in the U.S. or similar regulatory authorities elsewhere in the world in a timely manner, if at all. If we fail to successfully develop and commercialize one or more of our product candidates, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

Delays in clinical testing could increase our costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Before we can receive regulatory approval for the commercial sale of our potential products, the FDA and comparable authorities in non-U.S. jurisdictions require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Significant delays in preclinical and clinical testing could materially impact our product development costs and delay regulatory approval of our product candidates. Our ability to complete clinical trials in a timely manner could be impacted by, among other factors:

- delay or failure in reaching agreement with the FDA or comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delay or failure in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board (“IRB”) approval or the approval of other reviewing entities, including comparable foreign entities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

- delay or failure in obtaining clinical materials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- feedback from the FDA, the IRB, data safety monitoring boards, or comparable foreign entities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol;
- decision by the FDA, the IRB, comparable foreign regulatory entities, or recommendation by a data safety monitoring board or comparable foreign regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug;
- manufacturing issues, including problems with manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials; and
- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the ability to obtain and maintain patient consents, whether enrolled subjects drop out before completion, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their activities, we have limited influence over their actual performance.

Our failure to successfully establish, recruit for, and oversee our clinical trials could delay our product development efforts and negatively impact our business. If we experience delays in the completion of any ongoing study, the commercial prospects of HTX-011, HTX-019 or any of our other product candidates could be harmed, and our ability to generate product revenue will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidates' development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may not obtain regulatory approval for any of our product candidates. Regulatory approval may also be delayed or revoked or may impose limitations on the indicated uses of a proposed product. If we are unable to obtain regulatory approval for SUSTOL or any of our other product candidates, our business will be substantially harmed.

The process for obtaining regulatory approval of a new drug is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. Any product that we or our potential future collaborative partners develop must receive all necessary regulatory agency approvals or clearances before it may be marketed in the U.S. or other countries. Human pharmaceutical products are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the U.S. and similar health authorities in foreign countries. We may not receive necessary regulatory approvals or clearances to market SUSTOL or any other product candidate in the U.S. or in other jurisdictions, as a result of changes in regulatory policies prior to approval or other events. Additionally, data obtained from preclinical and clinical activities, or from stability or bioequivalence studies, are susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances.

SUSTOL or any of our other product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that the product candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- the failure of third parties to manage and conduct the trials or perform necessary oversight to meet expected deadlines or to comply with regulatory requirements;
- failure to demonstrate that the product candidate’s clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable non-U.S. regulatory authority may require additional preclinical or clinical data to support approval, such as confirmatory studies and other data or studies to address questions or concerns that may arise during the FDA review process.

Even if granted, regulatory approvals may include significant limitations on the uses for which products may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in warning letters, imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruption of clinical trials or manufacturing, injunctions and criminal prosecution.

In addition, the marketing and manufacturing of products are subject to continuing FDA review, and later discovery of previously unknown problems with a product, its manufacture or its marketing may result in the FDA requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market.

Failure to obtain regulatory approval in international jurisdictions would prevent SUSTOL or any of our other product candidates from being marketed abroad.

In the event we pursue the right to market and sell SUSTOL or any other product candidates in jurisdictions other than the U.S., we would be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements in each foreign country. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. In the event we choose to pursue them, we may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we are unable in the future to obtain approval of a product candidate by regulatory authorities in non-U.S. jurisdictions, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Even if SUSTOL or any of our other product candidates receives regulatory approval, it may still face future development and regulatory difficulties. If we fail to comply with continuing federal, state and foreign regulations, we could lose our approvals to market drugs, and our business would be seriously harmed.

Even if we obtain regulatory approval for SUSTOL or any of our other product candidates, it would be subject to ongoing requirements of the FDA and comparable foreign regulatory authorities, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping, and reporting of safety and other post-market information. Following initial regulatory approval of any drugs we may develop, including SUSTOL, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that may be reported after drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;

- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Additionally, such regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use or other inappropriate sales and marketing activities. Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice, and the Department of Health and Human Services' Office of Inspector General. Violations of applicable advertising and promotion laws and regulations, including promotion of products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business. If SUSTOL is approved, we will also be required to comply with the requirements to submit to governmental authorities information on payments to physicians and certain other third parties; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business.

We cannot predict whether any commercial use of our product candidates, if approved, will produce undesirable or unintended side effects that have not been evident in clinical trials conducted for such product candidates to date. Additionally, incidents of product misuse may occur. These events, including the reporting of adverse safety events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

We face intense competition from other companies developing products for the prevention of CINV or post-operative pain.

SUSTOL, if approved, will face significant competition upon commercial launch. In particular, competition may come from: ALOXI® (palonosetron; Eisai Inc. and Helsinn Therapeutics (U.S.), Inc.); AKYNZEO® (palonosetron/netupitant; Eisai Inc. and Helsinn Therapeutics (U.S.), Inc.); SANCUSO® (granisetron transdermal patch; Kyowa Kirin, Inc.); and generic forms of granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL) and ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN). Generic forms of palonosetron are also likely to be available after September 2018. If we are able to successfully develop HTX-019 for the treatment of CINV, we will compete with other NK_1 receptor antagonists, such as Merck & Co, Inc.'s EMEND® for Injection (fosaprepitant) and Tesaro, Inc.'s VARUBI™ (rolapitant).

If we are able to successfully develop HTX-011 for the prevention of post-operative pain, we will compete with Marcaine (bupivacaine; Hospira, Inc.) and generic forms of bupivacaine, Naropin (ropivacaine; Fresenius Kabi USA, LLC) and generic forms of ropivacaine, and EXPAREL® (bupivacaine liposome injectable suspension; Pacira Pharmaceuticals, Inc.).

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or

less costly than ours, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Our products may face competition from lower cost generic products offered by our competitors.

Pricing for therapeutics can be extremely competitive, and strict formulary guidelines enforced by payors may create significant challenges in the acceptance and profitability of branded products. The market for generic products can be very lucrative, and it is dominated by companies that may have much larger distribution capabilities than we may have in the future. It can be very difficult to predict the timing of the launch of generic products given the commonality of litigation with manufacturers over anticipated patent expiration. Our inability to accurately foresee and plan for generic product launches that may compete with our products may significantly impact our potential revenues from such products. Upon the expiration or loss of patent protection for a branded product, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a manufacturer of a generic version of a drug that may compete with one of our products, we could quickly lose a significant portion of our sales of that product. The inability for a branded product we may sell to successfully compete against generic products could negatively impact sales of our product, reduce our ability to grow our business, and significantly harm our business prospects.

If we cannot establish pricing of our product candidates acceptable to the U.S. or foreign governments, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales will be severely hindered.

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect our ability to generate adequate revenues and gross margins to make the products we develop commercially viable. Our ability to commercialize any product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of such products and related treatments and for what uses reimbursement will be provided.

In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, reducing the cost of prescription pharmaceuticals and reforming the Medicare and Medicaid systems. For example, the 2010 Patient Protection and Affordable Care Act ("PPACA") encourages comparative effectiveness research. Any adverse findings for our products from such research may negatively impact reimbursement available for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly asking manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Further, the trend toward managed health care in the U.S., which could significantly influence the purchase of health care services and products, may result in lower prices for our products, if they are approved for marketing. While we cannot predict whether any legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

If we cannot arrange for adequate third-party reimbursement for our products, our future revenue will suffer.

In both domestic and foreign markets, sales of our potential products, including SUSTOL, will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not

be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. Reimbursement policies utilized by our collaborators or ourselves may be challenged by regulatory entities, with resultant fines, negative publicity and the need to implement changes that reduce the utilization of our products. If any products we develop do not receive adequate reimbursement, our revenue could be severely limited.

The pharmaceutical industry is subject to significant regulation and oversight pursuant to anti-kickback laws, false claims statutes, and anti-corruption laws, which may result in significant additional expense and limit our ability to commercialize our products. In addition, any failure to comply with these regulations could result in substantial fines or penalties.

In the U.S., upon commercial launch of a product, we will be subject to health care fraud and abuse regulations that are enforced by both the federal government and the states in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product with marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products with marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following:

- the Federal health care programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal health care programs that are false or fraudulent. This false claims liability may attach in the event that a company is found to have knowingly submitted false average sales price, best price or other pricing data to the government or to have unlawfully promoted its products;
- federal "sunshine" laws, now known as Open Payments, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians and teaching hospitals; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened many of these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Finally, some states such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws.

In addition, a number of states have laws that require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other health care professionals and entities. Similarly, the federal Physician Payments Sunshine Act within PPACA requires pharmaceutical companies to report to the federal government certain payments to physicians and teaching hospitals. The Physician Payments Sunshine Act provisions required manufacturers that participate in federal health care programs to begin collecting such information after a six-month period following commercial launch of a product; however state law equivalents may require compliance beginning at commercial launch.

In addition, we may in the future be subject to the Foreign Corrupt Practices Act of 1997 ("FCPA"). The FCPA and 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 U.S. 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.

Changes in laws affecting the healthcare industry could also adversely affect our revenues and profitability, including new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, healthcare availability, and product pricing and marketing. Changes in FDA regulations and regulations issued by other regulatory agencies inside and outside of the U.S., including new or different approval requirements, timelines and processes, may also delay or prevent the approval of product candidates, require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, like Medicare and Medicaid, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Health care reform could increase our expenses and adversely affect the commercial success of our products.

The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately upon enactment of the law, and others of which are scheduled to take effect over the next several years. For example, the PPACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in

the U.S. The PPACA also requires increased disclosure obligations—including those required under the "sunshine" laws—and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. These and other aspects of the PPACA, including the regulations that may be imposed in connection with the implementation of the PPACA, could increase our expenses and adversely affect our ability to successfully commercialize our products and product candidates.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We are subject to certain data privacy and security requirements, which are very complex and difficult to comply with at times. Any failure to ensure adherence to these requirements could subject us to fines and penalties, and damage our reputation.

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, which govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe products we may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). We are not a HIPAA covered entity, do not intend to become one, and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable

information of clinical trial participants and employees. Similarly, our third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Our use of hazardous materials could subject us to liabilities, fines and sanctions.

Our laboratory and clinical testing sometimes involve use of hazardous, radioactive or otherwise toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials.

Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result, and we could also be subject to fines and penalties and such liability and costs could exceed our financial resources. If we fail to comply with these regulations and standards or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. Compliance with environmental and other laws may be expensive and current or future regulations may impair our product development efforts.

Risks Related to Our Intellectual Property

If we are unable to adequately protect or enforce our intellectual property rights, we may lose valuable assets or incur costly litigation to protect our rights.

Our success will depend in part on our ability to obtain patents and maintain trade secret protection, as well as successfully defending these patents against challenges, while operating without infringing the proprietary rights of others. We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. As of June 30, 2016, we had a total of 15 issued U.S. patents and an additional 47 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2017 and March 2026. Currently, SUSTOL is covered by 7 patents issued in the U.S. and by 26 patents issued in foreign countries including Austria, Belgium, Canada, Denmark, the EU, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. U.S. patents covering SUSTOL have expiration dates ranging from May 2021 to November 2024; foreign patents covering SUSTOL have expiration dates ranging from May 2021 to September 2025. Our policy is to actively seek patent protection in the United States and to pursue equivalent patent claims in selected foreign countries, thereby seeking patent coverage for novel technologies and compositions of matter that may be commercially important to the development of our business. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our existing patents may not cover future products, additional patents may not be issued, and current patents, or patents issued in the future, may not provide meaningful protection or prove to be of commercial benefit.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications may not issue into

patents, and any issued patents may not provide sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive technologies or may be held invalid if challenged or circumvented. Patent applications in the U.S. are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. laws.

We may enter into collaborative agreements which may subject us to obligations that must be fulfilled and require us to manage complex relationships with third parties. In the future, if we are unable to meet our obligations or manage our relationships with our collaborators under these agreements our revenue may decrease. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration, requiring us to divert management time and resources to such dispute.

Because the patent positions of pharmaceutical and biotechnology companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to products and processes, including ours, in the U.S., remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. The recently enacted America Invents Act, which reformed certain patent laws in the U.S., may create additional uncertainty. Patents, if issued, may be challenged, invalidated or circumvented. As more products are commercialized using our proprietary product platforms, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We may infringe on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to the composition of a variety of polymers, specific products, product

groups and processing technology, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. Therefore, there is risk that third parties may make claims of infringement against our products or technologies. We may not be able to design around the patented technologies or inventions of others, and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing the proprietary rights of others, we will not be able to develop or commercialize some or all of our product candidates, and consequently will not be able to earn product revenue.

There is considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by any future manufacture, use or sale of our products. In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights. We may have to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patent or trademark applications. For example, in the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file Abbreviated New Drug Applications ("ANDA") and, in doing so, certify that their products either do not infringe the innovator's patents or that the innovator's patents are invalid. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known as "Paragraph IV" litigation in the U.S. These litigations could result in new or additional generic competition to any of our products that may be marketed in the future and a potential reduction in product revenue.

If we are required to defend ourselves in a patent-infringement lawsuit, we could incur substantial costs, and the lawsuit could divert management attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to redesign affected products or obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the U.S. or in countries outside the U.S., or litigation against our partners may be costly and time-consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets, in general, and in particular with respect to biotech and life sciences companies, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility. Our stock price may be particularly volatile given the stage of our business, which is pre-commercial and subject to more speculation by stock market investors.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and our company's resources.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, our certificate of incorporation and our bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, 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 or remove our board of directors. These provisions include authorizing the issuance of "blank check" preferred stock without any need for action by stockholders.

In addition, Section 203 of Delaware General Corporation Law, which is applicable to us, may discourage, delay or prevent a change in control of our company by prohibiting stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain approvals are obtained.

Conversion of our Convertible Notes would result in substantial dilution for our existing stockholders.

Our outstanding Convertible Notes bear interest at a rate of 6% per annum, payable quarterly in cash or in kind, at the election of the holders of the Convertible Notes. The Convertible Notes are convertible into shares of our common stock at a rate of 1,250 shares for every $1,000 of principal and accrued interest that is being converted. In the event the holders of the Convertible Notes were to opt to convert in full the outstanding principal and accrued interest due under the Convertible Notes as of June 30, 2016, we would be required to issue an aggregate of approximately 7,300,751 shares, representing approximately 16% of our outstanding shares, after giving effect to such conversion. This would result in substantial dilution of our existing stockholders.

Concentration in stockholder ownership could influence strategic actions.

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a significant percentage of our outstanding common stock. Based on information set forth in a Form 4 filed with the SEC on June 20, 2016, the beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, of Tang Capital Partners, LP ("TCP") was approximately 5,873,891 shares, or approximately 15%. In addition, as of June 30, 2016, TCP has the right to acquire approximately 5,840,601 shares upon conversion of the Convertible Notes.

Such a substantial concentration of common stock ownership or control could significantly influence corporate actions on various strategic matters, including, for example, receptivity to collaborations and merger or sale overtures to the extent that stockholder approval is required for such transactions. Further, covenants contained in the Secured Notes would require approval from the noteholders for any change of control transaction we might consider. Accordingly, we may only be able to pursue transactions that are supported by these large stockholders. In addition, the conversion of the Convertible Notes, the exercise of these warrants, or the sale by our current stockholders of a substantial number of shares, or the expectation that such exercises or sales may occur, could significantly reduce the market price of our common stock.

Future utilization of net operating loss carry-forwards may be impaired due to recent changes in ownership.

We believe our net operating losses and tax attributes may be subject to limitation under Section 382 of the Internal Revenue Code of 1986. As a result, our deferred tax assets, and related valuation allowance, have been reduced for the estimated impact of the net operating losses and credits that we currently estimate may expire unused. Utilization of our remaining net operating loss and research and development credit carry-forwards may still be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions for ownership changes after December 31, 2015, including those that may come in conjunction with future equity financings or market trades by our stockholders.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to uncertainty;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our stockholders.

These actions could cause the market price of our common stock to experience periods of volatility.

If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our common stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the NASDAQ Stock Market or other regulatory authorities.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the source of gain for our stockholders.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our current and future earnings to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

In August 2016, we entered into an agreement with Tang Capital Partners, LP (“TCP”) whereby TCP will lend us up to $100 million. The loan has a two-year term and bears interest of 8% per annum. The first close of $50 million occurred on August 5, 2016. The second close of an additional $50 million is subject to the achievement of a corporate milestone. There are no fees, no warrants and no equity conversion feature associated with this transaction. The loan is secured by a second-priority lien on substantially all of our assets. TCP is controlled by Tang Capital Management, LLC (“TCM”). The manager of TCM is Kevin C. Tang, who serves as the Chairman of our Board of Directors. The terms of the loan were determined by our independent directors to be no less favorable than terms that would be obtained in an arm’s length financing transaction.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	Fourth Amendment to Lease, effective as of April 11, 2016, by and between Heron Therapeutics, Inc. and Metropolitan Life Insurance Company (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on April 15, 2016)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification 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 Extension Definition
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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.

Heron Therapeutics, Inc.

Date: August 8, 2016

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.
Chief Executive Officer
(As Principal Executive Officer)

/s/ Brian G. Drazba

Brian G. Drazba
Vice President, Finance and Chief Financial Officer
(As Principal Financial and Accounting Officer)

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HERON THERAPEUTICS, INC.

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EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Barry D. Quart, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Heron Therapeutics, 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 8, 2016

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.
Chief Executive Officer (As Principal Executive Officer)

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Heron Therapeutics, 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 8, 2016

/s/ Brian G. Drazba

Brian G. Drazba
Vice President, Finance and
Chief Financial Officer (As
Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned, in his capacity as Chief Executive Officer and Chief Financial Officer, respectively, of Heron Therapeutics, Inc. (the "Registrant"), hereby certifies, for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge that:

- the Quarterly Report of the Registrant on Form 10-Q for the quarter ended June 30, 2016 (the "Report"), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such quarter and the results of operations of the Registrant for such quarter.

Dated: August 8, 2016

/s/ Barry D. Quart
Barry D. Quart, Pharm.D.
Chief Executive Officer (As Principal Executive Officer)

/s/ Brian G. Drazba
Brian G. Drazba
Vice President, Finance and Chief Financial Officer (As Principal Financial and Accounting Officer)

This certification accompanies the Report to which it relates, is not deemed to be filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Heron Therapeutics, 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 Report), irrespective of any general incorporation language contained in such filing.

Note: A signed original of this written statement required by Section 906 has been provided to Heron Therapeutics, Inc. and will be retained by Heron Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.