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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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

HERON THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

The number of shares of the registrant's common stock, par value $0.01 per share, outstanding as of October 29, 2014 was 29,180,099.

HERON THERAPEUTICS, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS — UNAUDITED

HERON THERAPEUTICS, INC.

Condensed Balance Sheets
(in thousands)

	September 30, 2014 (Unaudited)	December 31, 2013 (Note 2)
ASSETS		
Current assets:		
Cash	$ 86,212	$ 72,287
Prepaid expenses and other current assets	3,030	638
Total current assets	89,242	72,925
Property and equipment, net	2,910	2,882
Other long-term assets	130	130
Total assets	$ 92,282	$ 75,937
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,475	$ 1,264
Accrued clinical liabilities	4,530	1,773
Accrued payroll and employee-related liabilities	2,601	2,566
Other accrued expenses	1,218	364
Convertible notes payable to related parties, net of discount	1,450	1,025
Total current liabilities	11,274	6,992
Stockholders' equity:		
Common stock	292	237
Additional paid-in capital	375,329	307,578
Accumulated deficit	(294,613)	(238,870)
Total stockholders' equity	81,008	68,945
Total liabilities and stockholders' equity	$ 92,282	$ 75,937

See accompanying notes.

HERON THERAPEUTICS, INC.

Condensed Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 14,731	$ 6,216	$ 40,929	$ 24,162
General and administrative	4,222	6,448	14,137	16,464
Total operating expenses	18,953	12,664	55,066	40,626
Loss from operations	(18,953)	(12,664)	(55,066)	(40,626)
Interest and other expense	(241)	(209)	(677)	(614)
Net loss	$(19,194)	$(12,873)	$(55,743)	$(41,240)
Basic and diluted net loss per share	$ (0.66)	$ (0.84)	$ (2.17)	$ (2.69)
Shares used in computing basic and diluted net loss per share	29,004	15,375	25,679	15,305

See accompanying notes.

HERON THERAPEUTICS, INC.

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

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(55,743)	$(41,240)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	389	237
Stock-based compensation expense	5,809	8,333
Amortization of debt discount	425	396
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,392)	(202)
Accounts payable	211	514
Accrued clinical liabilities	2,757	302
Accrued payroll and employee-related liabilities	35	454
Other accrued expenses	1,084	70
Net cash used for operating activities	(47,425)	(31,136)
Investing activities:		
Purchases of property and equipment	(417)	(1,518)
Net cash used for investing activities	(417)	(1,518)
Financing activities:		
Proceeds from warrant exercises	—	600
Proceeds from purchases under the Employee Stock Purchase Plan	19	25
Proceeds from stock option exercises	2,832	1,120
Net proceeds from sale of common stock and pre-funded warrants	58,916	—
Net cash provided by financing activities	61,767	1,745
Net increase (decrease) in cash	13,925	(30,909)
Cash at beginning of period	72,287	53,506
Cash at end of period	$ 86,212	$ 22,597

See accompanying notes.

HERON THERAPUETICS, 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 biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. Our proprietary Biochronomer® polymer-based drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by extending the duration of action of known active ingredients. Our product development program also focuses on identifying new delivery methods and formulations utilizing known compounds that may expand or extend the therapeutic effort, or eliminate the drawbacks of current therapies.

Our lead investigational product candidate, APF530, which we intend to market as SUSTOL® (granisetron injection, extended release), subject to regulatory approval, is being developed for the prevention of both acute- and delayed-onset chemotherapy induced nausea and vomiting ("CINV"). In 2014, we initiated a Phase 3 clinical study with APF530 for the prevention of delayed-onset CINV in patients receiving highly emetogenic chemotherapy ("HEC study"). 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_3 receptor antagonist approved for the prevention of delayed-onset CINV in patients receiving moderately emetogenic chemotherapy; none are approved for delayed-onset CINV in patients receiving highly emetogenic chemotherapy.

SUSTOL contains the 5-HT_3 receptor antagonist granisetron formulated in the Company's proprietary Biochronomer polymer-based drug delivery platform, which has been shown in clinical studies to maintain therapeutic drug levels of SUSTOL for up to five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset 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") with the U.S. Food and Drug Administration ("FDA") seeking approval for SUSTOL for the prevention of acute-onset CINV in patients receiving both moderately and highly emetogenic chemotherapy and delayed-onset CINV in patients receiving moderately emetogenic chemotherapy. The FDA issued a Complete Response Letter ("CRL") for the SUSTOL NDA in March 2010. In September 2012, we resubmitted our NDA for SUSTOL and, in March 2013, we received a second CRL, which identified several remaining issues that need to be addressed prior to approval of the SUSTOL NDA. We believe that we have substantially addressed those issues raised in the March 2013 CRL. We are anticipating completing enrollment of our ongoing HEC study in the first quarter of 2015. We intend to include the results of the study in the resubmission of the SUSTOL NDA, which we anticipate filing shortly thereafter.

Our Biochronomer technology, on which SUSTOL and certain of 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 prevention of CINV, pain management and control of inflammation, among others. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to potentially multiple weeks. As part of our product development efforts, we are researching the potential use of our Biochronomer technology with other drugs for the clinical development of other drug candidates.

In November 2013, we initiated a program to expand our pipeline of sustained-release products, including a new program targeting pain management. Our lead product candidate for this program is HTX-011, a combination of local anesthetic bupivacaine and the anti-inflammatory meloxicam in a formulation utilizing our proprietary Biochronomer polymer-based drug delivery platform. We are in the process of commencing a Phase 1 study in Europe to examine the product candidate in human

candidates. As of 2012, approximately 25 million[1] procedures associated with post-operative pain were conducted in the U.S. In addition, post-operative pain market sales were approximately $3.1 billion[2] in 2012.

In November 2014, we announced our product development program for HTX-019. The investigational product HTX-019 is a proprietary intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist used in combination with a 5-HT_3 for the prevention of CINV. HTX-019 does not contain polysorbate 80. By eliminating the use of surfactant polysorbate 80, HTX-019 may reduce the hypersensitivity reactions observed with fosaprepitant formulations containing this component. At present, there is only one intravenous NK_1 receptor antagonist approved in the U.S. for the prevention of CINV.

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, common stock underlying convertible notes and warrants outstanding were 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 $294.6 million as of September 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 September 30, 2014, we had cash on hand of $86.2 million.

We believe that our current working capital is sufficient to fund operations into 2015, including pursuing regulatory approval to market SUSTOL, and beginning human clinical studies relative to our HTX-011 and HTX-019 development programs. In the event we were to pursue clinical product development in other areas, potentially acquire other strategic assets, or begin to make significant investments in preparing for commercialization of SUSTOL, we would need to raise additional capital. 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 nine months ended September 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 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

1 Custom Research Project by Design Resources completed in 2013.
2 Decision Resources, Acute Pain, December 2012.

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.

Cash

We had cash of $86.2 million and $72.3 million at September 30, 2014 and December 31, 2013, respectively. We did not hold any cash equivalents or investment securities as of both dates. Our bank accounts have been placed under a control agreement in accordance with the Senior Secured Convertible Notes (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 all 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 September 30,	
	2014	2013
Stock options outstanding	6,456	6,270
Warrants outstanding	4,108	3,969
Common stock underlying convertible notes outstanding	6,578	6,198

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 our net loss and there were no other changes in equity from non-owner sources.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* ("ASU 2014-15"). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one

year after the date that the financial statements are issued (or available to be issued). The amendments in ASU 2014-15 are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. We plan to adopt the provisions on ASU 2014-15 in 2016. We do not expect the adoption of this ASU to have a material impact on our results of operations or financial condition.

In June 2014, FASB issued 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 our results of operations or financial condition.

In July 2013, the FASB issued ASU 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 September 30, 2014, we were in compliance with all 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 underlying the Notes. The registration statement was declared effective on July 29, 2011. The Note holders have agreed to waive their right to require us to maintain the effectiveness of the registration statement and to register the additional shares underlying the 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 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 September 30, 2014, accrued interest of approximately $78,000 was paid-in-kind and rolled into the Note principal balance, which resulted in an additional debt discount of approximately $78,000. For the three months ended September 30, 2014 and 2013, interest expense relating to the stated rate was approximately $79,000 and $74,000, respectively, and interest expense relating to the amortization of the debt discount was approximately $145,000 and $135,000, respectively. For the nine months ended September 30, 2014 and 2013, interest expense relating to the stated rate was approximately $233,000 and $218,000, respectively, and interest expense relating to the amortization of the debt discount was approximately $425,000 and $396,000, respectively.

As of September 30, 2014, the carrying value of the Notes was approximately $1,450,000, which is comprised of the $5,262,000 principal amount of the Notes outstanding, less debt discount of $3,812,000. If the $5,262,000 principal amount of Notes is converted, we would issue approximately 6,578,000 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 nine months ended September 30, 2014, warrant holders exercised 460,706 warrants under the cashless exercise provision in the warrant agreement, which resulted in the net issuance of 303,614 shares of common stock and no net cash proceeds to us. During the nine months ended September 30, 2013, we received $0.6 million for cash exercises of these warrants.

2012 Private Placement

In July 2012, we sold approximately 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.

2013 Common Stock Offering

In November 2013, we sold approximately 8.6 million shares of our common stock 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 an effective registration statement, which was previously filed with the SEC and was declared effective.

2014 Common Stock Offering

In June 2014, we sold approximately 4.8 million shares of our common stock 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 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 an effective registration statement, which was previously filed with the SEC and was declared effective.

Stock Option Exercises

For the nine months ended September 30, 2014, approximately 550,000 shares of common stock were issued pursuant to the exercise of stock options, resulting in proceeds to us of approximately $2.8 million.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 715	$ 702	$2,423	$ 1,492
General and administrative	1,045	3,393	3,386	6,841
Stock-based compensation expense included in operating expenses	$ 1,760	$ 4,095	$5,809	$ 8,333
Impact on basic and diluted net loss per share	$ 0.06	$ 0.27	$ 0.23	$ 0.54

As of September 30, 2014, there was approximately $26.8 million of total unrecognized compensation cost related to non-vested, stock-based payment awards granted pursuant to our equity compensation arrangements. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We expect to recognize this compensation cost over a period of 2.5 years, which is the weighted-average vesting period for all stock-based compensation awards.

We 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:

	September 30,	
	2014	2013
Risk-free interest rate	2.0%	1.0%
Dividend yield	0.0%	0.0%
Volatility	102.9%	104.2%
Expected life (years)	6.0	6.0

We estimated 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. There were no new offering periods for the quarters ended September 30, 2014 and 2013.

The following table summarizes the stock option activity for the nine months ended September 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	1,631	$ 9.95	
Exercised	(719)	$ 6.29	
Expired and forfeited	(812)	$ 9.82	
Balance at September 30, 2014	6,456	$ 8.67	8.18

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 our ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. We continue to maintain a full valuation allowance against its deferred tax assets as of September 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 our 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 September 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 included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (the "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:

- *estimates of the timing of our resubmission of the New Drug Application ("NDA") for SUSTOL, and potential regulatory approval for and commercial launch of SUSTOL;*
- *the anticipated progress of our research and development and programs, including the commencement of new clinical trials and preclinical testing;*
- *if approved, the market conditions at commercial launch of SUSTOL or other future product candidates;*
- *our ability to successfully market, commercialize and achieve market acceptance for SUSTOL or other future product candidates, including our positioning relative to competing products;*
- *our ability to successfully develop and achieve regulatory approval for other drug candidates utilizing our proprietary Biochronomer polymer-based drug delivery platform;*
- *our ability to establish key collaborations for our technology, SUSTOL and other future product candidates;*
- *our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;*
- *unanticipated delays due to manufacturing difficulties, supply constraints, or changes in the regulatory environment;*
- *our ability to successfully establish and maintain key vendor relationships necessary for the manufacture of our products;*
- *uncertainties associated with obtaining and enforcing patents to protect our products, and our ability to successfully defend ourselves against unforeseen third party infringement claims; 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 biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. Our proprietary Biochronomer® polymer-based drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by extending the duration of action of known active ingredients. Our product development program also focuses on identifying new delivery methods and formulations utilizing known compounds that may expand or extend the therapeutic effort, or eliminate the drawbacks of current therapies.

Our lead investigational product candidate, APF530, which we intend to market as SUSTOL® (granisetron injection, extended release), subject to regulatory approval, is being developed for the prevention of both acute- and delayed-onset chemotherapy induced nausea and vomiting ("CINV"). In 2014, we initiated a Phase 3 clinical study with APF530 for the prevention of delayed-onset CINV in patients receiving highly emetogenic chemotherapy ("HEC study"). 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_3 receptor antagonist approved for the prevention of delayed-onset CINV in patients receiving moderately emetogenic chemotherapy; none are approved for delayed-onset CINV in patients receiving highly emetogenic chemotherapy.

SUSTOL contains the 5-HT_3 receptor antagonist granisetron formulated in the Company's proprietary Biochronomer polymer-based drug delivery platform, which has been shown in clinical studies to maintain therapeutic drug levels of SUSTOL for up to five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset 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") with the U.S. Food and Drug Administration ("FDA"), seeking approval for SUSTOL for the prevention of acute-onset CINV in patients receiving both moderately and highly emetogenic chemotherapy and delayed-onset CINV in patients receiving moderately emetogenic chemotherapy. The FDA issued a Complete Response Letter ("CRL") for the SUSTOL NDA in March 2010. In September 2012, we resubmitted our NDA for SUSTOL and, in March 2013, we received a second CRL, which identified several remaining issues that need to be addressed prior to approval of the SUSTOL NDA. We believe that we have substantially addressed those issues raised in the March 2013 CRL. We are anticipating completing enrollment of our ongoing HEC study in the first quarter of 2015. We intend to include the results of the study in the resubmission of the SUSTOL NDA, which we anticipate filing shortly thereafter.

Our Biochronomer technology, on which SUSTOL and certain of 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 prevention of CINV, pain management and control of inflammation, among others. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to potentially multiple weeks. As part of our product development efforts, we are researching the potential use of our Biochronomer technology with other drugs for the clinical development of other drug candidates.

In November 2013, we initiated a program to expand our pipeline of sustained-release products, including a new program targeting pain management. Our lead product candidate for this program is HTX-011, a combination of local anesthetic bupivacaine and the anti-inflammatory meloxicam in a formulation utilizing our proprietary Biochronomer polymer-based drug delivery platform. We are in the process of commencing a Phase 1 study in Europe to examine the product candidate in human candidates. As of 2012, approximately 25 million[3] procedures associated with post-operative pain were conducted in the U.S. In addition, post-operative pain market sales were approximately $3.1 billion[4] in 2012.

In November 2014, we announced our product development program for HTX-019. The investigational product HTX-019 is a proprietary intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist used in combination with a 5-HT_3 for the prevention of CINV. HTX-019 does not contain polysorbate 80. By eliminating the use of surfactant polysorbate 80, HTX-019 may reduce the hypersensitivity reactions observed with fosaprepitant formulations containing this component. At present, there is only one intravenous NK_1 receptor antagonist approved in the U.S. for the prevention of CINV.

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 SEC 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 Nine Months Ended September 30, 2014 and 2013

Research and Development Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
SUSTOL related costs	$ 9,478	$3,489	$26,601	$17,061
New product development related costs	1,505	195	3,183	531
Personnel and related costs	2,165	1,172	6,036	3,290
Stock-based compensation expense	715	702	2,423	1,492
Facility related costs	460	449	1,540	1,364
Other	408	209	1,146	424
Total research and development expense	$14,731	$6,216	$40,929	$24,162

3 Custom Research Project by Design Resources completed in 2013.

4 Decision Resources, Acute Pain, December 2012.

For the three and nine months ended September 30, 2014, research and development expense increased to $14.7 million and $40.9 million, respectively, from $6.2 million and $24.2 million, respectively, for the same periods in 2013, primarily as a result of an increase in SUSTOL related costs due to the initiation of the Phase 3 HEC study of APF530 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 $1.0 million and $2.7 million, respectively, mainly due to additional headcount to support the increased development activities noted above, and an increase for the nine month period due to additional non-cash, stock-based compensation expense of approximately $0.9 million.

General and Administrative Expense

For the three and nine months ended September 30, 2014, general and administrative expense decreased to $4.2 million and $14.1 million, respectively, from $6.4 million and $16.5 million, respectively, for the same periods in 2013, primarily as a result of higher stock-based compensation expense in 2013 resulting from the resignation of our former chief executive officer in August 2013. For the three and nine months ended September 30, 2014, general and administrative expenses consist primarily of salaries and related expenses, professional fees, pre-commercialization costs and insurance expense.

Interest and Other Expense

Interest and other expense was $0.2 million and $0.7 million, respectively, for the three and nine months ended September 30, 2014, which was comparable to $0.2 million and $0.6 million for the same periods in 2013. Interest and other expense consists primarily of interest expense and amortization of debt discount related to the Senior Secured Convertible Notes (“Notes”).

Capital Resources and Liquidity

As of September 30, 2014, we had approximately $86.2 million in cash, compared to $72.3 million as of December 31, 2013. The net increase in cash of approximately $13.9 million was primarily due to the cash proceeds of approximately $58.9 million received from the common stock offering completed in June 2014 and $2.8 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.

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 we received approximately $22.8 million of proceeds, net of issuance costs.

In July 2012, we closed a private placement of common stock whereby we received approximately $50.5 million of proceeds, net of issuance costs.

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

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

We believe that our current working capital is sufficient to fund operations into 2015, including pursuing regulatory approval to market SUSTOL, and beginning human clinical studies relative to our HTX-011 and HTX-019 development programs. In the event we were to pursue clinical product development in other areas, potentially acquire other strategic assets, or begin to make significant investments in preparing for commercialization of SUSTOL, we would need to raise additional capital. 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; the scope, rate of progress, results and costs of preclinical testing and clinical trials, including our Phase 3 clinical trial of APF530 for the prevention of delayed-onset 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 if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

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

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts related to any of our product candidates will be 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. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by our failure to achieve significant business objectives, covenants contained in the Notes, and numerous other factors.

Contractual Obligations

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

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$1,753	$ 832	$ 921	$ —	$ —

The holders of the Notes 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 September 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

None

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this quarterly report on Form 10-Q 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 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.

Risks Related To Our Business

We are substantially dependent upon the approval and success of our investigational product APF530, also referred to as SUSTOL.

We have invested a significant portion of our time and financial resources in the development of our most advanced product candidate, APF530, which we intend to market as SUSTOL subject to regulatory approval, and has been studied in the prevention of acute-onset chemotherapy-induced nausea and vomiting ("CINV") in patients undergoing both moderately and highly emetogenic chemotherapy and for the prevention of delayed-onset CINV for patients undergoing moderately emetogenic chemotherapy ("MEC"). In 2014, we initiated a Phase 3 clinical study with APF530 for the prevention of delayed-onset CINV in patients receiving highly emetogenic chemotherapy ("HEC study"). We are anticipating completing enrollment of the HEC study in the first quarter of 2015. We intend to include the results of the study in the resubmission of our New Drug Application ("NDA") for SUSTOL, which we anticipate filing shortly thereafter. There can be no assurance that the HEC study will conclude on a timely basis, or that the results will be positive for us.

Our ability to generate revenue in the next one to two years 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 September 2012, we resubmitted the NDA seeking approval for APF530 with the U.S. Food and Drug Administration ("FDA"). In March 2013, we received a Complete Response Letter ("CRL") from the FDA pertaining to our resubmission of our NDA for APF530. The CRL identified several remaining issues that need to be addressed prior to approval of our NDA for APF530 including issues relating to: manufacturing of SUSTOL, the administration of SUSTOL and our analysis of efficacy data for SUSTOL under more recent guidelines classifying chemotherapy regimens. We believe we have substantially addressed the issues identified by the FDA in the CRL, although there can be no assurance that the FDA will agree. 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 includes our desired product indications covering acute and delayed-onset CINV, for use in both HEC and MEC regimens; and
- the methods used in manufacturing SUSTOL and the controls used to maintain its quality are adequate to preserve chain of identity, strength, quality and purity.

Delays in obtaining regulatory approval for SUSTOL, or the issuance of another CRL by the FDA, would, among other consequences, delay the launch of SUSTOL and impact our ability to raise additional capital, which would have a material adverse effect on our business and financial condition.

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

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;

- the perception of physicians and other members of the health care community of the safety and efficacy and cost-competitiveness relative to that of competing products;
- acceptance by institutional formulary committees;
- patient and physician satisfaction with the product;
- our ability to have SUSTOL manufactured at a commercial production level successfully and on a timely basis;
- the cost and availability of raw materials;
- the size of the potential market for 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;
- 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;
- regulatory developments related to the manufacture or continued use of the product;
- the extent and effectiveness of sales and marketing and distribution support for the product; and
- our competitors' decisions as to the timing of competing product launches, pricing and discounting.

Our revenue will be adversely affected if, due to these or other factors, our commercialization of SUSTOL does not achieve the acceptance and demand to sustain product revenue growth.

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 have used contract research organizations to date to oversee our clinical trials for APF530 and we expect to use the same or similar organizations for our future clinical trials and pipeline programs. There can be no assurance that these organizations will perform their obligations at all times in a competent or timely fashion, and we must rigorously oversee their activities in order to place confidence in their conduction of these trials on our behalf. Different cultural and operational issues in foreign countries could cause delays or unexpected problems with patient enrollment or with the data obtained from those locations. If we experience significant delays in the progress of our clinical trials or experience doubts with respect to the quality of data derived from our clinical trials, we could face significant delays in gaining necessary product approvals.

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

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

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

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

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

We do not manufacture SUSTOL ourselves 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 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 by regulatory authorities for us to begin marketing a product may be delayed, existing product batches may be compromised, and we may experience delays in the availability of SUSTOL for commercial distribution.

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

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

To date, APF530 has been manufactured primarily in small quantities for preclinical studies and clinical trials. If in the future APF530 or any of our product candidates are approved for commercial sale, we will need to be able to consistently manufacture our products in larger quantities. The commercial success of our products will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture. 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 regulatory approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

We expect to depend on contract manufacturers for manufacturing any future products we develop, and if our contract manufacturers do not perform as expected, our business could suffer.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of any product. Our ability to develop and commercialize any products we may develop will depend in part on our ability to manufacture, or arrange for other parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and eventual commercialization. We currently rely on a small number of third-party manufacturers to produce compounds used in our product development activities and expect to continue to do so to meet the preclinical and clinical requirements of our potential products and for all of our commercial needs. Certain of our contract manufacturers are at present our sole resource to manufacture certain key components of SUSTOL, and for products in preclinical testing in our research and development program. We may not be able to successfully negotiate long-term agreements with any of these third parties. Further, we may have difficulties with these relationships, and we may not be able to find replacement contract manufacturers on satisfactory terms or on a timely basis.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our products and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in an enforcement action such as product recall or prevent commercialization of our product candidates and delay our business development activities.

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

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

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

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

We do not currently have an internal sales organization for the sale, marketing and distribution of SUSTOL, or for any other products we may develop. In order to successfully commercialize SUSTOL or any other product, we must build our sales, marketing, distribution and other non-technical capabilities or make arrangements with third parties to perform these services. Our Company has no direct experience in developing, training or managing a marketing and sales organization. The establishment and development of a sales organization to market SUSTOL and our other product candidates will be expensive and time consuming and could delay product launch, and we cannot be certain that we will be able to successfully develop this capacity. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

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

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

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

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

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

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

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

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 and product candidates 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.

Under agreements with any collaborators we may work with in the future, 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.

We may not be successful in establishing and overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative relationships our business prospects could suffer.

Risks Related to our Financial Condition

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

We have incurred significant operating losses and negative cash flows from operations and had an accumulated deficit of $294.6 million through September 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 and marketing organization and commence commercialization of SUSTOL, if approved;

- expand product development activities with respect to our product pipeline;
- conduct preclinical development and clinical trials for our product candidates;
- pursue regulatory approvals for any product candidates we may develop in the future; and
- engage in commercialization efforts with respect to any future approved product candidates.

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.

At September 30, 2014, the Company had cash and cash equivalents in the amount of $86.2 million. We believe that our current working capital balance is sufficient to fund operations into 2015; including pursuing regulatory approval to market SUSTOL, and beginning human clinical studies relative to our HTX-011 and HTX-019 development programs. In the event we were to pursue clinical product development in other areas, potentially acquire other strategic assets, or begin to make significant investments in preparing for commercialization of SUSTOL, we would need to raise additional capital. 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 potential timing of the resubmission of our NDA for SUSTOL and the results of the regulatory review by the FDA, costs related to manufacturing of SUSTOL, if approved, technological and market developments of drugs that may compete with SUSTOL, the amount of revenues, if any, generated by SUSTOL, and the timing of clinical trials we may conduct in order to potentially expand our product pipeline. 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.

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

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

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

- the status of regulatory approval of any pending applications with the FDA, as the case may be, and the costs involved with pursuing regulatory approvals;
- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of preclinical testing and clinical trials;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates;

- the cost and timing of establishing sales and marketing capabilities if we commercialize any products independently; and
- the cost of establishing supply arrangements for clinical and commercial development of our product candidates and any products that we may develop.

If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment, and such issuance may adversely affect the market price of our common stock. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. Our Senior Secured Convertible Notes ("Notes") also include restrictions on our use of cash and financial activities. 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.

Provisions contained in our Notes limit our ability to incur additional indebtedness.

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

Risks Related to our Industry

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 APF530 and, even if approved, it may not result in a commercially viable product. 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;
- the inability to find partners;
- the failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- the failure by us or third-party investigators, contract research organizations, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;

- the failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- any delay in completion of clinical trials, resulting in increased costs; and
- 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 contract research organizations;
- obtaining institutional review board approval to conduct a study at a prospective site; and
- recruiting patients to participate in a study.

Our failure to successfully establish, recruit for, and oversee our clinical trials could delay our product development effects and negatively impact our business.

We may not obtain regulatory approval for any of our product candidates. Regulatory approval may also be delayed or revoked or may impose limitations on the indicated uses of a proposed product.

The process for obtaining approval of a new drug is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. The regulatory process 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 necessary regulatory agency approvals or clearances before it may be marketed in the United States or other countries. 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 APF530 or any other product candidate, as a result of changes in FDA policies prior to approval or other events. 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.

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 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 or other inappropriate sales and marketing activities. 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.

We face intense competition from other companies developing products in the CINV indication, including those with potentially competitive delivery technologies.

SUSTOL, if approved, is expected to face significant competition for the prevention of CINV. In particular, competition may come from Eisai's branded drug Aloxi (palonosetron), a 5-HT_3 antagonist, and also generic versions of the product which may become available on the market as soon as October 2015 following expiration of the relevant patent. In addition to Aloxi and any future generic versions, SUSTOL will compete with entrenched generic forms of granisetron (formerly marketed by Roche as Kytril) and ondansetron (formerly marketed by GlaxoSmithKline as Zofran). We are also aware of several companies that have developed, or are developing, both generic and new formulations of granisetron, including those using alternative delivery methods, such as transdermal formulations such as ProStrakan's Sancuso (granisetron transdermal patch), which was approved in 2008 and Eisai's Akynzeo, an oral combination product consisting of netupitant, an NK_1 receptor antagonist, and palonosetron, indicated for the treatment of CINV in both highly emetogenic and moderately emetogenic chemotherapy regimes, which was approved in October 2014.

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. Companies with focused efforts that may compete with our product development program relative to a pain management product are Durect Corporation, and Pacira Pharmaceuticals, Inc., each of whom are developing or marketing products that could compete with us.

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 care reform, reducing 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 products, if approved for marketing. While we cannot predict whether any legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

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

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

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

Our success will depend in part on our ability to obtain patents and maintain trade secret protection, as well as successfully defending these patents against challenges, while operating without infringing the proprietary rights of others. We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. 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 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 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 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 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.

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

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

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

Provisions of Delaware law, our certificate of incorporation and our bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include authorizing the issuance of “blank check” preferred stock without any need for action by stockholders.

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

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

Our outstanding Notes bear interest at a rate of 6% per annum, payable quarterly in cash or in kind, at the election of the holders of the Notes. 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 that is being converted. In the event the holders of the Notes were to opt to convert in full the outstanding principal and accrued interest due under the Notes as of September 30, 2014, we would be required to issue an aggregate of 6.6 million shares, representing approximately 23% of our outstanding shares, after giving effect to such conversion. This would result in substantial dilution of our existing stockholders.

Concentration in stockholder ownership could influence strategic actions.

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a significant percentage of our outstanding common stock. In addition, certain of our principal stockholders hold outstanding warrants that are exercisable for additional shares of our common stock. As of September 30, 2014, Tang Capital Partners, LP and its affiliates' ("TCP") beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, was approximately 17%, excluding the exercise of outstanding warrants. In addition, TCP has the right to acquire up to an additional 5.3 million shares upon conversion of the Notes. 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 substantial concentration of common stock ownership or control could significantly influence corporate actions on various strategic matters, including, for example, receptivity to collaborations and merger or sale overtures to the extent that stockholder approval is required for such transactions. Further, covenants contained in the Notes would require approval from the Note holders for any change of control transaction we might consider. Accordingly, we may only be able to pursue transactions that are supported by these large stockholders. In addition, the conversion of the Notes, the exercise of these warrants, or the sale by our current stockholders of a substantial number of shares, or the expectation that such exercises or sales may occur, could significantly reduce the market price of our common stock.

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
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.

Heron Therapeutics, Inc.

Date: November 6, 2014

/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)

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HERON THERAPEUTICS, INC.

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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Barry D. Quart, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary 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: November 6, 2014

/s/ Barry D. Quart

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

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Brian G. Drazba, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary 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: November 6, 2014

/s/ Brian G. Drazba

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

EXHIBIT 32.1

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

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

- the Quarterly Report of the Registrant on Form 10-Q for the quarter ended September 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: November 6, 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.