# 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, 2009

OR

□ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from

Commission File Number 001-33221

# A.P. PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

to

123 Saginaw Drive Redwood City CA (Address of principal executive offices) 94-2875566 (I.R.S. Employer Identification No.)

> 94063 (Zip Code)

> > Accelerated filer

Small reporting company

X

(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  $\Box$  No  $\Box$ 

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 
Non-accelerated filer

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

At November 9, 2009, the number of outstanding shares of the Company's common stock, par value \$.01, was 39,376,111.

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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. (unaudited		<u>cember 31, 2008</u> (Note 1)
Assets			
Current assets:			
Cash and cash equivalents	\$ 1	.,569 \$	9,967
Marketable securities		39	571
Accounts receivable		486	32
Prepaid expenses and other current assets		219	246
Total current assets	2	2,313	10,816
Property and equipment, net		596	881
Other long-term assets		128	103
Total assets	\$ 3	\$,037	11,800
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$	231 \$	344
Accrued expenses	1	,332	2,222
Deferred revenue		220	
Accrued disposition costs		621	621
Total current liabilities	2	2,404	3,187
Deferred revenue		151	1,000
Other long-term liabilities		—	15
Total liabilities	2	2,555	4,202
Stockholders' equity:			
Common stock	139	,650	138,692
Accumulated deficit	(139	),168)	(131,051)
Accumulated other comprehensive loss			(43)
Total stockholders' equity		482	7,598
Total liabilities and stockholders' equity	\$ 3	\$,037	11,800

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,		ths Ended iber 30,
	2009	2008	2009	2008
Contract revenue	\$ 1,117	\$ 64	\$ 1,139	\$ 348
Operating expenses:				
Research and development	1,418	5,069	6,376	16,747
General and administrative	912	1,272	2,905	3,215
Total operating expenses	2,330	6,341	9,281	19,962
Operating loss	(1,213)	(6,277)	(8,142)	(19,614)
Interest income (expense), net	(1)	111	26	547
Other income, net		1	1	8
Loss from continuing operations	(1,214)	(6,165)	(8,115)	(19,059)
Loss from discontinued operations	—	(40)	—	(120)
Net loss	\$ (1,214)	\$ (6,205)	\$ (8,115)	\$(19,179)
Basic and diluted net loss per share:				
Loss from continuing operations	\$ (0.04)	\$ (0.20)	\$ (0.26)	\$ (0.62)
Net loss	\$ (0.04)	\$ (0.20)	\$ (0.26)	\$ (0.62)
Shares used to compute basic and diluted net loss per share	31,234	30,819	31,041	30,806

See accompanying notes to condensed financial statements.

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

	Nine Months E	nded September 30,
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (8,115)	\$ (19,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from discontinued operations		120
Depreciation and amortization	270	310
Stock-based compensation expense	894	906
Stock issued in lieu of bonus	34	—
Loss on retirement of fixed asset	17	—
Changes in operating assets and liabilities:		
Accounts receivable	(454)	100
Prepaid expenses and other current assets	28	260
Other long-term assets	(25)	(28)
Accounts payable	(113)	(722)
Accrued expenses	(906)	(22)
Deferred revenue	(629)	_
Net cash used in continuing operating activities	(8,999)	(18,255)
Net cash provided by discontinued operations		19
Net cash used in operating activities	(8,999)	(18,236)
Cash flows from investing activities:		
Purchases of property and equipment	(2)	(291)
Maturities of marketable securities	574	668
Net cash provided by investing activities	572	377
Cash flows from financing activities:		
Proceeds from the exercise of stock options	6	2
Proceeds from the issuance of shares under the Employee Stock Purchase Plan	23	27
Net cash provided by financing activities	29	29
Net decrease in cash and cash equivalents	(8,398)	(17,830)
Cash and cash equivalents, beginning of the period	9,967	33,510
Cash and cash equivalents, end of the period	\$ 1,569	\$ 15,680

See accompanying notes to condensed financial statements.

# Notes to Condensed Financial Statements September 30, 2009 and 2008 (unaudited)

# (1) BUSINESS AND BASIS OF PRESENTATION

A.P. Pharma, Inc. (the "Company", "we", "our", or "us") is a specialty pharmaceutical company focused on developing pharmaceutical products using our proprietary Biochronomer<sup>™</sup> polymer-based drug delivery technology. Our primary focus is on our lead product candidate, APF530, which during 2008 completed a pivotal Phase III clinical trial for the prevention of chemotherapy-induced nausea and vomiting ("CINV"). In May 2009 we submitted our new drug application ("NDA") for approval of APF530 to the U.S. Food and Drug Administration ("FDA"). The NDA was accepted for review by the FDA in July 2009 and based on the Prescription Drug User Fee Act ("PDUFA"), the FDA has issued an action date of March 18, 2010.

Our core Biochronomer technology, on which APF530 and our other products are based, consists of bioerodible polymers designed to release drugs over a defined period of time. We have completed over 100 *in vivo* and *in vitro* studies demonstrating that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including prevention of nausea and vomiting, pain management, control of inflammation and treatment of ophthalmic diseases. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to several months.

In addition to our lead drug candidate, we have a pipeline of other product candidates that use our Biochronomer technology. One product candidate, an undisclosed opiate for a long-acting pain management product, has been licensed on a world-wide basis to Merial Limited ("Merial") for use with cats and dogs. Further development of our pipeline products has been temporarily deferred in order to focus our resources on the APF530 NDA and negotiations of a commercialization partnership for this product.

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 November 16, 2009, which is the date that these financial statements were issued. Operating results for the three and nine months ended September 30, 2009 are not indicative of the results that may be expected for the year ending December 31, 2009 or for any other period. The condensed balance sheet as of December 31, 2008 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 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, 2008 filed with the Securities and Exchange Commission (the "SEC") on March 31, 2009 (our "2008 10-K").

#### **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 significantly from those estimates. On an on-going basis, we evaluate our critical accounting policies and estimates. 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 2008 10-K.

# Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

#### **Accounting Pronouncements**

With the exception of those discussed below, and those adopted and discussed in Note 2, there have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended September 30, 2009, as compared to the recent accounting pronouncements described in our 2008 10-K, that are of significance, or potential significance to the Company.

In June 2009, the Financial Accounting Standards Board ("FASB") approved the "FASB Accounting Standards Codification" ("ASC"), as the single source of authoritative nongovernmental Generally Accepted Accounting Principles, or GAAP, in the United States. The ASC was effective for interim and annual periods ending after September 15, 2009, and we adopted it July 1, 2009. The adoption of the ASC did not have a material impact on our financial position or results of operations.

In October 2009, the FASB issued ASU No. 2009-13, "*Multiple-Deliverable Revenue Arrangements*" or ASU 2009-13. ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification, or ASC 605-25 (previously included within EITF 00-21, "*Revenue Arrangements with Multiple Deliverables*" or EITF 00-21). The consensus to EITF Issue No. 08-01, "*Revenue Arrangements with Multiple Deliverables*" or EITF 00-21). The consensus to EITF Issue No. 08-01, "*Revenue Arrangements with Multiple Deliverables*" or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard on our financial position and results of operations.

# (2) CASH EQUIVALENTS AND MARKETABLE SECURITIES

At September 30, 2009 and December 31, 2008, the amortized cost and estimated fair value of investments in debt securities and cash equivalents are set forth in the tables below:

September 30, 2009 <u>(in thousands)</u> Available-for-sale:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Asset-backed securities (included in marketable securities)	\$ 39	\$ —	\$ —	\$ 39
Money market fund (included in cash and cash equivalents)	1,505			1,505
Total available-for-sale	\$ 1,544	\$ —	\$ —	\$ 1,544

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

December 31, 2008 <u>(in thousands)</u> Available-for-sale:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Asset-backed securities	\$ 614	\$ —	\$ (43)	\$ 571
Money market fund (included in cash and cash equivalents)	9,882	—		9,882
Total available-for-sale	\$ 10,496	\$	\$ (43)	\$ 10,453

At September 30, 2009 and December 31, 2008 all available-for sale investments are expected to mature within one year.

We consider our investments in marketable securities as available-for-sale and, accordingly, we have recorded these investments at fair value. Our cash, cash equivalents and marketable securities as of September 30, 2009 and December 31, 2008 consist of approximately 97% and 95%, respectively, of a money market fund containing U.S. Government-backed or collateralized overnight securities and the remainder in asset-backed securities with the underlying assets consisting of pools of residential mortgages. There is no decline in the fair value of the asset–backed securities as of September 30, 2009. There were no realized gains or losses for the three or nine months ended September 30, 2009 or 2008.

#### **Fair Value Measurements**

Asset-backed securities

Total

The tables that follow summarize the basis used to measure certain assets at fair value on a recurring basis in our balance sheet at September 30, 2009 and December 31, 2008 (in thousands).

The three tier 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. On a recurring basis, we measure our available-for-sale securities at fair value.

		Basis of Fair Value	Measurements	
	Balance at September 30, 2009	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 1,505	\$ 1,505	\$	\$
Asset-backed securities	39	—	39	
Total	\$ 1,544	\$ 1,505	\$ 39	\$
		Basis of Fair Value	Measurements	
	Balance at December 31, 2008	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 9,882	\$ 9,882	\$	\$ _

8

\$

571

\$

9.882

10,453

571

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

The following methods and assumptions were used to determine the fair value of each class of assets recorded at fair value in the balance sheets:

*Cash equivalents*: Cash equivalents consist of highly rated money market funds with maturities of one year or less, and are purchased daily at par value with specified yield rates. Due to the high ratings and short-term nature of these funds, we consider all cash equivalents as Level 1 inputs.

Short-term available-for-sale investments at fair value: Fair values are based on quoted market prices, where available. These fair values are obtained from third party pricing services, which generally use Level 1 or Level 2 inputs for the determination of fair value. Third party pricing services normally derive the security prices through recently reported trades for identical or similar securities making adjustments through the reporting date based upon available market observable information. For securities not actively traded, the third party pricing services may use quoted market prices of comparable instruments or discounted cash flow analyses, incorporating inputs that are currently observable in the markets for similar securities. Inputs that are often used in valuation methodologies include, but are not limited to, benchmark yields, reported trades, broker/dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. We utilize third party pricing services to obtain fair value and we generally obtain one price for each individual security. We review the fair value hierarchy classification. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse impact on our results of operations or stockholders' equity.

The carrying amounts reflected in our balance sheets for cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the short-term nature of these items.

Effective January 1, 2009, we implemented ASC 820-10 (previously known as Statement of Financial Standards No. 157, "*Fair Value Measurements*," or SFAS 157), for our non-financial assets and liabilities that are re-measured at fair value on a non-recurring basis. The adoption of SFAS 157 for our non-financial assets and liabilities that are re-measured at fair value on a non-recurring basis did not have an impact on our financial position or results of operations; however, could have an impact in future periods.

Effective the second quarter of 2009, we implemented ASC 820-10-65-4, (previously known as FSP FAS 157-4, "*Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*," or FSP FAS 157-4). FSP FAS 157-4 provides additional guidelines for making fair value measurements more consistent with the principles presented in SFAS 157 and provides guidance in determining whether a market is active or inactive, and whether a transaction is distressed. This FSP is applicable to all assets and liabilities (i.e. financial and non-financial) and requires enhanced disclosures, including interim and annual disclosure of the input and valuation techniques (or changes in techniques) used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of this FSP did not have a material impact our financial position or results of operations.

Effective the second quarter of 2009, we implemented ASC 825-10-65-1, previously known as FSP FAS 107-1 and APB 28-1, "*Interim Disclosures about Fair Value of Financial Instruments*," or FSP FAS 107-1. FSP FAS 107-1 amended Statement of Financial Accounting Standards No. 107, "*Disclosures about Fair Value of Financial Instruments*," and APB Opinion No. 28, "*Interim Financial Reporting*" to require disclosures about the fair value of financial instruments. The adoption of this FSP did not have a material impact our financial position or results of operations.

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, *"Measuring Liabilities at Fair Value,*" or ASU 2009-05. ASU 2009-05 amends ASC Topic 820, *"Fair Value Measurements*". Specifically, ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of Topic 820 of the ASC (e.g. an income approach or market approach). ASU 2009-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of this standard did not have an impact on our financial position or results of operations; however, this standard may impact us in future periods.

#### Impairments

We adopted the provisions of ASC 320-10-65-1 (previously known as FSP FAS 115-2/124-2) on April 1, 2009. FSP No. FAS 115-2 and FAS 124-2, "*Recognition and Presentation of Other-than-Temporary Impairments*," amended the other-than-temporary impairment model for debt securities. The impairment model for equity securities was not affected.

Under this FSP, an other-than-temporary impairment must be recognized through earnings if an investor has the intent to sell the debt security or if it is more likely than not that the investor will be required to sell the debt security before recovery of its amortized cost basis. However, even if an investor does not expect to sell a debt security, it must evaluate expected cash flows to be received and determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized in income. The amount of loss relating to other factors is recorded in accumulated other comprehensive income. The FSP also requires additional disclosures regarding the calculation of credit losses and the factors considered in reaching a conclusion that an investment is not other-than-temporarily impaired. The adoption of the FSP did not have a material impact on our financial position or results of operations.

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with FSP FAS 115-1, "*The Meaning of Otherthan-Temporary Impairment and its Application to Certain Investments*," or FSP FAS 115-1, and FSP FAS 115-2. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in fair value below our cost basis is other-than-temporary, we consider the fair market value of the security, the duration of the security's decline, and the financial condition of the issuer. We then consider our intent and ability to hold the equity security for a period of time sufficient to recover our carrying value. Where we have determined that we lack the intent and ability to hold an equity security to its expected recovery, the security's decline in fair value is deemed to be other-than-temporary and is recorded within earnings as an impairment loss.

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

No impairment losses were recognized through earnings related to available-for-sale securities during the three or nine months ended September 30, 2009 or 2008.

For the three and nine months ended September 30, 2009 and 2008, we recognized in other comprehensive income (loss), \$5,000, \$43,000, (\$9,000) and (\$25,000), respectively, in gains (charges) associated with the temporary impairment of available-for-sale securities primarily related to mortgage and assetbacked securities.

# (3) NET LOSS PER SHARE INFORMATION

Basic and diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share excludes the effect of potentially dilutive securities because they are anti-dilutive. Such potentially dilutive securities at September 30, 2009 include outstanding stock options for 3,231,840 common shares and unearned restricted stock awards for 140,000 common shares.

## (4) STOCK-BASED COMPENSATION

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

	T	Three Months Ended September 30,			Nine Months Ended September 30,	
	20	09	2008	2009	2008	
Operating expenses:						
Research and development	\$	71	\$ 98	8 \$ 199	\$ 383	
General and administrative		203	230	) 695	523	
Total stock-based compensation expense	\$	274	\$ 328	8 \$ 894	\$ 906	
Impact on basic and diluted net loss per common share	\$	.01	\$.01	\$.03	\$.03	

The following table summarizes option activity for the nine months ended September 30, 2009:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2009	2,701,073	\$ 2.38	8.41
Granted	991,500	\$ 0.67	
Exercised	(8,594)	\$ 0.71	
Expired and forfeited	(452,139)	\$ 2.29	
Outstanding at September 30, 2009	3,231,840	\$ 1.87	8.28

*Employee Stock Purchase Plan.* We adopted an Employee Stock Purchase Plan (the "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. 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 in the nine month periods ended September 30, 2009 and 2008 were 57,336 and 26,103 shares at an average price of \$0.42 and \$1.03, respectively. Shares available for future purchase under the Purchase Plan are 200,007 at September 30, 2009.

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

## (5) COMPREHENSIVE LOSS

Comprehensive loss for the three and nine months ended September 30, 2009 and 2008 consists of the following (in thousands):

		Three Months Ended September 30,				
	2009	2008	2009	2008		
Net loss	\$(1,214)	\$(6,205)	\$(8,115)	\$(19,179)		
Unrealized gains (losses) on available-for-sale marketable securities	5	(9)	43	(25)		
Comprehensive loss	\$(1,209)	\$(6,214)	\$(8,072)	\$(19,204)		

#### (6) INCOME TAXES

There is no provision for income taxes for the three or nine months ended September 30, 2009 or 2008 because we incurred net operating losses.

#### (7) STOCKHOLDERS' EQUITY

At our annual meeting in May 2009, our shareholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance from 50,000,000 to 100,000,000 shares. They also approved an amendment to increase by 200,000 the number of shares of common stock reserved for issuance under our Employee Stock Purchase Plan.

On December 18, 2006, we entered into a Preferred Shares Rights Agreement. As part of this agreement, preferred stock purchase rights ("the rights") were distributed to stockholders of record as of January 2, 2007 (and to each person who acquires our common stock after that date unless determined otherwise by the board of directors) at the rate of one right for each share of common stock held. The rights become exercisable only upon the acquisition, or the acquisition of the right to acquire, by a person or group of affiliated or associated persons, of 20% (amended to 34% or more with regard to Tang Capital Partners, LP and its affiliates and 30% or more with regard to Baker Brothers Investments in conjunction with our October 2009 financing – see Note 10) or more of the outstanding shares of our common stock. Once exercisable, each right entitles the holder to purchase, at a price of \$44.00, one one-thousandth of a share of Series A Participating Preferred Stock. For a limited period of time following the announcement of any such acquisition or offer, the rights are redeemable by us at a price of \$0.01 per right. If the rights are not redeemed or exchanged, each right will then entitle the holder to receive, upon exercise of such right, a number of shares of our common stock having a then current value equal to two times the purchase price of such right. Similarly, if the rights are not redeemed or exchanged and following the acquisition of 20% (amended to 34% or more with regard to Tang Capital Partners, LP and its affiliates an 30% or more with regard to Baker Brothers Investments) or more of the outstanding shares of our common stock by a person or group of affiliated or associated persons, (i) we consolidate with or merge into another entity, (ii) another entity consolidates with or merges into us or (iii) we sell or otherwise transfer 50% or more of its consolidated assets or earning power, each right will then entitle the holder to receive, upon exercise of such right, a number of shares of common stock of the acquiring company having a then current value equal to two times the purchase price. For a limited period of time after the exercisability of the rights, each right, at the discretion of the board of directors, may be exercised for such number of shares of common stock determined in accordance with the rights agreement. We have initially reserved 200,000 shares of preferred stock pursuant to the exercise of these rights. These rights expire on December 31, 2016.

#### Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

#### (8) DISCONTINUED OPERATIONS

We completed the sale of certain assets of our Analytical Standards division as well as certain technology rights for our topical pharmaceutical and cosmeceutical product lines and other assets ("cosmeceutical and toiletry business") in February 2003 and July 2000, respectively.

The Analytical Standards division and cosmeceutical and toiletry business are reported as discontinued operations for all periods presented in the accompanying Condensed Statements of Operations.

Loss from discontinued operations represents primarily the 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,		nths Ended mber 30,
	2009	2008	2009	2008
Analytical Standards Division				
Royalties earned in excess of minimum amount recorded	\$ —	\$ —	\$ —	\$ —
Cosmeceutical and Toiletry Business				
Change in estimates for gross profit guarantees		(40)		(120)
Total loss from discontinued operations	\$ —	\$ (40)	\$ —	\$ (120)

Basic and diluted loss per common share from discontinued operations was nil and less than \$0.01 per share for the three and nine months ended September 30, 2009 and 2008, respectively.

The cash provided by discontinued operations of \$19,000 in 2008 relates primarily to royalties received from GFS Chemicals, Inc. ("GFS"), a privately held company based in Columbus, Ohio, from sales of Analytical Standards products.

On February 13, 2003, we completed the sale of our Analytical Standards division to GFS. In this transaction, we received \$2.1 million on closing and were entitled to receive royalties on sales of Analytical Standards products for a period of five years following the sale at rates ranging from 5% to 15%. As of March 31, 2008, all royalties due from GFS have been received.

In conjunction with the terms of an agreement with RP Scherer, a subsidiary of Cardinal Health, pursuant to which we sold certain technology rights associated with our cosmeceutical and toiletry business, we guaranteed a minimum gross profit percentage on RP Scherer's combined sales of products to Ortho Neutrogena and Dermik ("Gross Profit Guaranty"). The guaranty period initially commenced on July 1, 2000 and was to end on the earlier of July 1, 2010 or the end of two consecutive guaranty periods where the combined gross profit on sales to Ortho and Dermik equals or exceeds the guaranteed gross profit (the "two period test"). The Gross Profit Guaranty expense totaled \$944,000 for the first seven guaranty years and in those years profits did not meet the two period test. 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. This new agreement potentially extends the Gross Profit Guaranty period an additional three years to July 1, 2013, unless it is terminated earlier with the two period test. Amcol has indicated that its costs differ from those it charged historically to the RP Scherer successor company to produce the products. We have not paid any Gross Profit Guaranty amount asserted by Amcol, and have requested documentation of their actual costs. As there is no minimum amount of Gross Profit Guaranty due, no accrual for the guaranty is estimable for future years. A liability of \$621,000 related to the amount due under Gross Profit Guarantees is included in accrued disposition costs as of September 30, 2009 and December 31, 2008.

# Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

# (9) SIGNIFICANT AGREEMENTS

#### Merial

In September 2009, we entered into a world-wide license and development agreement with Merial, a world leading animal health company, for a long-acting pain management product for cats and dogs. The license and development agreement follows a successful proof-of concept agreement. Under the terms of the new agreement, we received an upfront license fee and will receive development funding and potential future milestones that are in addition to royalties following commercialization.

Remaining deliverables associated with the license relate primarily to improvements during the development phase. Given the unique nature of the improvements, we are unable to obtain objective, reliable evidence of its fair value and as a result, we considered the license and improvements as one unit of accounting and will recognize as revenue the upfront license fee based on proportional performance over the development phase.

Development funding will be recognized as revenue as services are delivered and the milestone payment when the performance milestone is achieved.

We recognized \$106,000 related to development services to Merial in the third quarter of 2009.

#### **RHEI Pharmaceuticals**

On September 29, 2009 we terminated the License Agreement ("Agreement") dated October 1, 2006 between us and RHEI. RHEI owed the Company a milestone payment following the announcement of acceptance for filing of a NDA for our APF530 product candidate by the FDA on July 20, 2009. RHEI did not make such milestone payment in the time required under the terms of the Agreement and was provided notice by us of RHEI's cure period. RHEI remained in default of this payment and, as a result, the Company elected to terminate the Agreement for cause. No material termination penalties apply to the Company for the termination of the Agreement.

Revenue of \$1million, previously deferred, in conjunction with the RHEI Agreement was recognized in September 2009 and is included in contract revenue.

#### (10) SUBSEQUENT EVENTS

In October 2009, in a private placement, we sold approximately 8 million shares of our common stock at a price of \$0.88 per share and warrants to purchase approximately 4 million shares of our common stock, exercisable through January 7, 2015, at \$0.88 per share. The purchasers paid \$0.125 per underlying share for the warrants. Additionally, the purchasers have the right to purchase up to 5.2 million shares of common stock (second tranche) at \$0.97 per share prior to May 14, 2010 and paid \$0.125 per share for the right to purchase such shares in the second tranche. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants or in connection with the second tranche may be adjusted in certain circumstances

Aggregate proceeds from the October 2009 financing were approximately \$8.1 million.

In connection with the financing, we will prepare and file a registration statement with the SEC within 30 days of the closing of the October 2009 financing for purposes of registering the resale of the shares purchased, as well as the shares of common stock issuable upon exercise of the warrants. We will use our best efforts to cause the registration statement to be declared effective by the SEC within 90 days of the closing of the October 2009 financing (or 120 days in the event the registration statement is reviewed by the SEC). If we fail to meet either of these deadlines, fail to meet filing or effectiveness deadlines with respect to any additional registration statements required by our agreement or fail to keep any registration statements continuously effective (with limited exceptions), we may be obligated to pay to the holders of the shares and warrants liquidated damages in the amount of 1% per month of the purchase price for the shares and warrants, up to a maximum cap of 8%.

## Notes to Condensed Financial Statements—(Continued) September 30, 2009 and 2008 (unaudited)

Effective October 28, 2009, we transferred the listing of our common stock from The NASDAQ Global Market to the NASDAQ Capital Market. Our securities continue to trade under the symbol "APPA". As of the date of this filing, we believe the October 2009 financing enables us to meet the initial equity listing requirements for The NASDAQ Capital Market as illustrated in the table below.

The table below presents a summary of our balance sheet as of September 30, 2009 on an actual basis and on a pro forma as adjusted basis to include the net proceeds of our October 2009 financing.

	Septembe	r 30, 2009
	Actual (In tho	Pro Forma as <u>Adjusted</u> usands)
Balance Sheet Data:		
Cash and cash equivalents and marketable securities	\$ 1,608	\$ 9,651
Working capital(1)	(91)	7,952
Total assets	3,037	11,080
Long-term liabilities	151	151
Accumulated deficit	(139,168)	(139,168)
Total shareholders' equity	482	8,525

(1) Working capital is calculated by subtracting total current liabilities from total current assets.

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

#### Forward-looking Statements

This Form 10-Q contains "forward-looking statements" as defined by the Private Securities Reform Act of 1995. These forward-looking statements involve risks and uncertainties including uncertainties associated with capital resources and liquidity, timely development and regulatory approval of product candidates, establishment of new corporate alliances, progress in research and development programs, launch and acceptance of new products and other risks and uncertainties identified in the 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 intend to update them except as required by law.

#### Results of Operations for the Three and Nine Months Ended September 30, 2009 and 2008

Contract revenue, which is derived from work performed under collaborative research and development arrangements, was \$1.1 million, \$0.1 million, \$1.1 million and \$0.3 million for the three months ended September 30, 2009 and 2008 and the nine months ended September 30, 2009 and 2008, respectively. Contract revenues for the three and nine months ended September 30, 2009 include \$1,000,000 of revenue recognized on termination of our agreement with RHEI (see Note 9 – Significant Agreements to our financial statements). The amount of contract revenue varies from period to period depending on the level of activity requested of us by our collaborators. In September 2009, we entered into an agreement with Merial for a long-acting pain management product for cats and dogs. As a result of this agreement, we anticipate contract revenues over the near term to increase.

Our revenue has been derived principally from contract revenue. In January 2006, we completed the sale of our rights to royalties on sales of Retin-A Micro® and Carac® for up to \$30 million. We received proceeds of \$25 million upon the closing of the transaction and received a \$2.5 million milestone payment in June 2007. We may receive up to an additional \$2.5 million based on the satisfaction of certain predetermined milestones. As a result of this transaction, there were no royalties for the nine months ended September 30, 2009 or 2008. We will not record additional royalty revenue on sales of Retin-A Micro® and Carac® in future periods.

Research and development expense for the three months ended September 30, 2009 decreased to \$1.4 million from \$5.1 million for the three months ended September 30, 2008. Research and development expense for the nine months ended September 30, 2009 decreased to \$6.4 million from \$16.7 million for the nine months ended September 30, 2008. The decreases in research and development expenses for the three and nine months ended September 30, 2009 as compared with comparable periods in 2008 are primarily due to decreased expenditures related to APF530, largely as a result of the completion of our Phase III trial and related costs for APF530. Additionally, in late 2008 we placed our other product candidates "on hold" to focus our financial and managerial resources on APF 530. As a result, we had reductions in force in November 2008 and May 2009, resulting in lower payroll and related expenses. Research and development expense is expected to increase as a result of pre-commercialization activities.

General and administrative expense decreased for the three months ended September 30, 2009 to \$0.9 million from \$1.3 million for the three months ended September 30, 2008. General and administrative expense decreased to \$2.9 million for the nine months ended September 30, 2009 as compared with \$3.2 million for the comparable period of 2008. General and administrative expense decreased primarily as a result of decreases in professional fees, outside services and other general and administrative expenses as a result of cost containment measures. Changes in the rate of general and administrative expenses for the remaining quarters of 2009 will depend primarily on the achievement of corporate goals and stock-based compensation and/or retention efforts.

Net interest income was \$0.0 million, \$0.1 million, \$0.0 million, and \$0.5 million for the three months ended September 30, 2009 and 2008 and the nine months ended September 30, 2009 and 2008, respectively. The decrease was primarily due to lower average balances of cash, cash equivalents and marketable securities, as a result of operating losses and lower interest rates. In response to the current world-wide financial situation, we have invested most of our available cash equivalents in a lower risk money market fund containing U.S. Government-backed or collateralized overnight securities.

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Loss from discontinued operations represents the gross profit guarantee from the cosmeceutical and toiletries business which was sold to RP Scherer Corporation in July 2000. We have been unable to obtain information regarding quantities or costs associated with the gross profit guarantee and as a result have not recorded any gross profit guarantee in 2009.

#### Capital Resources and Liquidity

Cash, cash equivalents and marketable securities decreased to \$1.6 million at September 30, 2009 from \$10.5 million at December 31, 2008 due primarily to our net loss for the nine months ended September 30, 2009, which includes \$1million of revenue from termination of the RHEI agreement (see Note 9 – Significant Agreements)

Net cash used in continuing operating activities for the nine months ended September 30, 2009 was \$9.0 million, compared to net cash used of \$18.3 million for the nine months ended September 30, 2008. The decrease in net cash used by continuing operating activities in 2009 was mainly due to the decreased loss for the nine months ended September 30, 2009, as well as changes in accrued expenses, deferred revenue and accounts receivable, as compared to the same period in 2008.

Net cash provided by investing activities for the nine months ended September 30, 2009 was \$0.6 million compared to net cash provided of \$0.4 million from investing activities for the nine months ended September 30, 2008. The change in 2009 from 2008 in cash flows associated with investing activities was primarily due to minimal purchases of property and equipment.

To date, we have financed our operations, including technology and product research and development, through the sale of common stock, royalties received on sales of Retin-A Micro® and Carac®, income from collaborative research and development fees, the proceeds received from the sales of our Analytical Standards division and our cosmeceutical and toiletry business, interest earned on short-term investments and the sale of our interest in the royalty income from Retin-A Micro® and Carac®.

At September 30, 2009, we had cash, cash equivalents and marketable securities of \$1.6 million and working capital of (\$0.1) million. In October 2009, we sold approximately 8 million shares of common stock, and warrants to purchase additional stock for gross proceeds of approximately \$8.1 million. We believe this financing enables us to meet the initial equity listing requirements for The NASDAQ Capital Market, as well as enable us to fund our operations through 2010, based on our expected spending levels and certain anticipated positive cash inflows.

Our capital requirements going forward will depend on numerous factors including, among others: our ability to enter into licensing agreements and collaborative research and development arrangements; time required to gain regulatory approvals for our product candidates; progress of product candidates; investment in new research and development programs; resources that we devote to self-funded products; potential acquisitions of technology, product candidates or businesses; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology.

Below is a summary of fixed payments related to certain contractual obligations (in thousands). This table excludes amounts already recorded on our condensed balance sheet as current liabilities at September 30, 2009.

	Total	Less than 1 year	2 to 3 years	4 to 5 Years	More than 5 years
Operating Leases	\$859	\$ 565	\$287	\$7	\$ —

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

As of September 30, 2009 we did not have any off-balance sheet arrangements.

#### Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments. We manage our interest rate risk by maintaining an investment portfolio primarily consisting of debt instruments of high credit quality and relatively short average maturities. Due to the financial crisis and our anticipated cash flow requirements, we have 97% of our available cash, cash equivalents and marketable securities in cash and a money market fund containing U.S. Government-backed or collateralized overnight securities.

#### 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 the Chief Executive Officer and Chief 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 Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2009, the end of period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls: During the three months ended September 30, 2009, there have been no significant 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

Not applicable.

#### Item 1A. Risk Factors

The following are new or modified risk factors that should be read in conjunction with the risk factors disclosed in our 2008 10-K:

# Our common stock may be delisted from The NASDAQ Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is now listed on The NASDAQ Capital Market. The listing standards of The NASDAQ Capital Market require that a company maintain stockholders' equity of at least \$2.5 million. While our financing in October 2009 (see Note 10) results in proceeds to us of approximately \$8.1 million, we are awaiting acknowledgement by The NASDAQ Stock Market, or NASDAQ, that we meet the \$2.5 million stockholders' equity requirement for continued listing on The NASDAQ Capital Market. Separately, as announced on September 21, 2009, we received notice from NASDAQ that we did not satisfy the \$1.00 minimum bid price requirement, and that we have been granted through March 15, 2010 to regain compliance with the minimum bid price requirement. If we are not in compliance with the minimum bid price requirement by that date, we will be entitled to a second 180-calendar day grace period, through September 13, 2010, to evidence compliance with the minimum bid price requirement so long as we satisfy all criteria for initial listing on The Nasdaq Capital Market (except for bid price) as of March 15, 2010.

Should we fail to comply with the minimum listing standards applicable to issuers listed on The NASDAQ Capital Market, our common stock may be delisted from The NASDAQ Capital Market. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Capital Market could also result in other negative implications, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

## Further concentration in shareholder ownership could influence strategic actions.

In October 2009, Tang Capital Partners, LP and its affiliates, including Tang Capital Management, LLC and its Managing Director, Kevin C. Tang, increased their ownership of our common stock to 29%, and Baker Brothers Investments and its affiliates increased their beneficial ownership of our common stock to 17%. Mr. Tang 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.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

#### Item 3. Defaults Upon Senior Securities

Not applicable.

# Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

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#### Item 5. Other Information

Not applicable.

#### Item 6. Exhibits

\*\*Exhibit 10.1 Development and License Agreement dated as of September 11, 2009, between the Company and Merial Limited.

Exhibit 10.2 Securities Purchase Agreement, dated as of October 19, 2009, by and among the Company and the purchasers listed therein, filed as Exhibit 10.1 to the Company's Form 8-K filed on October 22, 2009 and incorporated by reference herein.

Exhibit 10.3 Registration Rights Agreement, dated as of October 22, 2009, by and among the Company and the purchasers listed therein, filed as Exhibit 10.2 to the Company's Form 8-K filed on October 22, 2009 and incorporated by reference herein.

Exhibit 10.4 Form of Warrant to Purchase Shares of Common Stock, filed as Exhibit 10.3 to the Company's Form 8-K filed on October 22, 2009 and incorporated by reference herein

Exhibit 10.5 Second Amendment to Preferred Shares Rights Agreement, dated as of October 20, 2009, by and between the Company and Computershare Trust Company N.A., filed as Exhibit 10.4 to the Company's Form 8-K filed on October 22, 2009 and incorporated by reference herein.

Exhibit 31.1 Certification of Chief Executive Officer pursuant to Rules 13A-15(f) Promulgated under the Securities Exchange Act of 1934 as amended.

Exhibit 31.2 Certification of Chief Financial Officer pursuant to Rules 13A-15(f) Promulgated under the Securities Exchange Act of 1934 as amended.

Exhibit 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>\*\*</sup> Certain portions of this Exhibit, for which confidential treatment has been requested, have been omitted and filed separately with the Securities and Exchange Commission.

# 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.

Date: November 16, 2009

/s/ RONALD J. PRENTKI

Ronald J. Prentki President and Chief Executive Officer [\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# A.P. PHARMA, INC.

and

# MERIAL LIMITED

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- [\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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(iii)

**THIS DEVELOPMENT AND LICENSE AGREEMENT** ("Agreement") is made effective September 4, 2009, by and between **A.P. PHARMA, INC.**, a Delaware corporation with offices at 123 Saginaw Drive, Redwood City, CA 94063 USA (hereinafter "**APP**"), and **MERIAL LIMITED**, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at P.O. Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG England, and domesticated in Delaware, USA as Merial LLC, with a principal place of business at 3239 Satellite Boulevard, Duluth, Georgia 30096 USA ("**Merial**"). References to Merial hereinafter shall include Merial's Affiliates.

# RECITALS

- A WHEREAS, APP has identified and owns certain rights, patents, technical information, formulations, processes, know-how, data, specifications, characterization methods, characterization results, and other proprietary information relating to their Biochronomer semi-solid poly (ortho ester) drug delivery system, whether or not patented or patentable; and
- **B** WHEREAS, APP and Merial entered into a Research and Development Agreement, effective January 22, 2007, and as amended on December 10, 2007 and May 20, 2008, to undertake the proof-of-concept phase ("POC Phase") of a collaborative research program ("Program") to produce and test a slow release **[\*]** product using the Technology for dogs and cats;
- C WHEREAS, APP and Merial substantially completed the POC Phase and now are prepared to undertake the full development phase of the Program ("FD Phase");
- **D** WHEREAS, Merial wishes to conduct additional clinical trials in relation to the Technology and the Licensed Product(s), to conduct, jointly with APP, other development activities in relation to the Technology and Licensed Product, and
- E WHEREAS, the Parties have the capability, experience, and know-how to undertake their respective duties under the FD Phase; and
- **F** WHEREAS, Merial believes the Technology may have commercial application in the Field and wishes to exclusively Exploit the Licensed Product(s) in the Field in the Territory, and Merial has the capability, experience, and know-how to Exploit the Licensed Product(s) in the Field in the Territory; and
- **G** WHEREAS, APP has agreed to grant a license to Merial to conduct such clinical trials and other development activities on the Licensed Product(s) and the Technology and to Exploit the Licensed Product(s) in the Field in the Territory on the terms of this Agreement.

# NOW, THEREFORE, FOR AND IN CONSIDERATION OF THE PREMISES AND MUTUAL PROMISES, TERMS AND CONDITIONS HEREINAFTER SET FORTH, AND OTHER GOOD AND VALUABLE CONSIDERATION, THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, THE PARTIES DO HEREBY AGREE AS FOLLOWS:

#### INTERPRETATION

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#### 1.1 Definitions

As used in this Agreement, the following defined terms shall have the following respective meanings:

"Affiliate" means any corporation or business entity which controls, is controlled by or is under common control with a Party, where a corporation or business entity shall be deemed to control another corporation or business entity if it owns, directly or indirectly, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest of such corporation or business entity.

"Agency" means any government regulatory entity in the United States ("U.S.") or European Union ("E.U.") that reviews and grants product licenses for new animal health products.

"**APP Background IP**" means the Intellectual Property Rights, particularly know-how, Patent, and copyrights, owned or licensed by APP and utilized in the performance of the Program which were in existence (as can be documented to Merial's reasonable satisfaction or otherwise demonstrated by competent proof in a court of law) prior to initiation of the Program.

"**APP Know-How**" means (1) all ideas, technologies, and processes disclosed and claimed in the Patent and any related know-how, technologies, methodologies and processes made in the course of research by APP and (2) all ideas, concepts and information in any form relating to the Patent, including trade secrets based thereon and any technical and other information, standards, procedures, methods, techniques, samples and advice, which has been developed or acquired by APP before the Commencement Date or which is developed solely by APP or jointly by APP and Merial if it relates **[\*]**, during the course of the Program.

"APP Trademarks" means any registered and unregistered trademarks, trade names and logos that APP may grant Merial the right to use in relation to the Licensed Product from time to time.

"**Biochronomer Technology**" means bioerodible polymer compositions comprising poly (ortho esters) that may be prepared and formulated to provide the controlled delivery of biologically active agents. Such compositions, their methods of preparation and their uses are covered in APP Background IP and APP Know How.

"Budget" means the budget set out in Exhibit B.

"Business Day" means a day which is not a Saturday, Sunday, or bank or federal holiday in Atlanta, Georgia, USA.

- "Change of Control" means a transaction or series of transactions the result of which is:
- (a) the transfer of ownership or voting control of more than 50% of the shares or ownership of APP if that transfer is to a competitor of Merial or
- (b) either Party sells or otherwise transfers all or substantially all of its assets other

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than by operation of law or through the licensing by APP of its key programs, including APF530.

For the sake of clarity, **Change of Control** does not include the refinancing of debt which does not result in either (a) or (b) above.

"**Commencement Date**" means the date specified in the preamble to this Agreement.

"Commercially Reasonable Efforts" means the level of efforts, resources and diligence, devoted in a sustained manner, that would be typically devoted by a company in the business of developing and commercializing, as applicable, animal health products with similar or comparable commercial or market potential at a similar stage in their development or lifecycle stages, similar or comparable profit potential and other relevant commercial, scientific and technical considerations reasonably and customarily taken into account in the industry. Such efforts, resources and diligence shall in no event be less than the efforts that the party applies with respect to its other programs and products with similar commercial potential consistent with the exercise of good business judgment for the maximization of Licensed Product profits. Commercially Reasonable Efforts requires that the Party, at a minimum: (a) promptly assign responsibility for such obligations to specific, qualified employee(s) who are held accountable for progress and monitor such progress on an ongoing basis; (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

"Confidential Information" means any information specified in Clause 12.

"Exploit" means to develop, manufacture, have made, market, have marketed, hire, sell, have sold, license or otherwise dispose of or use for commercial purposes, and "Exploitation" has a corresponding meaning.

"FD Phase" means the phase set out in the third WHEREAS clause

"Field" means applications in dogs and cats.

"Financial Year" means any 12-month period ending on 31 December and will include the period between the Commencement Date and the next 31 December to occur.

"**Improvement**" means any and all patentable or unpatentable improvements or enhancements to, modifications of, or developments or inventions arising from or based on the FD Phase during the term of this Agreement, including but not limited to patentable changes in specifications, enhanced features, upgrades, design changes or revisions to the Technology.

"Intellectual Property Rights" means all patent rights (including patent applications), copyrights (including future copyrights), trademarks, trade secrets, designs, and confidential and/or proprietary chemical substances, technical information, data and assays necessary or useful to the FD Phase, trade, business or company names, or other proprietary rights, common law and equitable rights relating to Confidential Information.

"License" means the license specified in Clause 2.1.

"Licensed Product" means any product made, used, sold through or by means of the

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Technology licensed under this Agreement and incorporating [\*] as the active ingredient which is intended for administration to a non-human animal.

"Licensed Rights" means the rights to employ the Technology solely within the Field, including the specific Patents described, and any Improvement patents, divisions, continuations, continuations-in-part, and reissues of any patent that issues therefrom.

"**Merial Background IP**" means the Intellectual Property Rights, particularly know-how, patent rights, and copyrights, owned or licensed by Merial and utilized in the performance of the Program which was in existence (as can be documented to APP's satisfaction or otherwise demonstrated by competent proof in a court of law) prior to initiation of the Program.

"Merial Know-How" means all ideas, concepts and information in any form that Merial has relating to the development, production, exploitation, and marketing of animal health products, including ideas, concepts, information, and trade secrets based thereon and any technical and other information, standards, procedures, methods, techniques, samples and advice, including any such know-how in relation to manufacturing, which has been developed or acquired by Merial before the Commencement Date or which is developed solely by Merial or jointly by Merial and APP if it [\*] during the course of the Program

"Net Sales" means the net amount invoiced for sales of Licensed Product by Merial, its Affiliates, licensees and assigns to non-affiliated third party customers following deductions from gross sales for items listed in (i) through (iv) below that either (a) [\*], or (b) [\*]:

- (i) **[\*]**;
- (ii) **[\*]**;
- (iii) **[\*]**; and
- (iv) [\*].

Such amounts shall be determined from Merial's books and records maintained in accordance with US GAAP. For the avoidance of doubt, in no event shall Net Sales hereunder be construed to require Merial or it Affiliates to pay a Royalty on more than one sale/transfer of the Licensed Product(s).

"**Net Sales**" shall not include a sale or transfer to an Affiliate, licensee, or assignee, but the resale or transfer by such Affiliate, licensee or assign shall be included in the Net Sales.

"Party" or "Parties" means either Merial or APP or both, as the case may be.

"**Patent**" means the patents and patent applications listed on Exhibit A and (i) any re-examinations, revalidations, reissues, renewals, extensions, supplementing protection certificates and term restorations, any confirmation patent or registration patent or patent of addition based on any such patent, and (ii) pending applications for patents including continuations, continuations in part, divisional, provisional, statutory registrations, utility models, design patents, confirmations, revalidations, and substitute applications and inventors certificates, together with applicable foreign counterpart

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patens and patent applications, and all right to obtain patents and registrations with respect thereto.

"**Person**" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

**"Program Data**" means all data, results and all other data and information generated as a result of the implementation of the Program. Program Data includes all XP files, XP reports, development reports, analytical methods, SOPs and instructions, and validation reports related to the Program.

"Program" means the collaborative development work which is based on Merial Know-How and APP Know-How and is described in Exhibit "B".

"**Registrations**" means such government approvals as are necessary to sell, promote or distribute the Licensed Product(s) in the United States or in any other country in the Territory within which Merial in its sole discretion determines to Exploit the Licensed Product(s) in the Field in the Territory.

"Royalty" means the royalty calculated and payable in accordance with Clause 4.4, and "Royalties" has a corresponding meaning.

"Task" means the separate tasks set out in Exhibit B.

"Technology" means the Patent and the APP Know-How, including Biochronomer Technology.

**"Technology File**" means the file specified in **Clause 8.4**.

"Term" means the period specified in Clause 11.1.

"Territory" means the world.

"U.S. FDA" means the Food and Drug Administration of the United States of America.

"Valid Claim" means a claim of an unexpired issued patent which shall not have been withdrawn, cancelled, or disclaimed, nor held unenforceable, unpatentable, or invalid by a court, tribunal, arbitrator or government agency of competent jurisdiction in a final or unappealed or unappealable decision and which has not been admitted to be invalid or unenforceable through reissue or disclaimer.

#### 1.2 Construction

Unless expressed to the contrary, in this document:

- (a) words in the singular include the plural and vice versa;
- (b) any gender includes the other genders;
- (c) if a word or phrase is defined its other grammatical forms have corresponding meanings;

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- (d) "includes" means includes without limitation;
- (e) no rule of construction will apply to a clause to the disadvantage of a party merely because that party put forward the clause or would otherwise benefit from it;
- (f) a reference to:
  - (i) a person includes a natural person, partnership, joint venture, unincorporated association, corporation, a limited liability company, any government or statutory body or authority, or any other entity or organization;
  - (ii) a person includes the person's legal personal representatives, successors, assigns and persons substituted by novation;
  - (iii) time is to local time in New York, N.Y;
  - (iv) "\$" or "dollars" is a reference to United States currency;
  - (v) writing includes any mode of representing or reproducing words in tangible and permanently visible form, and includes fax and e-mail transmissions;
  - (vi) this Agreement includes all schedules and exhibits to it; and
  - (vii) a clause, schedule or exhibit is a reference to a clause, schedule or exhibit, as the case may be, of this Agreement;
- (g) if the date on or by which any act must be done under this document is not a Business Day, the act must be done on or by the next Business Day; and
- (h) where time is to be calculated by reference to a day or event, that day or the day of that event is excluded.

#### 1.3 Headings

Headings do not affect the interpretation of this document.

#### 2 GRANT OF LICENSE AND OTHER RIGHTS

#### 2.1 Grant of License

- (a) Subject to the terms and conditions of this Agreement, for the term of the Agreement, APP hereby grants to Merial an exclusive, sub-licensable license to APP's rights in the Technology and the Improvements (i) to Exploit Licensed Products in the Field in the Territory and (ii) to conduct such clinical and laboratory trials and other research and development activities in relation to the Technology and the Licensed Product(s), as set forth in the Program, in order to make the Licensed Product(s) and to enable Merial to obtain all appropriate approvals and Registration(s) of the Licensed Product(s) necessary to permit full Exploitation in the Field in the Territory ("License").
- (b) Merial shall have the right to sub-license its License in the

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Field. [\*] Merial shall include this expected royalty in any terms negotiated with the sub-licensee.

#### 3 RESEARCH PROGRAM

#### 3.1 Implementation

- (a) The Parties agree to use Commercially Reasonable Efforts to undertake the FD Phase of the Program, as drafted and as reasonably modified by agreement of the Parties. As of the signing of this Agreement based on the information known to date, APP believes that the Tasks will be completed according to the timelines set out in Exhibit B. Promptly after, but no later than after [\*] business days, APP becomes aware of any matter (including but not limited to an event, change or issue, technical or otherwise) that could have an adverse impact on the Program's timeline, APP will bring such matter to the attention of Merial's technical lead on the Steering Committee for consideration. The timelines can be adjusted only by written agreement of the Parties and only if the Parties have mutually identified and agreed to such adjustment in a writing signed by both Parties. APP does not covenant or warrant any research results or achievement of milestones and expressly disclaims any such warranties, express or implied.
- (b) The Parties agree to undertake the Program set out in Exhibit B to this Agreement for the Budget set forth in such exhibit. Promptly after APP becomes aware of any matter (including but not limited to an event, change or issue, technical or otherwise) that could have an adverse impact on the Budget ascribed to any task, APP will bring such matter to the attention of the Steering Committee for consideration. The Budget can be adjusted only by written agreement of the Parties and only if the Parties have mutually identified and agreed to such adjustment in a writing signed by both Parties. [\*] APP will submit an invoice for services performed in the prior [\*]. The invoice [\*] will both be broken out by separate Tasks, the hours spent, [\*], as the case may be in [\*] Task in the relevant time period covered by the invoice. [\*] Task in the relevant time period, and the [\*] in the relevant time period, and [\*] through the time period covered by the invoice. [\*] now written objection from Merial is received by APP within [\*] business days of Merial's receipt of the anticipated work schedule, [\*]. If Merial submits a written objection to Tasks identified in [\*] work schedule, APP can proceed with the Tasks scheduled for the [\*], provided APP has not made any changes to those Tasks from the most recent [\*] schedule of work which APP provided [\*], and the parties will use their best efforts to resolve Merial's objection(s) within [\*]. Notwithstanding the foregoing, APP shall be entitled to submit to Merial an invoice for documented costs incurred by APP in the course of performing Tasks conducted [\*] in connection with the Program and as consistent with the Budget and Exhibit C within [\*], and Merial shall reimburse APP for such costs incurred in connection with such Tasks within [\*] days after receiving such invoice.
- (c) APP shall use its Commercially Reasonable Efforts to supply Merial with all required materials, [\*], to allow Merial to conduct all applicable studies and evaluations needed to complete Agency license applications, as well as to complete product license applications for other countries. APP will provide reasonable technical assistance and advice, consultation, opinion papers, reviews, white papers, research protocols, pertinent data and data interpretation, results, and information to Merial related to the Technology reasonably available to it and

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any newly produced research within any of the Licensed Rights conducted by its employees or its agents in the conduct of clinical and laboratory trials, registrations and related work. Merial shall pay APP for the provision of such services, information, assistance and advice in accordance with **Clause 4.1** below.

- (d) Both Parties will carry out the work associated with the Program in accordance with the highest academic and professional standards. Furthermore, the Parties shall use [\*] to achieve the degree of reliability and accuracy that is appropriate and accepted within the industry for work of this kind. APP and Merial each represents that it has the requisite expertise, ability and legal right to render the work and will perform the work in an efficient and ethical manner. Both Parties will abide by all laws, rules and regulations that apply to the performance of the work.
- (e) Unless otherwise specified in this Agreement or its Appendices and subject to the terms of **Article 4**, each Party shall provide the personnel, offices, laboratory facilities, animals, animal housing, equipment, field space, utilities, techniques, reagents, and other supplies as needed by that Party for the performance of that Party's responsibilities under the Program. All equipment purchased and paid for by either Party from its own funds, and for which they are not reimbursed by the other Party, for the performance of the Program shall be the property of that Party.
- (f) The Parties recognize and acknowledge that APP contemplates using the services of contract manufacturing and analytical organizations for the FD Phase of the Program, and, further, that if the Parties agree that APP is to carry out research and development work [\*], APP would do so through a contract research organization. All third parties hired by APP to perform some or all of the research contemplated hereunder must be approved in writing by Merial prior to the third party beginning work which approval may not be unreasonably withheld, except APP may, without Merial's consent, hire an individual(s) to perform R&D contract services under the Agreement at APP's facilities under the supervision of APP personnel.
- (g) In an effort to minimize the cost-of-goods associated with the Licensed Product(s), the Parties agree to work collaboratively during the FD Phase to optimize the sourcing and procurement of the License Product components and the methods and/or site of manufacture. The selection of third parties for procurement and manufacture requires the written consent of both Parties, such consent not to be unreasonably withheld.
- (h) Merial shall be allowed to use and register its own trademarks for any of the Licensed Products, and any such trademarks shall be the exclusive property of Merial. Responsibility for trademark registrations in the Territory, as well as the expenses associated with such registration(s), will be borne exclusively by Merial.
- (i) Merial will at all times recognize the validity of any licensed trademarks owned, used by, or licensed to APP and will undertake no actions to dilute the value of such trademarks
- (j) APP will at all times recognize the validity of any licensed trademarks owned, used by, or licensed to Merial and will undertake no actions to dilute the value of

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such trademarks.

#### 3.2 Reports and Data

- (a) All data and reports regarding the Program data shall be treated as confidential information in accordance with Article 12 of this Agreement. Each Party shall record all Program Data. [\*]. Merial shall have full access to and use of all Program Data, [\*], as needed for Merial to exercise the rights granted to it under this Agreement.
- (b) APP shall record all Program Data APP generates in XP files, and the XP files shall contain full details and information on all tests carried out, procedures used, and other data and information generated, whether successful or not. [\*].
- (c) APP will **[\*]** during the FD Phase. APP and its Affiliates and licensees shall **[\*]** provided at least one of the following conditions has been met: (i) **[\*]**; (ii) **[\*]**; (iii) **[\*]**; (iv) **[\*]**, (v) **[\*]**, or (vi) **[\*]**. The Parties shall attempt to resolve all disputes, controversies or differences which may arise between the Parties hereto, out of or in relation to or in connection with this Clause through discussions held between the heads of Research and Development of the respective Parties, and if after **[\*]** the dispute remains unresolved, the dispute shall be resolved in accordance with **Article 15**.
- (d) APP agrees to make reasonable modifications [\*] in the event [\*] take other appropriate action to protect its intellectual property rights.
- (e) Where useful for development and registration of a Licensed Product in the Field, APP shall provide Merial with [\*], provided that APP is not under an obligation to a third party to keep such data confidential, in which event APP will use reasonable efforts to obtain the consent of the third party to release the information to Merial.
- (f) During the Term, APP can request, on behalf of itself and/or its Affiliates and licensees, [\*].

#### 4 CONSIDERATION

#### 4.1 Program R&D Contract Services Fees and Costs

In order to implement the Program, Merial shall, upon execution of this Agreement by both parties and receipt of an invoice from APP, [\*], as set forth in Exhibit B. Then going forward, Merial shall [\*]. For clarity, APP shall have the right to subcontract out the performance of R&D contract services by APP, subject to Section 3.1(f), and such services shall [\*]. The total budget cannot [\*]. APP can [\*], and APP must receive [\*]. APP can [\*]. The parties expressly acknowledge that they agree for [\*] the costs of individual purchases of materials or other consumables or the fees and expenses of agreed-upon third party expenditures which are outside of the budget [\*]. APP shall invoice Merial [\*], and payment shall be due within [\*] of receipt of APP's invoice by Merial. [\*].

#### 4.2 License Fee

In consideration of the license and other rights granted to Merial under this Agreement by

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APP, Merial agrees to pay to APP by electronic funds transfer to a bank account nominated by APP in writing [\*] dollars) upon receipt of a fully executed original of this Agreement and an invoice from APP.

#### 4.3 Milestones

In partial consideration for APP conducting work under the FD Phase, Merial agrees to pay APP by electronic funds transfer to a bank account nominated by APP in writing the following non-refundable amounts at the defined milestones described below:

- (a) [\*] dollars) within [\*] of the [\*] for [\*] and Merial's receipt of an invoice from APP; and
- (b) [\*] dollars) within [\*] of the [\*] and Merial's receipt of an invoice from APP.

#### 4.4 Royalties

In addition to the license fees specified in **Clause 4.2** and as partial consideration for the license and other rights granted to Merial hereunder, Merial agrees to pay to APP a Royalty on the Net Sales of Licensed Product during the Term of this Agreement **[\*]** as follows:

- (a) in the jurisdictions of the Territory **[\*]**:
  - (i) [\*] of the portion of Net Sales less than and including [\*] in a Financial Year;
  - (ii) [\*] of the portion of Net Sales greater than [\*] but equal to or less than [\*] in a Financial Year; and
  - (iii) **[\*]** of the portion of Net Sales greater than **[\*]** in a Financial Year.
- (b) In the jurisdiction(s) of the Territory **[\*]**, would be:
  - (i) **[\*]** of the portion of Net Sales less than and including **[\*]** in a Financial Year;
  - (ii) [\*] of the portion of Net Sales greater than [\*] but equal to or less than [\*] in a Financial Year; and
  - (iii) **[\*]** of the portion of Net Sales greater than **[\*]** in a Financial Year.
- (c) In the event that Merial, [\*]. Merial's royalty obligation to APP on Net Sales in any given country or market, [\*].
- (d) In addition, APP will be entitled to receive from Merial **[\*]**, payment to be made within **[\*]** from receipt by Merial.

# 4.5 Exchange Rate

All payments due under this Agreement shall be paid to APP in United States currency in New York, NY, or at such other place as APP may reasonably designate consistent with the laws and regulations controlling in any foreign country, but not in any other currency. When Licensed Products are sold by Merial and its Affiliates or sublicensees

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for monies other than United States dollars, the sales shall be converted to equivalent United States dollars on a monthly basis, and then the earned Royalties will be determined on that amount. The exchange rate will be the monthly periodic average rate that **[\*]**. Merial will include the exchange rate **[\*]** in the statements described in Section 5.2.

# ACCOUNTS AND PAYMENT OF ROYALTIES

# 5.1 Accounts and Records

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Throughout the Term, Merial must keep, in accordance with US generally accepted accounting practices ("US GAAP"), true and accurate accounts and records of all Net Sales and all other matters necessary to enable calculation of the Royalties payable to APP under **Clause 4.4**.

#### 5.2 Statements and Payments

Within [\*] after the close of each calendar quarter of the Financial Year (*i.e.* the last day of the months of March, June, September and December) in which Merial makes the first commercial sale of a Licensed Product in the Territory, and within [\*] after the end of each subsequent quarter, Merial shall:

- (a) provide to APP a statement:
  - (i) specifying all Net Sales of the Licensed Product(s) [\*] during that quarter or, if there were no sales and/or no Net Sales during that quarter , a statement to that effect; and
  - (ii) showing the calculation of the Royalties payable to APP for that quarter **[\*]**; and
- (b) pay by electronic funds transfer into the bank account nominated by APP in writing the Royalties due to APP under Clause 4.4 for that quarter.
- (c) Additionally, if applicable laws or regulations require the withholding of taxes, the taxes will be deducted by Merial from the Royalty Payments and remitted by Merial to the proper tax authority. Proof of payment shall be provided to APP within sixty (60) days after payment. Merial will cooperate in pursuing the refund of such tax, if such refund is appropriate in APP's determination.

#### 5.3 Inspection and Audit

5.3.1 No more than [\*] and on at least [\*] prior written request by APP and confirmed by Merial, Merial shall allow an independent certified public accounting firm in the United States, selected by APP and reasonably acceptable to Merial, to inspect and audit during normal business hours the accounts and records kept by Merial under Clause 5.1, as may be reasonably necessary for the purposes of verifying the accuracy of Merial's Royalty statement and Royalty calculation, pursuant to Clauses 4.4 and 5.2, respectively, for any quarter or Financial Year ending not more than [\*] months prior to the date of such requests. Such accounting firm may only disclose to APP information relating to the accuracy or inaccuracy of the Royalty statements and Royalty calculation hereunder. APP and/or APP's accountant shall not disclose the contents to any third party without the prior

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written consent of Merial except as required by government agencies or other bodies that have the statutory or regulatory authority to receive such information. Merial shall have the right to inspect any audit reports derived from any such audit.

- 5.3.2 Where, as a result of such an inspection or audit, it is discovered that the accounts and records are inaccurate or the Royalties paid differ from the Royalties payable under **Clause 4.4**, such difference, payments or adjustments shall be made to the other Party to address such inaccuracy or differences within **[\*]** after the inspection or audit report revealing the inaccuracy. APP shall pay any and all costs and expenses associated with the inspection and audit of Merial's records, unless a difference, favorable to APP, between the Royalties paid and the Royalties payable exists and exceeds **[\*]** of the payable Royalties for the period under audit, in which case Merial shall pay for the cost and expenses associated with that inspection.
- 5.3.5 Upon expiration of **[\*]** following the end of any Financial Year, the calculation of Royalties payable with respect to such Financial Year shall be binding and conclusive upon APP, and Merial shall be released from any liability or accountability with respect to Royalties for such Financial Year. **[\*]**.

# 6 MERIAL'S RESEARCH, DEVELOPMENT AND EXPLOITATION OBLIGATIONS

- (a) Subject to **Clause 6(b)**, Merial shall use Commercially Reasonable Efforts to Exploit the Licensed Product(s) in the Field in the Territory, as soon as practicable, consistent with sound and reasonable business practices and judgment, as applied to the current market and as permitted by this Agreement.
- (b) Merial shall use Commercially Reasonable Efforts to obtain and maintain [\*] all necessary government or other permits, approvals, consents, certifications, authorizations and Registrations necessary to Exploit the Licensed Product(s) under this agreement in the Field in the Territory.
- (c) Merial shall use Commercially Reasonable Efforts to obtain and comply with all Registrations obtained and all applicable laws in Exploiting the Licensed Product(s) in the Field in the Territory under this Agreement.
- (d) Merial shall undertake its obligations under the FD Phase of the Program that will include potential use of the Licensed Product(s) for the treatment of pain in cats and dogs in the Field. The implementation of the Program will provide a better opportunity for Merial to maximize the value of the Licensed Product(s) and the amount of Royalties to be paid to APP. Both Parties, however, understand and acknowledge the vagaries inherent in clinical trials and of the regulatory environment and agree that the Program cannot produce guaranteed financial results.

### 7 TRIALS REQUIRED FOR REGULATORY APPROVAL

#### 7.1 Acknowledgment

The Parties acknowledge that, as at the Commencement Date, the Technology, and Licensed Product do not have regulatory approval in the Territory and that further clinical trials in relation to the Technology and Licensed Product are required in order to apply

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and be granted such regulatory approval in the Territory. The Parties agree to cooperate with each other in regard to all technical assistance and documentation regarding the Licensed Rights and the requirements to obtain Agency licenses for the Licensed Product(s).

# 7.2 Merial's Obligation

Merial, using the Merial Know-How, shall conduct clinical and laboratory trials in relation to the Technology and the Licensed Product(s), as permitted by this Agreement, and as may be necessary to obtain and maintain all Registrations, **[\*]**, Merial may employ third parties to conduct some or all of these tests. The draft reports of all such trials **[\*]**. Such draft reports shall be considered Merial's Confidential Information and treated in accordance with **Article 12**.

# 7.3 Steering Committee

- (a) The Parties shall, as soon as practicable after the Commencement Date, form a Steering Committee comprising [\*] nominated by Merial and [\*] nominated by APP to oversee and make recommendations in relation to the clinical and laboratory trials conducted by Merial under this Article
   7. In addition to these [\*] members, a Merial employee responsible for managing and protecting Merial's intellectual property shall be entitled to attend the Steering Committee meetings in order to ensure timely patent filings.
- (b) The Steering Committee shall meet semi-annually face-to-face or by telephone or other electronic means. Until Merial has obtained regulatory approval of a Licensed Product and if the Steering Committee meets face-to-face, every second face-to-face meeting will be held at APP's premises, unless the Steering Committee determines otherwise.
- (c) The Steering Committee will decide in good faith and based upon the best available scientific and technical practices and results when the tasks of the FD Phase of the Program should be launched and when the deliverables are achieved.

## 7.4 Assistance from APP

In addition to participation on the Steering Committee, and prior to obtaining Registrations for the Licensed Product(s) filed by Merial, APP shall, upon Merial's reasonable request, provide or cause to be provided, as may be available to APP, any consultation, opinion papers, reviews, white papers, research protocols, data interpretation, expert opinions, and/or technical assistance and advice in the conduct of its clinical and laboratory trials and related work under **Clause 7.2**. Merial will reimburse reasonable and documented expenses incurred by APP specifically linked to the preparation or delivery of the requested work, including costs of materials, animal per diem costs, and lab test expenses, if the expenses are approved in advance in writing by an authorized representative of Merial. If the expenses are not so approved, APP shall have no obligation to incur them.

# 8 APP'S MATERIAL OBLIGATIONS

APP acknowledges and agrees that in order for Merial to be able to meet its obligations to obtain Registration(s) for the Licensed Product(s) and to Exploit the Licensed Product(s)

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in the Field in the Territory, APP must provide certain assistance and comply with certain obligations, and that compliance with these obligations is partial consideration for the Royalty payment made hereunder ("APP Material Obligations"). For purposes of this Agreement, APP Material Obligations shall include the following obligations of APP:

- (a) undertaking its responsibilities under the FD Phase of the Program;
- (b) transferring APP Know-How and all information related to research and development of Licensed Product not already transferred to Merial within thirty (30) days of execution of the Agreement;
- (c) transferring APP Know-How and all information necessary to file for approval of the Licensed Product(s) with the U.S. FDA or other applicable regulatory agency, including manufacturing know-how as required;
- (d) provision of technical support to Merial during the FD Phase and registration of Licensed Product, as set forth in Article 7 above, upon Merial's written request. Merial will pay reasonable and documented expenses incurred by APP specifically linked to the provision of such technical support If the expenses are not so approved, APP shall have no obligation to incur them; and
- (e) **[\*]**. Merial shall be entitled **[\*]** upon (i) any commencement of a bankruptcy proceeding by or against APP which has not been dismissed within ninety (90) days, upon Merial's written request therefor, unless APP or a party designated by APP elects to continue to perform, and has the ability to so perform, all of its obligations hereunder, or (ii) if not delivered under (i) above, following the final rejection of this Agreement by or on behalf of APP in such bankruptcy proceeding and in accordance with applicable law, upon Merial's written request therefor.

## 9 IMPROVEMENTS

#### 9.1 **Representations and Warranties**

9.1.1 Except as each Party has otherwise advised the other Party in writing prior to the Commencement Date, each Party represents and warrants to the other Party that as of the Commencement Date, (a) it has sufficient legal and/or beneficial title and ownership under its Intellectual Property rights necessary for it to fulfill its obligations under this Agreement and to grant any rights thereto, including the right to grant a license thereto; and (b) to the best of its knowledge, there is no material unauthorized use, infringement, or misappropriation of any of its Intellectual Property rights by third parties relevant to the Program or other rights granted under this Agreement.

9.1.2 APP represents and warrants that to the extent permitted by applicable law each of its employees has entered into an agreement with APP that provides for the assignment to APP of all inventions made by such employee during the course of the employee's employment with APP.

9.1.3 Merial represents and warrants that to the extent permitted by applicable law each of its employees has entered into an agreement with Merial that provides for the assignment to Merial of all inventions made by such employee during the course of the employee's employment with Merial.

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# 9.2 Pre-Existing Intellectual Property

Background IP owned by or licensed to either Party prior to the execution of this Agreement shall remain the exclusive property of that Party.

# 9.3 Inventorship

Inventorship of Improvements shall be determined in accordance with United States Patent law.

# 9.4 Notification of Improvements

If at any time during the Term either Party becomes possessed of any Improvement (whether patentable or not), it must [\*] days from such event communicate that Improvement to the other Party providing full particulars.

# 9.5 Ownership

Any Improvement which relates [\*] and those which are made [\*] shall [\*]. Any Improvement which relates [\*] and those which are made [\*] shall be [\*]. All other Improvements shall be [\*]. Notwithstanding the other provisions of this Clause, Improvements which relate solely to [\*], whereas Improvements which relate solely to [\*].

# 9.6 Filing, Prosecution and Maintenance of Patents on Improvements

- 9.6.1 Merial shall have the right, but not the obligation, to (in its sole discretion and at its own cost) file, prosecute, and maintain where so filed in the Territory any patent applications and patent(s) **[\*]** and on the Licensed Product(s), including conducting any interferences, reissues, examinations, oppositions, nullity proceedings and any similar proceedings. **[\*]**. If **[\*]** agrees to grant and hereby does grant **[\*]** the right to so proceed separately **[\*]** and to have **[\*]** such other terms as are mutually agreed upon by the Parties. Both Parties shall keep the other advised of the status of actual and prospective patent filings and upon request, provide advanced copies of any papers related to such filings, prosecutions, and maintenance.
- 9.6.2 If [\*] files a patent application in its own name for [\*] to grant and hereby does grant to [\*]. If [\*] otherwise owns an Improvement [\*] agrees to grant and hereby does grant [\*].
- 9.6.3 Merial acknowledges ownership of the Technology by APP and does not represent that it has any ownership rights in the Technology.

# 9.7 APP's Obligations

APP shall provide such necessary and reasonable assistance as Merial may reasonably request in the [\*].

## 10 INFRINGEMENTS

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# 10.1 Obligation to Report

Each Party must promptly report in writing to the other:

- (a) any actual or suspected infringement by a third party of any Patents or other Intellectual Property Rights subsisting in the Improvements, Licensed Product or the Technology; and
- (b) any allegation or claim by a third party of invalidity or unenforceability of the Patents or other Intellectual Property Rights in the Technology, the Improvements, or the Licensed Product(s) or that the Patents or other Intellectual Property Rights in the Technology, the Improvements, or the Licensed Product(s) infringe(s) that third party's rights.

#### 10.2 Enforcement and Defense

- (a) [\*], shall have the first right to initiate and prosecute such legal action in the Field at its own expense (either in its own name or in the name of both Parties) or to control any Opposition or Re-examination Proceeding or declaratory judgment action relating to the Patents, the Improvements, and the Technology, as they relate to the Licensed Product(s) in the Field. [\*], to either initiate and prosecute such action or to control any Opposition or Re-examination Proceeding or such declaratory judgment action. [\*] after the date of notice of infringement, [\*] have the right to bring suit. In any legal action, the non-initiating Party shall have the right, at its expense, to be represented by legal counsel of its choice.
- (b) For any action to terminate any infringement of Patent or any misappropriation or misuse of Technology, in the event that either Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its sublicensees to execute all documents necessary for the other Party to initiate litigation to prosecute and maintain such action. In connection with any action, both Parties will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of the developments in any action or proceeding, including, to the extent permissible by law, the status of any settlement negotiations and the terms of any offer related thereto.
- (c) [\*] to settle any such legal action by granting a sublicense under the Technology to the Licensed Product(s) in the Field. [\*] to settle any such legal action by granting a sublicense under the Technology to the Licensed Product(s) in the Field [\*] provided that such sublicense complies with Section 2.1(b). Except as otherwise provided herein, neither Party shall have the right to settle any legal action by granting a sublicense under the Technology for the Licensed Product(s) in the Field.
- (d) Any recovery obtained by either or both Parties in connection with or as a result of any action contemplated by this **Article 10**, whether by settlement or otherwise, shall be shared in order as follows:
  - (i) [\*] costs and expenses incurred in connection with the action;

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- (ii) [\*] costs and expenses incurred in connection with the action; and
- (iii) the Parties shall be compensated from the balance of the recovery [\*].
- (e) If, as a result of any final, unappealable or unappealed legal action, the Patents or other Intellectual Property Rights in the Technology or the Licensed Product(s) are deemed invalid or unenforceable or a determination is made that the Patents or other Intellectual Property Rights in the Technology or the Licensed Product(s) infringes a third party's rights, [\*].

## **10.3** Patent Term Restoration

The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Patents. In the event that elections with respect to obtaining such patent term restoration are to be made, the patent owner shall have the right to make the election and the other Party agrees to abide by such election.

## 11 TERM AND TERMINATION

# 11.1 Term

- (a) The term of the Program shall begin upon the Commencement Date and, unless sooner terminated as hereinafter provided, shall continue in full force and effect through the filing of the first NADA **[\*]** or the **[\*]** anniversary of the Commencement Date whichever comes first ("Term").
- (b) The term of the license granted by APP to Merial according to **Clause 2.1** shall begin upon the Commencement Date and, subject to earlier termination in accordance with its provisions, will continue until the date of expiry of the last Patent.

## 11.2 Termination by Merial Without Cause

During the FD Phase, Merial may terminate this agreement for any reason on ninety (90) days prior written notice to APP. Once a Licensed Product has been sold, Merial may terminate the agreement for any reason on six (6) months prior written notice to APP. Notwithstanding the preceding, Merial shall not terminate this Agreement per this clause, within six (6) months following the Commencement Date.

#### 11.3 Termination by Merial for Cause

- (a) Merial may terminate this Agreement immediately on written notice to APP if APP:
  - (i) is in material breach of any of APP Material Obligations and fails to rectify such breach within sixty (60) days after receipt of written notice from Merial specifying the breach; or
  - (ii) during the FD Phase, is or becomes insolvent, is unable to pay its debts as and when they become due, ceases to carry on business, or

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proceedings are commenced, and not dismissed [\*] after notice to APP, to have it wound up or a receiver and manager (or other administrator) is appointed to all or any part of its assets and undertakings.

(b) For the purposes of this **Clause 11.3**, APP Material Obligations are limited to the APP Obligations set forth in the following **Articles** and **Clauses: 2, 3, 4.1, 7.1, 7.3, 7.4, 8, 9.5, 9.7, 10, 12, 13, 14.1, 17.1** and **18** and **Exhibit B**.

# 11.4 Termination by APP for Cause

- (a) APP may terminate this Agreement immediately on written notice to Merial if Merial:
  - (i) upon sixty (60) days prior written notice to Merial if Merial has either not filed an administrative NADA for a Licensed Product within
     [\*] of the Commencement Date or not commercialized a Licensed Product within [\*] of receiving approval of the administrative NADA and assignment of a NADA number from the U.S. FDA;
  - (ii) is in material breach of any of the Merial Material Obligations under this agreement and fails to rectify such breach within sixty (60) days after receipt of written notice from APP specifying the breach; or
  - (ii) is or becomes insolvent, ceases to carry on business, or proceedings are commenced to have it wound up or a receiver and manager (or other administrator) is appointed to all or any part of its assets and undertakings.
- (b) For the purposes of this **Clause 11.4**, Merial's Material Obligations under this Agreement are limited to those set forth in the following **Articles** and **Clauses:** 3, 4, 5, 6, 7.1, 7.2, 7.3, 9.5, 9.6, 10, 12, 13, 17.2, and 18, and **Exhibit B**.

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# 11.5 Termination for Change of Control

If there is a Change in Control of a party, that party must notify the other party in writing on or before the date the Change of Control takes effect. The other party may then, within three (3) months after receiving such notice of Change of Control, terminate this agreement on twelve (12) months' notice to the first party.

# 11.6 Other Consequences of Termination

On the expiry or termination of this Agreement for any reason, and without limiting the parties' other obligations on termination specified in this Article **11**:

- (a) Merial must pay to APP within [\*] after the effective date of termination all Royalties and license fees due and owing up to the effective date of termination;
- (b) Merial may complete the manufacture or provision of any Licensed Products in accordance with any contract it has entered into with any third party in respect of such Licensed Products, not to exceed [\*] from the date of termination or expiration, and may sell its existing stocks of Licensed Products provided it complies with its obligations to pay Royalties in accordance with Article 4 and provide statements in accordance with Article 5;
- (c) Merial must cease using the Technology other than as necessary under this Clause 11.6; and
- (d) Merial must promptly return to APP all materials, technical data and any other information (including APP Know-How) supplied to Merial by APP, and all copies of such materials in Merial's possession, power or custody;
- (e) If termination is by APP for cause or by Merial without cause, [\*], including termination of any third-party contracts, disposal of raw materials and work relating to the Program actually performed as of the time of termination [\*];
- (f) If termination is by Merial for cause under **Clause 11.3(a)**, [\*]. For the sake of clarity, Merial shall retain all of its rights to bring an action against APP for any other damages and any other remedy in law or equity; and
- (g) If a Licensed Product(s) has been launched by Merial prior to termination for any reason except for termination for cause by Merial and Merial is interested in licensing its rights in the Licensed Product(s) and the Improvements to another party, APP shall have a first right of negotiation to acquire a license, on commercially reasonable terms negotiated in good faith, to Exploit in the Field in the Territory Merial's rights in the Licensed Product(s) and the Improvements.

# 11.7 Survival

The provisions of **Articles 9**, **10**, **11**, **12**, **14**, **15**, **16**, **and 17** shall survive the termination or expiry of this Agreement. In the event that a third party acquires substantially all of the assets of either Party, the third party shall be bound by the terms of this Agreement through the remaining term. All rights, options, assignments, and licenses granted under or pursuant to this Agreement by either Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S.

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Bankruptcy Code. The Parties agree that Merial, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code which has not been dismissed within ninety (90) days, and subject to any applicable law, the Party hereto that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property with respect to the Program (including the Technology File as defined above), and same, if not already in their possession, will be promptly delivered to them (i) upon their written request there for, unless the Party subject to such bankruptcy proceeding or a party designated by such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following the final rejection of this Agreement in such bankruptcy proceeding by or on behalf of the Party subject to such proceeding in accordance with applicable law, upon written request there for by the non-subject Party.

# 12 CONFIDENTIAL INFORMATION

## 12.1 Definition

In the course of satisfying their obligations hereunder, it is anticipated that the Parties will have access to and/or learn confidential and/or proprietary information and/or trade secrets of the other Party. Confidential and/or proprietary information and materials ("Confidential Information") means any information that is provided to one Party ("Recipient") by the other Party ("Discloser") or accessed by the Recipient in connection with this Agreement (whether received before or after the Commencement Date) and shall include, but are not limited to: (1) organizational structure, responsibilities and plans; (2) methods of business operations, processes and practices; (3) sales and financial data, projections and plans; (4) customer, client and employee information; (5) business and marketing objectives, strategies and plans; (6) know-how, research and scientific and technological developments; (7) product information which by its nature is confidential; and (11) information the Recipient knows or ought reasonably to know is confidential. The Discloser may disclose Confidential Information to the Recipient either: (a) in writing; (b) by delivery of items; (c) by access to information that may be contained in a data base; (d) by verbal discussion and/or visual presentation; or (e) by any other means Discloser determines necessary. "Trade Secrets" shall be defined as information, without respect to form, belonging to the Discloser and licensed by it, including information which: (i) derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by other persons or entities who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

# 12.2 General Obligations

(a) Recipient agrees that any Confidential Information disclosed by Discloser under this Agreement shall be maintained as confidential and that Recipient shall not disclose any Confidential Information to any third party, except as provided below, during the duration of this Agreement and for a period for [\*] after the termination or expiration of this Agreement. Confidential Information disclosed to Recipient by Discloser shall be used only for the purpose of performing Recipient's obligations under this Agreement, and Recipient must seek prior written approval

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from Discloser for any vendors, contractors, subcontractors, and third parties that Recipient proposes to use to perform its obligations hereunder. Any such vendors, contractors, subcontractors, and third parties must be bound by a confidential disclosure agreement approved by the Discloser and containing terms equivalent to those contained herein.

- (b) Nothing in this Clause 12.2 shall be construed to prevent Recipient from disclosing Confidential Information of the Discloser to its Affiliates and their respective employees, officers, directors and professional advisors (for the purpose of seeking professional advice) on a "needs-to-know" basis, provided that Recipient ensures such Confidential Information is treated as confidential by such Affiliates and their respective employees, officers, directors and professional advisors.
- (c) Recipient shall not have any obligation of confidentiality with respect to Confidential Information that is in the public domain by use and/or publication at the time of Recipient's receipt from Discloser or thereafter becomes publicly available through means other than disclosure by Recipient; was already in Recipient's possession prior to receipt from Discloser; is properly obtained by Recipient from a third party with a valid right to disclose such Confidential Information and such third party is not under any confidentiality obligation to Discloser; or is disclosed by Discloser to any third party without an obligation of confidentiality.
- (d) Recipient may disclose Confidential Information to the extent required by law. In the event that disclosure of Confidential Information is required by law, Recipient shall notify legal counsel for Discloser of such requirement within five (5) business days of learning of the disclosure requirement and shall allow Discloser an opportunity to oppose such process and seek a protective order.
- (e) Merial may disclose its own Confidential Information and the Confidential Information of APP as required and necessary to the applicable regulatory agency, including the U.S. FDA, in order to obtain Registration(s) of the Licensed Product(s); however, Confidential Information that is so disclosed shall remain Confidential Information for all other purposes. For clarity, notwithstanding anything to the contrary in this Agreement, neither Party shall have the right to disclose Confidential Information belonging to the other Pary in any patent filings without the other Party's prior written consent.
- (f) Upon the expiration or termination of this Agreement, any and all Confidential Information received by Recipient or in Recipient's possession, custody or control or the possession, custody or control of Recipient's employees, officers, agents or contractors, including any documents generated or created by Recipient containing any Confidential Information, shall either be promptly returned or destroyed, as certified by Recipient, except Recipient may retain in Recipient's confidential legal files solely for record purposes one copy of any document created or generated by Recipient containing Confidential Information.
- (g) Recipient shall treat as confidential and shall not disclose, publish or use (other than for purposes of this Agreement) and shall maintain as confidential, any information which constitutes Discloser's trade secrets (whether or not the trade secrets are in written or tangible form) for as long as they remain trade secrets

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under applicable law.

- (h) Neither Party will originate any publicity, news release, public comment or other public announcement, written or oral, whether to the press, to stockholders, or otherwise, relating to this Agreement, without the written consent of the other Party, which consent shall not be unreasonably withheld or delayed, except for such announcement which, in accordance with the advice of legal counsel to the Party making such announcement, is required by law or the regulations of the securities exchange on which such Party's securities are traded, if any. The Party making any required announcement will, unless prohibited by law, give the other Party an opportunity to review the form and content of such announcement and comment before it is made. Either party shall have the right to make such filings with governmental agencies, including the United States Securities and Exchange Commission, as to the contents and existence of this Agreement as it shall reasonably deem necessary or appropriate.
- (i) Notwithstanding anything in this Agreement to the contrary, any previous Confidentiality Agreements between the Parties shall continue in full force pursuant to the terms thereunder with respect to information exchanged between the Parties prior to the Effective Date.

# 13 REGISTRATION OF THE LICENSED PRODUCT IN THE TERRITORY

#### 13.1 Ownership of Licensed Product Registration

(a) Merial shall use Commercially Reasonable Efforts to obtain and maintain at its own cost and expense and in its own name all Registrations, and upon issuance, Merial shall be the sole owner of such Licensed Product Registrations.

#### 13.2 Additional Testing

Subject to the terms of **Clause 7.4**, in the event that there is a need to conduct tests or studies in addition to the clinical tests necessary for obtaining or maintaining a Registration for the Licensed Product(s) or subsequent to obtaining Registration, any such activities will be performed by Merial at its own expense.

### 13.3 Contacts with the U.S. FDA and Other Regulatory Agencies

- (a) Merial exclusively shall deal with the U.S. FDA and any other regulatory agencies from which Merial seeks approval of the Licensed Product(s).
- (b) Each Party shall promptly notify the other Party of any and all inquiries received from the U.S. FDA and/or any other Regulatory Agency concerning the Technology and/or Licensed Product(s) during the term of this Agreement, and it shall notify the other Party of any information it receives from any source regarding any threatened or pending action by a Regulatory Agency. Each Party shall promptly provide to the other Party notice of and summary reports regarding of any communications and/or meetings with the U.S. FDA or other Regulatory Agencies. If the matter relates exclusively to the Licensed Product(s) in the Field, Merial shall determine in its sole discretion the response, [\*]. If the matter relates to the Technology but not its inclusion in the Licensed Product in the Field, APP shall determine in its sole discretion the response, [\*].

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## 13.4 APP's Cooperation to Obtain and Maintain Registration

APP acknowledges and agrees that it maintains, or will maintain in the future, certain information, including manufacturing know-how, that is necessary for the approval and maintenance of the Registration of the Licensed Product(s) in the Field in the United States and elsewhere in the Territory, and APP agrees to share with Merial all such information within APP's control necessary to obtain and maintain such Registration(s).

# 14 LICENSED PRODUCT BRANDING

# 14.1 APP Trademarks

- (a) APP grants to Merial a non-exclusive royalty-free license during the Term to use the APP Trademarks nominated by APP from time to time to brand, package, promote, and advertise the Licensed Product(s) and to use in promotional and instructional materials produced by Merial for the Licensed Product(s). APP shall provide to Merial upon request a copy of the relevant APP Trademarks of a quality suitable for reproduction.
- (b) Merial may only use such APP Trademarks with the prior approval of APP for each type of use or application, such approval not to be unreasonably withheld.
- (c) When using an APP Trademark under this **Clause 14.1**, Merial must not allow the appearance of the APP Trade Mark to be altered in any way (other than proportional size adjustment) without APP's prior approval, such approval not to be unreasonably withheld.
- (d) Notwithstanding anything herein to the contrary, Merial shall not be required to use the APP Trademark to Exploit the Licensed Product(s) in the Field in the Territory.

# 14.2 Merial Branding

Merial may elect to brand the Licensed Product(s) sold in the Territory with a Merial brand name or trademark and will own all Intellectual Property Rights in such brand name or trademark. At no time during this Agreement or after the expiration or termination hereof shall APP have any interest in or ownership of the Merial trademark or brand name selected by Merial to brand the Licensed Product(s) in the Territory.

# 15 DISPUTE RESOLUTION

#### 15.1 Notice of Dispute

- (a) If a difference or dispute (together called a "**Dispute**") between the Parties arises out of or relates to this agreement, either Party may give the other party a written notice of dispute adequately identifying and providing details of the Dispute ("**Notice of Dispute**").
- (b) Notwithstanding the existence of a Dispute, the Parties will, subject to this agreement, continue to perform their obligations under this agreement.

# 15.2 Dispute Resolution

Once a Notice of Dispute has been given under Clause 15.1, the Parties must

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take the steps required by this Clause 15.2 and use all reasonable endeavors to resolve the dispute by negotiating in good faith:

- (a) initially between the chief executive officers of each Party or their delegates, who must confer and endeavor to resolve the Dispute within fifteen (15) Business Days, or such other period as they may agree. All aspects of every such conference, except the fact of its occurrence, will be confidential; and
- (b) if the Dispute is not resolved under **Clause 15.2(a)**, then the chief executive officers or their delegates may refer the Dispute for resolution by mediation under **Clause 15.3**.

# 15.3 Mediation

- (a) If the Parties agree to refer the Dispute for resolution by non-binding mediation, then the Parties agree to endeavor in good faith to settle the Dispute by mediation before resorting to litigation.
- (b) The mediation will be conducted in Chicago, Illinois, before a mediator jointly selected by the Parties. If the Parties are unable to agree on the selection of the mediator, the Parties agree that the American Arbitration Association shall select the mediator.
- (c) If the Dispute cannot be resolved within twenty (20) Business Days of commencement of mediation or such other period as the Parties agree, either Party may, after notice in writing of not less than ten (10) Business Days to the other, commence legal proceedings in relation to that Dispute.
- (d) The Parties must bear equally the costs of the mediation, excluding each Party's legal costs.

# 15.4 Exchange of Information

The Parties acknowledge that the purpose of any exchange of information or documents or the making of any offer of settlement pursuant to this clause is to attempt to settle the Dispute between the Parties. Neither Party may use any information or documents obtained through the Dispute resolution process established by this **Article 15** for any purpose other than an attempt to settle a Dispute between the Parties.

## 15.5 Legal Proceedings

Except with respect to intellectual property matters, neither Party may commence legal proceedings, other than proceedings seeking urgent interlocutory relief, in respect of the Dispute without first complying with **Clauses 15.1**, **15.2** and **15.3**.

# 16 REPRESENTATIONS AND WARRANTIES

#### 16.1 Corporate Existence and Power

- (a) As of the Commencement Date, APP represents and warrants to Merial that it:
  - (i) is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated, and

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- (ii) has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and is contemplated in this Agreement, including, without limitation, the right to grant the licenses granted hereunder.
- (b) As of the Commencement Date, Merial represents and warrants to APP that it:
  - (i) a company limited by shares registered in England and Wales and domesticated in Delaware, USA as Merial LLC, and
  - (ii) has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and is contemplated in this Agreement, including, without limitation, the right to grant the licenses granted hereunder.

# 16.2 Authority

As of the Commencement Date, each Party represents and warrants to the other that it:

- (a) has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder;
- (b) has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and
- (c) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms.

## 16.3 Absence of Litigation

As of the Commencement Date, Merial and APP each represent and warrant to each other that each is not aware of any pending or threatened litigation (and has not received any communication relating thereto) which alleges that the activities of Merial or APP, with respect to the Technology, Patent, or Licensed Product, or otherwise related to this Agreement, have infringed or misappropriated, or that by conducting the activities as contemplated herein by APP or Merial would infringe or misappropriate any Intellectual Property Rights of any other Person.

## 16.4 No Approvals or Consents Required

Except as otherwise described in this Agreement, each Party represents and warrants to the other that all necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with entry into this Agreement have been obtained.

#### 16.5 Patents; Prior Art

Except as each Party has otherwise advised the other Party in writing prior to the Commencement Date, each Party represents and warrants to the other Party that as of the Commencement Date, (a) to the best of its knowledge, it has sufficient legal and/or

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beneficial title and ownership under its intellectual property rights necessary for it to fulfill its obligations under this Agreement; and (b) to the best of its knowledge, there is no material unauthorized use, infringement, or misappropriation of any of its intellectual property rights by third parties relevant to the Program or other rights granted under this Agreement. As used herein, "intellectual property rights" shall mean all patent rights, copyrights, trademarks, trade secrets, and confidential and/or proprietary chemical substances, technical information, data and assays necessary or useful to the Program.

# 16.6 No Conflict

Each Party represents and warrants to the other that the execution and delivery of the Agreement by such Party and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or regulation or any provision of articles of incorporation or by laws of such Party in any material way and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

## 16.7 No Prior Licenses

APP represents and warrants to Merial that prior to the Commencement Date, neither it nor any APP Affiliate has granted any licenses or covenants-notto-sue to Third Parties with respect to the Licensed Product(s), including, the right to Exploit the Licensed Product(s) in the Field in the Territory.

## 17 INDEMNITY

## 17.1 Indemnification by APP

APP hereby agrees to indemnify, hold harmless and defend Merial against any and all expenses, costs of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Merial becomes legally obligated to pay because of any third party claim or claims against it to the extent that such claim or claims (i) arise out of the breach or alleged breach of any representation or warranty by APP hereunder, or (ii) are due to the negligence or misconduct of APP; provided that (a) Merial provides APP with prompt notice of any such claim and the exclusive ability to defend (with the reasonable cooperation of Merial) and settle any such claim and (b) such indemnities shall not apply to the extent such claims are covered by Merial's indemnity set forth in **Clause 17.2** below.

## 17.2 Indemnification By Merial

Merial hereby agrees to indemnify, hold harmless and defend APP against any and all expenses, costs of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts APP becomes legally obligated to pay because of any third party claim or claims against it to the extent that such claim or claims (i) arise out of the breach or alleged breach of any representation or warranty by Merial hereunder, (ii) are due to the negligence or misconduct of Merial, or (iii) arise out of the possession, manufacture, use, sale or administration of the Licensed Product(s) by Merial or Merial's Affiliates or sublicensees; provided that (a) APP provides Merial with prompt notice of any such claim and the exclusive ability to defend (with the reasonable cooperation of APP) or settle any such claim and (b) such indemnities shall not apply to the extent such claims are covered by

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## 17.3 Mechanics

In the event that the Parties cannot agree as to the application of **Clauses 17.1** and **17.2** above to any particular loss or claim, the parties may conduct separate defenses of such claim. Each Party further reserves the right to claim indemnity from the other in accordance with **Clauses 17.1** and **17.2** above upon resolution of the underlying claim, notwithstanding the provisions of **Clauses 17.1** and **17.2** above requiring the indemnified Party to tender to the indemnifying party the exclusive ability to defend such claim or suit.

# 18 INSURANCE

Each Party represents and warrants that it is covered and will continue to be covered by a comprehensive general liability insurance program which covers all of its own activities and obligations hereunder. Each Party shall provide the other Party with written notice at least fifteen (15) days prior to any cancellation or material change in such insurance program. Each Party shall maintain such insurance program, or other program with comparable coverage, beyond the expiration or termination of this Agreement during (i) the period that any Licensed Product is being commercially distributed or sold other than for the purpose of obtaining regulatory approvals by Merial or by a sublicensee, Affiliate or agent of Merial and (ii) a commercially reasonable period thereafter.

## **19** NOTICES

# 19.1 General

Any notice or other written communications required or permitted to be made or given hereunder may be made or given by either Party by fax communication to the fax number set forth below, and such notice shall be followed up by depositing the same in the mail, certified delivery, return receipt requested, postage prepaid, and addressed to the mailing address set forth below.

## **19.2** Particulars for Delivery of Notices

(a) The particulars for delivery of notices are initially:

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# APP

VP R&D A.P. Pharma, Inc. 123 Saginaw Drive, Redwood City, CA 94063 Fax: +1 650 365 9452 or +1 650 365 6490

Attention: Dr. John Barr

# With a copy to:

Chief Executive Officer A.P Pharma, Inc. 123 Saginaw Drive Redwood City, CA 94063 Fax: +1 650 365 9452 or +1 650 365 6490

## And a copy to:

Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94025 Fax: +1 650 463 2600 Attention: Alan Mendelson

## Merial

General Counsel 3239 Satellite Boulevard Duluth, Georgia USA 30096 Fax: (678) 638-3960

## With a copy to:

Global Head of R&D 3239 Satellite Boulevard Duluth, Georgia USA 30096 Fax: (678) 638-3600

# And for Intellectual Property Matters a copy to:

Global Head of IP 3239 Satellite Boulevard Duluth, Georgia USA 30096 Fax: (678) 638-3350

(b) Each Party may change its particulars for delivery of notices by written notice to the other Party.

## **19.3** After Hours Communications

If a communication is given:

- (a) after 5:00 p.m. in the place of receipt; or
- (b) on a day which is a Saturday, Sunday, or bank or public or federal holiday in the

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#### place of receipt,

it is taken as having been given at 9:00 a.m. on the next day which is not a Saturday, Sunday, or bank or public or federal holiday in that place.

#### 19.4 Process Service

Any process or other document relating to litigation, administrative or mediation proceedings relating to this Agreement may be served by any method contemplated by this **Article 19** or in accordance with any applicable law.

# 20 Force Majeure

- (a) For the purposes of this clause, "Force Majeure" means any circumstance beyond the reasonable direct or indirect control and without the fault or negligence of the Party claiming Force Majeure, including any act of God, act of war, cyclone, fire, flood, explosion, storm or earthquake.
- (b) Delays in or failure of performance by a Party shall not constitute a breach of this agreement by that Party if and to the extent any delay or failure is caused by a Force Majeure, provided the Party claiming Force Majeure:
  - (i) notifies the other Party in writing within three (3) Business Days of the occurrence of the Force Majeure providing details of the Force Majeure and its anticipated likely duration and effect; and
  - (ii) uses its reasonable best endeavors to resume fulfilling its obligations as promptly as possible and provides the other Party with written notice within three (3) Business Days of the cessation of the Force Majeure.
- (c) If a delay caused by Force Majeure continues for more than [\*] days, either Party may terminate this agreement by giving thirty (30) days' notice to the other Party.

## 21 GENERAL

#### 21.1 Legal Costs

Except as expressly stated otherwise in this document, each Party must pay its own legal and other costs and expenses of negotiating, preparing, executing, and performing its obligations under this Agreement.

## 21.2 Amendment

This Agreement may not be amended, replaced or varied, except in writing, signed by both Parties, and making reference to this Agreement.

#### 21.3 Waiver and Exercise of Rights

(a) A single or partial exercise or waiver by a Party of a right relating to this document does not prevent any other exercise of that right or the exercise of any other right.

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(b) A Party is not liable for any loss, cost, or expense of any other Party caused or contributed to by the waiver, exercise, attempted exercise, failure to exercise or delay in the exercise of a right.

## 21.4 Rights Cumulative

Except as expressly stated otherwise in this document, the rights of a Party under this document are cumulative and are in addition to any other rights of that Party.

# 21.5 Further Steps

Each Party must promptly do whatever any other Party reasonably requires of it to give effect to this document and to perform its obligations under it.

# 21.6 Governing Law

This Agreement is governed by and is to be construed in accordance with the laws of the State of Delaware.

# 21.7 Assignment

- (a) A Party may not assign this Agreement or any right or obligation hereunder without the prior written consent of the other Party. Notwithstanding the foregoing, Merial shall have the right to assign this Agreement to any of its Affiliates without prior consent from APP; APP shall have the right to receive any consideration due from Merial to APP under the Agreement, including royalties, to a third party without prior consent from Merial; and either Party shall have the right to assign, without prior consent of the other Party, its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets to which this Agreement relates.
- (b) Any purported dealing in breach of this clause is of no effect.

# 21.8 Liability

An obligation of two or more persons binds them separately and together.

# 21.9 Counterparts

This document may consist of a number of counterparts and, if so, the counterparts taken together constitute one document.

# 21.10 Entire Understanding

(a) Any previous confidentiality agreements between the Parties hereto shall remain in full force and effect. Subject to the foregoing, this Agreement contains the entire understanding between the Parties as to the subject matter hereof; provided, however, that (i) this Agreement shall not supersede the letter agreement between the parties dated July 17, 2009, which shall continue in full force and effect as provided therein, and (ii) this Agreement shall not supersede the terms of the Research and Development Agreement effective January 22, 2007, as amended, between the parties as to activities conducted pursuant to the POC Phase prior to the Effective Date, and such Research and Development Agreement shall continue in full force and effect to govern the

Parties' rights and obligations with respect to the POC Phase as conducted thereunder.

- (b) All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. No Party is liable to any other Party in respect of those matters.
- (c) No oral explanation or information provided by any Party to another:
  - (i) affects the meaning or interpretation of this document; or
  - (ii) constitutes any collateral agreement, warranty or understanding between any of the Parties.

## 21.11 Relationship of Parties

This document is not intended to create a partnership, joint venture, employment, or agency relationship between the Parties.

#### 21.12 Ethical Business Practices

- (a) The Parties shall adhere to business practices in connection with this Agreement which are in accordance with the letter and spirit of applicable laws and ethical principles. Each Party represents and warrants to the other that all transactions will be accurately reflected in their respective books and records, and that no funds or other assets will be paid directly or indirectly to government officials (or persons acting on their behalf) for the purpose of influencing government decisions or actions. Violation of this policy may result in the immediate termination of this Agreement.
- (b) No employee of Merial will have authority to give any direction, written or oral, relating to the making of any commitment by APP or its agents to any third party in violation of the terms of this Clause 21.12.

**IN WITNESS THEREOF**, the authorized representatives of the Parties hereto have executed this Agreement effective on the day and the year first set forth above.

# A.P. PHARMA INC.

/s/ Ronald Prentki

(Signature)

Ronald Prentki Name (print)

President and CEO Title

## MERIAL LIMITED:

/s/ Jose G. R. Barella (Signature)

Jose G. R. Barella Name (print)

Executive Chairman Title

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# **Relevant Intellectual Property**

# Patents

[\*]

1

# **RESEARCH PROGRAM**

[\*]

2

Exhibit C

[\*]

- 3
- [\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# SECTION 302 CERTIFICATIONS

I, Ronald J. Prentki, 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 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 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 16, 2009

/s/ Ronald J. Prentki Ronald J. Prentki President and Chief Executive Officer

# SECTION 302 CERTIFICATIONS

I, John B. Whelan, 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 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 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 16, 2009

/s/ John B. Whelan

John B. Whelan Chief Financial Officer

Exhibit 32

# 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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald J. Prentki, President and 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 result of operations of the Company.

November 16, 2009

/s/ Ronald J. Prentki

Ronald J. Prentki, President and Chief Executive Officer

# 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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John B. Whelan, Chief 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 result of operations of the Company.

November 16, 2009

/s/ John B. Whelan

John B. Whelan, Chief Financial Officer