

# A.P. Pharma Announces Third Quarter 2010 Financial Results

November 15, 2010

REDWOOD CITY, Calif., Nov 15, 2010 (BUSINESS WIRE) -- A.P. Pharma, Inc. (NASDAQ: APPA), a specialty pharmaceutical company, today reported financial results for its third quarter ended September 30, 2010.

### **Operational Highlights**

"A. P. Pharma has been working diligently to address the issues raised in the U.S. Food and Drug Administration's Complete Response Letter of March 2010," said John Whelan, A.P. Pharma's acting chief executive officer. "Our goal is to schedule what we hope will be a productive End of Review meeting with the agency as soon as the necessary information is available. The primary focus of a meeting with the agency would be to discuss the next steps for the APF530 New Drug Application."

In November, A.P. Pharma received notice that it was awarded a non-taxable grant from the United States government under the Qualifying Therapeutics Discovery Project (QTDP) program in the amount of \$244,479. Grants were awarded to projects that show reasonable potential to produce new therapies, address unmet medical needs, and reduce the long-term growth of health care costs in the U.S. The QTDP program is a part of the Patient Protection and Affordable Health Care Act of 2010.

### **Results of Operations**

A.P. Pharma's net loss for the third quarter of 2010 was \$1.7 million, or \$0.04 per share, compared with a net loss of \$1.2 million, or \$0.04 per share, for the third quarter of 2009. Net loss was higher in the current fiscal quarter primarily due to \$1.0 million of income recognized in the prior year quarter in connection with the termination of a license agreement for APF530 with RHEI Pharmaceuticals, N.V. Revenue for the third quarter of 2010 was \$0.4 million compared with revenue of \$1.1 million for the third quarter of 2009. Revenue in 2010 was primarily related to research and development work performed under an agreement with Merial Limited entered into in September 2009 for a long-acting pain management product for companion animals. The \$0.7 million decrease in revenue in the current fiscal quarter was partially offset by \$0.3 million of lower spending resulting from continuing cost containment actions undertaken by the Company.

Cash and cash equivalents as of September 30, 2010 were \$3.0 million, compared with \$7.6 million at December 31, 2009.

In March 2010, A.P. Pharma received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) on the APF530 New Drug Application (NDA). The full extent of activities, costs and time required to address the FDA's questions is not currently known; however, A.P. Pharma expects to clarify the actions required for resubmission and approval of its NDA at an End of Review meeting. Based on a current analysis of anticipated expenses to prepare for an End of Review meeting, the Company believes it has sufficient cash resources to fund operations into the first quarter of 2011. A.P. Pharma is currently seeking debt or equity financing to fund its operations. Multiple factors, including market conditions, may prevent the Company from obtaining adequate financing to support its operations, or obtaining financing that will be on terms favorable to A.P. Pharma or its stockholders.

### **About APF530**

A.P. Pharma's lead product candidate, APF530, is being developed for the prevention of both acute and delayed onset chemotherapy-induced nausea and vomiting (CINV). APF530 contains the 5-HT<sub>3</sub> antagonist, granisetron, formulated in the Company's proprietary Biochronomer(TM) drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Intravenous and oral formulations containing granisetron are approved for the prevention of acute-onset CINV, but not for delayed-onset CINV. Granisetron was selected because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

### About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer(TM) polymer-based drug delivery technology. The Company's primary focus is on its lead product, APF530, for the prevention of CINV. A.P. Pharma received a Complete Response Letter on the APF530 NDA in March 2010 and is in the process of preparing a resubmission responsive to the deficiencies listed in the Complete Response Letter. The Company has additional clinical and preclinical stage programs in the area of pain management, all of which utilize its bioerodible injectable and implantable delivery systems. Further work on these programs has been deferred while the Company focuses on the approval of APF530. For further information, visit the Company's web site at <a href="https://www.appharma.com">www.appharma.com</a>.

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

Three Months Ended Nine Months Ended 2010 2009 2010 2009

Contract revenue	\$ 3	51	\$	1,117	\$	1,122	\$	1,139
Operating expenses:								
Research and development	1,5	41		1,418		5,762		6,376
General and administrative	4	45		912		3,561	_	2,905
Total operating expenses	1,9	86		2,330		9,323	_	9,281
Operating loss	(1,6	35)		(1,213)		(8,201)		(8,142)
Gain on sale of royalty interest	-			-		2,500		-
Interest income (expense), net		(1)		(1)		(2)		27
Loss from continuing operations	(1,6	36)		(1,214)		(5,703)		(8,115)
Loss from discontinued operations	(	(36)		-		(47)		-
Net loss	\$ (1,6	72)	\$	(1,214)	\$	(5,750)	\$	(8,115)
Basic and diluted net loss per share:								
Loss from continuing operations	\$ (0.	.04)	\$	(0.04)	\$	(0.14)	\$	(0.26)
Net loss	\$ (0.	.04)	\$	(0.04)	\$	(0.15)	\$	(0.26)
Shares used to compute basic and diluted net								
loss per share	39,507		31,234		39,481		_	31,041

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

#### September 30, 2010 December 31, 2009 **Assets** Current assets: Cash and cash equivalents 3,015 7,593 Accounts receivable 328 171 Prepaid expenses and other current assets 286 549 Total current assets 3,629 8,313 Property and equipment, net 407 510 Other long-term assets 53 128 Total assets \$ 4,089 8,951 Liabilities and Stockholders' Equity Current liabilities: 162 Accounts payable 157 1,080 Accrued expenses 517 92 Deferred revenue 95 600 553 Accrued disposition costs Total current liabilities 1,369 1.887 Deferred revenue 189 268 Total liabilities 1,558 2,155 Stockholders' equity: Common stock 401 394 148,959 147,481 Additional paid-in capital Accumulated deficit (146,829)(141,079)2,531 Total stockholders' equity 6,796 Total liabilities and stockholders' equity \$ 4,089 \$ 8,951

# **Forward-looking Statements**

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with capital resources and liquidity, timely development and regulatory approval of product candidates, satisfactory completion of clinical studies, progress in research and development programs, launch and acceptance of new products and other risks and uncertainties identified in the Company's 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.

SOURCE: A.P. Pharma, Inc.

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