



## **A.P. Pharma Reports 2004 Fourth Quarter and Full Year Results; IND Submitted for APF530; Phase 2 Study Cleared to Begin in 2Q05**

March 10, 2005

REDWOOD CITY, Calif.--(BUSINESS WIRE)--March 10, 2005--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today reported financial results for the three and 12 months ended December 31, 2004.

### **Recent and Financial Highlights**

- APF530 in development for the prevention of acute and delayed chemotherapy-induced nausea and vomiting progresses to Phase 2.
  - Dose-ranging study confirms dose linearity and safety in healthy volunteers.
  - Highest dose (20 mg dose of granisetron) added.
  - Clearance received from the FDA to initiate a Phase 2 study following IND submission.
  - Phase 2 study in cancer patients expected to commence in 2Q05.
- Total royalties for the fourth quarter increased 13%, compared with the prior year's fourth quarter.
  - Royalties from sales of Carac(TM) increased 18%.
  - Royalties from sales of Retin-A Micro(R) increased 10%.
- Cash, cash equivalents and short-term investments were \$13.6 million as of December 31, 2004.

### **Financial Results**

A.P. Pharma reported royalties for the fourth quarter of 2004 of \$1,457,000, compared with \$1,291,000 for the fourth quarter of 2003, an increase of 13%. Fourth quarter royalties on sales of Retin-A Micro and Carac grew by 10% and 18%, respectively. Contract revenues totaled \$25,000, compared with \$67,000 for the fourth quarter of 2003. Total revenues for the fourth quarter of 2004 totaled \$1,482,000, compared with \$1,358,000 for the fourth quarter of 2003, an increase of \$124,000 or 9%.

The Company reported that revenues for 2004 totaled \$5,404,000, compared with \$4,848,000 in 2003, an increase of \$556,000 or 11%. Full-year 2004 royalties were \$4,972,000, an increase of \$470,000 or 10%, compared with the prior year. Royalties on sales of Retin-A Micro and Carac grew by 10% and 12%, respectively. Full-year contract revenues increased by \$86,000 or 25% to \$432,000, compared with \$346,000 in the prior year.

Compared to the corresponding periods in the prior year, research and development expense increased by \$867,000 or 40% to \$3,055,000 for the fourth quarter of 2004, and increased by \$3,074,000 or 37% to \$11,495,000 for the year ended December 31, 2004. The increase is due to the cost of the Phase 2 clinical trial using APF112 for the treatment of post-surgical pain, in addition to toxicology studies and a Phase 1 clinical trial using APF530 for the prevention of acute and delayed chemotherapy-induced nausea and vomiting.

General and administrative expense increased by \$78,000 or 11% to \$765,000 for the fourth quarter of 2004, and by \$186,000 or 6% to \$3,225,000 for the year ended December 31, 2004, due primarily to expenses associated with the requirements of the Sarbanes-Oxley Act of 2002.

The loss from continuing operations in the fourth quarter of 2004 was \$2,263,000, compared with a loss from continuing operations in the fourth quarter of 2003 of \$1,464,000. The loss from continuing operations for the 12 months ended December 31, 2004 was \$9,092,000, compared with a loss from continuing operations for the prior year of \$6,208,000. The increase in loss from continuing operations for the fourth quarter and the full year resulted primarily from the increased spending on clinical trials with APF112 and APF530.

### **Clinical Update**

Our lead product candidate APF530, which is being tested for the prevention of acute and delayed chemotherapy-induced nausea and vomiting using a single subcutaneous injection, is about to enter Phase 2 clinical testing. In the fourth quarter of 2004, we evaluated 2.5 mg, 5 mg, and 10 mg doses of the anti-nausea drug granisetron, the active pharmacological agent in APF530, in a Phase 1 clinical trial and saw sustained plasma levels over a four-day period. We added and have now completed a fourth cohort to this safety study using a 20 mg dose. Preliminary results again indicate a dose-proportionate increase in plasma levels of granisetron. Meaningful plasma levels were observed over a five-day period.

We believe these results are particularly important because published data suggest that appropriate plasma levels of granisetron can potentially predict the therapeutic effect on both acute and delayed chemotherapy-induced nausea and vomiting.

A.P. Pharma filed an IND with the FDA in early 2005, and following FDA clearance we now expect to initiate a Phase 2 clinical trial with APF530 during the second quarter of 2005. The protocol design is an open label, ascending single dose in patients undergoing moderately emetogenic chemotherapy for cancer. The primary endpoints are pharmacokinetics, safety and tolerability.

With regard to APF112 for the treatment of post-surgical pain, we have designed a further Phase 2 trial to evaluate a combination therapy using

bupivacaine for immediate pain relief and APF112 for longer-term post-surgical pain relief. Our goal is to eliminate the need for opioids, which can have serious side effects. We plan to initiate this next study after securing an appropriate partner for this product application.

#### 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 4453327.

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(TM). 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.  
Income Statement Highlights  
(in thousands, except per share data)

	Three Months Ended		Twelve Months Ended	
	December 31, 2004	December 31, 2003	December 31, 2004	December 31, 2003(1)
Royalties	\$1,457	\$1,291	\$4,972	\$4,502
Contract Revenues	25	67	432	346
Total Revenues	1,482	1,358	5,404	4,848
Operating Expenses:				
Research & Development	3,055	2,188	11,495	8,421
General & Administrative	765	687	3,225	3,039
Total Operating Expenses	3,820	2,875	14,720	11,460
Operating Loss	(2,338)	(1,517)	(9,316)	(6,612)
Interest and Other, Net	75	53	224	404
Loss from Continuing Operations	(2,263)	(1,464)	(9,092)	(6,208)
Gain (Loss) on Disposition of Discontinued Operations	6	86	(129)	1,845
Net Loss	\$(2,257)	\$(1,378)	\$(9,221)	\$(4,363)

#### Basic and Diluted Loss

Per Share:

Loss from Continuing Operations	\$ (0.09)	\$ (0.07)	\$ (0.40)	\$ (0.30)
	=====	=====	=====	=====
Net Loss	\$ (0.09)	\$ (0.07)	\$ (0.40)	\$ (0.21)
	=====	=====	=====	=====

Shares Used in  
Calculating Loss Per  
Share:

Basic and Diluted	25,000	20,632	22,909	20,553
	=====	=====	=====	=====

(1) Information derived from audited financial statements included in the Company's 2003 Form 10-K.

A.P. PHARMA, INC.  
Balance Sheet Highlights  
(in thousands)

December 31, December 31,  
2004 2003

Assets

Cash, Cash Equivalents and Marketable Securities	\$13,596	\$9,484
Accounts Receivable, Net	1,506	1,340
Other Current Assets	394	434
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Total Current Assets	15,496	11,258
Property & Equipment, Net	1,235	1,430
Other Non-Current Assets	283	467
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Total Assets	\$17,014	\$13,155
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Liabilities and Shareholders' Equity

Current Liabilities	\$2,860	\$1,892
Shareholders' Equity	14,154	11,263
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Total Liabilities and Shareholders' Equity	\$17,014	\$13,155
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SOURCE: A.P. Pharma, Inc.