

# A.P. Pharma Reports Third Quarter Financial Results; APF530 Phase 1 Study Successfully Completed

November 15, 2004

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov. 15, 2004--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today reported financial results for the three months ended September 30, 2004, reflecting increased royalty income and contract revenues as well as higher research and development expense due to the company's Phase 2 trial with APF112 (mepivacaine) and Phase 1 trial with APF530 (granisetron).

#### **Current Highlights**

- Total revenues for the third quarter increased 15% to \$1,458,000.
- Royalty income from Carac(TM) and Retin-A Micro(R) grew 10% compared to third quarter 2003.
- APF530 for the prevention of acute and delayed chemotherapy-induced nausea and vomiting:
  - o Pre-clinical toxicology studies and Phase 1 dose-ranging study in U.K. completed.
  - APF530 successfully met its target kinetic profile in healthy volunteers.
  - o Clinical plan anticipates Phase 2 clinical study in patients in early 2005.
- APF112 for the treatment of post-surgical pain:
  - Phase 2b clinical study in advanced stage of planning.
  - Study to proceed after securing corporate partner or additional resources.
- Cash, cash equivalents and short-term investments were \$15.2 million at September 30, 2004.

## Financial Results

Total revenues for the third quarter of 2004 increased 15% to \$1,458,000, compared with \$1,268,000 for the third quarter of 2003. This increase was primarily due to a continuing increase in royalty income from both Carac, marketed by Dermik Laboratories, an Aventis company, and Retin-A Micro, marketed by OrthoNeutrogena, a Johnson & Johnson company. Contract revenues for reimbursable research and development feasibility studies also increased primarily due to a collaboration for an ophthalmic application.

Research and development expense for the third quarter of 2004 increased to \$2,656,000 from \$1,854,000 for the third quarter of 2003. This increase was mainly due to the cost of the Phase 2 clinical study using APF112 for the treatment of post-surgical pain, which was completed during the quarter, and a Phase 1 study using APF530 for the prevention of acute and delayed chemotherapy-induced nausea and vomiting.

The net loss for the third quarter of 2004 was \$1,921,000, or \$0.08 per share, compared with a net loss for the third quarter of 2003 of \$1,058,000, or \$0.05 per share.

Cash, cash equivalents and marketable securities were \$15.2 million at September 30, 2004.

# Clinical Update

The Phase 1 study was recently completed in the U.K. in healthy volunteers with three doses of APF530 for the prevention of acute and delayed chemotherapy-induced nausea and vomiting. Preliminary results indicate that APF530 successfully met its target kinetic profile in healthy volunteers. At the highest dose, the product showed meaningful plasma levels within 1 hour post dosing and these were maintained for up to 4 days. The company believes that meeting target plasma levels is a critical step prior to establishing efficacy in the treatment of acute and delayed chemotherapy-induced nausea and vomiting. In addition, the escalating doses led to predicted increases in plasma levels of granisetron. A regulatory submission to the FDA is planned for early in 2005 and the company expects to initiate pivotal studies later in 2005.

A Phase 2b clinical study using APF112 for the treatment of post-surgical pain is in the advanced stages of planning. However, due to the current and anticipated demands on resources for the planned clinical program with APF530, the company will delay the start of further studies with APF112 until a partner or additional resources have been secured.

#### Conference Call

Management will be hosting an investment community conference call beginning at 11:00 a.m. Eastern Time (8:00 a.m. Pacific Time) today to discuss the financial results, further details on the clinical trial results and to answer questions.

To participate in the live call by telephone, please dial 888-803-8275 from the U.S. or 706-634-1287 from outside the U.S. A telephone replay will be available for 48 hours by dialing 800-642-1687 from the U.S. or 706-645-9291 from outside the U.S., and entering reservation number 1565399.

Individuals interested in listening to the conference call via the Internet may do so by visiting http://www.appharma.com. A replay will be available on the Company's Web site for 30 days.

#### About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company focused on the development of ethical (prescription) pharmaceuticals utilizing its proprietary polymer-based drug delivery systems. The Company's primary focus is the development and commercialization of its bioerodible injectable and implantable systems under the trade name Biochronomer(TM). Initial target areas of application for the Company's drug delivery technology include pain management, anti-nausea, inflammation and ophthalmic applications. The Company's product development programs are funded by the sale of common stock in June 2004, royalties from topical products currently marketed by pharmaceutical partners, proceeds from the divestitures of its cosmeceutical and analytical standards product lines and by fees it receives from collaborative partners. For further information visit the Company's web site at http://www.appharma.com.

## Forward-looking Statements

Except for historical information, this news release contains certain forward-looking statements that involve risks and uncertainties including, among others, uncertainty associated with timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances and progress in research and development programs. Other risks and uncertainties associated with the Company's business and prospects are identified in the Company's filings with the Securities and Exchange Commission. The Company does not undertake to revise these forward-looking statements to reflect events or circumstances occurring in the future.

A.P. Pharma, Inc.
Statement of Operations Highlights
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30, 2004 2003			
Royalties Contract Revenues		\$ 1,149 S		
Total Revenues		1,268		
Operating Expenses: Research & Development General & Administrative	2,656 760	1,854 649	8,655 2,245	6,391 2,193
Total Operating Expenses	3,416	2,503	10,900	8,584
Operating Loss	(1,958)	(1,235)	(6,978)	(5,094)
Interest Income and Other, Net		220		
Loss from Continuing Operations	(1,887)	(1,015)	(6,829)	(4,744)
Gain (Loss) on Disposition of Discontinued Operations		(43)	(135)	1,759
Net Loss		(\$1,058)		
Basic and Diluted Loss per Common Share: Loss from Continuing				
Operations		(\$0.05)		
Net Loss	(\$0.08)	(\$0.05)	(\$0.31)	(\$0.15)
Shares used in Calculating Loss per Share:				
Basic and Diluted		20,571		•

# Balance Sheet Highlights (in thousands)

S	September	December
	30,	31,
	2004	2003
(U	naudited)	
Cash, Cash Equivalents and Marketable Securities	\$15.24	7 \$ 9.484
Accounts Receivable, Net		1,340
Other Current Assets	500	•
Other Current Assets		
Total Current Assets		11,258
Property, Plant & Equipment, Net	1 313	1,430
Other Non-Current Assets	· ·	467
Other Non-Current Assets	201	407
Total Assets	\$18,579	\$13,155
	======	======
Liabilities and Shareholders' Equity		
Current Liabilities	\$ 2 252	\$ 1,892
Shareholders' Equity		11,263
Diateroracio Equicy	10,327	· ·
Total Liabilities and Shareholders' Equity		9 \$13,155
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SOURCE: A.P. Pharma, Inc.