



## **A.P. Pharma Reports Second Quarter Financial Results; Patient Enrollment for APF530 Phase 2 Trial Successfully Completed**

August 8, 2005

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 8, 2005--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today reported financial results for the three months ended June 30, 2005.

### **Recent and Financial Highlights**

- Patient enrollment in the open-label APF530 Phase 2 clinical trial has been successfully completed. APF530 is designed for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) and contains the anti-nausea drug granisetron, formulated with the Company's proprietary Biochronomer(TM) system.
- The Phase 2 study was designed for patients receiving moderately emetogenic chemotherapy for cancer to evaluate pharmacokinetics, safety and tolerability. Measures of efficacy were also introduced into the study.
- Three dose groups involving more than 40 patients were treated in an ascending dose study.
- Preliminary safety and pharmacokinetic data to date are very encouraging, and all clinical endpoints were achieved. Sustained plasma levels of granisetron were observed over five days.
- Greater than 90% of patients experienced only mild nausea, no vomiting, and did not need to take any rescue medication in either the acute or delayed phase of CINV.
- Preparations are underway for a Phase 3 clinical trial planned to begin in the fourth quarter of 2005.
- Royalties for the second quarter of 2005 grew by 8%, driven by sales of Carac(R), which increased by 25% compared with the prior year's second quarter.
- Cash, cash equivalents and marketable securities were \$9.7 million at June 30, 2005.

### **Financial Results**

A.P. Pharma reported an 8% increase in total royalties for the second quarter of 2005 to \$1,187,000, compared with \$1,103,000 for the second quarter of 2004. Second quarter royalties on sales of Carac by Sanofi-Aventis grew by 25% and royalties on sales of Retin-A Micro(R) by Johnson & Johnson grew by 1% over the corresponding quarter of the prior year. Contract revenues for the second quarter of 2005 totaled \$63,000, compared with \$181,000 for the second quarter of 2004. Total revenues for the second quarter of 2005 decreased \$34,000, or 3%, to \$1,250,000, compared with \$1,284,000 for the second quarter for 2004.

Research and development expense increased by \$173,000, or 6%, to \$3,078,000 for the second quarter of 2005, compared with \$2,905,000 for the second quarter of the prior year. The increase is primarily attributable to the APF530 Phase 2 clinical study, which was initiated during the second quarter of 2005, and manufacturing expenses that were incurred in anticipation of a Phase 3 clinical study, which is planned to be initiated in the fourth quarter of 2005.

General and administrative expense increased by \$3,000 to \$823,000 for the second quarter of 2005, compared with \$820,000 for the second quarter of 2004.

The loss from continuing operations in the second quarter of 2005 was \$2,564,000, compared with a loss from continuing operations of \$2,392,000 in the second quarter of 2004. The net loss for the second quarter of 2005 was \$2,608,000, or \$0.10 per share, compared with a net loss of \$2,444,000, or \$0.12 per share, in the second quarter of 2004.

### **APF530 Clinical Update**

APF530, which contains the anti-nausea drug granisetron, formulated with the Company's proprietary Biochronomer(TM) bioerodible drug delivery system, is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV). Following a single subcutaneous injection prior to the initiation of chemotherapy, APF530 is designed to provide therapeutic plasma levels of granisetron for four to five days in order to prevent CINV during this period. The Phase 2 study was designed as an open-label, dose-ascending trial in patients undergoing moderately emetogenic chemotherapy for cancer. Patients in the study received an injection of APF530 containing one of three doses of granisetron: 5, 10 or 15 milligrams. The primary endpoints include an evaluation of pharmacokinetics, safety and tolerability. In addition, efficacy endpoints were evaluated relating to emetic events and the use of rescue medication.

Preliminary data to date are very encouraging, and all clinical endpoints were achieved in the first patient group treated. From the Phase 1 study in healthy volunteers, it was anticipated that plasma levels of granisetron would be sustained over four to five days. Based on literature, it was anticipated

that the plasma levels in chemotherapy patients would be approximately twice the drug levels seen in healthy volunteers, given equivalent doses. The pharmacokinetic data from the first APF530 patients who received 5 milligrams of granisetron indicate that the plasma levels were four-fold greater, with sustained levels of granisetron measured at day 5. We believe these results are particularly important based on published data that suggest plasma levels of granisetron can potentially predict therapeutic response in patients for both acute and delayed CINV.

To date, safety and tolerability data in patients receiving the APF530 doses have been excellent, with no drug-related serious adverse events. Injections of APF530 were well tolerated, and there was only one report of mild discomfort at the site of injection. Overall, side effects with regard to the APF530 formulation appear to be minimal.

Efficacy assessments in the first two groups of this open-label study are excellent, with more than 90% of the patients achieving a "complete response," meaning that there were no episodes of vomiting and no requirements for rescue medication, and that no more than mild nausea was experienced. It is interesting to note that published response rates for other approved 5HT(3) antagonists are considerably lower.

#### Conference Call Information

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 this announcement 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 8037521.

Individuals interested in listening to the conference call via the Internet may do so by visiting [www.appharma.com](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. Initial target areas of application for the Company's drug delivery technology include anti-nausea, pain management, 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 [www.appharma.com](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; 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		Six Months Ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Royalties	\$ 1,187	\$ 1,103	\$ 2,469	\$ 2,257
Contract Revenues	63	181	142	206
Total Revenues	1,250	1,284	2,611	2,463
Operating Expenses:				
Research & Development	3,078	2,905	4,900	5,919
General & Administrative	823	820	1,672	1,566
Total Operating Expenses	3,901	3,725	6,572	7,485
Operating Loss	(2,651)	(2,441)	(3,961)	(5,022)
Interest Income and Other, Net	87	49	147	79
Loss from Continuing Operations	(2,564)	(2,392)	(3,814)	(4,943)
Loss from Discontinued Operations	(44)	(52)	(50)	(101)

Net Loss	(\$2,608)	(\$2,444)	(\$3,864)	(\$5,044)
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Basic and Diluted Loss per  
Share:

Loss from Continuing Operations	(\$0.10)	(\$0.11)	(\$0.15)	(\$0.24)
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Net Loss	(\$0.10)	(\$0.12)	(\$0.15)	(\$0.24)
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Shares used in Calculating  
Loss per Share:

Basic and Diluted	25,107	21,048	25,073	20,850
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A.P. Pharma, Inc.  
Balance Sheet Highlights  
(in thousands)

June 30, 2005 (Unaudited)	December 31, 2004
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Assets

Cash, Cash Equivalents and Marketable

Securities	\$	9,747	\$	13,596
Accounts Receivable, Net		1,393		1,506
Other Current Assets		439		394

Total Current Assets		11,579		15,496
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Property, Plant & Equipment, Net		1,115		1,235
Other Non-Current Assets		177		283
Total Assets	\$	12,871	\$	17,014

Liabilities and Shareholders' Equity

Current Liabilities	\$	2,430	\$	2,860
Shareholders' Equity		10,441		14,154

Total Liabilities and Shareholders' Equity	\$	12,871	\$	17,014
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SOURCE: A.P. Pharma, Inc.