



## **A.P. Pharma Reports 2003 Fourth Quarter and Full Year Results; Reports Results of Open-Label APF112 Phase 2 study**

March 12, 2004

REDWOOD CITY, Calif.--(BUSINESS WIRE)--March 12, 2004--A.P. Pharma, Inc. (Nasdaq:APPA), a specialty pharmaceutical company, today reported financial results for the three and 12 months ended December 31, 2003, and results from Part 1 of the APF112 Phase 2 clinical study.

### **Recent and Financial Highlights**

- APF112 Phase 2 study for the treatment of pain following inguinal hernia procedures is designed in two parts:
  - Part 1 open-label study has been successfully completed. Results are summarized below.
  - Part 2 blinded study is underway and the Company expects preliminary data by mid-year.
- The Company expects to commence human clinical studies with APF530 for the prevention of nausea and vomiting following chemotherapy or surgery in the second quarter of 2004.
- Results from a study conducted at MIT indicate that a Biochronomer(TM) formulation could advance DNA vaccine usage against viral infections and cancers. This study was reported in the February 2004 issue of Nature Materials.
- 2003 royalty income of \$4.5 million increased 12% over the prior year, driven primarily by 21% growth of Retin-A Micro(R).
- Net cash burn for 2003 was \$4.6 million.
- Cash, cash equivalents and short-term investments were \$9.5 million at December 31, 2003.

### **APF112 Open-Label Study Results**

The open-label study focused on pharmacokinetics, safety and pain management in patients who had undergone inguinal hernia repair.

- The pharmacokinetic measurements in this 10 patient open-label study demonstrated meaningful levels of mepivacaine over a three-day period consistent with observations made in preclinical studies with APF112. In addition, there was good patient-to-patient consistency in this group.
- No severe or serious adverse events were reported. Nausea was the most frequent reported untoward effect but this event was considered to be associated with the general anesthesia. Wound healing in all patients was observed to be normal.
- Both patients and physicians reported good to very good quality of pain control. However, it should be stressed that this was an open-label part of the study with no control group.

"We are especially gratified by the outcomes of the first part of the Phase 2 trial, which not only provided us with excellent safety and pharmacokinetic information, but also facilitated our selection of dosage levels for the second part of the study," said A.P. Pharma President and CEO Michael O'Connell.

The second part of the Phase 2 trial is a 90-patient blinded study comparing two doses of APF112 with current standard treatments for post-surgical pain. The endpoints for the trial will include a visual analog score of pain intensity, the standard means of measuring pain, and patient reduction in opioid-type pain medication.

APF112 combines A.P. Pharma's proprietary Biochronomer(TM) bioerodible drug delivery system with mepivacaine, an off-patent analgesic. APF112 is designed to provide 24 to 36 hours of pain relief while minimizing the use of opioid-type drugs, which are used extensively in post-operative pain management.

### **Financial Results**

The Company reported royalties for the fourth quarter of 2003 of \$1,291,000, compared with \$1,258,000 for the fourth quarter of 2002. Contract revenues totaled \$67,000, compared with \$214,000 for the fourth quarter of 2002. The fourth quarter of 2002 also included the recognition of deferred revenues of \$237,000 resulting from the forfeiture by a partner of certain rights to a proprietary Microsponge(R) formulation.

The Company reported full-year 2003 total royalties of \$4,502,000, an increase of \$476,000 or 12%, compared with the prior year. Full year royalties on sales of Retin-A Micro grew by 21% over the prior year. Contract revenues for 2003 totaled \$346,000, compared with \$407,000 in the prior year. Total revenues for 2003 totaled \$4,848,000, compared with \$4,670,000 in 2002, an increase of \$178,000 or 4%.

Research and development expense for the fourth quarter of 2003 increased by \$813,000 or 56% to \$2,269,000, due to initiation of the APF112 Phase 2 clinical trial for the treatment of pain following inguinal surgery repair. Research and development expense for the 12 months ended December 31, 2003 increased by \$1,961,000 or 29% to \$8,660,000, reflecting the entry of APF112 into the Phase 2 clinical trial, together with costs associated with

the manufacturing of GMP materials.

The loss from continuing operations in the 2003 fourth quarter was \$1,464,000, compared with a loss from continuing operations in the 2002 fourth quarter of \$413,000. The loss from continuing operations for the 12 months ended December 31, 2003 was \$6,208,000, compared with a loss from continuing operations for the prior year of \$4,395,000. The loss from continuing operations for the fourth quarter and the full year resulted primarily from the increased spending on the Phase 2 trials.

#### 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. Joining management on this conference call will be Dan J. Kopacz, M.D. of Virginia Mason Medical Center, to discuss progress with the APF112 Phase 2 trial.

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 5937837.

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 pain management, anti-nausea, inflammation, oncology and ophthalmology applications. The Company's product development programs are funded by royalties from topical products currently marketed by pharmaceutical partners, by 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	December	December	December
	31,	31,	31,	31,
	2003	2002	2003	2002
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Royalties	\$ 1,291	\$ 1,258	\$ 4,502	\$ 4,026
Contract Revenues	67	214	346	407
License Fees	--	237	--	237
Total Revenues	1,358	1,709	4,848	4,670
Operating Expenses:				
Research & Development	2,269	1,456	8,660	6,699
General & Administrative	606	807	2,800	3,024
Total Operating Expenses	2,875	2,263	11,460	9,723
Operating Loss	(1,517)	(554)	(6,612)	(5,053)
Interest and Other, Net	53	141	404	658
Loss from Continuing Operations	(1,464)	(413)	(6,208)	(4,395)
Gain (Loss) on Disposition of Discontinued Operations	86	186	1,845	617

Net Loss	\$ (1,378)	\$ (227)	\$ (4,363)	\$ (3,778)
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Basic and Diluted Loss

Per Share:

Loss from Continuing Operations	\$ (0.07)	\$ (0.02)	\$ (0.30)	\$ (0.22)
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Net Loss	\$ (0.07)	\$ (0.01)	\$ (0.21)	\$ (0.19)
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Shares Used in

Calculating Loss Per Share:

Basic and Diluted	20,632	20,456	20,553	20,409
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(1) Information derived from audited financial statements included in the Company's 2002 Form 10-K.

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

December 31, 2003 (Unaudited)	December 31, 2002 (1)
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Assets

Cash, Cash Equivalents and Marketable

Securities	\$ 9,484	\$14,121
Accounts Receivable, Net	1,340	1,340
Assets Held for Sale	--	225
Other Current Assets	434	280

Total Current Assets	11,258	15,966
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Property & Equipment, Net	1,430	1,626
Other Non-Current Assets	467	189
Total Assets	\$13,155	\$17,781

Liabilities and Shareholders' Equity

Current Liabilities	\$ 1,892	\$ 1,977
Long-Term Deferred Revenues	--	345
Shareholders' Equity	11,263	15,459

Total Liabilities and Shareholders' Equity	\$13,155	\$17,781
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(1) Information derived from audited financial statements included in the Company's 2002 Form 10-K.

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SOURCE: A.P. Pharma, Inc.