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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2018

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.)**
4242 Campus Point Court, Suite 200 San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 251-4400

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 April 25, 2018 was 71,951,009.

HERON THERAPEUTICS, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

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PART I. FINANCIAL STATEMENTS (Unaudited)

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — UNAUDITED

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2018 (unaudited)	December 31, 2017 (see Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,575	$ 144,583
Short-term investments	67,363	27,796
Accounts receivable, net	37,713	41,874
Inventory	19,418	10,108
Prepaid expenses and other current assets	5,494	3,702
Total current assets	176,563	228,063
Property and equipment, net	6,504	5,981
Other assets	316	263
Total assets	$ 183,383	$ 234,307
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,458	$ 18,769
Accrued clinical liabilities	24,934	26,920
Accrued payroll and employee liabilities	5,248	8,860
Other accrued liabilities	20,643	17,175
Deferred revenue	—	2,763
Promissory note payable to related party	25,000	25,000
Convertible notes payable to related parties, net of discount	3,894	3,684
Total current liabilities	91,177	103,171
Stockholders' equity:		
Common stock	650	646
Additional paid-in capital	925,745	913,955
Accumulated other comprehensive loss	(42)	(10)
Accumulated deficit	(834,147)	(783,455)
Total stockholders' equity	92,206	131,136
Total liabilities and stockholders' equity	$ 183,383	$ 234,307

See accompanying notes.

HERON THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Net product sales	$ 11,567	$ 3,632
Operating expenses:		
Cost of product sales	3,133	1,186
Research and development	39,561	33,384
General and administrative	7,028	6,742
Sales and marketing	13,835	11,619
Total operating expenses	63,557	52,931
Loss from operations	(51,990)	(49,299)
Other expense, net	(275)	(1,030)
Net loss	(52,265)	(50,329)
Other comprehensive loss:		
Unrealized loss on short-term investments	(32)	(13)
Comprehensive loss	$(52,297)	$(50,342)
Basic and diluted net loss per share	$ (0.81)	$ (1.00)
Shares used in computing basic and diluted net loss per share	64,724	50,530

See accompanying notes.

HERON THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2018	2017
Operating activities:		
Net loss	$ (52,265)	$ (50,329)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation expense	7,701	8,021
Depreciation and amortization	381	329
Amortization of debt discount	210	185
Loss on disposal of property and equipment	—	5
Accretion of discount on short-term investments	(211)	(13)
Change in operating assets and liabilities:		
Accounts receivable	4,161	(8,367)
Prepaid expenses and other current assets	(1,845)	274
Inventory	(9,508)	699
Accounts payable	(7,311)	(2,337)
Accrued clinical liabilities	(1,986)	(1,983)
Accrued payroll and employee liabilities	(3,612)	(2,292)
Deferred revenue	—	4,136
Other accrued liabilities	2,572	1,091
Net cash used for operating activities	(61,713)	(50,581)
Investing activities:		
Purchases of short-term investments	(39,388)	(69,374)
Maturities and sales of short-term investments	—	25,395
Purchases of property and equipment	(904)	(938)
Net cash used for investing activities	(40,292)	(44,917)
Financing activities:		
Net proceeds from sale of common stock	(205)	163,747
Proceeds from stock option exercises	4,202	1,850
Net cash provided by financing activities	3,997	165,597
Net (decrease) increase in cash and cash equivalents	(98,008)	70,099
Cash and cash equivalents at beginning of year	144,583	13,414
Cash and cash equivalents at end of period	$ 46,575	$ 83,513
Supplemental disclosure of cash flow information:		
Interest paid	$ 500	$ 1,000
Cumulative effect of adoption of new accounting standard	$ 1,573	$ —

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," "us," "our" and similar terms refer to Heron Therapeutics, Inc. Heron Therapeutics®, the Heron logo, SUSTOL®, CINVANTI® 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

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments that address some of the most important unmet patient needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain.

On August 9, 2016, our first commercial product, SUSTOL® (granisetron) extended-release injection ("SUSTOL"), was approved by the U.S. Food and Drug Administration ("FDA"). SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT_3 receptor antagonist that utilizes Heron's Biochronomer® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ³5 days. We commenced commercial sales of SUSTOL in the U.S. in October 2016.

On November 9, 2017, our second commercial product, CINVANTI® (aprepitant) injectable emulsion ("CINVANTI"), was approved by the FDA. CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI is an intravenous formulation of aprepitant, a substance P/neurokinin-1 ("NK_1") receptor antagonist. CINVANTI is the only IV formulation of an NK_1 receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC that is free of polysorbate 80 or any other synthetic surfactant. We commenced commercial sales of CINVANTI in the U.S. in January 2018.

HTX-011, which utilizes Heron's Biochronomer® polymer-based drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction.

In March 2018, Heron reported positive topline results from EPOCH1 and EPOCH2, its pivotal Phase 3 studies of HTX-011 in bunionectomy and hernia repair, respectively. All primary and key secondary endpoints were achieved in these studies. Furthermore, HTX-011 is the only long-acting local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control, through 72 hours. HTX-011 was well tolerated in both studies, with a safety profile comparable to placebo and bupivacaine solution. HTX-011 continues to be investigated in ongoing Phase 2 studies in breast augmentation and total knee arthroplasty. HTX-011 was granted Fast Track Designation from the FDA in the fourth quarter of 2017. In the second half of 2018, Heron expects to file an NDA to the FDA for HTX-011.

We have incurred significant operating losses and negative cash flows from operations. As of March 31, 2018, our accumulated deficit was $834.1 million, and we had $113.9 million in cash, cash equivalents and short-term investments. In April 2018, we received net cash proceeds of $168.7 million from a public offering of our common stock. As of March 31, 2018, our pro-forma cash, cash equivalents and short-term investments, adjusting for the April 2018 public offering, was $282.6 million. Based on our current operating plan and projections, management believes that available cash, cash equivalents and short-term investments are sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission ("SEC").

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 months ended March 31, 2018 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2018. The condensed consolidated balance sheet as of December 31, 2017 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 year ended December 31, 2017, which was filed with the SEC on February 27, 2018.

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 revenue recognition, inventory, accrued clinical liabilities, income taxes and stock-based compensation. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Short-term Investments

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

Short-term investments consist of securities with contractual maturities of greater than three months to one year. We have classified our short-term investments as available-for-sale securities in the accompanying unaudited condensed consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive loss and realized gains and losses included in other expense, net. 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.

The following is a summary of our short-term investments (in thousands):

	March 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. corporate debt securities	$ 16,202	$ —	$ (42)	$ 16,160
U.S. commercial paper	17,402	—	—	17,402
Foreign commercial paper	33,801	—	—	33,801
Total	$ 67,405	$ —	$ (42)	$ 67,363

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. corporate debt securities	$ 13,003	$ —	$ (10)	$ 12,993
U.S. commercial paper	4,929	—	—	4,929
Foreign commercial paper	9,874	—	—	9,874
Total	$ 27,806	$ —	$ (10)	$ 27,796

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. We regularly monitor and evaluate the realizable value of our marketable securities. We did not recognize any impairment losses for each of the three months ended March 31, 2018 and 2017.

Realized gains and losses associated with our investments, if any, are reported in the statements of operations and comprehensive loss. There were no realized gains or losses for each of the three months ended March 31, 2018 and 2017.

Our bank and investment accounts have been placed under control agreements in accordance with our Senior Secured Convertible Notes (“Convertible Notes”) and our Subordinated Secured Promissory Note (“Promissory Note”) (see Note 7).

Concentration of Risk

Cash, cash equivalents and short-term investments are financial instruments that potentially subject us to concentrations of credit risk. We deposit our cash in financial institutions. At times, such deposits may be in excess of insured limits. We may also invest our excess cash in money market funds, U.S. government and agencies, corporate debt securities and commercial paper. We have established guidelines relative to our diversification of our cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Sales of SUSTOL to two customers accounted for 10% or more of our net product sales for the three months ended March 31, 2018. Sales of CINVANTI to three customers accounted for 10% or more of our net product sales for the three months ended March 31, 2018. The loss of any of these customers could materially and adversely affect our business, results of operations, financial condition and cash flows.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out, or FIFO, basis. We periodically analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory quantities that are in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product sales.

As of March 31, 2018, inventory totaled $19.4 million, which consisted of raw materials of $5.0 million, work in process of $8.1 million and finished goods of $6.3 million. As of March 31, 2018, total inventory included $8.5 million related to SUSTOL and $10.9 million related to CINVANTI. As of December 31, 2017, inventory totaled $10.1 million, which consisted of raw materials of $2.7 million, work in process of $4.2 million and finished goods of $3.2 million. As of December 31, 2017, total inventory included $7.1 million related to SUSTOL and $3.0 million related to CINVANTI.

For the three months ended March 31, 2018, we recognized cost of product sales of $3.1 million for sales of SUSTOL and CINVANTI. For the three months ended March 31, 2017, we recognized $1.2 million for sales of SUSTOL. Cost of product sales primarily included raw materials, labor and overhead related to the manufacturing of SUSTOL and CINVANTI, as well as shipping and distribution costs.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers* (“Topic 606”). Topic 606 is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Topic 606 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Accordingly, in the first quarter of 2018, we adopted Topic 606 using the modified retrospective approach. Under this approach, incremental disclosures are provided to present each financial statement line item for 2018 under the prior standard. As a result of the adoption of Topic 606, we recorded a cumulative adjustment to retained earnings of $1.6 million on January 1, 2018. This adjustment reflects the acceleration of $2.9 million in gross product sales less $1.1 million in product sales allowances and $0.2 million in cost of product sales (see Note 5).

Comprehensive Loss

Comprehensive 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 both periods presented.

Net Loss per Share

Basic net loss per share 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 net loss per share 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 shares of common stock underlying Convertible Notes are considered to be common stock equivalents and are included in the calculation of diluted net loss per share only when their effect is dilutive.

Because we have incurred a net loss for both periods presented in the unaudited condensed consolidated statements of operations and comprehensive loss, stock options, warrants and shares of 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 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 March 31,	
	2018	2017
Stock options outstanding	12,906	11,849
Warrants outstanding	640	625
Shares of common stock underlying Convertible Notes outstanding	8,103	7,634

Recent Accounting Pronouncements

Recently Adopted

In May 2017, FASB issued ASU No. 2017-09, *Compensation – Stock Compensation: Scope of Modification Accounting* ("ASU 2017-09"). The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. In the first quarter of 2018, we adopted the provisions of ASU 2017-09, which did not have a material impact on our results of operations or financial condition.

Not Yet Adopted

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, and we are currently evaluating the impact on our results of operations and 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 — Observable inputs such as 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 March 31, 2018 and December 31, 2017 were as follows (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Balance at March 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 37,883	$ 37,883	$ —	$ —
U.S. corporate debt securities	16,160	—	16,160	—
U.S. commercial paper	17,402	—	17,402	—
Foreign commercial paper	36,641	—	36,641	—
Total	$108,086	$ 37,883	$ 70,203	$ —

		Fair Value Measurements at Reporting Date Using		
	Balance at December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 91,386	$ 91,386	$ —	$ —
U.S. corporate debt securities	17,520	—	17,520	—
U.S. commercial paper	39,863	—	39,863	—
Foreign commercial paper	19,854	—	19,854	—
Total	$ 168,623	$ 91,386	$ 77,237	$ —

As of March 31, 2018, cash equivalents included $2.8 million of available-for-sale securities with contractual maturities of three months or less, and short-term investments included $67.4 million of available-for-sale securities with contractual maturities of three months to one year. As of December 31, 2017, cash equivalents included $49.4 million of available-for-sale securities with contractual maturities of three months or less, and short-term investments included $27.8 million of available-for-sale securities with contractual maturities of three months to one year. The money market funds as of March 31, 2018 and December 31, 2017 are included in cash and cash equivalents on the unaudited condensed consolidated balance sheets.

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.

Financial instruments, including cash, cash equivalents, receivables, inventory, prepaid expenses, other current assets, accounts payable and accrued expenses are carried at cost, which is considered to be representative of their respective fair values because of the short-term maturity of these instruments. Short-term available-for-sale investments are carried at fair value. Our Convertible Notes and Promissory Note outstanding at March 31, 2018 and December 31, 2017 do not have readily available ascertainable market values; however, the carrying values are considered to approximate their fair values.

5. Revenue Recognition

Product Sales

SUSTOL is distributed in the U.S. through a limited number of specialty distributors (“Customers”) that resell SUSTOL to healthcare providers, the end users of SUSTOL. CINVANTI is distributed in the U.S. through a limited number of specialty distributors and full line wholesalers (“Customers”) that resell CINVANTI to healthcare providers and hospitals, the end users of CINVANTI.

Adoption of Topic 606

On January 1, 2018, we adopted Topic 606 using the modified retrospective approach applied to those contracts that were not completed as of January 1, 2018. Results from reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under the FASB Accounting Standards Codification (“ASC”) Topic 605, *Revenue Recognition* (“Topic 605”). Prior to the adoption of Topic 606, we recognized product sales as revenue to the extent that our Customers had resold our products to end users (sell-through approach). With the adoption of Topic 606, we recognize product sales as revenue when our products are sold to our Customers (sell-in approach). Product sales under both Topic 605 and 606 are reported net of product sales allowances, which include product returns.

Revenue is recognized in an amount that reflects the consideration that we expect to receive in exchange for our products. To determine revenue recognition for contracts with customers within the scope of Topic 606, we performed the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations of the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract(s); and (v) recognize revenue when (or as) we satisfy the performance obligations.

The following table shows the reconciliation of assets and liabilities disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, as adjusted, due to the modified retrospective adoption of Topic 606 on January 1, 2018 (in thousands):

	As Reported Under Topic 605	Effect of Change	As Adjusted Under Topic 606
Inventory	$ 10,108	$ (198)	$ 9,910
Other accrued liabilities	17,175	992	18,167
Deferred revenue	2,763	(2,763)	—
Retained earnings	(783,455)	1,573	(781,882)

The following table shows the unaudited condensed consolidated financial statement line items for the first quarter of 2018, as if revenue from contracts with customers had been accounted for under Topic 605 (in thousands, except per share data):

	As Reported Under Topic 606	Effect of Change	As Revised Under Topic 605
Consolidated Balance Sheet:			
Inventory	$ 19,418	$ 610	$ 20,028
Other accrued liabilities	20,643	(538)	20,105
Deferred revenue	—	2,345	2,345
Retained earnings	(834,147)	(1,197)	(835,344)
Consolidated Statement of Operations and Comprehensive Loss:			
Net product sales	$ 11,567	$ (36)	$ 11,531
Cost of product sales	3,133	(412)	2,721
Loss from operations	(51,990)	376	(51,614)
Net loss	(52,265)	376	(51,889)
Basic and diluted net loss per share	(0.81)	0.01	(0.80)
Consolidated Statement of Cash Flows:			
Net loss	$ (52,265)	$ 376	$ (51,889)
Adjustments to reconcile net loss to net cash used in operating activities:			
Inventory	(9,508)	(412)	(9,920)
Other accrued liabilities	2,572	454	3,026
Deferred revenue	—	(418)	(418)

Product Sales Allowances

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with Customers, historical product returns, rebates or discounts taken, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our product sales allowances include:

- Product Returns — We allow our Customers to return product for credit 12 months after its product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product.
- Distributor Fees — We offer contractually determined discounts to our Customers. These discounts are paid no later than two months after the quarter in which product was shipped.
- Group Purchasing Organization (“GPO”) Discounts and Rebates — We offer cash discounts to GPO members. These discounts are taken when the GPO members purchase SUSTOL or CINVANTI from our Customers, who then charge back to us the discount amount. Additionally, we offer volume and contract-tier rebates to GPO members. Rebates are based on actual purchase levels during the quarterly rebate purchase period.
- GPO Administrative Fees — We pay administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPO’s members.

- Medicaid Rebates — We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within three months after the quarter in which SUSTOL or CINVANTI was sold.

We believe our estimated allowance for product returns requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. We believe our estimated allowances for distributor fees, GPO discounts, rebates and administrative fees and Medicaid rebates do not require a high degree of judgment because the amounts are settled within a relatively short period of time.

Our product sales allowances and related accruals are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Changes in sales allowance estimates could materially affect our results of operations and financial position.

The following table provides a summary of activity with respect to our product returns, distributor fees and discounts, rebates and administrative fees for the three months ended March 31, 2018, which are included in other accrued liabilities on the unaudited condensed consolidated balance sheets (in thousands):

	Product Returns	Distributor Fees	Discounts, Rebates and Administrative Fees	Total
Balance at December 31, 2017	$ 521	$ 580	$ 8,218	$ 9,319
Provision	142	1,160	11,446	12,748
Payments/credits	—	(706)	(8,757)	(9,463)
Balance at March 31, 2018	$ 663	$ 1,034	$ 10,907	$12,604

6. Realignment of Goals and Objectives and New Development Focus

Following the approval of SUSTOL and consistent with our transition into a commercial-stage biotechnology company, we realigned our goals and objectives and refocused our development efforts to the area of postoperative pain management. On October 18, 2016, we entered into a lease agreement for new office and laboratory space in San Diego, California, which became our corporate headquarters in December 2016. On September 30, 2016, the Board of Directors accepted the resignations of three executive officers, and these executive officers and other employees directly affected by the realignment and refocusing were or will be provided with one-time severance payments upon termination, continued benefits for a specified period of time and outplacement assistance.

The total expense for these activities was $9.6 million, $5.7 million of which is primarily for severance and $3.9 million of which is for non-cash, stock-based compensation expense. The total expense was recognized between September 30, 2016 and December 31, 2017.

We expect to make the final payment resulting from the realignment of our goals and objectives and new development focus in the third quarter of 2018. As of March 31, 2018, we have paid $5.3 million of the total $5.7 million cash severance charges.

In March 2018, we shut down operations at our Redwood City facility and entered into a sublease agreement for the remainder of the lease term. The fair value of the cease-use liability was calculated using the remaining lease payments, offset by future sub-lease payments, deferred rent amortization and prepaid rent amounts. For the three months ended March 31, 2018, we recorded expense of $0.5 million to general and administrative expense as a loss on the lease.

We have accounted for these expenses in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations*.

7. Secured Notes to Related Party

Convertible Notes

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 a rate of 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 March 31, 2018, we were in compliance with all covenants under the Convertible Notes. On 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 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 outstanding 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 three months ended March 31, 2018, accrued interest of $0.1 million was paid-in-kind and rolled into the Convertible Note principal balance, which resulted in an additional debt discount of $0.1 million. For the three months ended March 31, 2018 and 2017, interest expense relating to the stated rate was $0.1 million and $0.1 million, respectively, and interest expense relating to the amortization of the debt discount was $0.2 million and $0.2 million, respectively.

As of March 31, 2018, the carrying value of the Convertible Notes was $3.9 million, which is comprised of the $6.5 million principal amount of the Convertible Notes outstanding, less debt discount of $2.6 million. At March 31, 2018, the Convertible Notes were convertible into 8.1 million shares of our common stock.

Promissory Note

In August 2016, we entered into the Promissory Note with TCP whereby TCP agreed to lend us up to $100.0 million. The Promissory Note has a two-year term and bears interest at a rate of 8% per annum. The first close of $50.0 million occurred on August 5, 2016. The second close of an additional $50.0 million was not drawn and has expired. There are no fees, no warrants and no equity conversion features associated with this transaction. The Promissory Note is secured by a second-priority lien on substantially all of our assets. TCP is controlled by TCM. The manager of TCM is Kevin C. Tang, who serves as the Chairman of our Board of Directors. The terms of the Promissory Note were determined by our independent directors to be no less favorable than terms that would be obtained in an arm's length financing transaction.

For the three months ended March 31, 2018, interest expense was $0.5 million, compared to $1.0 million for the three months ended March 31, 2017. As of March 31, 2018, the outstanding principal amount of the Promissory Note was $25.0 million.

8. Stockholders' Equity

Common Stock Offerings

In January 2017, we sold 14.1 million shares of our common stock at a public offering price of $12.20 per share. We received total net proceeds of $163.7 million (net of $8.8 million in issuance costs) from the sale of the common stock.

In December 2017, we sold 9.7 million shares of our common stock at a public offering price of $15.50 per share. We received total net proceeds of $142.6 million (net of $7.4 million in issuance costs) from the sale of the common stock.

In April 2018, we sold 6.9 million shares of our common stock at a public offering price of $26.00 per share. We received total net cash proceeds of $168.7 million (net of $9.3 million in issuance costs) from the sale of the common stock (See Note 10).

Stock Option Activity

The following table summarizes the stock option activity for the three months ended March 31, 2018:

	Shares (in thousands)	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (Years)
Balance at December 31, 2017	13,463	$ 15.03	8.01
Granted	122	$ 23.06	
Exercised	(435)	$ 9.66	
Expired and forfeited	(244)	$ 19.02	
Balance at March 31, 2018	12,906	$ 15.22	7.86

For the three months ended March 31, 2018, 435,000 shares of common stock were issued pursuant to the exercise of stock options, resulting in net proceeds of $4.2 million.

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 months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	$ 3,036	$ 3,208
General and administrative	2,276	2,374
Sales and marketing	2,389	2,439
Total stock-based compensation expense	$ 7,701	$ 8,021

As of March 31, 2018, there was $79.7 million 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 2.8 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:

	March 31,	
	2018	2017
Risk-free interest rate	2.6%	2.1%
Dividend yield	0.0%	0.0%
Volatility	71.4%	87.3%
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. There were no new offering periods for the three months ended March 31, 2018 and 2017.

9. 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 March 31, 2018.

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 be recognized when it is more likely than not of being sustained. In 2017, we adopted ASU 2016-09, which resulted in the recognition of $3.6 million of previously unrecognized tax benefits in deferred tax assets, fully offset by a valuation allowance. The disclosures included in our Annual Report on Form 10-K for the year ended December 31, 2017 continue to be accurate for the three months ended March 31, 2018.

10. Subsequent Events

In April 2018, we sold 6.9 million shares of our common stock at a public offering price of $26.00 per share. We received total net cash proceeds of $168.7 million (net of $9.3 million in issuance costs) from the sale of the common stock.

In connection with the public offering, TCP executed a waiver (the "Waiver") pursuant to which TCP waived: (i) our obligation under the Securities Purchase Agreement, dated April 24, 2011, among us, TCP and certain other investors to maintain a sufficient number of authorized shares of our common stock to permit the conversion of TCP's outstanding principal and interest under the Convertible Notes to our common stock; and (ii) its right to convert the Convertible Notes for the duration of the Waiver. The Waiver will remain effective until the earliest to occur of: (i) a change in the control of the Company; (ii) the Company's stockholders approving an increase of the number of authorized shares of our common stock; and (iii) September 28, 2018. If, upon the expiration of the Waiver, TCP seeks to convert part or all of the Convertible Notes and we do not have a sufficient number of authorized shares of our common stock to permit the conversion of the portion of the Convertible Notes being converted, then we will be obligated to make a cash payment to TCP equal to the value of the underlying shares of common stock that we are unable to deliver on conversion based on the price of our common stock at such time.

On May 8, 2018, we entered into a Second Amendment to Lease (the "Lease Amendment") with AP3-SD1 Campus Point LLC (the "Landlord"), amending that certain Lease, dated October 18, 2016, by and between us and the Landlord, as amended by that certain First Amendment to Lease, dated March 15, 2017 (the "Lease"). The Lease Amendment provides for us to lease additional office space in the building located at 4242 Campus Point Court, San Diego, California, for a period of 87 months, beginning on the date that our improvements to the premises are substantially complete. Pursuant to the Lease Amendment, we have agreed to pay a basic annual rent that increases incrementally over the term of the Lease Amendment from $0.9 million for the first 12 months of the Lease Amendment (inclusive of certain rent abatements) to a prorated portion of a basic annual rent of $1.4 million for the last three months of the Lease Amendment, and such other amounts as set forth in the Lease Amendment. We also paid to the Landlord an additional security deposit in the amount of $0.1 million. Except as modified by the Lease Amendment, all of the provisions of the Lease will continue unmodified and in full force and effect.

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 related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the U.S. Securities and Exchange Commission ("SEC") on February 27, 2018.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other 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 our anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that might cause these differences include the following:

- our ability to successfully commercialize, market and achieve market acceptance of SUSTOL® (granisetron) extended-release injection ("SUSTOL"), CINVANTI® aprepitant injectable emulsion ("CINVANTI") and future product candidates, including our positioning relative to competing products;
- estimates of the outcome of the commercial launch of CINVANTI;
- whether the HTX-011 Phase 2 and Phase 3 study results are indicative of the results in future studies;
- the timing of the New Drug Application ("NDA") submission to the U.S. Food and Drug Administration ("FDA") for HTX-011 and potential regulatory approval for and commercial launch of HTX-011;
- the potential market opportunities for SUSTOL, CINVANTI and HTX-011;

- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting;
- whether safety and efficacy results of our clinical trials and other required tests for approval of our product candidates provide data to warrant progression of clinical trials, potential regulatory approval or further development of any of our product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies, and our ability to submit for and obtain regulatory approval for product candidates, in our anticipated timing, or at all;
- our ability to meet the postmarketing study requirements within the FDA's mandated timelines and to obtain favorable results and comply with standard postmarketing requirements including U.S. federal advertising and promotion laws, federal and state anti-fraud and abuse laws, healthcare information privacy and security laws, safety information, safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities for SUSTOL, CINVANTI or any of our product candidates;
- our ability to successfully develop and achieve regulatory approval for other future product candidates utilizing our proprietary Biochronomer® sustained-release drug delivery technology ("Biochronomer technology");
- our ability to establish key collaborations and vendor relationships 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 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.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q. You should carefully review all of these factors. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements were based on information, plans and estimates as of the date of this Quarterly Report on Form 10-Q, and except as required by law, 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. These risk factors may be updated from time to time by our future filings under the Securities Exchange Act of 1934. You should carefully review all information therein.

Overview

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments that address some of the most important unmet patient needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain.

On August 9, 2016, our first commercial product, SUSTOL, was approved by the FDA. SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT_3 receptor antagonist that utilizes Heron's Biochronomer® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ³5 days. We commenced commercial sales of SUSTOL in the U.S. in October 2016.

On November 9, 2017, our second commercial product, CINVANTI, was approved by the FDA. CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI is an intravenous formulation of aprepitant, a substance P/neurokinin-1 ("NK_1") receptor antagonist. CINVANTI is the only IV formulation of an NK_1 receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC that is free of polysorbate 80 or any other synthetic surfactant. We commenced commercial sales of CINVANTI in the U.S. in January 2018.

HTX-011, which utilizes Heron's proprietary Biochronomer® polymer-based drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction.

In March 2018, Heron reported positive topline results from EPOCH1 and EPOCH2, its pivotal Phase 3 studies of HTX-011 in bunionectomy and hernia repair, respectively. All primary and key secondary endpoints were achieved in these studies. Furthermore, HTX-011 is the only long-acting local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control, through 72 hours. HTX-011 was well tolerated in both studies, with a safety profile comparable to placebo and bupivacaine solution. HTX-011 continues to be investigated in ongoing Phase 2 studies in breast augmentation and total knee arthroplasty. HTX-011 was granted Fast Track Designation from the FDA in the fourth quarter of 2017. In the second half of 2018, Heron expects to file an NDA to the FDA for HTX-011.

CINV Product Portfolio

SUSTOL

SUSTOL was our first commercial product. SUSTOL was approved by the FDA on August 9, 2016, and we commenced commercial sales in the U.S. in October 2016.

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-hydroxytryptamine type 3 ("5-HT_3") receptor antagonist that utilizes our Biochronomer technology to maintain therapeutic levels of granisetron for ³5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0-24 hours following chemotherapy) and the delayed phase (24-120 hours following chemotherapy).

SUSTOL is the first extended-release 5-HT_3 receptor antagonist approved for the prevention of acute and delayed nausea and vomiting associated with both MEC and AC combination chemotherapy regimens. A standard of care in the treatment of breast cancer and other cancer types, AC regimens are among the most commonly prescribed HEC regimens, as defined by both the National Comprehensive Cancer Network ("NCCN") and the American Society of Clinical Oncology.

In February 2017, the NCCN included SUSTOL as a part of its NCCN Clinical Practice Guidelines in Oncology for Antiemesis Version 1.2017. The NCCN has given SUSTOL a Category 1 recommendation, the highest level category of evidence and consensus, for use in the prevention of acute and delayed nausea and vomiting in patients receiving HEC or MEC regimens. The guidelines now identify SUSTOL as a "preferred" agent for preventing nausea and vomiting following MEC. Further, the guidelines highlight the unique, extended-release formulation of SUSTOL.

In January 2018, a product-specific billing code, or permanent J-code ("J-code"), for SUSTOL became available. The new J-code was assigned by the Centers for Medicare and Medicaid Services and will help simplify the billing and reimbursement process for prescribers of SUSTOL.

CINVANTI

CINVANTI is our second commercial product. CINVANTI was approved by the FDA on November 9, 2017, and we commenced commercial sales in the U.S. in January 2018.

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

CINVANTI is an intravenous formulation of aprepitant, an NK_1 receptor antagonist. CINVANTI is the first intravenous ("IV") formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK_1 receptor antagonist to significantly reduce nausea and vomiting in both the acute phase (0 – 24 hours after chemotherapy) and the delayed phase (24 – 120 hours after chemotherapy). CINVANTI is the only IV formulation of an NK_1 receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC that is free of polysorbate 80 or any other synthetic surfactant.

NK_1 receptor antagonists are typically used in combination with 5-HT3 receptor antagonists. The only other injectable NK_1 receptor antagonist currently approved in the U.S. for both acute and delayed CINV, EMEND® IV (fosaprepitant), contains polysorbate 80, a synthetic surfactant, which has been linked to hypersensitivity reactions, including anaphylaxis, and infusion site reactions. The CINVANTI formulation does not contain polysorbate 80 or any other synthetic surfactant. Our CINVANTI data has demonstrated the bioequivalence of CINVANTI to EMEND IV, supporting its efficacy for the prevention of both acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC. Results also showed CINVANTI was better tolerated in healthy volunteers than EMEND IV, with significantly fewer adverse events reported with CINVANTI.

Pain Management Product Portfolio

HTX-011

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

In March 2018, we reported positive topline results from EPOCH1 and EPOCH2, our pivotal Phase 3 studies of HTX-011 in bunionectomy and hernia repair, respectively. All primary and key secondary endpoints were achieved in these studies. Furthermore, HTX-011 is the only long-acting local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control, through 72 hours.

The primary and key secondary endpoints for both Phase 3 studies were identical. The primary endpoint was pain intensity as measured by the Area Under the Curve ("AUC") score from 0 to 72 hours post-surgery ("AUC 0-72") compared to placebo. Key secondary endpoints in order of evaluation were:

- comparison of AUC 0-72 of pain intensity to bupivacaine solution;
- the total amount of opioid rescue medication consumption compared to placebo through 72 hours after surgery;
- the proportion of patients who received no opioid rescue medication after surgery compared to bupivacaine solution; and
- the total opioid consumption through 72 hours after surgery compared to bupivacaine.

Bunionectomy — Study 301/EPOCH1 Results

EPOCH1 was a randomized, placebo- and active-controlled, double-blind, Phase 3 clinical study evaluating the efficacy and safety of locally administered HTX-011 at 60 mg compared to the standard dose of bupivacaine solution (50 mg) and placebo for post-operative pain control following bunionectomy surgery in 412 subjects. All primary and key secondary endpoints were achieved:

- There was a 27% reduction in pain intensity as measured by AUC 0-72 when comparing HTX-011 to placebo ($p<0.0001$);
- There was an 18% reduction in pain as measured by AUC 0-72 when comparing HTX-011 to bupivacaine solution ($p=0.0002$);
- Over 72 hours post-surgery, patients receiving HTX-011 consumed 37% less opioids than placebo patients ($p<0.0001$) and 25% less opioids than patients receiving bupivacaine solution ($p=0.0022$); and
- 29% of patients receiving HTX-011 required no opioid medication for 72 hours post-surgery compared to only 2% receiving placebo ($p<0.0001$) and 11% receiving the standard-of-care, bupivacaine solution ($p=0.0001$). These results parallel the significantly reduced incidence of severe pain in patients receiving HTX-011 compared to both placebo (36% reduction; $p<0.0001$) and bupivacaine (29% reduction; $p<0.0001$).

Hernia Repair — Study 302/EPOCH2 Results

EPOCH2 was a randomized, placebo- and active-controlled, double-blind, Phase 3 clinical study evaluating the efficacy and safety of locally administered HTX-011 at 300 mg compared to the standard dose of bupivacaine solution (75 mg) and placebo for post-operative pain control following hernia repair surgery in 418 subjects. All primary and key secondary endpoints were achieved:

- There was a 23% reduction in pain intensity as measured by AUC 0-72 when comparing HTX-011 to placebo ($p=0.0004$);
- There was a 21% reduction in pain as measured by AUC 0-72 when comparing HTX-011 to bupivacaine solution ($p<0.0001$);

- Over 72 hours post-surgery, patients receiving HTX-011 consumed 38% less opioids than placebo patients (p=0.0001) and 25% less opioids than patients receiving bupivacaine solution (p=0.0240); and
- 51% of patients receiving HTX-011 required no opioid medication for 72 hours post-surgery compared to only 22% receiving placebo (p<0.0001) and 40% receiving the standard-of-care, bupivacaine solution (p=0.0486). These results parallel the significantly reduced incidence of severe pain in patients receiving HTX-011 compared to both placebo (40% reduction; p<0.0001) and bupivacaine (19% reduction; p=0.0372).

HTX-011 was well tolerated in both studies, with a safety profile comparable to placebo and bupivacaine solution. There were no drug-related serious adverse events or discontinuations due to drug-related adverse events in HTX-011-treated patients, and there were fewer opioid-related adverse events in HTX-011-treated patients.

HTX-011 is the only long-acting anesthetic designed to address both postoperative pain and inflammation in a single administration at the surgical site. The unique synergy of bupivacaine and meloxicam in HTX-011 has consistently been shown to reduce pain over 72 hours significantly better than bupivacaine alone in multiple diverse surgical models. HTX-011 is administered as a single-dose application via needle-free syringe to directly coat the affected tissue within the surgical site prior to suturing, which makes HTX-011's route of administration faster, easier and potentially safer compared to numerous injections required with current local anesthetics.

In October 2017, we announced that we have been granted Fast Track designation for HTX-011 by the FDA for local administration into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours. Fast Track designation is intended to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA.

Biochronomer Technology

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

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed 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 revenue recognition, inventory, accrued clinical liabilities, income taxes and stock-based compensation. 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: revenue recognition, inventory, accrued clinical liabilities, income taxes, and stock-based compensation. There have been no material changes to our critical accounting policies and estimates disclosures included in our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on February 27, 2018, other than disclosed in Note 3 to the unaudited condensed consolidated financial statements in Item 1 of this Quarterly Report on Form 10-Q with respect to the adoption of Topic 606.

Recent Accounting Pronouncements

See Note 3 to the unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations for the Three Months Ended March 31, 2018 and 2017

Net Product Sales

For the three months ended March 31, 2018, we recognized net product sales of $11.6 million for sales of SUSTOL and CINVANTI. For the three months ended March 31, 2017, we recognized net product sales of $3.6 million for sales of SUSTOL. We commenced commercial sales of CINVANTI in the U.S. in January 2018.

Cost of Product Sales

For the three months ended March 31, 2018 and 2017, we recognized cost of product sales of $3.1 million and $1.2 million, respectively. Cost of product sales primarily included raw materials, labor and overhead related to the manufacturing of SUSTOL and CINVANTI, as well as shipping and distribution costs.

Research and Development Expense

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

	Three Months Ended March 31,	
	2018	2017
HTX-011-related costs	$26,976	$14,192
CINVANTI-related costs	2,018	5,927
SUSTOL-related costs	956	3,163
Personnel costs and other expenses	6,575	6,894
Stock-based compensation expense	3,036	3,208
Total research and development expense	$39,561	$33,384

For the three months ended March 31, 2018, research and development expense increased to $39.6 million from $33.4 million for the same period in 2017. The increase in research and development expense was primarily due to an increase in costs related to HTX-011 of $12.8 million. This increase was partially offset by a decrease in costs related to CINVANTI of $3.9 and SUSTOL of $2.2 million.

General and Administrative Expense

For the three months ended March 31, 2018 and 2017, general and administrative expense remained comparable at $7.0 million and $6.7 million, respectively.

Sales and Marketing Expense

For the three months ended March 31, 2018, sales and marketing expense increased to $13.8 million from $11.6 million for the same period in 2017. The increase in sales and marketing expense was primarily due to external costs to support the commercialization of SUSTOL and CINVANTI and market research and planning for our HTX-011 program.

Other Expense, Net

For the three months ended March 31, 2018, other expense, net, decreased to $0.3 million from $1.0 million for the same period in 2017. This decrease was due to a decrease in interest expense related to our Subordinated Secured Promissory Note ("Promissory Note"), as well as an increase in interest income from short-term investments.

Liquidity and Capital Resources

As of March 31, 2018, we had cash, cash equivalents and short-term investments of $113.9 million, compared to $172.4 million as of December 31, 2017. In April 2018, we received net cash proceeds of $168.7 million from a public offering of our common stock. As of March 31, 2018, our pro-forma cash, cash equivalents and short-term investments, adjusting for the April 2018 public offering, was $282.6 million. Based on our current operating plan and projections, we believe that available cash, cash equivalents and short-term investments, including the net cash proceeds from our recent public offering, are sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC.

Our net loss for the three months ended March 31, 2018 was $52.3 million, or $0.81 per share, compared to a net loss of $50.3 million, or $1.00 per share for the same period in 2017. Our net cash used for operating activities for the three months ended March 31, 2018 was $61.7 million, compared to net cash used for operating activities of $50.6 million for the same period in 2017. The increase in net loss in 2018 as compared to 2017 was primarily due to continued development of HTX-011. The increase in net cash used for operating activities was due to an increase in net loss and changes in working capital associated with the launch of SUSTOL and CINVANTI.

Our net cash used for investing activities for the three months ended March 31, 2018 was $40.3 million, compared to net cash used for investing activities of $44.9 million for the same period in 2017. The decrease in cash used for investing activities was due to the net decrease in purchases and maturities of short-term investments.

Our net cash provided by financing activities for the three months ended March 31, 2018 was $4.0 million, compared to net cash provided by financing activities of $165.6 million for the same period in 2017. In January 2017, we completed a public offering of common stock as a result of which we received $163.7 million in proceeds, net of issuance costs.

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

In 2017, we completed two public offerings of common stock as a result of which we received $306.3 million in proceeds, net of issuance costs. In April 2018, we received net cash proceeds of $168.7 million from a public offering of our common stock.

In August 2016, we entered into the Promissory Note with Tang Capital Partners, LP ("TCP") whereby TCP agreed to lend us up to $100.0 million. The Promissory Note has a two-year term and bears interest at a rate of 8% per annum. The first close of $50.0 million occurred on August 5, 2016. The second close of an additional $50.0 million was not drawn and has expired. There are no fees, no warrants and no equity conversion features associated with this transaction. The Promissory Note is secured by a second-priority lien on substantially all of our assets. TCP is controlled by Tang Capital Management ("TCM"). The manager of TCM is Kevin C. Tang, who serves as the Chairman of our Board of Directors. The terms of the Promissory Note were determined by our independent directors to be no less favorable than terms that would be obtained in an arm's length financing transaction. As of March, 31 2018, the outstanding principal amount of the Promissory Note was $25.0 million.

Contractual Obligations

We 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.

In addition, we entered into executive employment or management retention agreements with our executive officers and certain other key employees that, under certain cases, provide for a one-time severance payment and certain other benefits if these executives or employees are terminated under special circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. In connection with our realignment of goals and objectives and new development focus following the approval of SUSTOL, certain employees have received or will receive a one-time severance payment upon termination, as well as other benefits as required by the executive employment or management retention agreements. We expect to fulfill our remaining obligation under these agreements in the third quarter of 2018 (see Note 6 to the unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q).

On May 8, 2018, we entered into a Second Amendment to Lease (the “Lease Amendment”) with AP3-SD1 Campus Point LLC (the “Landlord”), amending that certain Lease, dated October 18, 2016, by and between us and the Landlord, as amended by that certain First Amendment to Lease, dated March 15, 2017 (the “Lease”). The Lease Amendment provides for us to lease additional office space in the building located at 4242 Campus Point Court, San Diego, California, for a period of 87 months, beginning on the date that our improvements to the premises are substantially complete. Pursuant to the Lease Amendment, we have agreed to pay a basic annual rent that increases incrementally over the term of the Lease Amendment from $0.9 million for the first 12 months of the Lease Amendment (inclusive of certain rent abatements) to a prorated portion of a basic annual rent of $1.4 million for the last three months of the Lease Amendment, and such other amounts as set forth in the Lease Amendment. We also paid to the Landlord an additional security deposit in the amount of $0.1 million. Except as modified by the Lease Amendment, all of the provisions of the Lease will continue unmodified and in full force and effect.

Off-Balance Sheet Arrangements

We are not involved in any “off-balance sheet arrangements” within the meaning of the rules of the SEC.

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 mitigate default risk by investing in short-term investment grade securities, such as treasury-backed money market funds, U.S. treasury and agency securities, 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 March 31, 2018. 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 operations and 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. The Promissory Note also carries a fixed interest rate. 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 Exchange Act 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.

During the three months ended March 31, 2018, we implemented certain internal controls in connection with our adoption of Topic 606. There were no other changes in our internal control over financial reporting that occurred during the quarter covered by this report that materially affected, or are 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

We are substantially dependent on the success of SUSTOL® and CINVANTI®, and if either SUSTOL or CINVANTI do not attain market acceptance by healthcare professionals and patients, our business and results of operations will suffer.

The success of our business is substantially dependent on our ability to commercialize our approved products, SUSTOL® (granisetron) extended-release injection ("SUSTOL") and CINVANTI® aprepitant injectable emulsion ("CINVANTI"). Although members of our management team have prior experience launching new drugs, SUSTOL and CINVANTI are the first two products that we have launched.

Further, even if our sales organization performs as expected, the revenue that we may receive from the sales of SUSTOL and CINVANTI may be less than anticipated due to factors that are outside of our control. These factors that may affect revenue include:

- the scope of our approved product labels;
- 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;
- our ability to maintain successful sales, marketing and educational programs for certain physicians and other health care providers;
- our ability to raise patient and physician awareness of chemotherapy-induced nausea and vomiting ("CINV") associated with anthracycline and cyclophosphamide ("AC") combination chemotherapy regimens, moderately emetogenic chemotherapy ("MEC") or highly emetogenic chemotherapy ("HEC") and encourage physicians to look for incidence of CINV among patients;
- the cost-effectiveness of our products;
- acceptance by institutional formulary committees;
- patient and physician satisfaction with our products;
- the size of the potential market for our products;
- our ability to obtain adequate reimbursement from government and third-party payors;
- unfavorable publicity concerning our products or similar products;
- the introduction, availability and acceptance of competing treatments;
- adverse event information relating to our products or similar classes of drugs;

- product liability litigation alleging injuries relating to the products or similar classes of drugs;
- our ability to maintain and defend our patents for SUSTOL and CINVANTI;
- our ability to continue to have SUSTOL and CINVANTI manufactured at commercial production levels successfully and on a timely basis;
- the availability of raw materials necessary to manufacture SUSTOL and CINVANTI;
- our ability to access third parties to manufacture and distribute our products on acceptable terms or at all;
- regulatory developments related to the manufacture or continued use of our products;
- conduct of post-approval study requirements and the results thereof;
- the extent and effectiveness of sales and marketing and distribution support for our products;
- 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 commercialization of our products.

Our business will be adversely affected if, due to these or other factors, our commercialization of SUSTOL or CINVANTI does not achieve the acceptance and demand necessary to sustain revenue growth. If we are unable to successfully commercialize SUSTOL or CINVANTI, our business and results of operations will suffer.

If we are unable to develop and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to sell and market SUSTOL, CINVANTI or any other products we may develop, our product sales may be adversely affected.

We have established an internal sales organization for the sale, marketing and distribution of SUSTOL and CINVANTI, and we have entered into an arrangement with a third-party for the provision of related supplemental services for CINVANTI. In order to successfully commercialize any other product we may develop, we must increase our sales, marketing, distribution and other non-technical capabilities or make arrangements with third parties to perform these services. The development of a sales organization to market SUSTOL, CINVANTI or any other product we may develop, is expensive and time consuming, and we cannot be certain that we will be able to successfully develop this capacity or that this function will execute as expected. 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 our business and results of operations will suffer.

If we cannot establish satisfactory pricing of SUSTOL, CINVANTI or any other products we may develop that is also acceptable to the U.S. government, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales may be adversely affected and our future revenue may suffer.

The continuing efforts of the U.S. government, 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 SUSTOL, CINVANTI or any other product we may develop commercially viable. Our ability to commercialize SUSTOL, CINVANTI or any other product we may develop 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.

Adoption of SUSTOL, CINVANTI or any other product we may develop by the medical community may be limited if third-party payors will not offer adequate coverage. In addition, third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. In many cases, uncertainty exists as to the adequate reimbursement status of newly approved healthcare products. Accordingly, SUSTOL, CINVANTI or any other product we may develop may not be reimbursable by certain third-party payors at the time of commercial launch and potentially for an extended period of time thereafter. In addition, 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 and any such changes could further limit reimbursement. Cost control initiatives may decrease coverage and payment levels for SUSTOL, CINVANTI or any other product we may develop and, in turn, the reimbursement that we receive. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to SUSTOL, CINVANTI or any other product we may develop. If SUSTOL, CINVANTI or any other products we develop do not receive adequate reimbursement, our revenue could be severely limited.

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 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 SUSTOL, CINVANTI or any other product we may develop 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 fail to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs, we could be subject to additional reimbursement requirements, penalties and fines, which could have a material adverse effect on our business, financial condition, and results of operations.

The Medicare program and certain government pricing programs, including the Medicaid drug rebate program, the Public Health Services’ 340B drug pricing program, and the pricing program under the Veterans Health Care Act of 1992 impact the reimbursement we may receive from sales of SUSTOL, CINVANTI or any other products that are approved for marketing. Pricing and rebate calculations vary among programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. We are required to submit a number of different pricing calculations to government agencies on a quarterly basis. Failure to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs may result in additional payments, penalties and fines due to government agencies, which may have a material adverse effect on our business, financial condition and results of operations.

Because the results of preclinical studies and clinical trials 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 studies or trials or receive regulatory approval.

Positive results from preclinical studies or clinical trials should not be relied on as evidence that later or larger-scale studies or trials will succeed. Even if our product candidates achieve positive results in early-stage preclinical studies or clinical trials, we will be required to demonstrate that these product candidates are safe and effective for use in Phase 3 studies before we can seek regulatory approvals for their commercial sale. Even if our early-stage preclinical studies or clinical trials achieve the specified endpoints, the U.S. Food and Drug Administration ("FDA") may determine that these data are not sufficient to allow the commencement of Phase 3 studies. There is an extremely high historical rate of failure of product candidates proceeding through clinical trials 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 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 preclinical study or clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that product candidate. In addition, product candidates in Phase 3 studies may fail to show the desired safety and efficacy despite having progressed through preclinical and earlier stage clinical trials, which could delay, limit or prevent regulatory approval. Further, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. If we delay or abandon our efforts to develop any of our product candidates, 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 on the successful development of products through 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").

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 our 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 conduct 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, CINVANTI and HTX-011, 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 on inspection by a given regulatory authority, such regulatory authority will determine that any of our ongoing or future clinical trials comply with cGCP. In addition, all of our clinical trials must be conducted with product produced under cGCP. 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 are unable to manufacture in commercially viable quantities, we could face delays in our ability to commercialize SUSTOL, CINVANTI or any other products we may develop, our costs will increase and our product sales may be severely hindered.

If in the future 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 to the FDA in the manufacture of our products at commercial scale as compared to development batch size. The commercial success of our products will be dependent on 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. We have scaled-up manufacturing for SUSTOL and CINVANTI in order to realize important economies of scale, and these activities took time to implement, required 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 scaled-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 depend on third-party suppliers and contract manufacturers to manufacture SUSTOL and CINVANTI, and we expect to do the same for 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 commercial or clinical quantities of any product, including SUSTOL and CINVANTI. Our ability to successfully commercialize SUSTOL and CINVANTI, as well as any other products or product candidates that we may develop, depends in part on our ability to arrange for and rely on 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. 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 and CINVANTI, as well as key components for product candidates in clinical and preclinical testing in our research and development program. Although we entered into single-source, long-term commercial manufacturing agreements for the manufacture of SUSTOL and CINVANTI, and we have a long-term agreement for the manufacture of our Biochronomer technology, we might not be able to successfully negotiate long-term agreements with any additional third parties, or we might not receive all required regulatory approvals to utilize such third parties, and, accordingly, we might not be able to reduce or remove our dependence on a single supplier for the commercial manufacturing of SUSTOL, CINVANTI or any other product we may develop for marketing. 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 cGMP 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, 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 a 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, CINVANTI, HTX-011 or any of our other product candidates may be in competition with other products for access to the facilities of third parties. Consequently, SUSTOL, CINVANTI, HTX-011 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, CINVANTI, HTX-011 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, CINVANTI, HTX-011 and our other product candidates are sourced from a single vendor.

Some of the critical materials and components used in manufacturing SUSTOL, CINVANTI, HTX-011 and our other product candidates are sourced from single suppliers. An interruption in the supply of a key material could significantly delay 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 that provides 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.

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

SUSTOL faces significant competition. Currently available 5-hydroxytryptamine type 3 ("5-HT_3") receptor antagonists include: AKYNZEO® (palonosetron, a 5-HT_3 receptor antagonist, combined with netupitant, a neurokinin-1 ("NK_1") receptor antagonist, marketed by Eisai, Inc.); SANCUSO® (granisetron transdermal patch, marketed by ProStrakan Group Plc); and generic products including ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN), granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL) and palonosetron (formerly marketed by Eisai in conjunction with Helsinn Healthcare S.A. as ALOXI). Currently, palonosetron is the only 5-HT_3 receptor antagonist other than SUSTOL that is approved for the prevention of delayed CINV associated with MEC regimens. SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of MEC or AC combination chemotherapy, which is considered to be a HEC regimen by the NCCN and the American Society of Clinical Oncology. No other 5-HT_3 receptor antagonist is specifically approved for the prevention of delayed CINV associated with a HEC regimen.

NK_1 receptor antagonists are also administered for the prevention of CINV, in combination with 5-HT_3 receptor antagonists, to augment the therapeutic effect of the 5-HT_3 receptor antagonist. CINVANTI faces significant competition. Currently available NK_1 receptor antagonists include: AKYNZEO® (palonosetron, a 5-HT_3 receptor antagonist, combined with netupitant, an NK_1 receptor antagonist, marketed by Eisai, Inc.); EMEND® (aprepitant, marketed by Merck & Co, Inc.); EMEND® IV (fosaprepitant, marketed by Merck & Co); VARUBI® (rolapitant, marketed by Tesaro, Inc.) and potentially other products that include an NK_1 receptor antagonist that reach the market.

If we are able to successfully develop HTX-011 for the prevention of postoperative pain, we will compete with MARCAINE (bupivacaine, marketed by Hospira, Inc.) and generic forms of bupivacaine; NAROPIN (ropivacaine, marketed by Fresenius Kabi USA, LLC) and generic forms of ropivacaine; EXPAREL® (bupivacaine liposome injectable suspension, marketed by Pacira Pharmaceuticals, Inc.) and potentially other products in development for the prevention of postoperative pain that reach the market.

Small 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. On the expiration or loss of patent protection for a branded product, or on 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. For example, while we had expected that generic versions of ALOXI (palonosetron) would launch in September 2018, a U.S. Court of Appeals decision in May 2017 ruled in favor of a generic drug company challenging the ALOXI patents. Accordingly, we expect increased competition for SUSTOL, which could reduce SUSTOL sales and harm our business prospects. These and other risks related to the potential entry of generic product competing with SUSTOL are difficult to assess in terms of timing and impact on our operations and prospects.

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 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, licenses or investments in strategic technologies, products or businesses. Future acquisitions, licenses 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 or licensed 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 or licensed technology and/or products sufficient to meet our objectives in undertaking the acquisition or license 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 or license.

In connection with an acquisition or license, 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, may 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 on 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 researching our product candidates pursuant 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 on 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.

Natural disasters, acts of war or terrorism or resource shortages could disrupt our investigational drug candidate development and approved drug commercialization efforts and adversely affect results.

Our ongoing or planned clinical studies and approved drug commercialization efforts could be delayed or disrupted indefinitely on the occurrence of a natural disaster or act of war or terrorism. We are also vulnerable to damage from other disasters, such as power loss, fire, floods, hurricanes and similar events. For example, a natural disaster, or act of war or terrorism, and the resulting damage could negatively impact enrollment and participation in our clinical studies, divert attention and resources at our research sites, cause unanticipated delays in the collection and receipt of data from our clinical studies, cause unanticipated delays in communications with, and any required approvals from, the FDA and other regulatory authorities, and cause unanticipated delays in the manufacturing and distribution of SUSTOL, CINVANTI and any other products we may develop. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial condition.

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 $834.1 million through March 31, 2018. We expect to continue to generate substantial losses over at least the next several years as we:

- 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 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, including our current work commercializing SUSTOL and CINVANTI. 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 March 31, 2018, we had cash, cash equivalents and short-term investments of $113.9 million. In April 2018, we received net cash proceeds of $168.7 million from a public offering of our common stock. 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 timing and costs associated with the commercial launch of CINVANTI; the degree of commercial success of SUSTOL and CINVANTI; the scope, rate of progress, results and costs of preclinical testing and clinical trials; the timing and cost to manufacture our products; 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 needed 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:

- our ability to successfully commercialize, market and achieve market acceptance of SUSTOL and CINVANTI;
- 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 or enlarging sales and marketing capabilities; 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 new 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 ("Promissory 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 Promissory Note (collectively, "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 contain provisions that trigger events of default on 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. SUSTOL, CINVANTI, 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 incurred significant expenses in developing SUSTOL and CINVANTI, with no guarantees that doing so would 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 in the future impose more stringent requirements than are currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfying the FDA's, and other regulatory agencies', requirements typically takes a significant number of years and can vary substantially based on 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;
- 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 caused by a regional disturbance where we or our collaborative partners are enrolling patients in clinical studies, such as a pandemic, terrorist activities, or war, political unrest, a natural disaster or any other reason or event, resulting in increased costs;
- any delay in obtaining advice from the FDA or similar regulatory authorities; 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 of subjects completing a trial or returning 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 Institutional Review Board ("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;
- decisions by the FDA, the IRB, comparable foreign regulatory entities, or recommendations 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 profiles 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 investigate. 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 CROs' 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 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 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 our product candidates in development. 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 our product candidates in development, our business will be substantially harmed.

The process for obtaining regulatory approval of a new drug is time consuming, is 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 our product candidates currently in development 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.

Our 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. Additionally, in 2013, the U.S. federal government entered a shutdown suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations in 2014. Our development and commercialization activities could be harmed or delayed by a similar shutdown of the U.S. federal government in the future, which may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could have a material adverse effect on our business.

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, CINVANTI or any other products we may develop from being marketed abroad.

In the event we pursue the right to market and sell SUSTOL, CINVANTI or any other products we may develop 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 our product candidates in development receive regulatory approval, they 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 our product candidates in development, they remain 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 postmarket information. Following initial regulatory approval for drugs we develop, including SUSTOL, CINVANTI or any other products we may develop, we remain 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 postmarketing 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 postmarket 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. We are also 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, once 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.

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 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, once 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.

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.

We are 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 payor, 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 require 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 1977, as amended ("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 ("SEC"). 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.

We may incur significant liability if it is determined that we are promoting the "off-label" use of drugs or promoting in a non-truthful and misleading way.

We are prohibited from promoting SUSTOL, CINVANTI or any other products we may develop for "off-label" uses or promoting in a non-truthful and misleading way that are not described in its labeling and that differ from the uses approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. The FDA and other regulatory agencies do not regulate a physician's choice of treatments. However, they do restrict pharmaceutical companies and their sales representatives' dissemination of information concerning off-label use. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of products for off-label uses and the promotion of products for which marketing authorization has not been obtained. A company that is found to have promoted products for off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchanges concerning their products.

The FDA or other regulatory authorities may conclude that we have violated applicable laws, rules or regulations, and we may therefore be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. Such enforcement actions could cause us reputational harm and divert the attention of our management from our business operations. Likewise, our distribution and contracting partners and those providing vendor support services may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label promotion of SUSTOL, CINVANTI or any other products we may develop, which may adversely impact sales of SUSTOL, CINVANTI or any other products we may develop or trigger indemnification obligations. These consequences, could, in turn, have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

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 on 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, 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, such as the General Data Protection Regulation in the European Union that becomes effective in May 2018. 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 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 March 31, 2018, we had a total of 22 issued U.S. patents and an additional 28 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between June 2018 and March 2026. Currently, SUSTOL is covered by seven patents issued in the U.S. and by 27 patents issued in foreign countries including Austria, Belgium, Canada, Denmark, the EU, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. U.S. patents covering SUSTOL have expiration dates ranging from May 2021 to September 2024; foreign patents covering SUSTOL have expiration dates ranging from May 2021 to September 2025. Currently, CINVANTI is covered by two patents issued in the U.S. with expiration dates of September 2035. HTX-011 is protected by seven patents issued in the U.S. with expiration dates ranging from May 2021 to April 2035 and one patent issued in Mexico with expiration date of March 2034. Our policy is to actively seek patent protection in the U.S. 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 that 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 on the scope of protection decided on by the patent offices, courts and lawmakers in these countries. The America Invents Act, which was enacted in 2011 and 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 on 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 that 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.

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 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 March 31, 2018, we would be required to issue an aggregate of 8,102,702 shares, representing 11% of our outstanding shares, after giving effect to such conversion. This would result in substantial dilution of our existing stockholders.

On March 28, 2018, the Company and Tang Capital Partners, LP ("TCP") executed a waiver (the "Waiver") pursuant to which TCP waived: (i) our obligation under the Securities Purchase Agreement, dated April 24, 2011, among us, TCP and certain other investors to maintain a sufficient number of authorized shares of our common stock to permit the conversion of TCP's outstanding principal and interest under the Convertible Notes to our common stock; and (ii) its right to convert the Convertible Notes for the duration of the Waiver. The Waiver will remain effective until the earliest to occur of: (i) a change in the control of the Company; (ii) the Company's stockholders approving an increase of the number of authorized shares of our common stock; and (iii) September 28, 2018. If, upon the expiration of the Waiver, TCP seeks to convert part or all of the Convertible Notes and we do not have a sufficient number of authorized shares of our common stock to permit the conversion of the portion of the Convertible Notes being converted, then we will be obligated to make a cash payment to TCP equal to the value of the underlying shares of common stock that we are unable to deliver on conversion based on the price of our common stock at such time.

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 April 2, 2018, the beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, of TCP was 8,525,215 shares, or 12% of our outstanding shares of common stock on April 3, 2018. In addition, as of March 31, 2018, TCP has the right to acquire 6,482,161 shares on 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 carryforwards 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, 2016, 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 Capital 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

On May 8, 2018, we entered into a Second Amendment to Lease (the “Lease Amendment”) with AP3-SD1 Campus Point LLC (the “Landlord”), amending that certain Lease, dated October 18, 2016, by and between us and the Landlord, as amended by that certain First Amendment to Lease, dated March 15, 2017 (the “Lease”). The Lease Amendment provides for us to lease additional office space in the building located at 4242 Campus Point Court, San Diego, California, for a period of 87 months, beginning on the date that our improvements to the premises are substantially complete. Pursuant to the Lease Amendment, we have agreed to pay a basic annual rent that increases incrementally over the term of the Lease Amendment from $0.9 million for the first 12 months of the Lease Amendment (inclusive of certain rent abatements) to a prorated portion of a basic annual rent of $1.4 million for the last three months of the Lease Amendment, and such other amounts as set forth in the Lease Amendment. We also paid to the Landlord an additional security deposit in the amount of $0.1 million. Except as modified by the Lease Amendment, all of the provisions of the Lease will continue unmodified and in full force and effect.

The foregoing description of the terms of the Lease Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Lease Amendment, a copy of which is attached hereto as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	Second Amendment to Lease, dated May 8, 2018, by and between Heron Therapeutics, Inc. and AP3-SD1 Campus Point LLC
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: May 10, 2018

/s/ Barry D. Quart

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

/s/ Robert E. Hoffman

Robert E. Hoffman
Chief Financial Officer and
Senior Vice President, Finance
(As Principal Financial and Accounting Officer)

SECOND AMENDMENT TO LEASE
(Genesis Campus Point)

THIS SECOND AMENDMENT TO LEASE ("**Second Amendment**") is made and entered into as of the 8th day of May, 2018, by and between AP3-SD1 CAMPUS POINT LLC, a Delaware limited liability company ("**Landlord**") and HERON THERAPEUTICS, INC., a Delaware corporation ("**Tenant**").

R E C I T A L S:

A. Landlord and Tenant entered into that certain Lease dated as of October 18, 2016 (the "**Original Lease**"), as amended by (i) that certain Notice of Lease Term Dates dated December 14, 2016 ("**Commencement Notice**") and (ii) that certain First Amendment to Lease dated as of March 15, 2017 by and between Landlord and Tenant ("**First Amendment**"), whereby Landlord leases to Tenant and Tenant leases from Landlord, certain space in the building (the "**Building**") located at 4242 Campus Point Court, San Diego, California 92121. The Original Lease, as modified by the Commencement Notice and the First Amendment, may be referred to herein as the "**Lease**."

B. By this Second Amendment, Landlord and Tenant desire to expand the Existing Premises (defined below) and to otherwise modify the Lease as provided herein.

C. Unless otherwise defined herein, capitalized terms as used herein shall have the same meanings as given thereto in the Lease.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

A G R E E M E N T:

1. Existing Premises. Landlord and Tenant hereby acknowledge that pursuant to the Lease, Landlord currently leases to Tenant and Tenant currently leases from Landlord that certain space in the Building containing approximately 28,275 rentable square feet square feet of space on the second (2nd) floor of the Building and commonly known as Suite 200 (the "**Existing Premises**"), all as more particularly described in the Lease.

2. Expansion of the Existing Premises; Expansion Commencement Date.

2.1. Expansion Space. That certain space commonly known as Suite 400 and comprised of 23,873 rentable square feet located on the fourth (4th) floor of the Building, as outlined on the floor plan attached hereto as Exhibit A and made a part hereof, may be referred to herein as the "**Expansion Space**."

2.2. Expansion Commencement Date. Effective as of the date the Expansion Space is Ready for Occupancy (as defined in the Tenant Work Letter attached hereto as Exhibit B) ("**Expansion Commencement Date**"), Tenant shall lease from Landlord and Landlord shall lease to Tenant, the Expansion Space. The anticipated Expansion

Commencement Date is September 1, 2018. Upon the Expansion Commencement Date, the Existing Premises shall be deemed increased to include the Expansion Space. Landlord and Tenant hereby agree that such addition of the Expansion Space to the Existing Premises shall, effective as of the Expansion Commencement Date, increase the number of rentable square feet leased by Tenant in the Building to a total of 52,148 rentable square feet. Effective as of the Expansion Commencement Date, all references to the "**Premises**" shall mean and refer to the Existing Premises as expanded by the Expansion Space. Effective as of the date hereof, Section 1.3 of the Original Lease is hereby deemed deleted in its entirety. Tenant's early entry/early occupancy rights with respect to the Expansion Space are set forth in Section 5.1 of Exhibit B.

3. Expansion Space Term. The Term of Tenant's lease of the Expansion Space ("**Expansion Space Term**") shall commence on the Expansion Commencement Date and shall expire on the last day of the month in which the eighty-seventh (87th) monthly anniversary of the Expansion Commencement Date occurs ("**Expansion Termination Date**"), subject to Tenant's extension rights in the Lease. Landlord may deliver to Tenant an amendment or confirmation memorandum in the form of Exhibit C of the Original Lease (confirming the Expansion Commencement Date and Expansion Termination Date) and such other matters desired by Landlord), which amendment or confirmation memorandum Tenant shall execute and return to Landlord within five (5) business days of receipt thereof.

4. Base Rent for Expansion Space. Notwithstanding anything to the contrary in the Lease, commencing on the Expansion Commencement Date, Tenant shall pay, in accordance with the provisions of this Section 4 but subject to abatement as provided in Section 5 below, Base Rent for the Expansion Space as follows:

Months of Expansion Space Term	Annualized Base Rent	**Monthly Installment of Base Rent	Monthly Rental Rate per Rentable Square Foot
*1 – 12	$1,174,551.60	$ 97,879.30	$ 4.10
13 – 24	$1,209,788.16	$100,815.68	$ 4.22***
25 – 36	$1,246,081.80	$103,840.15	$ 4.35***
37 – 48	$1,283,464.20	$106,955.35	$ 4.48***
49 – 60	$1,321,968.12	$110,164.01	$ 4.61***
61 – 72	$1,361,627.16	$113,468.93	$ 4.75***
73 – 84	$1,402,476.00	$116,873.00	$ 4.90***
85 – 87	$1,444,550.28	$120,379.19	$ 5.04***

*Subject to abatement as provided in Section 5 below.

**The initial monthly installment of Base Rent amount was calculated by multiplying the initial monthly Base Rent rate per rentable square foot amount by the number of rentable square feet of space in the Expansion Space. In all subsequent Base Rent payment periods, the calculation of each monthly installment of Base Rent amount reflects an annual increase of three percent (3.0%).
***The amounts identified in the column entitled "Monthly Rental Rate per Rentable Square Foot" are rounded amounts provided for informational purposes only.

5. Monthly Base Rent Abatement. Notwithstanding anything to the contrary contained in the Lease or in this Second Amendment, Landlord hereby agrees to abate Tenant's obligation to pay (i) one hundred percent (100%) of Tenant's monthly Base Rent for the first (1st) full month of the Expansion Space Term, and (ii) fifty percent (50%) of Tenant's monthly Base Rent for the second (2nd), third (3rd), fourth (4th) and fifth (5th) full months of the Expansion Space Term (collectively, the "**Base Rent Abatement**"). During such abatement period, Tenant shall still be responsible for the payment of all of its other monetary obligations under the Lease, as amended by this Second Amendment. The foregoing Base Rent Abatement has been granted to Tenant as additional consideration for entering into this Second Amendment, and for agreeing to pay the Rent and performing the terms and conditions otherwise required under this Lease. If Tenant shall be in Economic Default or Material Non-Economic Default under the Lease (as modified by this Second Amendment) at any time during the Base Rent Abatement Period beyond the expiration of all applicable notice and cure periods, if any, then the unamortized portion of the Base Rent Abatement granted to Tenant pursuant to this Section 5 may be considered when determining the remedies available to Landlord pursuant to the terms of Article 19 of the Original Lease.

6. Condition of Premises and Landlord's Work.

6.1. Condition of Premises. Tenant hereby agrees to accept the Premises (including the Existing Premises and the Expansion Space) in its "as-is" condition and Tenant hereby acknowledges that Landlord, except as otherwise provided in this Second Amendment shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises. Tenant also acknowledges that Landlord has made no representation or warranty regarding the condition of the Premises. Notwithstanding the foregoing, Landlord shall deliver the Expansion Space to Tenant on the Expansion Commencement Date in good working order, condition and repair.

6.2. Landlord's Work. Landlord shall, as soon as reasonably possible following the full execution and delivery of this Second Amendment by Landlord and Tenant, construct, in Landlord's Building-standard manner and using Building-standard materials, the Tenant Improvement work in the Expansion Space pursuant to (and subject to) the Tenant Work Letter attached hereto.

7. Parking. Commencing as of the Expansion Commencement Date, Tenant shall be entitled to lease seventy-one (71) additional unreserved parking spaces at no additional cost. Tenant's use of all such additional parking spaces shall be subject to the terms and conditions of the Lease.

8. Tenant's Share of Direct Expenses, Tax Expenses and Utilities Costs. Notwithstanding anything to the contrary in the Lease, commencing as of the Expansion Commencement Date, Tenant's Share of Direct Expenses shall be deemed increased to 39.25%.

9. Brokers. Each party represents and warrants to the other that, except for Cushman & Wakefield ("**Tenant's Broker**") and Jones Lang LaSalle ("**Landlord's Broker**"), no broker, agent or finder negotiated or was instrumental in negotiating or consummating this Second Amendment. Each party further agrees to defend, indemnify and hold harmless the other party from and against any claim for commission or finder's fee by any person or entity (other than Tenant's Broker and Landlord's Broker) who claims or alleges that they were retained or engaged by the first party or at the request of such party in connection with this Second Amendment.

10. Security Deposit. Concurrently with Tenant's execution of the Lease (and pursuant to Article 21 of the Original Lease), Tenant provided Landlord with a Security Deposit in the amount of One Hundred Thirty-Three Thousand One Hundred Eighty-Seven and 04/100 Dollars ($133,187.04). Concurrently with Tenant's execution and delivery of this Second Amendment, Tenant shall deliver to Landlord an additional Security Deposit amount equal to One Hundred Twenty Thousand Three Hundred Seventy-Nine and 19/100 Dollars ($120,379.19) (for a total Security Deposit equal to Two Hundred Fifty-Three Thousand Five Hundred Sixty-Six and 23/100 Dollars ($253,566.23)). From and after the Effective Date, all references in the Lease to the Security Deposit shall mean and refer to the Security Deposit as increased pursuant to this Second Amendment.

11. Restoration. Notwithstanding anything in the Lease to the contrary, at Landlord's election (in Landlord's sole discretion), such election to be made no later than ninety (90) days prior to the Expansion Termination Date, Tenant shall, at Tenant's sole cost and expense, restore the lab portion(s) of the Tenant Improvements constructed by Landlord (and depicted on Exhibit C), back to the condition existing as of the date hereof and repair any damage to the Building caused by such restoration. Landlord's failure to make such election shall be deemed Landlord's election that Tenant so restore such lab portion(s). Notwithstanding the foregoing, Tenant shall have the right to consult with Landlord to confirm such restoration obligation.

12. Storage Areas. Tenant shall be allowed to use the general storage area depicted on the attached Exhibit D for general storage and the hazardous materials storage area depicted on the attached Exhibit E for hazardous materials storage. Such storage areas are provided to Tenant in their as-is condition and Landlord shall not be obligated to make any improvements or repairs to such storage areas.

13. Signing Authority. Each individual executing this Second Amendment on behalf of Landlord and Tenant hereby represents and warrants that each person, respectively, is authorized to do so. Each of Landlord and Tenant represents and warrants that it is a duly formed and existing entity qualified to do business in the State of California and has full right and authority to execute and deliver this Second Amendment.

14. Defaults. Each party hereby represents and warrants to the other party that, as of the date of this Second Amendment, such party is in full compliance with all terms, covenants

and conditions of the Lease and that there are no breaches or defaults under the Lease by Landlord or Tenant, and that each party knows of no events or circumstances which, given the passage of time, would constitute a default under the Lease by either Landlord or Tenant.

15. No Further Modification. Except as set forth in this Second Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.

[SIGNATURES APPEAR ON FOLLOWING PAGE]

IN WITNESS WHEREOF, this Second Amendment has been executed as of the day and year first above written.

"LANDLORD"	AP3-SD1 CAMPUS POINT, LLC, a Delaware limited liability company By: /s/ W. Neil Fox III Name: W. Neil Fox III Its: Chief Executive Officer
"TENANT"	HERON THERAPEUTICS, INC., a Delaware corporation By: /s/ David Szekeres Name: David Szekeres Its: SVP, General Counsel & Business Development

EXHIBIT A

EXPANSION SPACE

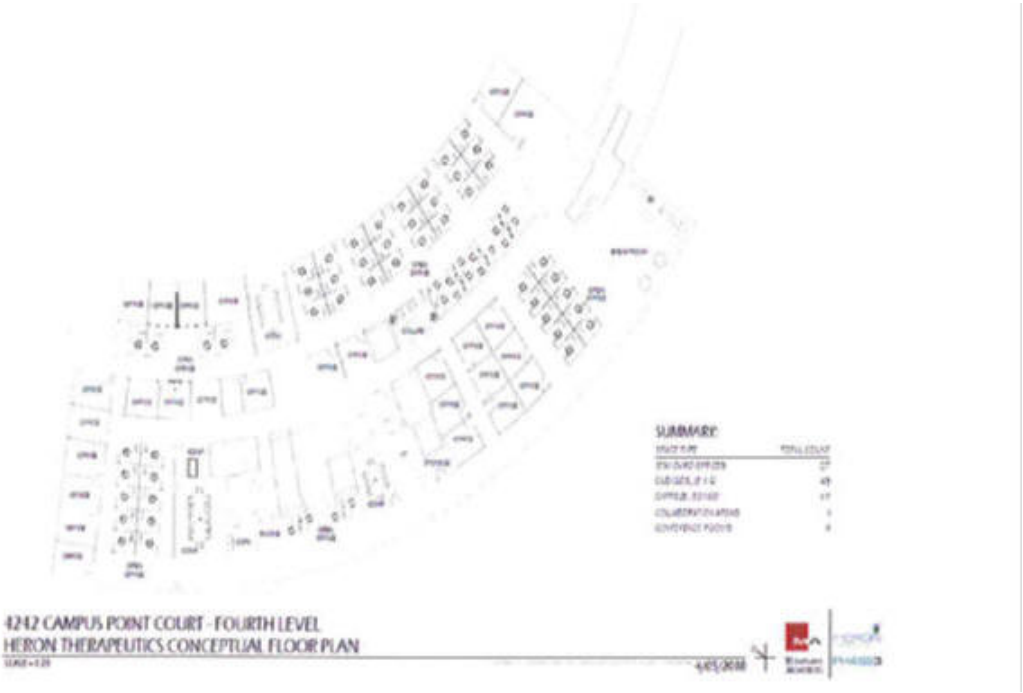

EXHIBIT B

TENANT WORK LETTER

This Tenant Work Letter ("**Tenant Work Letter**") sets forth the terms and conditions relating to the construction of improvements for the Expansion Space. All references in this Tenant Work Letter to the "**Second Amendment**" shall mean the relevant portions of the Second Amendment to which this Tenant Work Letter is attached as **Exhibit B**.

SECTION 1

BASE, SHELL AND CORE

Landlord has previously constructed the base, shell and core (i) of the Premises and (ii) of the floor(s) of the Building on which the Expansion Space is located (collectively, the "**Base, Shell and Core**"), and Tenant shall accept the Base, Shell and Core in its current "As-Is" condition existing as of the date of the Second Amendment and the Expansion Commencement Date. Except as otherwise provided below, Landlord shall not be obligated to make or pay for any alterations or improvements to the Expansion Space, the Building or the Project.

SECTION 2

CONSTRUCTION DRAWINGS FOR THE EXPANSION SPACE

Prior to the execution of the Second Amendment, Landlord and Tenant have approved a detailed space plan for the construction of certain improvements in the Expansion Space, which space plan has been prepared by McFarlane Architects, dated April 5, 2018 (the "**Final Space Plan**"), which Final Space Plan is attached hereto as **Schedule 1**. Based upon and in conformity with the Final Space Plan, Landlord shall cause its architect and engineers to prepare and deliver to Tenant, for Tenant's approval, detailed specifications and engineered working drawings for the tenant improvements shown on the Final Space Plan (the "**Working Drawings**"). The Working Drawings shall incorporate modifications to the Final Space Plan as necessary to comply with the floor load and other structural and system requirements of the Building. To the extent that the finishes and specifications are not completely set forth in the Final Space Plan for any portion of the tenant improvements depicted thereon, the actual specifications and finish work shall be in accordance with the specifications for the Building's standard tenant improvement items, as determined by Landlord. Within five (5) business days after Tenant's receipt of the Working Drawings, Tenant shall approve or disapprove the same, which approval shall not be unreasonably withheld; provided, however, that Tenant may only disapprove the Working Drawings to the extent such Working Drawings are inconsistent with the Final Space Plan and only if Tenant delivers to Landlord, within such five (5) business day period, specific changes proposed by Tenant which are consistent with the Final Space Plan and do not constitute changes which would result in any of the circumstances described in items (i) through (iii) hereinbelow. If any such revisions are timely proposed by Tenant, Landlord shall cause its architect and engineers to revise the Working Drawings to incorporate such revisions and submit the same for Tenant's approval in accordance with the foregoing provisions, and the parties shall follow the

foregoing procedures for approving the Working Drawings until the same are finally approved by Landlord and Tenant. Upon Landlord's and Tenant's approval of the Working Drawings, the same shall be known as the "**Approved Working Drawings**". The tenant improvements shown on the Approved Working Drawings shall be referred to herein as the "**Tenant Improvements**". Once the Approved Working Drawings have been approved by Landlord and Tenant, Tenant shall make no changes, change orders or modifications thereto without the prior written consent of Landlord, which consent may be withheld in Landlord's sole discretion if such change or modification would: (i) be of a quality lower than the quality of the standard tenant improvement items for the Building; and/or (ii) require any changes to the Base, Shell and Core or structural improvements or systems of the Building and/or (iii) delay Substantial Completion of the Expansion Space. The Final Space Plan, Working Drawings and Approved Working Drawings shall be collectively referred to herein as, the "**Construction Drawings**".

SECTION 3

CONSTRUCTION AND PAYMENT FOR COSTS OF TENANT IMPROVEMENTS

Landlord shall cause a general contractor designated by Landlord (the "**Contractor**") to construct the Tenant Improvements as depicted on the Approved Working Drawings, in compliance with all applicable laws in effect at the time of construction, and in good workmanlike manner. Landlord shall pay for the costs of the design, permitting and construction of the Tenant Improvements in an amount up to, but not exceeding, Thirty Dollars ($30.00) per rentable square foot of the Expansion Space (i.e., up to Seven Hundred Sixteen Thousand One Hundred Ninety Dollars ($716,190.00), based on 23,873 rentable square feet of the Expansion Space) (the "**Allowance**"). The cost of the design, permitting and construction of the Tenant Improvements shall include Landlord's construction supervision and management fee in an amount equal to the product of (i) three percent (3%) and (ii) the amount equal to the sum of the Allowance and the Over-Allowance Amount (as such term is defined below); such supervision fee shall be deducted by Landlord from the Allowance. Tenant shall pay for all costs of the design, permitting and construction of the Tenant Improvements in excess of the Allowance ("**Over Allowance Amount**"), which payment shall be made to Landlord in cash within five (5) business days after Tenant's receipt of invoice therefor from Landlord and, in any event, prior to the date Landlord causes the Contractor to commence the actions described in the first sentence of this Section 3. If after Tenant pays the Over-Allowance Amount Tenant requests any changes, change orders or modifications to the Approved Working Drawings (which Landlord approves pursuant to Section 2 above) which increase the costs of the design, permitting and construction of the Tenant Improvements, Tenant shall pay such increased cost to Landlord within five (5) business days after Landlord's request therefor, and, in any event, prior to the date Landlord causes the Contractor to commence construction of the changes, change orders or modifications. Except as otherwise provided below, in no event shall Landlord be obligated to pay for, the costs of any of Tenant's furniture, computer systems, telephone systems, equipment or other personal property which may be depicted on the Construction Drawings; the costs of such items shall be paid for by Tenant from Tenant's own funds. Tenant shall not be entitled to receive in cash or as a credit against any rental or otherwise, any portion of the Allowance not used to pay for the costs of the design, permitting and construction of the Tenant Improvements; provided, however, that Tenant may, subject to the terms hereof, use any unused amount of the Allowance to pay for costs of furniture, fixtures and equipment for the Premises and costs of

installing cabling for the Premises (collectively, the "**Other Costs**"). Prior to Tenant ordering or contracting for services associated with the Other Costs, Tenant shall submit to Landlord, for Landlord's reasonable approval, a schedule of the estimated Other Costs based on estimates provided to Tenant by vendors selected by Tenant and reasonably approved by Landlord. Landlord shall disburse from the Allowance such amounts to pay for such Other Costs previously approved by Landlord pursuant to the immediately preceding sentence and actually incurred by Tenant, within thirty (30) days after the later of (i) Landlord's receipt of invoices evidencing Tenant's Other Costs and (ii) the Expansion Commencement Date. Any portion of the Allowance which is not so requested by Tenant on or before the date which is thirty (30) days after the Expansion Commencement Date shall revert to Landlord. Notwithstanding anything above to the contrary, in no event shall any unused amount of the Allowance be applied for any Other Costs in excess of fifteen percent (15%) of the fair market value of all real and personal property in the Premises.

SECTION 4

READY FOR OCCUPANCY; SUBSTANTIAL COMPLETION OF THE TENANT IMPROVEMENTS

4.1 Ready for Occupancy; Substantial Completion. For purposes of the Second Amendment, including for purposes of determining the Expansion Commencement Date (as set forth in Section 2.2 of the Second Amendment), the Expansion Space shall be "**Ready for Occupancy**" upon Substantial Completion of the Expansion Space; and (ii) "**Substantial Completion of the Expansion Space**" shall occur upon the completion of construction of the Tenant Improvements in the Expansion Space pursuant to the Approved Working Drawings, with the exception of any punch list items that do not materially and adversely affect Tenant's use and occupancy of the Expansion Space and any tenant fixtures, work-stations, built-in furniture, or equipment to be installed by Tenant or under the supervision of the Contractor.

4.2 Delay of the Substantial Completion of the Expansion Space. If there shall be a delay or there are delays in the Substantial Completion of the Expansion Space as a result of any of the following (collectively, "**Tenant Delays**"):

4.2.1 Tenant's failure to timely approve the Working Drawings or any other matter requiring Tenant's approval;

4.2.2 a breach by Tenant of the terms of this Tenant Work Letter or the Lease (as modified by the Second Amendment);

4.2.3 Tenant's request for changes in any of the Construction Drawings;

4.2.4 Tenant's requirement for materials, components, finishes or improvements which are not available in a commercially reasonable time given the estimated date of Substantial Completion of the Expansion Space, as set forth in the Second Amendment, or which are different from, or not included in, Landlord's standard tenant improvement items for the Building;

4.2.5 changes to the Base, Shell and Core, structural components or structural components or systems of the Building required by the Approved Working Drawings;

4.2.6 any changes in the Construction Drawings and/or the Tenant Improvements required by applicable laws if such changes are directly attributable to Tenant's use of the Expansion Space or Tenant's specialized tenant improvement(s) (as determined by Landlord); or

4.2.7 any other acts or omissions of Tenant, or its agents, or employees;

then, notwithstanding anything to the contrary set forth in the Second Amendment and regardless of the actual date of Substantial Completion of the Expansion Space, the Expansion Commencement Date (as set forth in Section 2.2 of the Second Amendment) shall be deemed to be the date the Expansion Commencement Date would have occurred if no Tenant Delays, as set forth above, had occurred.

SECTION 5

MISCELLANEOUS

5.1 Tenant's Entry Into the Expansion Space Prior to Substantial Completion. Subject to the terms hereof and provided that Tenant and its agents do not interfere with the Contractor's work in the Expansion Space, at Landlord's reasonable discretion, Landlord shall use commercially reasonable efforts to allow Tenant access to the Expansion Space not less than thirty (30) days prior to the anticipated Substantial Completion of the Expansion Space for the purpose of Tenant installing equipment and/or fixtures (including Tenant's data and telephone equipment) and Tenant's furniture in the Expansion Space. Subject to Tenant's compliance with all applicable laws and subject to the terms hereof, Tenant shall also have the right to install cubicles in a portion of the Expansion Space reasonably approved by Landlord and to allow up to twenty-five (25) of Tenant's employees to work from such cubicles prior to the Expansion Commencement Date. Prior to Tenant's entry into and occupancy of the Expansion Space as permitted by the terms of this Section 5.1, Tenant shall submit a schedule to Landlord and the Contractor, for their approval (which approval shall not be unreasonably withheld or delayed), which schedule shall detail the timing and purpose of Tenant's entry. In connection with any such entry/occupancy, Tenant acknowledges and agrees that Tenant's employees, agents, contractors, consultants, workmen, mechanics, suppliers and invitees shall fully cooperate, work in harmony and not, in any manner, interfere with Landlord or Landlord's contractors (including the Contractor), agents or representatives in performing work in the Project, the Building and the Expansion Space, or interfere with the general operation of the Building and/or the Project. If at any time any such person representing Tenant shall not be cooperative or shall otherwise cause or threaten to cause any such disharmony or interference, including, without limitation, labor disharmony, and Tenant fails to immediately institute and maintain corrective actions as directed by Landlord, then Landlord may revoke Tenant's entry rights upon twenty-four (24) hours' prior written notice to Tenant. Tenant acknowledges and agrees that any such entry into and occupancy of the Expansion Space or any portion thereof by Tenant or any person or entity working for or on behalf of Tenant shall be deemed to be subject to all of the terms, covenants, conditions and provisions of the Lease, excluding only the covenant to pay Rent (until the

occurrence of the Expansion Commencement Date). Such requirements shall include, without limitation, that Tenant and any other parties allowed access to the Expansion Space shall provide Landlord with evidence of insurance as required by Landlord. Tenant further acknowledges and agrees that Landlord shall not be liable for any injury, loss or damage which may occur to any of Tenant's work made in or about the Expansion Space in connection with such entry or to any property placed therein prior to the Expansion Commencement Date, the same being at Tenant's sole risk and liability. Tenant shall be liable to Landlord for any damage to any portion of the Expansion Space, including the Tenant Improvement work, caused by Tenant or any of Tenant's employees, agents, contractors, consultants, workmen, mechanics, suppliers and invitees. If the performance of Tenant's work in connection with such entry causes extra costs to be incurred by Landlord or requires the use of any Building services, Tenant shall promptly reimburse Landlord for such extra costs and/or shall pay Landlord for such Building services at Landlord's standard rates then in effect. In addition, Tenant shall hold Landlord harmless from and indemnify, protect and defend Landlord against any loss or damage to the Expansion Space or Project and against injury to any persons caused by Tenant's actions pursuant to this Section 5.1.

5.2 Tenant's Representative. Tenant has designated David Szekeres as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Landlord, shall have full authority and responsibility to act on behalf of the Tenant as required in this Tenant Work Letter.

5.3 Landlord's Representative. Landlord has designated Evan Gutenberg as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of the Landlord as required in this Tenant Work Letter.

5.4 Time of the Essence in This Tenant Work Letter. Unless otherwise indicated, all references herein to a "number of days" shall mean and refer to calendar days. If any item requiring approval is timely disapproved by Landlord, the procedure for preparation of the document and approval thereof shall be repeated until the document is approved by Landlord. Both Landlord and Tenant shall use commercially reasonable, good faith, efforts and all due diligence to cooperate with each other to complete all phases of the Construction Drawings and the permitting process and to receive the permits, as soon as possible after the execution of the Second Amendment, and, in that regard, shall meet on a scheduled basis to be determined by Landlord and Tenant, to discuss progress in connection with the same.

5.5 Tenant's Lease Default. Notwithstanding any provision to the contrary contained in the Lease, if an event of default by Tenant of this Tenant Work Letter or the Lease (as modified by the Second Amendment) has occurred at any time on or before the Substantial Completion of the Expansion Space and remains uncured after the expiration of applicable notice and cure periods, then (i) in addition to all other rights and remedies granted to Landlord pursuant to the Lease, at law and/or in equity, Landlord shall have the right to cause the Contractor to suspend the construction of the Expansion Space (in which case, Tenant shall be responsible for any delay in the Substantial Completion of the Expansion Space caused by such work stoppage as a Tenant Delay as set forth in Section 4.2 above), and (ii) all other obligations of Landlord under the terms of this Tenant Work Letter shall be forgiven until such time as such default is cured pursuant to the terms of the Lease (in which case, Tenant shall be responsible for

any delay in the Substantial Completion of the Expansion Space caused by such inaction by Landlord as a Tenant Delay). In addition, if the Lease is terminated prior to the Expansion Commencement Date due to a default (beyond the expiration of all applicable notice and cure periods) by Tenant as described in Article 19 of the Original Lease or under this Tenant Work Letter, in addition to any other remedies available to Landlord under the Lease, at law and/or in equity, Tenant shall pay to Landlord, as Additional Rent under the Lease, within five (5) business days after Tenant's receipt of a statement therefor, any and all actual, documented and reasonable costs incurred by Landlord and not reimbursed or otherwise paid by Tenant through the date of such termination in connection with the Tenant Improvements to the extent planned, installed and/or constructed as of such date of termination, including, but not limited to, any actual, documented and reasonable costs related to the removal of all or any portion of the Tenant Improvements and restoration costs related thereto; provided, however, in no event shall Tenant's payment of the foregoing result in a double recovery of damages by Landlord.

SCHEDULE 1

FINAL SPACE PLAN

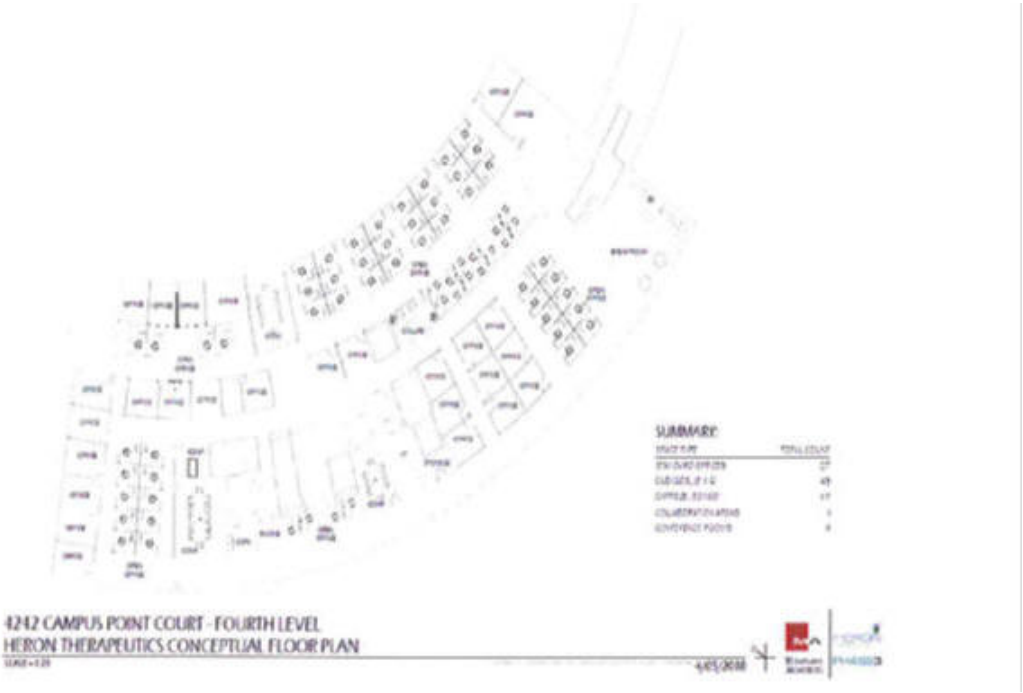

EXHIBIT C

LAB RESTORATION AREA

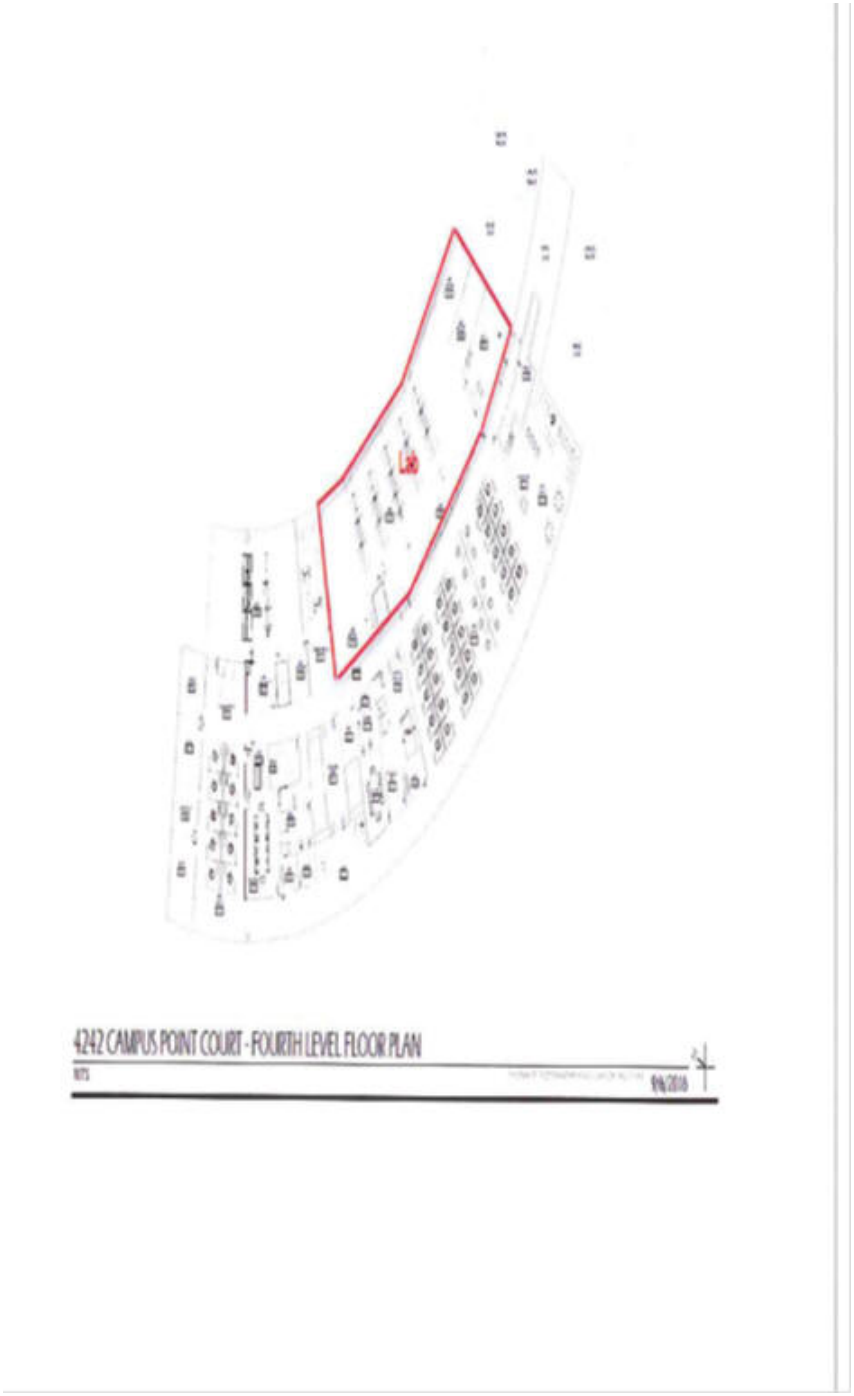

EXHIBIT D

GENERAL STORAGE AREA

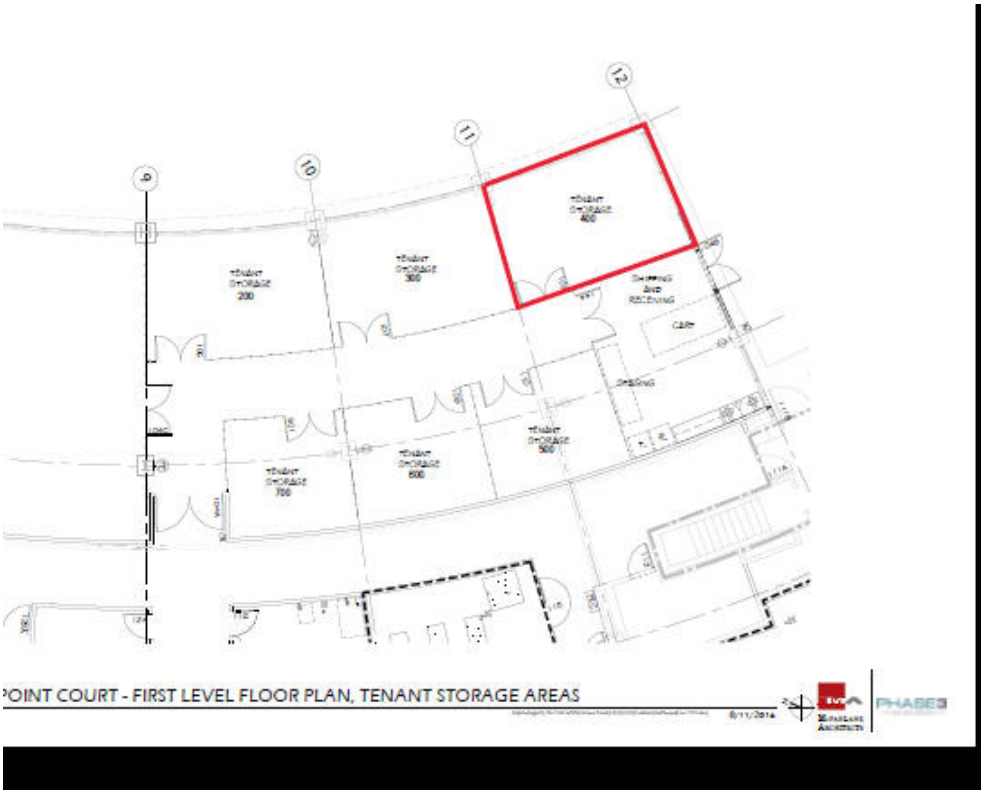

EXHIBIT E

HAZARDOUS MATERIALS STORAGE AREA

HERON THERAPEUTICS, INC.
Exhibit 31.1

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: May 10, 2018

/s/ Barry D. Quart

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

HERON THERAPEUTICS, INC.
Exhibit 31.2

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Robert E. Hoffman, 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: May 10, 2018

/s/ Robert E. Hoffman

Robert E. Hoffman
Chief Financial Officer and Senior Vice President, Finance
(As Principal Financial and Accounting Officer)

HERON THERAPEUTICS, INC.
Exhibit 32.1

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 March 31, 2018 (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: May 10, 2018

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

/s/ Robert E. Hoffman
Robert E. Hoffman
Chief Financial Officer and
Senior Vice President, Finance
(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.