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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 2014

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

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**HERON THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**123 Saginaw Drive**  
**Redwood City, CA**  
(Address of principal executive offices)

**94-2875566**  
(I.R.S. Employer  
Identification No.)

**94063**  
(Zip Code)

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

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

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

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

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

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

The number of shares of the registrant's common stock, par value \$0.01 per share, outstanding as of July 29, 2014 was 28,910,653.

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**HERON THERAPEUTICS, INC.**  
**FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2014**

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(in thousands)

	June 30, 2014 (Unaudited)	December 31, 2013 (Note 2)
<b>ASSETS</b>		
Current assets:		
Cash	\$ 105,012	\$ 72,287
Prepaid expenses and other current assets	518	638
Total current assets	105,530	72,925
Property and equipment, net	2,978	2,882
Other long-term assets	130	130
Total assets	<u>\$ 108,638</u>	<u>\$ 75,937</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,769	\$ 1,264
Accrued clinical liabilities	3,705	1,773
Accrued payroll and employee-related liabilities	1,835	2,566
Other accrued expenses	2,177	364
Convertible notes payable to related parties, net of discount	1,306	1,025
Total current liabilities	10,792	6,992
Stockholders' equity:		
Common stock	289	237
Additional paid-in capital	372,976	307,578
Accumulated deficit	(275,419)	(238,870)
Total stockholders' equity	97,846	68,945
Total liabilities and stockholders' equity	<u>\$ 108,638</u>	<u>\$ 75,937</u>

See accompanying notes.

**HERON THERAPEUTICS, INC.****Condensed Statements of Operations**  
(Unaudited)  
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	\$ 14,427	\$ 10,806	\$ 26,198	\$ 17,946
General and administrative	4,364	4,403	9,915	10,016
Total operating expenses	18,791	15,209	36,113	27,962
Loss from operations	(18,791)	(15,209)	(36,113)	(27,962)
Interest expense	(220)	(204)	(436)	(405)
Net loss	<u>\$(19,011)</u>	<u>\$(15,413)</u>	<u>\$(36,549)</u>	<u>\$(28,367)</u>
Basic and diluted net loss per share	<u>\$ (0.78)</u>	<u>\$ (1.01)</u>	<u>\$ (1.52)</u>	<u>\$ (1.86)</u>
Shares used in computing basic and diluted net loss per share	<u>24,266</u>	<u>15,285</u>	<u>23,989</u>	<u>15,269</u>

See accompanying notes.

**HERON THERAPEUTICS, INC.****Condensed Statements of Cash Flows**  
(Unaudited)  
(in thousands)

	Six Months Ended June 30,	
	2014	2013
Operating activities:		
Net loss	\$ (36,549)	\$ (28,367)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	239	149
Stock-based compensation expense	4,049	4,238
Amortization of debt discount	281	261
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	120	206
Accounts payable	505	2,849
Accrued clinical liabilities	1,932	2,127
Accrued payroll and employee-related liabilities	(731)	(110)
Other accrued expenses	1,965	(135)
Net cash used for operating activities	<u>(28,189)</u>	<u>(18,782)</u>
Investing activities:		
Purchases of property and equipment	(335)	(541)
Net cash used for investing activities	<u>(335)</u>	<u>(541)</u>
Financing activities:		
Proceeds from warrant exercises	—	600
Proceeds from purchases under the Employee Stock Purchase Plan	19	25
Proceeds from stock option exercises	2,308	41
Net proceeds from sale of common stock and pre-funded warrants	58,922	—
Net cash provided by financing activities	<u>61,249</u>	<u>666</u>
Net increase (decrease) in cash	32,725	(18,657)
Cash at beginning of period	72,287	53,506
Cash at end of period	<u>\$105,012</u>	<u>\$ 34,849</u>

See accompanying notes.

**HERON THERAPEUTICS, INC.**

**Notes to Condensed Financial Statements**

(Unaudited)

**1. Business**

Heron Therapeutics, Inc. (formerly A.P. Pharma, Inc.) (the “Company,” “we,” “us” and “our”) is a specialty pharmaceutical company developing product candidates using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks.

Our lead product candidate, SUSTOL™ (formerly known as APF530), is being developed for the prevention of acute chemotherapy-induced nausea and vomiting (“CINV”) for patients undergoing both moderately or highly emetogenic chemotherapy and for the prevention of delayed CINV for patients undergoing moderately emetogenic chemotherapy. In 2014, we initiated a Phase 3 clinical study with SUSTOL for the prevention of delayed CINV in patients receiving highly emetogenic chemotherapy, an indication for which no 5-HT<sub>3</sub> antagonist is approved. The 1,000 patient study is expected to be completed in late 2014. One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT<sub>3</sub> antagonist approved for the prevention of delayed-onset CINV, so this indication represents an area of particular unmet medical need. SUSTOL contains the 5-HT<sub>3</sub> antagonist granisetron formulated in our proprietary Biochronomer polymer-based drug delivery platform, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. This five-day range is designed to cover the delayed phase of CINV. Granisetron was selected for SUSTOL because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

In May 2009, we filed the original New Drug Application (“NDA”) seeking approval for SUSTOL with the U.S. Food and Drug Administration (“FDA”). The FDA issued a Complete Response Letter for the SUSTOL NDA in March 2010. In September 2012, we resubmitted our NDA for SUSTOL and, in March 2013, we received a second Complete Response Letter, which identified several remaining issues that need to be addressed prior to approval of the SUSTOL NDA. We are currently working on addressing these issues and expect to resubmit the SUSTOL NDA during the fourth quarter of 2014.

We own the worldwide rights to SUSTOL and are in the early stages of building the commercial infrastructure necessary to commercialize SUSTOL in the U.S. on our own, assuming approval by the FDA.

Our core Biochronomer technology, on which SUSTOL and our other product candidates are based, consists of bioerodible polymers designed to release drugs over a defined period of time. The results of over 100 *in vivo* and *in vitro* studies demonstrate that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including, among others, prevention of CINV, pain management and control of inflammation. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to potentially multiple weeks. We are exploring the potential use of our Biochronomer polymer with other drugs and intend to pursue the clinical development of one or more other drug candidates based on our proprietary delivery platform.

In November 2013, we initiated a program to expand our pipeline of sustained-release products, including a new program targeting the relief of post-surgical pain. We selected HTX-011, a unique combination of local analgesic agent bupivacaine and the anti-inflammatory drug meloxicam utilizing our Biochronomer extended release technology, as the lead product candidate for our post-surgical pain program. In a validated animal model, HTX-011 significantly reduced mean pain intensity compared to the current market leader, Exparel® for up to 72 hours following surgery. We expect to move this program into human

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clinical studies in the second half of 2014. As of 2012, approximately 25 million<sup>1</sup> procedures associated with post-operative pain were conducted in the U.S. In addition, post-operative pain market sales were approximately \$3.1 billion<sup>2</sup> in 2012.

In January 2014, we changed our name from A.P. Pharma, Inc. to Heron Therapeutics, Inc. Effective January 13, 2014, we effected a 1-for-20 reverse split of our outstanding common stock (“Reverse Stock Split”) (See Note 5). All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split. All stock options, convertible notes and warrants outstanding were appropriately adjusted to give effect to the Reverse Stock Split.

### **Liquidity**

We have incurred significant operating losses and negative cash flows from operations and we have an accumulated deficit of \$275.4 million as of June 30, 2014. Since 2011, we completed a total of five rounds of equity and/or debt financings, which provided us with cash of approximately \$194.3 million, net of issuance costs, to fund operations (see Notes 4 and 5). As of June 30, 2014, we had cash on hand of \$105.0 million.

We believe that our current working capital is sufficient to fund essential operations into 2015; provided, however, that if we pursue additional clinical studies or begin preparations for potential commercialization of SUSTOL, we will need to raise additional capital. We may require additional capital to fund our development pipeline programs. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities.

### **2. Basis of Presentation**

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2014. The condensed balance sheet at December 31, 2013 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. The presentation of prior year amounts was reclassified to conform to the current year presentation. For more complete financial information, these unaudited condensed financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2013 included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the Securities and Exchange Commission (“SEC”) on March 7, 2014.

### **3. Accounting Policies**

#### **Use of Estimates**

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to clinical trial accruals, income taxes and stock-based compensation. We base our estimates on historical experience and on assumptions that it believes 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.

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<sup>1</sup> Custom Research Project by Design Resources completed in 2013.

<sup>2</sup> Decision Resources, Acute Pain, December 2012.

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### **Cash and Cash Equivalents**

We consider all highly liquid investments with a maturity from the date of purchase of less than three months to be cash equivalents. We had cash of \$105.0 million and \$72.3 million at June 30, 2014 and December 31, 2013, respectively. There were no cash equivalents as of both dates. Our bank accounts have been placed under a control agreement in accordance with the April 2011 convertible note financing (see Note 4).

### **Earnings Per Share**

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

Because we have incurred a net loss for both periods presented in the unaudited condensed statements of operations, outstanding stock options, warrants and common stock underlying convertible notes are not included in the computation of net loss per share because their effect would be anti-dilutive.

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

	As of June 30,	
	2014	2013
Stock options outstanding	7,022	6,747
Warrants outstanding	4,425	4,052
Common stock underlying convertible notes outstanding	6,481	6,106

### **Comprehensive Income (Loss)**

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive net loss for all periods presented was comprised solely of its net loss and there were no other changes in equity from non-owner sources.

### **Recent Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-12, Compensation – Stock Compensation (Topic 718) ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The amendments in ASU 2014-12 may either be applied (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earlier annual period presented in the financial statements and to all new or modified awards thereafter. We plan to adopt the provisions of ASU 2014-12 in the first quarter of 2016. We do not expect the adoption of this ASU to have a material impact on its results of operations or financial condition.

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In July 2013, the FASB issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* (“ASU 2013-11”). This update provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. We adopted this guidance in 2014 and it did not have a material impact on our financial condition, results of operations or related financial statement disclosures.

#### **4. Convertible Notes to Related Parties**

In April 2011, we entered into a Securities Purchase Agreement for a private placement of up to \$4.5 million in Senior Secured Convertible Notes (“Notes”). We received a total of \$4.3 million, net of issuance costs, from the issuance of these Notes.

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

The 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 due under the Notes. There is no right to convert the 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 Notes can increase or decrease this beneficial ownership conversion limit by written notice to us, which will not be effective until 61 days after delivery of the notice.

As of June 30, 2014, we were in compliance with all debt-related covenants under the Notes. Upon the occurrence of an event of default under the Notes, the holders of the Notes have the right to require us to redeem all or a portion of their Notes.

We filed a registration statement with the SEC to register for resale 3.5 million shares (as adjusted for the Reverse Stock Split) underlying the Notes. The registration statement was declared effective on July 29, 2011. The Purchasers 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 Notes until they provide notice otherwise.

The Notes contain an embedded conversion feature that was in-the-money on the issuance dates. Based on an effective fixed conversion rate of 1,250 shares for every \$1,000 of principal and accrued interest due under the Notes, the total conversion benefit at issuance exceeded the loan proceeds. Therefore, a full debt discount was recorded in an amount equal to the face value of the Notes on the issuance dates and we began amortizing the resultant debt discount over the respective 10-year term of the Notes. During the period ended June 30, 2014, accrued interest of approximately \$77,000 was paid-in-kind and rolled into the Note principal balance, which resulted in an additional debt discount of approximately \$77,000. For the three months ended June 30, 2014 and 2013, interest expense relating to the stated rate was approximately \$78,000 and \$72,000, respectively, and interest expense relating to the amortization of the debt discount was approximately \$142,000 and \$132,000, respectively. For the six months ended June 30, 2014 and 2013, interest expense relating to the stated rate was approximately \$155,000 and \$144,000, respectively, and interest expense relating to the amortization of the debt discount was approximately \$281,000 and \$261,000, respectively.

As of June 30, 2014, the carrying value of the Notes was approximately \$1,306,000, which is comprised of the \$5,185,000 principal amount of the Notes outstanding, less debt discount of \$3,879,000. If the \$5,185,000 principal amount of Notes is converted, we would issue approximately 6,481,000 shares of our common stock.

## 5. Stockholders' Equity

### *Amendments to Articles of Incorporation – Reverse Stock Split*

Effective January 13, 2014, we amended our Certificate of Incorporation to change our name to Heron Therapeutics, Inc. and to effect a 1-for-20 reverse split of our outstanding common stock. The name change and Reverse Stock Split were approved by our stockholders on September 19, 2013. As a result of the Reverse Stock Split, the total authorized shares of common stock were reduced from 1,500,000,000 to 75,000,000 shares.

### *2011 Private Placement*

In June 2011, we sold 8.0 million shares of our common stock for net proceeds of \$22.8 million (net of approximately \$1.2 million in issuance costs). For each share purchased, the investors received one warrant to purchase 0.5 shares of common stock at an exercise price of \$3.60 per share. The warrants were immediately exercisable and expire on July 1, 2016. The warrants may be exercised for cash only, or, if a registration statement is not then effective and available for the resale of the shares of common stock issuable upon exercise of the warrants, by surrender of such warrant, or a portion of such warrant, by way of cashless exercise. There is no right to exercise the warrants to the extent that, after giving effect to such exercise the holder would beneficially own in excess of 9.99% of our outstanding shares of common stock or such other limit as may be designated by any particular purchaser. Each holder of the warrants can amend or waive the foregoing limitation by written notice to us, with such waiver taking effect only upon the expiration of a 61-day notice period.

On July 29, 2011, we filed a registration statement with the SEC to register for resale the shares and the shares of common stock issuable upon the exercise of the warrants. The registration statement was declared effective on August 4, 2011. We are obligated to maintain the effectiveness of the registration statement until the investors are able to sell shares and the shares of common stock underlying the warrants without limitation or restriction under Rule 144 of the Securities Act of 1933, as amended ("Rule 144"). There is currently only one investor who is an affiliate of ours and is therefore not able to sell without limitation under Rule 144, and that investor has agreed to waive its right to require us to maintain the effectiveness of the registration statement until it provides notice otherwise.

During the six months ended June 30, 2014, one warrant holder exercised 144,040 warrants under the cashless exercise provision in the warrant agreement, which resulted in the net issuance of 108,409 shares of common stock and no net cash proceeds to the Company. During the six months ended June 30, 2013, we received \$0.6 million for cash exercises of these warrants.

### *2012 Private Placement*

In July 2012, we sold 5.1 million shares of our common stock at a purchase price of \$10.50 per share, resulting in net proceeds of approximately \$50.5 million (net of approximately \$3.1 million in issuance costs).

On August 24, 2012, we filed a registration statement with the SEC to register these shares for resale. The registration statement was declared effective on September 6, 2012.

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### **2013 Common Stock Offering**

In November 2013, we entered into an underwriting agreement, pursuant to which we sold a total of approximately 8.6 million shares of our common stock to the underwriters at a public offering price of \$8.00 per share. We received total net proceeds of approximately \$57.8 million (net of approximately \$3.9 million in issuance costs).

The offering was made pursuant to our effective registration statement on Form S-3 (Registration No. 333-190550), which was previously filed with the SEC and was declared effective, and a prospectus supplement filed with the SEC. In the underwriting agreement, we agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments that the underwriters may be required to make because of such liabilities.

### **2014 Common Stock Offering**

In June 2014, we entered into an underwriting agreement, pursuant to which we sold a total of approximately 4.8 million shares of our common stock to the underwriters at a public offering price of \$11.75 per share. In addition, as a component of the offering, we sold 600,000 pre-funded warrants to purchase shares of our common stock to the underwriters at a public offering price of \$11.74 per share. The pre-funded warrants have an exercise price of \$0.01 per share and are exercisable for seven years from the date of issuance. We received total net proceeds of approximately \$58.9 million (net of approximately \$4.0 million in issuance costs) from the sale of the common stock and the pre-funded warrants.

The offering was made pursuant to our effective registration statement on Form S-3 (Registration No. 333-195928), which was previously filed with the SEC and was declared effective, and a prospectus supplement filed with the SEC. In the underwriting agreement, we agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments that the underwriters may be required to make because of such liabilities.

### **Stock Option Exercises**

For the six months ended June 30, 2014, approximately 0.4 million shares of common stock were issued pursuant to the exercise of stock options, resulting in proceeds to the Company of approximately \$2.3 million.

### **Stock-Based Compensation**

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2014 and 2013 related to stock options and Employee Stock Purchase Plan ("ESPP") purchase rights by expense category (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	\$ 446	\$ 541	\$1,708	\$ 790
General and administrative	634	1,862	2,341	3,448
Stock-based compensation expense included in operating expenses	<u>\$ 1,080</u>	<u>\$ 2,403</u>	<u>\$4,049</u>	<u>\$4,238</u>
Impact on basic and diluted net loss per share	<u>\$ 0.04</u>	<u>\$ 0.16</u>	<u>\$ 0.17</u>	<u>\$ 0.28</u>

As of June 30, 2014, there was approximately \$33.0 million of total unrecognized compensation cost related to non-vested, stock-based payment awards granted under all of the Company's equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize this compensation cost over a period of 2.3 years, which is the weighted-average vesting period for all stock-based compensation awards.

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

<i>Options:</i>	June 30,	
	2014	2013
Risk-free interest rate	2.0%	0.9%
Dividend yield	0.0%	0.0%
Volatility	104.0%	104.2%
Expected life (years)	6	6

The Company estimates the fair value of each purchase right granted under the ESPP at the beginning of each new offering period using the Black-Scholes option valuation model with the following assumptions:

<i>ESPP:</i>	June 30,	
	2014	2013
Risk-free interest rate	0.1%	0.1%
Dividend yield	0.0%	0.0%
Volatility	58.9%	88.3%
Expected life (months)	6	6

The following table summarizes the stock option activity for the six months ended June 30, 2014:

	Shares (in thousands)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Balance at January 1, 2014	6,356	\$ 8.22	8.14
Granted	1,239	\$ 10.06	
Exercised	(504)	\$ 6.22	
Expired and forfeited	(69)	\$ 14.70	
Balance at June 30, 2014	<u>7,022</u>	\$ 8.62	8.33

## 6. 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 the Company's ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. The Company continues to maintain a full valuation allowance against its deferred tax assets as of June 30, 2014.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There have been no material changes in the Company's unrecognized tax benefits since December 31, 2013 and as such, disclosures included in the Company's 2013 Annual Report on Form 10-K continue to be relevant for the period ended June 30, 2014.

**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 financial statements and related notes included in this quarterly report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2013 included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission, or SEC, on March 7, 2014.*

*This Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. You can identify forward-looking statements by the use of the words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project,” “will,” “should,” “may,” “plan,” “intend,” “assume” and other expressions which 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 the control of the Company. These risks, uncertainties and other factors may cause the actual results, performance or achievements of the Company to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.*

*Factors that might cause these differences include the following:*

- the anticipated progress of our research, development and clinical programs and timing of, and prospects for, regulatory approval and commercial introduction of SUSTOL™ and other future product candidates;*
- estimates of the timing of our resubmission of the New Drug Application (“NDA”) for SUSTOL;*
- if approved, the timing of market introduction of SUSTOL or other future product candidates;*
- our ability to successfully market, commercialize and achieve market acceptance for SUSTOL or other future product candidates;*
- our ability to successfully develop other drug candidates utilizing our proprietary Biochronomer polymer-based drug delivery platform;*
- our ability to establish collaborations for our technology, SUSTOL and other future product candidates;*
- uncertainties associated with obtaining and enforcing patents;*
- our estimates for future performance; and*
- our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.*

*These forward-looking statements were based on information, plans and estimates at the date of this Form 10-Q, and we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. In addition, please see the “Risk Factors” section of this Form 10-Q. 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 of these factors.*

Unless otherwise noted, all historical information in this Item 2 regarding share amounts of our common stock, prices per share of our common stock and loss per share has been adjusted to reflect, on a retroactive basis, the application of the 1-for-20 reverse stock split of our common stock that we effected on January 13, 2014 (the “Reverse Stock Split”).

## Overview

Heron Therapeutics, Inc. (formerly A.P. Pharma, Inc.) (the “Company,” “we,” “us” and “our”) is a specialty pharmaceutical company developing product candidates using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks.

Our lead product candidate, SUSTOL™ (formerly known as APF530), is being developed for the prevention of acute chemotherapy-induced nausea and vomiting (“CINV”) for patients undergoing both moderately or highly emetogenic chemotherapy and for the prevention of delayed CINV for patients undergoing moderately emetogenic chemotherapy. In 2014, we initiated a Phase 3 clinical study with SUSTOL for the prevention of delayed CINV in patients receiving highly emetogenic chemotherapy, an indication for which no 5-HT<sub>3</sub> antagonist is approved. The 1,000 patient study is expected to be completed in late 2014. One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT<sub>3</sub> antagonist approved for the prevention of delayed-onset CINV, so this indication represents an area of particular unmet medical need. SUSTOL contains the 5-HT<sub>3</sub> antagonist granisetron formulated in our proprietary Biochronomer polymer-based drug delivery platform, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. This five-day range is designed to cover the delayed phase of CINV. Granisetron was selected for SUSTOL because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

In May 2009, we filed the original NDA seeking approval for SUSTOL with the U.S. Food and Drug Administration (“FDA”). The FDA issued a Complete Response Letter for the SUSTOL NDA in March 2010. In September 2012, we resubmitted our NDA for SUSTOL and, in March 2013, we received a second Complete Response Letter, which identified several remaining issues that need to be addressed prior to approval of the SUSTOL NDA. We are currently working on addressing these issues and expect to resubmit the SUSTOL NDA during the fourth quarter of 2014.

We own the worldwide rights to SUSTOL and are in the early stages of building the commercial infrastructure necessary to commercialize SUSTOL in the U.S. on our own, assuming approval by the FDA.

Our core Biochronomer technology, on which SUSTOL and our other product candidates are based, consists of bioerodible polymers designed to release drugs over a defined period of time. The results of over 100 *in vivo* and *in vitro* studies demonstrate that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including, among others, prevention of CINV, pain management and control of inflammation. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to potentially multiple weeks. We are exploring the potential use of our Biochronomer polymer with other drugs and intend to pursue the clinical development of one or more other drug candidates based on our proprietary delivery platform.

In November 2013, we initiated a program to expand our pipeline of sustained-release products, including a new program targeting the relief of post-surgical pain. We selected HTX-011, a unique combination of local analgesic agent bupivacaine and the anti-inflammatory drug meloxicam utilizing our Biochronomer extended release technology, as the lead product candidate for our post-surgical pain program. In a validated animal model, HTX-011 significantly reduced mean pain intensity compared to the current market leader, Exparel® for up to 72 hours following surgery. We expect to move this program into human clinical studies in the second half of 2014. As of 2012, approximately 25 million<sup>3</sup> procedures associated with post-operative pain were conducted in the U.S. In addition, post-operative pain market sales were approximately \$3.1 billion<sup>4</sup> in 2012.

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<sup>3</sup> Custom Research Project by Design Resources completed in 2013.

<sup>4</sup> Decision Resources, Acute Pain, December 2012.

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### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to clinical trial accruals, income taxes 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.

There have been no material changes to the critical accounting policies as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the Securities and Exchange Commission on March 7, 2014.

### **Recent Accounting Pronouncements**

See Note 2 to the unaudited condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

### **Results of Operations for the Three and Six Months Ended June 30, 2014 and 2013**

#### Research and Development Expense

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
SUSTOL related costs	\$ 9,685	\$ 7,952	\$16,689	\$12,447
New product development related costs	1,171	211	1,677	336
Personnel and related costs	2,045	1,142	3,873	2,118
Stock-based compensation expense	446	541	1,708	790
Facility related costs	555	444	1,080	914
Other	525	516	1,171	1,341
Total research and development expense	<u>\$14,427</u>	<u>\$10,806</u>	<u>\$26,198</u>	<u>\$17,946</u>

For the three and six months ended June 30, 2014, research and development expense increased to \$14.4 million and \$26.2 million, respectively, from \$10.8 million and \$17.9 million, respectively, for the same period in 2013, primarily as a result of an increase in SUSTOL related costs due to the initiation of a Phase 3 label expansion study of SUSTOL in 2014 and other SUSTOL related activities. In addition, the increase in research and development expense was due to costs associated with new product development, including our new pain management program targeting the relief of post-surgical pain which was initiated in November 2013. Finally, the increase in research and development expense was due to an increase in personnel and related costs of approximately \$0.9 million and \$1.8 million, respectively, mainly due to additional headcount and infrastructure to support the increased development activities noted above, and an increase for the six month period due to additional non-cash, stock-based compensation expense of approximately \$0.9 million.

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### *General and Administrative Expense*

For the three and six months ended June 30, 2014, general and administrative expense was \$4.4 million and \$9.9 million, respectively, which was comparable to \$4.4 million and \$10.0 million, respectively, for the same periods in 2013. For the three and six months ended June 30, 2014, general and administrative expenses consist primarily of salaries and related expenses, professional fees, directors' fees, investor relations costs, pre-commercialization costs, insurance expense and related overhead cost allocation.

### *Interest Expense*

Interest expense was \$0.2 million for both the three months ended June 30, 2014 and 2013 and \$0.4 million for both the six months ended June 30, 2014 and 2013. Interest expense consists primarily of interest expense and amortization of debt discount related to the convertible notes.

### *Capital Resources and Liquidity*

As of June 30, 2014, we had approximately \$105.0 million in cash, compared to \$72.3 million as of December 31, 2013. The net increase in cash of approximately \$32.7 million was primarily due to the cash proceeds of approximately \$58.9 million received from the common stock offering completed in June 2014 and \$2.3 million from stock option exercises, partially offset by the use of cash to fund our continued development of SUSTOL, personnel costs and for other general corporate purposes.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock and other securities, royalties, revenues from collaboration arrangements, proceeds received from the sale of discontinued operations and interest earned on short-term investments.

In April 2011, we entered into definitive agreements for a convertible note financing of up to \$4.5 million. We received a total of approximately \$4.3 million, net of issuance costs, whereby \$4.5 million aggregate principal amount of convertible notes were issued.

In July 2011, we closed a unit financing where each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock; whereby the Company received approximately \$22.8 million of proceeds, net of issuance costs.

In July 2012, we closed a common stock financing whereby the Company received approximately \$50.5 million of proceeds, net of issuance costs.

In November 2013, we closed a common stock offering whereby the Company received approximately \$57.8 million of proceeds, net of issuance costs.

In June 2014, we closed an offering of common stock and pre-funded warrants whereby the Company received approximately \$58.9 million of proceeds, net of issuance costs.

We believe that our current working capital is sufficient to fund essential operations into 2015; provided, however, that if we pursue additional clinical studies or begin preparations for potential commercialization of SUSTOL, we will need to raise additional capital. We may require additional capital to fund our development pipeline programs. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities. Our capital requirements going forward will depend on numerous factors, including: an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program including the timing of clinical trials to expand our pipeline of sustained-release products; the scope, rate of progress, results and costs of preclinical testing and clinical trials, including our Phase 3 clinical trial of SUSTOL for the prevention of delayed CINV in patients receiving highly emetogenic chemotherapy; 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

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for a specialty sales force if we commercialize other products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

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

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts related to any of our product candidates will be successfully completed, that required regulatory approvals will be obtained, or that any products, if introduced, will be successfully marketed or achieve commercial acceptance. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by unfavorable economic conditions currently affecting financial markets and numerous other factors.

### **Contractual Obligations**

Below is a summary of fixed payments related to certain contractual obligations (in thousands), consisting solely of our operating lease obligations. This table excludes amounts already recorded on our balance sheet as current liabilities as of June 30, 2014.

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	<u>\$2,002</u>	<u>\$ 889</u>	<u>\$ 1,113</u>	<u>\$ —</u>	<u>\$ —</u>

The holders of the convertible notes issued in May 2011 and May 2012 may require prepayment of the Notes at any time at each holder's option. See Note 4 of Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

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

### **Off-Balance Sheet Arrangements**

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

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not hold any marketable securities at June 30, 2014. Our debt obligations of our convertible debt carry a fixed interest rate and, as a result, we are not exposed to interest rate risk on our convertible debt.

**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 Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There have been no material changes to the legal proceedings described in the Company's Annual Report on Form 10-K for the period ended December 31, 2013.

**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 and in our other filings with the SEC. 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. The risks described below may include certain additions and revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2013 and our subsequent filings with the SEC. Risk factors containing such additions and revisions are marked with an asterisk.*

## Risks Related To Our Business

***\*We are substantially dependent upon the success of our SUSTOL product candidate. Clinical trial results and the NDA resubmission for this product may not lead to regulatory approval.***

We have invested a significant portion of our time and financial resources in the development of our most advanced product candidate, SUSTOL, for which we are initially seeking FDA approval for the prevention of acute chemotherapy-induced nausea and vomiting (“CINV”) associated with both moderately and highly emetogenic chemotherapy and for the prevention of delayed CINV associated with moderately emetogenic chemotherapy (“MEC”). We are currently conducting a Phase 3 study which, if successful, may allow us to expand our product label to include delayed CINV associated with highly emetogenic chemotherapy (“HEC”).

Our near-term ability to generate revenues and our future success, in large part, depends on the approval and successful commercialization of SUSTOL. We will not be able to commercialize SUSTOL until we obtain regulatory approval in the United States or foreign countries. In order to satisfy FDA approval standards for the commercial sale of SUSTOL, we must first successfully resolve the issues identified in the Complete Response Letter received from the FDA in March 2013. This letter identified several issues that precluded the approval of SUSTOL NDA, including issues relating to: manufacturing of SUSTOL, the administration of SUSTOL and our analysis of efficacy data for SUSTOL under more recent guidelines classifying chemotherapy regimens. Although we are currently working to address these issues and currently expect to resubmit the SUSTOL NDA during the fourth quarter of 2014, there can be no assurance that these responses will be sufficient or that we will be able to resubmit within this time period. Further, the FDA’s review of our resubmission may not produce positive decisions as to whether:

- SUSTOL is safe and effective in its proposed use(s) and whether its benefits outweigh the risks;
- the proposed labeling for SUSTOL has our desired product indication regarding acute and delayed-onset CINV, as well as HEC and MEC regimens; and
- the methods used in manufacturing SUSTOL and the controls used to maintain its quality are adequate to preserve its identity, strength, quality and purity.

Deficiencies on any of the above, or other factors, could prevent or delay obtaining regulatory approval of SUSTOL, which would negatively affect our potential revenues, increase our costs and potentially impair our ability to continue as a going concern.

***\*We may not obtain regulatory approval for SUSTOL or any of our product candidates. Regulatory approval may also be delayed or cancelled or may entail limitations on the indicated uses of a proposed product.***

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. The regulatory process, particularly for pharmaceutical product candidates like ours, is uncertain, can take many years and requires the expenditure of substantial resources. Any product that we or our collaborative partners develop must receive all relevant regulatory agency approvals or clearances, if any, before it may be marketed in the United States or other countries. In particular, human pharmaceutical products are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the United States and similar health authorities in foreign countries. We may not receive necessary regulatory approvals or clearances to market SUSTOL or any other product candidate. In September 2012, we resubmitted the NDA seeking approval for SUSTOL with the FDA. In March 2013, we received a second Complete Response Letter, which identified several issues that precluded the approval of the SUSTOL NDA. We are currently working to address these issues and intend to resubmit the SUSTOL NDA during the fourth quarter of 2014. Our NDA resubmission for SUSTOL may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval prior to the FDA’s decision on our NDA.

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For example, although many drug products have been approved by the FDA in recent years under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of our NDA for SUSTOL. The review of our resubmitted NDA may also be delayed due to the FDA's internal resource constraints. Additionally, data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances. For example, the FDA may require additional 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.

Delays in obtaining regulatory approval for SUSTOL, or the issuance of a third Complete Response Letter, would, among other consequences, delay the launch of SUSTOL and adversely affect our ability to generate revenue from sales of this product and adversely affect our ability to raise additional capital that would be necessary to sustain our operations. Given the additional delays that we would face prior to obtaining approval for SUSTOL, if such approval is ever granted, we may need significant additional capital to fund our operations.

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 drugs and biological 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.

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

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

- the scope of our approved product label;
- perception of physicians and other members of the health care community of the safety and efficacy relative to that of competing products;
- cost-effectiveness;
- patient and physician satisfaction with the product;
- ability to manufacture commercial product successfully and on a timely basis;
- cost and availability of raw materials;
- market size for the product;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning the product or similar drugs;
- the introduction, availability and acceptance of competing treatments;

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- adverse event information relating to the product;
- product liability litigation alleging injuries relating to the product;
- product labeling or product insert language required by the FDA or regulatory authorities in other countries;
- the regulatory developments related to the manufacture or continued use of the product;
- extent and effectiveness of sales and marketing and distribution support for the product; and
- our collaborators' decisions as to the timing of product launches, pricing and discounting.

Our product revenue will be adversely affected if, due to these or other factors, the products we or our collaborators are able to commercialize do not gain significant market acceptance.

***\*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 recurring losses and had an accumulated deficit of \$275.4 million through June 30, 2014. Even if SUSTOL is approved, we expect to continue to generate substantial losses over at least the next several years as we:

- build a sales force and commence commercialization of SUSTOL, if approved;
- expand drug product development and commercialization efforts;
- conduct preclinical development and clinical trials; and
- pursue additional applications for our existing delivery technologies.

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

***\*Additional capital may be needed 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. Raising such capital may have to be accomplished on unfavorable terms, likely causing dilution to our existing stockholders.***

At June 30, 2014, the Company had cash and cash equivalents in the amount of \$105.0 million. We believe that our current working capital balance is sufficient to fund essential operations into 2015; provided, however, that if we pursue additional clinical studies or begin commercialization of SUSTOL, we will need to raise additional capital. We may require additional capital to fund our development pipeline programs. We are pursuing commercialization of SUSTOL without a partner for the U.S. market, which will likely require us to obtain additional funding and resources to sustain our operations until we can achieve profitability. The need for and amount of additional funding that we may require depends on various factors, including the results of the on-going regulatory review by the FDA of our SUSTOL NDA resubmission, the time and costs related to manufacturing of SUSTOL, if approved, technological and market developments of drugs that may compete with SUSTOL and the timing of clinical trials to expand our pipeline of sustained-release products. There can be no assurance that SUSTOL will be approved and, if approved, that we will be successful in obtaining the additional necessary financial resources and expertise, with or without a partner, that will be required to launch SUSTOL.

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

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

- 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;
- the time, cost and outcome involved in seeking 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 for a specialty sales force if we commercialize any 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.

If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment, and such issuance may adversely affect the market price of our common stock. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. 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 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 will have a material adverse effect on our business.

### ***The general economic environment in which we operate is experiencing continued weakness and volatility.***

Our ability to secure the additional capital that may be necessary for implementation of our longer-term business plans may be diminished due to the continuing volatile business conditions and financial markets. For example, the difficulty in obtaining additional capital necessary to develop our other product candidates has led us to temporarily suspend certain development programs in recent years. If the economic environment continues its weak recovery and financial markets continue to experience significant volatility, we may have increasing difficulty in raising additional capital when needed.

***We may depend on collaborators as a source of capital and to help us complete the process of developing and testing our products.***

Our strategy for the development, clinical testing and commercialization of our products may require entering into collaborations with corporate partners, licensors, licensees and others. These collaborations may be critical to funding our operations and our success in bringing our products and product candidates to the market and promoting such marketed products profitably. We could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to our research activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. We may prioritize other programs ahead of collaboration activities such that funding from these other parties could be reduced or deferred. Failure to make or maintain these arrangements, or a delay in a collaborative partner's performance, or factors that may affect our partner's sales may materially adversely affect our business, results of operations and financial condition.

Under agreements with collaborators, we may rely significantly on them, among other activities, to:

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

***\*Clinical trials are expensive and may not result in commercially viable products.***

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we have incurred significant expenses in developing SUSTOL and, even if approved, it may not result in a commercially viable product. We have initiated a Phase 3 study of SUSTOL designed to demonstrate the utility of SUSTOL in the treatment of delayed-onset CINV in patients receiving HEC regimens. If successful, we intend to submit the results of the study to the FDA to expand the label of SUSTOL to include delayed HEC. There can be no assurance that this study will be successful or that the FDA will grant any such label expansion. Before obtaining regulatory approvals for the commercial sale of any products, we, or our 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.

Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials. Factors impacting our ability to generate commercially viable products through the conduct of clinical trials include:

- insufficient funds to conduct clinical trials;
- inability to find partners;
- failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- failure by us or third-party investigators, contract research organizations, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- failure of preclinical testing and early clinical trials to predict results of later clinical trials;

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- delay in completion of clinical trials, resulting in increased costs; and
- 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 United States 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 requires 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. Completing clinical trials in a timely manner depends on, among other factors:

- obtaining regulatory approval to commence a trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical study terms with prospective sites and clinical research organizations;
- obtaining institutional review board approval to conduct a study at a prospective site; and
- recruiting patients to participate in a study.

### ***We rely on third parties to 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.***

We used clinical research organizations in the United States, Asia and Europe to oversee our clinical trials for SUSTOL and we expect to use the same or similar organizations for our future clinical trials and pipeline programs. There are numerous alternative sources to provide these services; however, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion, or if we are forced to change service providers. 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 problems with the quality of data derived from clinical trials, the prospects for approval would decrease.

### ***We have yet to demonstrate the full commercial viability of our delivery technology, and we cannot be certain that attainment of such a goal can be accomplished.***

Our bioerodible drug delivery technology is at an early stage of development. We may not be able to substantiate the capability of our drug delivery technology for a variety of reasons, including:

- selection of inappropriate therapeutic compound for delivery;
- selection of inappropriate use or application for the particular product candidate;
- failure to receive regulatory approval on a timely basis or at all; or

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- difficulties with manufacturing in commercial quantities at an acceptable cost.

Successful development of delivery technologies requires significant preclinical and clinical testing prior to regulatory approval. Because of these scientific, regulatory and commercial hurdles, any program could be abandoned or otherwise fail, even after significant resources have been expended.

***If our suppliers and contract manufacturers fail to complete pre-commercialization manufacturing development activities for SUSTOL on a timely basis or fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, SUSTOL, and our costs will increase.***

We do not manufacture SUSTOL and do not currently plan to develop any capacity to do so. Instead, we have relied on third parties to manufacture and perform important pre-commercialization manufacturing development activities for SUSTOL. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture SUSTOL are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes of our third-party suppliers and manufacturers, and data supporting the stability of SUSTOL. If our third-party suppliers and manufacturers are not in compliance with current Good Manufacturing Practice (“cGMP”) requirements, the approval of our marketing application may be delayed, existing product batches may be compromised, and we may experience delays in the availability of SUSTOL for commercial distribution.

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

**We depend on contract manufacturers and collaborators for manufacturing our products and provide them with technical expertise on the manufacturing process; we also perform quality control testing of the product; if we and our contract manufacturers do not perform as expected, our revenue and customer relations will suffer.**

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of any product. Our ability to develop and commercialize any products we may develop will depend in part on our ability to manufacture, or arrange for collaborators or 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 do not intend to develop or acquire facilities to manufacture any of our product candidates for clinical trials or commercial purposes in the foreseeable future. We rely on a small number of third-party manufacturers to produce our compounds 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, some of which are our sole source suppliers at present. We have no long-term agreements with any of these third parties. We may not be able to extend these agreements on satisfactory terms, or at all, and we may not be able to find a replacement contract manufacturer on satisfactory terms or on a timely basis. Additionally, difficult economic conditions may cause operational and financial problems for our third-party suppliers, resulting in their failure and disruption to our operations.

Further, we, along with our contract manufacturers and our collaborators, are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers, or our collaborators, may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture and will be subject to ongoing, periodic,

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unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we may experience manufacturing errors resulting in patient injury or death, 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 a Warning Letter or an enforcement action such as product seizure, recall, or injunction, prevent commercialization of our product candidates and impair our reputation and results of operations.

Any performance failure on the part of our contract manufacturers or by us could delay clinical development or regulatory approval of product candidates or commercialization of our future products, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins and limit our ability to commercialize products on a timely and competitive basis. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited, and the FDA must approve any replacement manufacturer before we can begin manufacturing SUSTOL or any of our other product candidates. Such approval would require new testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

SUSTOL or any of our other product candidates may be in competition with other products for access to the facilities of third parties. Consequently, SUSTOL or any of our other product candidates may be subject to manufacturing delays if collaborators or outside contractors give other companies' products greater priority than our products. For this and other reasons, our collaborators or third-party service providers may not be able to manufacture SUSTOL 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 or precluded.

To date, SUSTOL has been manufactured in small quantities for preclinical studies and clinical trials. If in the future SUSTOL or any of our product candidates are approved for commercial sale, we will need to manufacture our products in larger quantities. Significant scale-up of manufacturing may require additional process development and validation studies, which the FDA must review and approve. The commercial success of our products, including SUSTOL in the near-term, will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture. The ability to do so cannot be presumed. Significant additional development work is required prior to any commercial launch of a product. In the case of SUSTOL, the high viscosity of the product creates particularly challenging factors relative to attainable production rates and cost of manufacture. If SUSTOL receives regulatory approval, we plan to scale-up manufacturing for SUSTOL in order to realize important economies of scale. These scale-up activities would take time to implement, require additional capital investment, process development and validation studies, and FDA approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

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

We do not currently have a sales organization for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have started to establish internal sales and marketing capabilities for SUSTOL, but may enter into agreements with third parties to sell and market other products we may develop. Although we have hired sales and marketing personnel with prior commercial experience, our company has no direct experience in developing, training or managing a marketing and sales force. The establishment and development of a sales force to market SUSTOL will be expensive and time

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consuming and could delay product launch, and we cannot be certain that we will be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other nontechnical capabilities necessary to commercialize SUSTOL, we will need to contract with third parties to market and sell such products we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

***If we 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.***

Following initial regulatory approval of any drugs we may develop, including SUSTOL, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will 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 be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

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. Sales and marketing programs are under scrutiny for compliance with various mandated requirements, such as illegal promotions to healthcare professionals. We are establishing a sales force to market SUSTOL, which may include contracting with third parties to market and sell such products we may develop, and may be unable to ensure that our own employees as well as any third-party employees adhere to legal and regulatory requirements for product advertising and promotion. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business. If SUSTOL is approved, we will also be required to comply with the requirements to submit to governmental authorities information on payments to physicians and certain other third parties; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

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

We depend on a small number of key management and technical personnel. Retaining our current employees and recruiting qualified scientific personnel to perform future research and development and commercialization work will be critical to our success. While recent pharmaceutical and biotechnology industry layoffs have somewhat mitigated a usual shortage of skilled personnel in our industry, competition is always present for experienced scientists, and an inability to recruit or retain sufficient skilled personnel could result in delays to product development or approval, loss of sales and diversion of management resources. If we lose members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

***We face intense competition from other companies.***

SUSTOL is expected to face significant competition for the prevention of CINV, principally from Eisai's Aloxi (palonosetron). In addition to Aloxi, SUSTOL will compete with entrenched generic forms of granisetron (formerly marketed by Roche as Kytril) and ondansetron (formerly marketed by GlaxoSmithKline as Zofran). Generic versions of Aloxi may become available after its scheduled patent expiration date, which was recently extended to 2024. We are aware, however, of ongoing litigation challenging these patents and, if such challenges are successful, it is possible that generic versions of Aloxi could become available sooner. We are also aware of several companies that have developed, or are developing, both generic and new formulations of granisetron, including transdermal formulations such as ProStrakan's Sancuso® (granisetron transdermal patch), which was approved in 2008.

There are several companies that are developing new formulations of existing drugs across various therapeutic areas using novel drug delivery technologies. Many of these companies have substantially greater financial, research and development, manufacturing, sales and marketing and distribution resources and experience than we do. The following are some notable companies among drug delivery system developers: Alkermes, Inc., Durect Corporation, and Pacira Pharmaceuticals, Inc.

Smaller or early stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

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

The continuing efforts of the United States 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.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, 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

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care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may result in lower prices for our product candidates. 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.

***\*Our business strategy may include the entry into collaborative agreements. We may not be able to enter into additional 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 delivery technologies. 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 not consummate collaborative agreements, we may consume money 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.

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

In both domestic and foreign markets, sales of our potential products, including SUSTOL, will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. Reimbursement policies utilized by our collaborators or ourselves may be challenged by regulatory entities, with resultant fines, negative publicity and the need to implement changes that reduce the utilization of our products. If any products we develop do not receive adequate reimbursement, our revenue will be severely limited.

***Our inability to obtain specialized materials could slow down our product development process.***

Some of the critical materials and components used in producing SUSTOL are sourced from a single supplier. An interruption in supply of a key material could significantly delay our research and development process or increase our expenses.

Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in the technologies in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source of a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required or if the materials traditionally have not been used in pharmaceutical products.

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***If we are unable to adequately protect or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us.***

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. At December 31, 2013, we had a total of 15 issued U.S. patents and an additional 38 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2016 and April 2026. The product SUSTOL is covered by patents owned by Heron Therapeutics, Inc. that are granted in the United States and in foreign countries. Currently, the product SUSTOL is covered by six patents issued in the United States and by seven patents issued in foreign countries including Brazil, Canada, EU, Japan, and Taiwan. U.S. patents covering SUSTOL have expiration dates ranging from January 2016 to September 2024; foreign patents covering SUSTOL have expiration dates ranging from January 2017 to September 2025. 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, or those that are licensed to us, 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 United States are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. laws.

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

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference

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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 United States 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. 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.

If we are required to defend ourselves in a 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 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.

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.

***We are exposed to risks and increased expenses as a result of laws requiring filers to evaluate internal controls over financial reporting.***

Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") requires management to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year and to include a management report assessing the effectiveness of our internal control over financing reporting in our annual report on Form 10-K for each fiscal year. Our independent registered public accounting firm is required to report on the effectiveness of our internal control over financial reporting. We and our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. We have implemented an ongoing program to perform the system and process evaluation we believe to be necessary to comply with these requirements. However, we cannot assure you that we will be successful in our efforts. We expect to incur increased expense and to devote additional management resources to Section 404 compliance. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls

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in the future, which would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the price of our stock.

### ***Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenue or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future, and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, new SEC regulations and the Public Company Accounting Oversight Board pronouncements, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

### ***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 testing, manufacture, marketing and sale of our products involve an inherent risk that product liability claims will be asserted against us. 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.

### ***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 such liability 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 development or commercialization efforts.

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### ***Earthquake damage to our facilities could delay our research and development and quality control testing efforts and adversely affect our business.***

Our facility in Redwood City, California, is located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts and supplies of SUSTOL, if approved. In the event of an earthquake, if our facilities or the equipment in our facilities are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

### **Risks Related To Our Common Stock**

#### ***The price of our common stock has been and may continue to be volatile and our reverse stock split may further increase volatility or cause a decline in value.***

The stock markets, in general, and the markets for drug delivery and pharmaceutical stocks, in particular, 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.

Further, our stock price may be subject to additional volatility as a result of our Reverse Stock Split and relisting on The NASDAQ Capital Market. Following reverse splits, the prices of the stocks often trade below the immediate post-split value, resulting in a net loss in value for stockholders.

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 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.

#### ***\*Further concentration in stockholder ownership could influence strategic actions.***

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a majority of our outstanding securities. Tang Capital Partners, LP and its affiliates' beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, was approximately 17% as of June 2014, excluding potential further concentration underlying outstanding warrants and our convertible note facility. Kevin C. Tang, the Managing Director of Tang Capital Management, LLC, the general partner of Tang Capital Partners, LP, is also chairman of our board of directors.

Such a concentration of common stock ownership could significantly influence corporate actions on various strategic matters, including, for example, receptivity to collaborations and merger or sale overtures.

***Future sales of our common stock may cause our stock price to decline.***

Our principal stockholders and affiliated entities hold a substantial number of shares of our common stock that they are able to sell in the public market. In addition, they currently own convertible notes and outstanding warrants for additional shares of our common stock. The exercise of these warrants, conversion of the notes or the sale by our current stockholders of a substantial number of shares, or the expectation that such exercises or sales may occur, could significantly reduce the market price of our common stock.

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

We believe our net operating losses and tax attributes may be subject to limitation under Section 382 of the Internal Revenue Code of 1986. As a result, our deferred tax assets, and related valuation allowance, have been reduced for the estimated impact of the net operating losses and credits that we currently estimate may expire unused. Utilization of our remaining net operating loss and research and development credit carry-forwards may still be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions for ownership changes after December 31, 2013, including those that may come in conjunction with future equity financings or market trades by our stockholders.

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**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

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**ITEM 6. EXHIBITS**

<u>Exhibit Number</u>	<u>Description</u>
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification 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.

Date: August 4, 2014

Heron Therapeutics, Inc.

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.  
Chief Executive Officer  
(On behalf of the Registrant)

/s/ Brian G. Drazba

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

**HERON THERAPEUTICS, INC.**

**INDEX TO EXHIBITS**

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## 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 in order 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 is made known to us by others within this entity, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: August 4, 2014

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.  
Chief Executive Officer

## SECTION 302 CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Heron Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order 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 is made known to us by others within this entity, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: August 4, 2014

/s/ Brian G. Drazba

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

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

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

- the Quarterly Report of the Registrant on Form 10-Q for the quarter ended June 30, 2014 (the "Report"), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such quarter and the results of operations of the Registrant for such quarter.

Dated: August 4, 2014

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.  
Chief Executive Officer

/s/ Brian G. Drazba

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

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

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