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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2013

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

A.P. PHARMA, INC.
(Exact name of registrant as specified in its charter)

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

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

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 definition 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	☐	Small 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 ☒

As of October 31, 2013, 313,616,369 shares of the registrant's Common Stock, $0.01 par value per share, were outstanding.

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A.P. Pharma, Inc.

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PART I. Financial Information.

Item 1. Financial Statements.

A.P. Pharma, Inc.
Condensed Balance Sheets
(in thousands)

	September 30, 2013 (Unaudited)	December 31, 2012 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 22,597	$ 53,506
Prepaid expenses and other current assets	763	584
Total current assets	23,360	54,090
Property and equipment, net	2,857	1,752
Other long-term assets	153	130
Total assets	$ 26,370	$ 55,972
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,250	$ 1,912
Accrued expenses	2,360	1,750
Convertible notes payable to related parties, net of discount	888	492
Total current liabilities	5,498	4,154
Stockholders' equity:		
Common stock	3,110	3,024
Additional paid-in capital	242,589	232,381
Accumulated deficit	(224,827)	(183,587)
Total stockholders' equity	20,872	51,818
Total liabilities and stockholders' equity	$ 26,370	$ 55,972

See accompanying notes to condensed financial statements.

A.P. Pharma, Inc.
Condensed Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Operating expenses:				
Research and development	$ 5,885	$ 3,626	$ 23,188	$ 10,022
General and administrative	6,779	2,428	17,438	5,181
Total operating expenses	12,664	6,054	40,626	15,203
Operating loss	(12,664)	(6,054)	(40,626)	(15,203)
Interest expense, net	(209)	(195)	(614)	(402)
Loss from continuing operations	(12,873)	(6,249)	(41,240)	(15,605)
Income (loss) from discontinued operations	—	128	—	(6)
Net loss	$ (12,873)	$ (6,121)	$ (41,240)	$ (15,611)
Basic and diluted net loss per share:				
Loss from continuing operations	$ (0.04)	$ (0.02)	$ (0.13)	$ (0.07)
Net loss	$ (0.04)	$ (0.02)	$ (0.13)	$ (0.07)
Shares used to compute basic and diluted net loss per share	307,496	274,488	306,096	225,063

See accompanying notes to condensed financial statements.

A.P. Pharma, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$(41,240)	$(15,611)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from discontinued operations	—	6
Depreciation and amortization	237	147
Stock-based compensation	8,333	3,773
Amortization of debt discount	396	262
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(202)	(89)
Accounts payable	514	980
Accrued expenses	826	(352)
Net cash used in operating activities	(31,136)	(10,884)
Cash flows from investing activities:		
Purchases of property and equipment	(1,518)	(546)
Net cash used in investing activities	(1,518)	(546)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	—	50,491
Proceeds from convertible note financing	—	3,000
Proceeds from warrant exercise	600	—
Proceeds from stock option exercise	1,120	—
Proceeds from the issuance of shares under the Employee Stock Purchase Plan	25	13
Net cash provided by financing activities	1,745	53,504
Net increase (decrease) in cash and cash equivalents	(30,909)	42,074
Cash and cash equivalents, beginning of period	53,506	17,974
Cash and cash equivalents, end of period	$ 22,597	$ 60,048

See accompanying notes to condensed financial statements.

A.P. Pharma, Inc.

Notes to Condensed Financial Statements
(unaudited)

(1) BUSINESS AND BASIS OF PRESENTATION

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

The Company's lead product candidate, APF530, is being developed for the prevention of both acute chemotherapy-induced nausea and vomiting (CINV) for patients undergoing both moderately and highly emetogenic chemotherapy and for the prevention of delayed CINV for patients undergoing moderately emetogenic chemotherapy. One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuations of treatment. There is only one injectable 5-HT3 antagonist approved for the prevention of delayed-onset CINV, so this indication represents an area of particular unmet medical need. APF530 contains the 5-HT3 antagonist granisetron formulated in the Company's proprietary Biochonomer drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. This five-day range is designed to cover the delayed phase of CINV. Granisetron was selected for APF530 because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

In May 2009, we filed the original New Drug Application (NDA) seeking approval for APF530 with the U.S. Food and Drug Administration (FDA). The FDA issued a Complete Response Letter for the APF530 NDA in March 2010. In September 2012, we resubmitted the NDA seeking approval for APF530 with the FDA. On March 28, 2013, we announced that the FDA had issued a Complete Response Letter, which identifies several issues that preclude approval of the APF530 NDA in its current form. We believe the issues that remain are addressable, and we are working expeditiously to resubmit the APF530 NDA in the first quarter of 2014.

We own the worldwide rights to APF530 and are in the early stages of building the commercial infrastructure necessary to commercialize APF530 in the U.S. on our own.

In November 2013, we initiated a program to expand our pipeline of sustained release products, including a new program targeting the relief of post-surgical pain. We also announced we will pursue a post-approval expansion of APF530 with the goal of demonstrating the utility in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently there are no approved 5-HT3 receptor antagonists for the treatment of delayed HEC.

In September 2013, our stockholders approved an amendment to our certificate of incorporation to change our name from A.P. Pharma, Inc. to Heron Therapeutics, Inc. The name change is part of our recent corporate restructuring and rebranding of the Company. We believe the name change will emphasize our shift from a polymer development company to a commercial phase specialty pharmaceutical company, assuming approval of APF530.

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. All adjustments (all of which are of a normal recurring nature) considered necessary for a fair presentation have been included. We have evaluated subsequent events through the date that these financial statements were issued. Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 or for any other period. The condensed balance sheet as of December 31, 2012 has been derived from the audited financial statements as of that date, but it does not include all of the information and notes required by U.S. GAAP. These unaudited condensed financial statements and the notes thereto should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the Securities and Exchange Commission (SEC) on March 1, 2013 (2012 10-K).

Liquidity

We have incurred significant operating losses and negative cash flows from operations and have an accumulated deficit of $224.8 million as of September 30, 2013. During 2011 and 2012, we entered into three financing agreements, which provided us capital to fund operations. In April 2011, we entered into definitive agreements for a convertible note financing of up to $4.5 million. We received approximately $1.3 million, net of issuance costs, from the initial closing and an additional $3.0 million through the issuance of additional convertible notes in May 2012 as a result of the purchasers who participated in the April 2011 convertible note financing fully exercising their rights to purchase additional convertible notes (see Note 8). In June 2011, we entered into definitive agreements for a private placement of units, which were comprised of common stock and warrants (see Note 9). The unit financing, which closed in July 2011, provided us with approximately $22.8 million of proceeds, net of issuance costs. In July 2012, we closed a common stock financing whereby we received approximately $50.5 million of proceeds, net of issuance costs (see Note 9). As of September 30, 2013, we had cash and cash equivalents of $22.6 million.

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

We believe that our current working capital is sufficient to fund planned operations into 2014. However, we will require additional capital to fund our development and operating activities. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. We evaluate our critical accounting policies and estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our 2012 10-K.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended September 30, 2013, as compared to the recent accounting pronouncements described in our 2012 10-K, that we believe are of significance, or potential significance, to us.

(2) CASH EQUIVALENTS

Our available-for-sale securities as of December 31, 2012 consisted of money market funds primarily containing U.S. government-backed securities, with original maturities of ninety days or less. The carrying value of our money market funds was included in cash equivalents and approximated their fair value. We have no available-for-sale securities as of September 30, 2013. The Company's bank accounts have been placed under a control agreement in accordance with the April 2011 convertible note financing (see Note 8).

(3) FAIR VALUE MEASUREMENTS

The three-tier fair value hierarchy utilized prioritizes the inputs used in measuring fair value as follows: Level 1) observable inputs such as quoted prices in active markets; Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and Level 3) unobservable inputs in which there is little or no market data, which require us to develop our own assumptions. The hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. We measured our available-for-sale securities at fair value on a recurring basis. We used quoted prices in active markets (Level l) to measure the fair value of our cash equivalents on our Condensed Balance Sheets as of December 31, 2012. Cash equivalents consisted of highly rated money market funds with maturities of ninety days or less. Due to the high ratings and short-term nature of these funds, we considered the inputs used to value all cash equivalents as Level 1 inputs.

(4) NET LOSS PER SHARE

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the applicable period. Diluted net loss per share excludes the effect of outstanding potentially dilutive securities because they are anti-dilutive. The following table shows the outstanding potentially dilutive options, warrants and convertible notes for the nine months ended September 30, 2013 and 2012 (in thousands):

	Nine Months Ended September 30,	
	2013	2012
Options outstanding	125,392	67,940
Warrants outstanding	79,377	84,377
Common stock underlying convertible notes outstanding	123,957	116,790

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

(5) STOCK-BASED COMPENSATION

The following table summarizes the stock-based compensation expense for all awards (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Operating expenses:				
Research and development	$ 544	$ 397	$1,088	$1,061
General and administrative	3,551	1,583	7,245	2,712
Total stock-based compensation expense	$4,095	$ 1,980	$8,333	$3,773
Impact on basic and diluted net loss per common share	$ 0.01	$ 0.01	$ 0.03	$ 0.02

In the three months ended September 30, 2013, we recorded additional stock-based compensation expense as a result of accelerated vesting of stock options in connection with the resignation of our former chief executive officer.

The following table summarizes stock option activity for the nine months ended September 30, 2013:

	Shares (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding at January 1, 2013	86,478	$ 0.42	8.2
Granted	76,735	$ 0.40	
Exercised	(4,323)	$ 0.26	
Expired and forfeited	(33,498)	$ 0.47	
Outstanding at September 30, 2013	125,392	$ 0.40	8.0

Employee Stock Purchase Plan

We adopted an Employee Stock Purchase Plan (Purchase Plan) in 1997. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of our common stock under the Purchase Plan. In June 2011, our stockholders authorized an increase in the number of shares reserved for issuance under the Purchase Plan by 500,000, for a total of 1,000,000 shares reserved at September 30, 2013. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. Sales under the Purchase Plan during the nine months ended September 30, 2013 and 2012 consisted of 80,027 and 58,571 shares at an average price of $0.31 and $0.21, respectively. Shares available for future purchase under the Purchase Plan were 365,674 at September 30, 2013.

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

(6) COMPREHENSIVE LOSS

Comprehensive loss for the periods reported was comprised solely of our net loss. The comprehensive loss for the three and nine months ended September 30, 2013 was $12.9 million and $41.2 million, respectively. The comprehensive loss for the three and nine months ended September 30, 2012 was $6.1 million and $15.6 million, respectively. There were no changes in equity that were excluded from our net loss for all reported periods.

(7) DISCONTINUED OPERATIONS

Cosmeceutical and Toiletry Business

On July 25, 2000, we completed the sale of certain technology rights for our cosmeceutical and toiletry business to RP Scherer Corporation (RP Scherer), a subsidiary of Cardinal Health, Inc. Under the terms of the agreement, we guaranteed a minimum gross profit percentage on RP Scherer's combined sales of products to Ortho Dermatologics (Ortho) and Dermik Laboratories, Inc. (Dermik) (Gross Profit Guaranty), both of which were acquired by Valeant Pharmaceuticals in July 2011. The Gross Profit Guaranty expense totaled $944,000 for the first seven guaranty years. Effective March 2007, in conjunction with a sale of assets by RP Scherer's successor company to an Amcol International subsidiary (Amcol), a new agreement was signed between us and Amcol to provide continuity of product supply to Ortho and Dermik. We had previously recorded a liability of $1.1 million related to the amount that Amcol asserted was due under the Gross Profit Guaranty. In February 2013, an arbitrator ruled that no additional amounts were owed. This event qualified as an adjusting event under ASC 855, *Subsequent Event*, and in light of the arbitrator's decision in February 2013, which was final and binding, we reversed this accrual as of December 31, 2012.

The cosmeceutical and toiletry business is reported as discontinued operations for all periods presented in our accompanying Condensed Statements of Operations. Income (loss) from discontinued operations primarily represents the income (loss) attributable to changes in estimates of our cosmeceutical and toiletry business that was sold to RP Scherer on July 25, 2000, as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cosmeceutical and Toiletry Business				
Change in estimates for gross profit guarantees	$ —	$ 128	$ —	$ (6)

There was no material basic and diluted loss per common share resulting from discontinued operations for the three and nine months ended September 30, 2013 and 2012.

(8) CONVERTIBLE NOTES TO RELATED PARTIES

In April 2011, we entered into a Securities Purchase Agreement (Purchase Agreement) with certain institutional investors (Purchasers), including a fund affiliated with Kevin C. Tang, who is the Chairman of our Board of Directors (Board), for a private placement of up to $4.5 million in Senior Secured Convertible Notes due 2021 (Notes). The Purchase Agreement provided for the Purchasers to purchase $1.5 million aggregate principal amount of Notes at the initial closing. Pursuant to the Purchase Agreement, the Purchasers had the option to purchase an additional $3.0 million aggregate principal amount of Notes at any time until May 2, 2013 (Purchase Option). The Notes are convertible into shares of the Company's common stock at a rate of 25,000 shares for every $1,000 of principal and accrued interest due under the Notes (Conversion Shares).

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

The cash received from the initial closing of the Note financing, which resulted in the issuance of $1.5 million aggregate principal amount of Notes, was approximately $1.3 million, net of issuance costs. In May 2012, the Purchasers exercised their Purchase Option in full, and we received $3.0 million of cash through the issuance of the remaining $3.0 million aggregate principal amount of Notes. As a result of the exercise of the Purchase Option, the Purchasers have purchased the full amount of Notes that the Company was obligated to sell under the Purchase Agreement.

The Notes are secured by substantially all of the assets of the Company, including placing our bank accounts under a control agreement. The Notes initially bore interest at 20% per annum, payable quarterly in cash or in additional principal amount of Notes at the election of the Purchasers. In June 2011, the Notes were amended to reduce the interest rate to 6% per annum effective July 1, 2011. The Notes mature on May 2, 2021; however, the holders of the Notes may require prepayment of the Notes at any time beginning on or after May 2, 2012, at each holder's option.

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 the Company's outstanding common stock. Each holder of the Notes can increase or decrease this beneficial ownership conversion limit by written notice to the Company, which will not be effective until 61 days after delivery of the notice.

As of September 30, 2013, the Company was in compliance with all debt-related covenants under the Notes. Upon the occurrence of an event of default under the Notes, the holders of the Notes have the right to require the Company to redeem all or a portion of their Notes.

Pursuant to the Purchase Agreement, the Company filed a registration statement on Form S-1, registering for resale 69.6 million shares underlying the Notes. The registration statement was declared effective on July 29, 2011. The Purchasers have agreed to waive their right to require the Company 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 both issuance dates. Based on an effective fixed conversion rate of 25,000 shares for every $1,000 of principal and accrued interest due under the Notes, the total conversion benefit at issuance exceeded the loan proceeds. Therefore, a full debt discount was recorded in an amount equal to the face value of the Notes on the issuance dates, and the Company began amortizing the resultant debt discount over the respective 10-year or remaining term of the Notes. During the three months ended September 30, 2013, accrued interest of approximately $73,000 was paid-in-kind and rolled into the principal balance of the Notes, which resulted in an additional full debt discount for the respective periods. For the three and nine months ended September 30, 2013, interest expense relating to the stated rate of the Notes was approximately $74,000 and $218,000, respectively. Interest expense relating to the amortization of debt discount for the three and nine months ended September 30, 2013 was approximately $134,000 and $396,000, respectively.

As of September 30, 2013, the carrying value of the Notes was approximately $888,000, which is comprised of the $4,958,000 principal amount of the Notes outstanding, less debt discount of $4,070,000. If the $5.0 million principal amount of Notes is converted, the Company would issue 124.0 million shares of its common stock. Accrued interest on the principal balance was $74,000 at September 30, 2013.

(9) STOCKHOLDERS' EQUITY

Amendments to Articles of Incorporation

In June 2011, we amended our certificate of incorporation to increase the number of shares of authorized common stock to 1,500,000,000, par value $0.01 per share. Prior to the amendment, the number of shares of authorized common stock was 100,000,000, par value $0.01 per share. The certificate of amendment was approved by a majority of our stockholders on June 29, 2011.

In September 2013, our stockholders approved a proposal to authorize our Board to effect a reverse stock split of all outstanding shares of our common stock at any ratio at its discretion, from 1-for-10 to 1-for-20 and to grant the Board discretionary authority, within twelve months from September 19, 2013, to determine whether to effect the split and the exact whole number ratio within the range at which the split will be effected. The number of issued and outstanding shares of our common stock would be reduced in accordance with the ratio selected by the Board. The number of shares of common stock that are authorized for issuance under our certificate of incorporation would also be reduced proportionately based on the exchange ratio of the reverse stock split.

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

Stock Plans

At our annual meeting of stockholders in June 2011, our stockholders approved an amendment to our 2007 Equity Incentive Plan to increase the maximum number of shares of common stock available for grant by 90,000,000 shares of common stock, resulting in an aggregate of 95,000,000 shares of common stock authorized for issuance pursuant to awards granted under our 2007 Equity Incentive Plan. The stockholders also approved an amendment to our 1997 Employee Stock Purchase Plan to increase the number of shares of common stock reserved for issuance under the plan by 500,000, for a total of 1,000,000 shares reserved as of September 30, 2013.

2011 Private Placement

In June 2011, we entered into a Securities Purchase Agreement with certain purchasers (Securities Purchase Agreement), pursuant to which we agreed to sell 160,000,006 shares of our common stock (Shares) and warrants to purchase 80,000,005 shares of our common stock (Warrants) with an exercise price of $0.18 per share (2011 Private Placement), for an aggregate price of $24.0 million. The 2011 Private Placement closed on July 1, 2011. For each share purchased, the investors received one Warrant to purchase 0.5 shares of common stock (together with a Share, a Unit), at a purchase price of $0.15 per Unit. The Warrants were immediately exercisable and expire on the fifth anniversary of the closing date of July 1, 2011. 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 the Company, with such waiver taking effect only upon the expiration of a 61-day notice period.

Under the terms of the Securities Purchase Agreement, on July 29, 2011, the Company 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 Warrant Shares, and collectively with the Shares, the Registrable Securities). The registration statement was declared effective on August 4, 2011. The Company is obligated to maintain the effectiveness of the registration statement with respect to an investor's Registrable Securities until the investor is able to sell the Registrable Securities without limitation or restriction under Rule 144. There is currently only one investor who is an affiliate of the Company and is therefore not able to sell the Registrable Securities without limitation under Rule 144, and that investor has agreed to waive their right to require the Company to maintain the effectiveness of the registration statement until they provide notice otherwise. If the Company fails to keep the registration statement continuously effective for a designated time (with limited exceptions) during the period the Company is obligated to maintain the registration statement, the Company may be obligated to pay to the holders of the Registrable Securities liquidated damages in an amount equal to 1.0% per month of such holder's pro rata interest in the total purchase price of the Private Placement, capped at a total penalty of 6.0%.

The Company received total proceeds of $22.8 million from the 2011 Private Placement, which was net of issuance costs of approximately $1.2 million. During the nine months ended September 30, 2013, the Company received $0.6 million for an exercise of a Warrant.

2012 Private Placement

In July 2012, the Company entered into a securities purchase agreement with certain purchasers, pursuant to which the Company agreed to sell 102,000,000 shares of its common stock (2012 Shares) at a purchase price of $0.525 per share of common stock, for an aggregate price of approximately $53.6 million (2012 Private Placement). The 2012 Private Placement closed on July 30, 2012.

In connection with entering into the securities purchase agreement, the Company also entered into a registration rights agreement. On August 24, 2012, the Company filed a registration statement with the SEC to register the 2012 Shares for resale. The registration statement was declared effective on September 6, 2012. If the Company fails to keep the registration statements continuously effective for a designated time (with limited exceptions), the Company may be obligated to pay to each holder of the 2012 Shares an amount equal to 1.5% per month of the aggregate purchase price of the unregistered 2012 Shares held by such holder, capped at a total penalty of 9.0%.

A.P. Pharma, Inc.

Notes to Condensed Financial Statements – (Continued)
(unaudited)

The Company received total proceeds of $50.5 million from the 2012 Private Placement, which was net of issuance costs of approximately $3.1 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with: the FDA's response to our NDA when resubmitted; the progress of our research, development and clinical programs; the timing of regulatory approval and commercial introduction of APF530 and future product candidates; our ability to market, commercialize and achieve market acceptance for APF530 and other future product candidates; our ability to establish collaborations for our technology, APF530 and other future product candidates; our estimates for future performance; our estimates regarding our capital requirements and our needs for and ability to obtain additional financing; our ability to protect or enforce our intellectual property rights; volatility in the trading price of our common stock; and other risks and uncertainties identified in our filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not undertake to update them except as required by law.

Overview

We are a specialty pharmaceutical company developing products using our proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks.

Our lead product candidate, APF530, is being developed for the prevention of acute CINV for patients undergoing both moderately and highly emetogenic chemotherapy and for the prevention of delayed CINV for patients undergoing moderately emetogenic chemotherapy. One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuations of treatment. There is only one injectable 5-HT3 antagonist approved for the prevention of delayed-onset CINV, so this indication represents an area of particular unmet medical need. APF530 contains the 5-HT3 antagonist granisetron formulated in the Company's proprietary Biochronomer drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. This five-day range is designed to cover the delayed phase of CINV. Granisetron was selected for APF530 because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

In May 2009, we filed the original NDA seeking approval for APF530 with the FDA. The FDA issued a Complete Response Letter for the APF530 NDA in March 2010. In September 2012, we resubmitted the NDA seeking approval for APF530 with the FDA. On March 28, 2013, we announced that the FDA had issued a Complete Response Letter which identifies several issues that preclude approval of the APF530 NDA in its current form. We believe the issues that remain are addressable, and we are working expeditiously to resubmit the APF530 NDA in the first quarter of 2014.

We own the worldwide rights to APF530 and are in the early stages of building the commercial infrastructure necessary to commercialize APF530 in the U.S. on our own.

In November 2013, we initiated a program to expand our pipeline of sustained release products, including a new program targeting the relief of post-surgical pain. We also announced we will pursue a post-approval expansion of APF530 with the goal of demonstrating the utility in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently there are no approved 5-HT3 receptor antagonists for the treatment of delayed HEC.

In September 2013, our stockholders approved an amendment to our certificate of incorporation to change our name from A.P. Pharma, Inc. to Heron Therapeutics, Inc. The name change is part our recent corporate restructuring and rebranding of the Company. We believe the name change will emphasize our shift from a polymer development company to a commercial phase specialty pharmaceutical company, assuming approval of APF530.

Critical Accounting Policies and Estimates

We prepare our condensed financial statements in accordance with U.S. generally accepted accounting principles, which require management to make estimates and assumptions. Management bases these estimates and assumptions on historical results and known trends, as well as management forecasts. Actual results could differ from these estimates and assumptions. See our Annual Report on Form 10-K for the year ended December 31, 2012 (2012 10-K), Part II, Item 7 — "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates."

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended September 30, 2013, as compared to the recent accounting pronouncements described in our 2012 10-K, that we believe are of significance, or potential significance, to us.

Results of Operations for the Three and Nine Months Ended September 30, 2013 and 2012

Our research and development costs consist primarily of employee salaries and other personnel-related expenses, facility-related expenses, laboratory consumables, development manufacturing, and clinical and pre-clinical related services performed by clinical research organizations, research institutions and other outside service providers.

Research and development expense for the three months ended September 30, 2013 increased by $2.3 million to $5.9 million, from $3.6 million for the three months ended September 30, 2012. Research and development expense for the nine months ended September 30, 2013 increased by $13.2 million to $23.2 million, from $10.0 million for the nine months ended September 30, 2012. Compared to the comparable periods in the prior year, headcount-related costs and project spending for APF530 were higher in the current year periods as we worked to validate our manufacturing processes and increase the scale of production. We expect research and development expense for the year 2013 to be higher as compared to 2012 due to manufacturing-related expenses and additional efforts required to address issues raised in the Complete Response Letter we received in March 2013.

General and administrative expenses consist primarily of salaries and related expenses, professional fees, directors' fees, investor relations costs, pre-commercialization costs, insurance expense and related overhead cost allocation.

General and administrative expense for the three months ended September 30, 2013 increased by $4.4 million to $6.8 million, from $2.4 million for the three months ended September 30, 2012. General and administrative expense for the nine months ended September 30, 2013 increased by $12.2 million to $17.4 million, from $5.2 million for the nine months ended September 30, 2012. The increases in the current fiscal periods were primarily due to compensation expense incurred in the three months ended September 30, 2013 related to the resignation of our former chief executive officer, including stock compensation expense, higher headcount-related costs, market research, consulting costs and professional fees. We expect general and administrative expense for the year 2013 to be higher as compared to 2012 due to increased support costs, including headcount-related costs, and a full year of pre-commercialization activities.

Interest expense, net was $0.2 million for the three months ended September 30, 2013 and 2012, respectively. Interest expense, net was $0.6 million and $0.4 million for the nine months ended September 30, 2013 and 2012, respectively. Interest expense, net consists primarily of interest expense and amortization of debt discount related to the convertible note financing. Compared to the prior year periods, the increases in the current fiscal periods in interest expense, net were due to a greater amount of convertible notes outstanding as a result of such convertible note holders purchasing more convertible notes pursuant to their purchase option.

Income (loss) from discontinued operations represents the income (loss) attributable to the gross profit guaranty associated with the sale of our cosmeceutical and toiletry business. The income (loss) from discontinued operations was $0.0 million and $0.1 million for the three months ended September 30, 2013 and 2012, respectively. The income (loss) from discontinued operations was $0.0 million for both the nine months ended September 30, 2013 and 2012. See Note 7 of Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information.

Capital Resources and Liquidity

We had cash and cash equivalents of $22.6 million at September 30, 2013. Cash and cash equivalents decreased by $30.9 million from December 31, 2012 to September 30, 2013, primarily due to cash used in operations.

Net cash used in operating activities for the nine months ended September 30, 2013 was $31.1 million, compared to net cash used in operating activities of $10.9 million for the nine months ended September 30, 2012. The $20.2 million increase in net cash used was primarily due to the increase in operating loss which was partially offset by an increase in stock compensation expense.

Net cash used in investing activities for the nine months ended September 30, 2013 was $1.5 million, compared to $0.5 million for the nine months ended September 30, 2012. The net cash used in both periods was for purchases of property and equipment.

Net cash provided by financing activities for the nine months ended September 30, 2013 was $1.7 million, compared to $53.5 million for the nine months ended September 30, 2012. The decrease of $51.8 million was primarily due to $50.5 million of net proceeds received from the sale of common stock and $3.0 million of proceeds received from the issuance of convertible notes in the prior year period, which were partially offset by $1.1 million of proceeds from stock option exercises and $0.6 million of proceeds from a warrant exercise in the current year.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock and other securities, royalties received on sales of Retin-A Micro and Carac, the sale of our rights to royalties on sales of Retin-A Micro and Carac, income from collaborative research and development fees, proceeds received from the sales of our Analytical Standards division and our cosmeceutical and toiletry business, 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 approximately $1.3 million, net of issuance costs, from the initial closing, whereby $1.5 million aggregate principal amount of convertible notes was issued. In May 2012, the purchasers exercised their rights to purchase the remaining $3.0 million aggregate principal amount of convertible notes, and we received the additional $3.0 million of proceeds. In June 2011, we entered into definitive agreements for a private placement of units comprised of common stock and warrants, for which we received proceeds of $22.8 million, net of issuance costs of approximately $1.2 million. In July 2012, we closed a common stock financing whereby the Company received approximately $50.5 million of proceeds, net of issuance costs of approximately $3.1 million.

We believe that our current cash resources are sufficient to fund planned operations into 2014. However, we will require additional capital to fund our development and operating activities. Our capital requirements going forward will depend on numerous factors, including: our efforts to respond to the FDA's March 2013 Complete Response Letter; an approval decision by the FDA with respect to APF530; the timing of and cost related to the manufacturing and the commercial launch of APF530, if approved; the technological and market developments from drugs that may compete with APF530; the degree of commercial success of APF530; the number and characteristics of product development programs we pursue and the pace of each program; the scope, rate of progress, results and costs of preclinical testing and clinical trials; the time, cost and outcome involved in seeking 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 for a specialty sales force if we commercialize other products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

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

In September 2013, our stockholders approved a proposal to authorize our Board to effect a reverse stock split of all outstanding shares of our common stock at any ratio at its discretion, from 1-for-10 to 1-for-20 and to grant the Board discretionary authority, within twelve months from September 19, 2013, to determine whether to effect the split and the exact whole number ratio within the range at which the split will be effected. The primary objective in effecting a reverse split is to increase the per share trading price of our common stock. The Board believes that a reverse stock split would put the Company in a better position to have its shares listed on The NASDAQ Capital Market, facilitate higher levels of institutional stock ownership (as investment policies generally prohibit investments in lower-priced securities) and better enable the Company to raise funds to finance development and operations.

Contractual Obligations

Below is a summary of fixed payments related to certain contractual obligations (in millions), consisting solely of our operating lease obligations. This table excludes amounts already recorded on our balance sheet as current liabilities as of September 30, 2013.

	Total	Less than 1 year	2 to 3 years	4 to 5 years	More than 5 years
Operating lease obligations	$2.7	$ 1.0	$1.6	$0.1	$ —

The holders of the convertible notes issued in May 2011 and May 2012 may require prepayment of such notes at any time beginning on or after May 2, 2012 at each holder's option. See Note 8 of Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of September 30, 2013 we did not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is confined to our cash and cash equivalents. We did not hold any marketable securities at September 30, 2013.

Our debt obligations consist of our convertible debt, which carries 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

Evaluation of disclosure controls and procedures: We carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15(d)-15(e) of the Securities and Exchange Act of 1934. Based upon that evaluation, the Principal Executive Officer and Principal Financial Officer concluded that as of September 30, 2013, the end of period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting: During the three months ended September 30, 2013, there have been no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

There have been no material changes to the legal proceedings described in the Company's Annual Report on Form 10-K for the period ended December 31, 2012.

Item 1A. Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully these risk factors and all of the other information included in this Form 10-Q. Any of these risk factors could materially adversely affect our business, operating results and financial condition. These risks are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. 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. Before you decide whether to purchase any of our common stock, you should carefully consider the risk factors set forth below as may be updated from time to time by our future filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Risks Related To Our Business

We are substantially dependent upon the success of our APF530 product candidate. Clinical trial results and the NDA resubmission for this product may not lead to regulatory approval.

We have invested a significant portion of our time and financial resources in the development of our most advanced product candidate, APF530, for which we are initially seeking U.S. Food and Drug Administration (FDA) approval for the prevention of acute chemotherapy-induced nausea and vomiting (CINV) associated with both moderately and highly emetogenic chemotherapy and for the prevention of delayed CINV associated with moderately emetogenic chemotherapy (MEC). We currently also plan to conduct a Phase 3 study which, if successful, would allow us to expand our approved product label to include delayed CINV associated with highly emetogenic chemotherapy (HEC).

Our near-term ability to generate revenues and our future success, in large part, depends on the approval and successful commercialization of APF530. We will not be able to commercialize APF530 until we obtain regulatory approval in the United States or foreign countries. In order to satisfy FDA approval standards for the commercial sale of APF530, we must first successfully resolve the issues identified in the Complete Response Letter received from the FDA in March 2013. This letter identified several issues that precluded the approval of APF530 NDA in its current form, including issues relating to: manufacturing of APF530, the administration of APF530 and our analysis of efficacy data for APF530 under more recent guidelines classifying chemotherapy regimens. Although we are currently working to address these issues and currently expect to resubmit the APF530 NDA in the first quarter 2014, there can be no assurance that these responses will be sufficient or that we will be able to resubmit within this time period. Further, the FDA's review of our resubmission may not produce positive decisions as to whether:

- APF530 is safe and effective in its proposed use(s) and whether its benefits outweigh the risks;

- the proposed labeling for APF530 has our desired product indication regarding acute and delayed-onset CINV, as well as HEC and MEC regimens; and
- the methods used in manufacturing APF530 and the controls used to maintain its quality are adequate to preserve its identity, strength, quality and purity;

Deficiencies on any of the above, or other factors, could prevent or delay obtaining regulatory approval of APF530, which would negatively affect our potential revenues, increase our costs and potentially impair our ability to continue as a going concern.

We may not obtain regulatory approval for APF530 or any of our product candidates. Regulatory approval may also be delayed or cancelled or may entail limitations on the indicated uses of a proposed product.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. The regulatory process, particularly for pharmaceutical product candidates like ours, is uncertain, can take many years and requires the expenditure of substantial resources. Any product that we or our collaborative partners develop must receive all relevant regulatory agency approvals or clearances, if any, before it may be marketed in the United States or other countries. In particular, human pharmaceutical therapeutic 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. In September 2012, we resubmitted the NDA seeking approval for APF530 with the FDA. In March 2013, we received a second Complete Response Letter, which identified several issues that precluded the approval of APF530 NDA in its current form. We are currently working to address these issues and intend to resubmit the APF530 NDA in the first quarter 2014. Our NDA resubmission for APF530 may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval prior to the FDA's decision on our NDA.

For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) under the Federal Food, Drug, and Cosmetic Act, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of our NDA for APF530. The review of our resubmitted NDA may also be delayed due to the FDA's internal resource constraints. Additionally, data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances. For example, the FDA may require additional clinical data to support approval, such as confirmatory studies and other data or studies to address questions or concerns that may arise during the FDA review process.

Delays in obtaining regulatory approval for APF530, or the issuance of a third Complete Response Letter, would, among other consequences, delay the launch of APF530 and adversely affect our ability to generate revenue from sales of this product and adversely affect our ability to raise additional capital that would be necessary to sustain our operations. Given the additional delays that we would face prior to obtaining approval for APF530, if such approval is ever granted, we may need significant additional capital to fund our operations.

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

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

If APF530 is approved, but does not attain market acceptance by healthcare professionals and patients, our business prospects and results of operations will suffer.

Even if APF530 receives regulatory approval for commercial sale, the revenue that we may receive from the sale of APF530 may be less than expected and will depend on many factors that are outside of our control. Factors that may affect revenue from APF530, if approved, include;

- the scope of our approved product label;
- perception of physicians and other members of the health care community of the safety and efficacy relative to that of competing products;

- cost-effectiveness;
- patient and physician satisfaction with the product;
- ability to manufacture commercial product successfully and on a timely basis;
- cost and availability of raw materials;
- market size for the product;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning the product or similar drugs;
- the introduction, availability and acceptance of competing treatments, including those of our collaborators;
- adverse event information relating to the product;
- product liability litigation alleging injuries relating to the product;
- product labeling or product insert language required by the FDA or regulatory authorities in other countries;
- the regulatory developments related to the manufacture or continued use of the product;
- extent and effectiveness of sales and marketing and distribution support for the product; and
- our collaborators' decisions as to the timing of product launches, pricing and discounting.

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

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

We have incurred recurring losses and had an accumulated deficit of $225 million through September 30, 2013. Even if APF530 is approved, we expect to continue to generate substantial losses over at least the next several years as we:

- build a sales force and commence commercialization of APF530, if approved;
- expand drug product development and commercialization efforts;
- conduct preclinical development and clinical trials; and
- pursue additional applications for our existing delivery technologies.

To achieve and sustain profitability, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. If APF530 is approved for commercialization, we must successfully launch and commercialize the product. If APF530 is not approved, we will likely experience significant delays before we begin to recognize meaningful levels of revenue, if ever. We will incur substantial expenses in our efforts to develop and commercialize products and we may never generate sufficient revenue to become profitable or to sustain profitability.

Additional capital may be needed to enable us to implement our business plan, and we may be unable to raise capital, which would force us to limit or cease our operations and related product development programs. Raising such capital may have to be accomplished on unfavorable terms, likely causing dilution to our existing stockholders.

At September 30, 2013, the Company had cash and cash equivalents in the amount of $23 million. We believe that our current working capital balance is sufficient to fund our operations into 2014. We are pursuing commercialization of APF530 without a partner for the U.S. market, which will likely require us to obtain additional funding and resources to sustain our operations until we can achieve profitability. The need for and amount of additional funding that we may require depends on various factors, including the results of the on-going regulatory review by the FDA of our APF530 NDA resubmission, the time and costs related to manufacturing of APF530, if approved, and technological and market developments of drugs that may compete with APF530. There can be no assurance that APF530 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 APF530.

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

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

- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of preclinical testing and clinical trials;
- the time, cost and outcome involved in seeking regulatory approvals;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities for a specialty sales force if we commercialize any products independently;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and
- general market conditions.

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

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

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

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

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

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

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

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

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we have incurred significant expenses in developing APF530 and, even if approved, it may not result in a commercially viable product. We are planning a Phase 3 study of APF530 designed to demonstrate the utility of APF530 in the treatment of delayed-onset CINV in patients receiving HEC regimens. If successful, we intend to submit the results of the study in a post-approval application to expand the label of APF530 to include delayed HEC. There can be no assurance that this study will be successful or that the FDA will grant any such label expansion. Before obtaining regulatory approvals for the commercial sale of any products, we, or our partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and will continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials.

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

- insufficient funds to conduct clinical trials;
- inability to find partners;
- failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- failure by us or third-party investigators, contract research organizations, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- 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, or our collaborators, 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. For example, enrollment in the Phase 3 clinical trial for APF530 was slower than we expected, resulting in delays in our development timeline and increased costs. Completing clinical trials in a timely manner depends on, among other factors:

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

We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely and competent manner may delay development and commercialization of our product candidates.

We used clinical research organizations in the United States, Asia and Europe to oversee our clinical trials for APF530 and we expect to use the same or similar organizations for our future clinical trials. There are numerous alternative sources to provide these services; however, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion, or if we are forced to change service providers. Different cultural and operational issues in foreign countries could cause delays or unexpected problems with the patient enrollments or with the data obtained from those locations. If we experience significant delays in the progress of our clinical trials or problems with the quality of data derived from clinical trials, the prospects for approval would decrease.

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

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

- selection of inappropriate therapeutic compound for delivery;
- selection of inappropriate use or application for the particular product candidate;
- failure to receive regulatory approval on a timely basis or at all; or
- difficulties with manufacturing in commercial quantities at an acceptable cost.

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

If our suppliers and contract manufacturers fail to complete pre-commercialization manufacturing development activities for APF530 on a timely basis or fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, APF530, and our costs will increase.

We do not manufacture APF530 and do not currently plan to develop any capacity to do so. Instead, we have relied on third parties to manufacture and perform important pre-commercialization manufacturing development activities for APF530. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture APF530 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 APF530. If our third-party suppliers and manufacturers are not in compliance with current Good Manufacturing Practice (cGMP) requirements, the approval of our marketing application may be delayed, existing product batches may be compromised, and we may experience delays in the availability of APF530 for commercial distribution.

For example, our most recent Complete Response Letter from the FDA regarding our NDA resubmission for APF530 stated that the NDA could not be approved in its present form due to, among other issues, deficiencies observed during an inspection of the facilities used by our third-party suppliers and manufacturers to produce APF530. If the FDA is not satisfied with our response and any corrective actions taken by these third parties, we may be required to complete additional manufacturing development activities or provide other information to the FDA, which could cause substantial delays in obtaining regulatory approval for APF530, increase our costs and have a material adverse effect on our business and financial condition.

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

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

Further, we, along with our contract manufacturers and our collaborators, are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers, or our collaborators, may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA pre-approval inspection for conformity with cGMPs before we can obtain approval to manufacture 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 patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a Warning Letter or an enforcement action such as product seizure, recall, or injunction, prevent commercialization of our product candidates and impair our reputation and results of operations.

Any performance failure on the part of our contract manufacturers or by us could delay clinical development or regulatory approval of product candidates or commercialization of our future products, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins and limit our ability to commercialize products on a timely and competitive basis. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited, and the FDA must approve any replacement manufacturer before we can begin manufacturing APF530 or any of our other product candidates. Such approval would require new testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

APF530 or any of our other product candidates may be in competition with other products for access to the facilities of third parties. Consequently, APF530 or any of our other product candidates may be subject to manufacturing delays if collaborators or outside contractors give other companies' products greater priority than our products. For this and other reasons, our collaborators or third-party service providers may not be able to manufacture APF530 or any of our other product candidates in a cost-effective or timely manner. If not manufactured in a timely manner, the clinical development of any of our product candidates or their submission for regulatory approval could be delayed, and our ability to deliver products to market on a timely basis could be impaired or precluded.

To date, APF530 has been manufactured 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 manufacture our products in larger quantities. Significant scale-up of manufacturing may require additional process development and validation studies, which the FDA must review and approve. The commercial success of our products, including APF530 in the near-term, will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture. The ability to do so cannot be presumed. Significant additional development work is required prior to any commercial launch of a product. In the case of APF530, the high viscosity of the product creates particularly challenging factors relative to attainable production rates and cost of manufacture. If APF530 receives regulatory approval, we plan to scale-up manufacturing for APF530 in order to realize important economies of scale. These scale-up activities would take time to implement, require additional capital investment, process development and validation studies, and FDA approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

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

We do not currently have a sales organization for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have started to establish internal sales and marketing capabilities for APF530, but may enter into agreements with third parties to sell and market other products we may develop. Although we have hired sales and marketing personnel with prior commercial experience, our company has no direct experience in developing, training or managing a marketing and sales force. The establishment and development of a sales force to market APF530 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 our sales and marketing capability or any other non-technical capabilities necessary to commercialize APF530, we will need to contract with third parties to market and sell such products we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we fail to comply with continuing federal, state and foreign regulations, we could lose our approvals to market drugs, and our business would be seriously harmed.

Following initial regulatory approval of any drugs we may develop, including APF530, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

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

Additionally, such regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use. Sales and marketing programs are under scrutiny for compliance with various mandated requirements, such as illegal promotions to healthcare professionals. We are establishing a sales force to market APF530, which may include contracting with third parties to market and sell such products we may develop, and may be unable to ensure that our own employees as well as any third-party employees adhere to legal and regulatory requirements for product advertising and promotion. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business. If APF530 is approved, we will also be required to comply with the requirements to submit to governmental authorities information on payments to physicians and certain other third parties; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

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

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

We face intense competition from other companies.

APF530 is expected to face significant competition for the prevention of delayed CINV, principally from Eisai's Aloxi (palonosetron). In addition to Aloxi, APF530 will compete with entrenched generic forms of granisetron (formerly marketed by Roche as Kytril) and ondansetron (formerly marketed by GlaxoSmithKline as Zofran). Generic versions of Aloxi may become available after its scheduled patent expiration date, which was recently extended to 2024. There are ongoing challenges to the Aloxi patents which may shorten the effective patent term. We are also aware of several companies that have developed or are developing both generic and new formulations of granisetron, including transdermal formulations such as ProStrakan's Sancuso® (granisetron transdermal patch).

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

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

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

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

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may result in lower prices for our product candidates. While we cannot predict whether any legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

Our business strategy includes the entry into additional 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 includes the entry into additional collaborative agreements for the development and commercialization of our delivery technologies. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may consume money more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

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

In both domestic and foreign markets, sales of our potential products, including APF530, will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. Reimbursement policies utilized by our collaborators or ourselves may be challenged by regulatory entities, with resultant fines, negative publicity and the need to implement changes that reduce the utilization of our products. If any products we develop do not receive adequate reimbursement, our revenue will be severely limited.

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

Some of the critical materials and components used in producing APF530 are sourced from a single supplier. An interruption in supply of a key material could significantly delay our research and development process or increase our expenses.

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

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

Our success will depend in part on our ability to obtain patents and maintain trade secret protection, as well as successfully defending these patents against challenges, while operating without infringing the proprietary rights of others. We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. In addition to obtaining patents in a number of foreign countries, we have also filed U.S. and foreign patent applications on our polymer technology under the Patent Cooperation Treaty and with the European Patent Office, Australia, Canada, China, Hong Kong, Japan, South Korea, Singapore and Taiwan. At December 31, 2012, we had a total of 22 issued U.S. patents and an additional 54 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2016 and April 2026. In addition, APF530 is covered by multiple patents that will expire in 2024. Our existing patents may not cover future products, additional patents may not be issued, and current patents, or patents issued in the future, may not provide meaningful protection or prove to be of commercial benefit.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications, or those that are licensed to us, may not issue into patents, and any issued patents may not provide sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive technologies or may be held invalid if challenged or circumvented. Patent applications in the United States are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. laws.

We are party to collaborative agreements. These agreements subject us to obligations which must be fulfilled and require us to manage complex relationships with third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated or not extended on terms as beneficial as we anticipate, 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 are exposed to risks and increased expenses as a result of laws requiring filers to evaluate internal controls over financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) requires management to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year and to include a management report assessing the effectiveness of our internal control over financing reporting in our annual report on Form 10-K for each fiscal year. Starting with our annual report for the year ended December 31, 2012, our independent auditors are required to report on the effectiveness of our internal control over financial reporting. We and our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. We have implemented an ongoing program to perform the system and process evaluation we believe to be necessary to comply with these requirements. However, we cannot assure you that we will be successful in our efforts. We expect to incur increased expense and to devote additional management resources to Section 404 compliance. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future, which would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the price of our stock.

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

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

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

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

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

Our laboratory and clinical testing sometimes involve use of hazardous, radioactive or otherwise toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result and such liability could exceed our financial resources. If we fail to comply with these regulations and standards or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. Compliance with environmental and other laws may be expensive and current or future regulations may impair our development or commercialization efforts.

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

Our facility in Redwood City, California, is located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts and supplies of APF530, if approved. In the event of an earthquake, if our facilities or the equipment in our facilities are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

Risks Related To Our Common Stock

Our stock is considered a penny stock and is subject to additional restrictions on trading. Although we are seeking to relist on Nasdaq, we may be unable or unwilling to take actions required by Nasdaq to successfully relist.

In April 2011, our common stock was delisted from the Nasdaq Capital Market for non-compliance with Nasdaq's $1.00 per share minimum bid price continued listing requirement and is now quoted on the OTC Bulletin Board, thereby causing trading in our common stock to be limited by "penny stock" restrictions and our ability to raise additional capital to potentially be compromised.

With the delisting of our common stock and our current trading price, it comes within the definition of "penny stock" as defined in the Securities Exchange Act of 1934 and is covered by Rule 15g-9 of the Securities Exchange Act of 1934. That rule imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9 potentially affects the ability or willingness of broker-dealers to sell our securities and accordingly would also affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

Although we have filed a listing application to have our stock re-listed on the Nasdaq Capital Market, there can be no assurance that we will be successful in regaining our Nasdaq listing. For example, we currently do not satisfy the minimum bid price requirement and expect that we would need to effect a reverse split of our common stock to qualify. Further, our current board of directors does not satisfy Nasdaq's listing standards and we will need to make changes to our board composition to satisfy governance-related listing standards. However, we may be unable or unwilling to make the required changes in board composition, in which case we would not relist our common stock on Nasdaq and would expect to remain trading on the OTC Bulletin Board.

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

The stock markets, in general, and the markets for drug delivery and pharmaceutical stocks, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility.

Further, our stock price may be subject to additional volatility if we effect a reverse stock split in support of a listing application on Nasdaq. Following reverse splits, the prices of the stocks often trade below the immediate post-split value, resulting in a net loss in value for stockholders. We currently intend to pursue a reverse split of our common stock and we have stockholder authority to implement a split at a ratio of up to 1-for-20. Stockholders who purchase shares prior to our reverse split may lose value after the split is implemented.

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

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

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

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

Further concentration in stockholder ownership could influence strategic actions.

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a majority of our outstanding securities. Tang Capital Partners, LP and its affiliates' beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, was approximately 23% as of May 2013, excluding potential further concentration underlying outstanding warrants and our convertible note facility. Kevin C. Tang, the Managing Director of Tang Capital Management, LLC, the general partner of Tang Capital Partners, LP, is also a member of our board.

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

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

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

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

We believe our net operating losses and tax attributes may be subject to limitation under Section 382 of the Internal Revenue Code of 1986. As a result, our deferred tax assets, and related valuation allowance, have been reduced for the estimated impact of the net operating losses and credits that we currently estimate may expire unused. Utilization of our remaining net operating loss and research and development credit carry-forwards may still be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions for ownership changes after December 31, 2012, 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 31.1 –	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934 as amended.
Exhibit 31.2 –	Certification of Chief Operating Officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934 as amended.
Exhibit 32.1 –	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.2 –	Certification of Chief Operating Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Extension Definition
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 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.

A.P. PHARMA, INC.

/s/ Brian G. Drazba

Date: November 12, 2013

Brian G. Drazba
Chief Financial Officer

Exhibit 31.1

SECTION 302 CERTIFICATIONS

I, Barry D. Quart, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of A.P. Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer 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, 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 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 12, 2013

/s/ Barry D. Quart

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

Exhibit 31.2

SECTION 302 CERTIFICATIONS

I, Stephen R. Davis, Chief Operating Officer (Principal Financial Officer), certify that:

1. I have reviewed this quarterly report on Form 10-Q of A.P. Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer 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, 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 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 12, 2013

/s/ Stephen R. Davis

Stephen R. Davis
Chief Operating Officer (Principal Financial 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

In connection with the Quarterly Report of A.P. Pharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barry D. Quart, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2013

/s/ Barry D. Quart

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

Exhibit 32.2

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

In connection with the Quarterly Report of A.P. Pharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen R. Davis, Chief Operating Officer (Principal Financial Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2013

/s/ Stephen R. Davis

Stephen R. Davis
Chief Operating Officer (Principal Financial Officer)