## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) March 26, 2012

#### A.P. Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-33221 (Commission File Number) 94-2875566 (I.R.S. Employer Identification No.)

123 Saginaw Drive Redwood City CA (Address of principal executive offices)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

94063 (Zip Code)

Registrant's telephone number, including area code (650) 366-2626

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

#### ITEM 8.01 Other Events.

A.P. Pharma, Inc. (the "Company") will deliver a corporate presentation at meetings with investors during the week of March 26, 2012. The slides from the presentation are attached hereto as Exhibit 99.1. The attached materials have also been posted on the Company's website at www.appharma.com. The Company does not undertake to update this presentation.

#### ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit
No. Description

99.1 Corporate Presentation, dated March 2012

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.	
A.P. Pharma, Inc.	

Date: March 26, 2012

//s JOHN B. WHELAN

John B. Whelan

President and Chief Executive Officer



# **Company Overview**

OTCBB: APPA March 2012

### **Legal Disclaimer**

This presentation 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 timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances, progress in research and development programs and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. Actual results may differ materially from the results expected in our forward looking statements. 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.



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### **Stock Summary**

Company:	A.P. Pharma, Inc.
Ticker:	OTCBB: APPA.OB
Stock Price:	\$0.33 (3/23/12)
<b>Market Capitalization:</b>	\$111.2 million <sup>1</sup>
Cash:	\$18.0 million <sup>2</sup>
Debt:	\$1.57 million <sup>2</sup>



Based on 394.5 million fully diluted, as-converted common shares assuming the full conversion of convertible debt outstanding or subject to purchase rights and 80 million warrants using treasury stock method; not including options
 As of December 31, 2011

## Management

John B. Whelan	President, CEO & CFO	Raven Biotechnologies Eos Biotechnology Hewlett Packard/Agilent
Michael A. Adam, Ph.D.	Senior Vice President & Chief Operating Officer	Spectrum Pharmaceuticals Pfizer Bristol-Myers Squibb
Thomas Ottoboni, Ph.D.	Vice President, Pharmaceutical Development	Talima Therapeutics Point Biomedical InSite Vision
Kristin Ficks*	Head of Commercial Operations	Gemini Healthcare Celgene Eisai/MGI Pharma

\*Ms. Ficks is an employee of Gemini Healthcare, LLC, and a consultant to A.P. Pharma



### A.P. Pharma Highlights

- Lead product candidate, APF530, is long-acting, injectable product for chemotherapy-induced nausea and vomiting (CINV)
  - Incorporates widely used 5-HT3 anatgonist granisetron (Kytril®)
  - 5-day delivery profile
  - Reduces both acute- and delayed-onset CINV with single injection
- APF530 shown to be non-inferior to market leader Aloxi®
  - 1,341-patient, randomized, controlled, Phase 3 study
  - Presented at ASCO 2009
- Company is addressing issues raised in Complete Response Letter
  - End-of-review meetings held in 1Q 2011
  - Resubmission planned for mid-2012
- APF530 targets a \$900 million market opportunity in US alone
  - Could be second, long-acting, injectable product on market
- A.P. Pharma has the potential to leverage its Biochronomer<sup>™</sup> drug delivery technology into other opportunities



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# **Important APF530 Milestones**

Milestone	Timing	Status
Successful end-of-review meetings with FDA	1Q 2011	✓
\$24M New Funding	2Q 2011	✓
Successful Completion of Thorough QT Study	1Q 2012	✓
Successful Completion of Metabolism Study	1Q 2012	✓
Human Factors Validation Study	2Q 2012*	
Complete CMC Activities	2Q 2012*	
Resubmit NDA	Mid-2012*	
Expected NDA Approval Decision	~Year-end 2012*	



<sup>\*</sup> Indicates expected milestone timing





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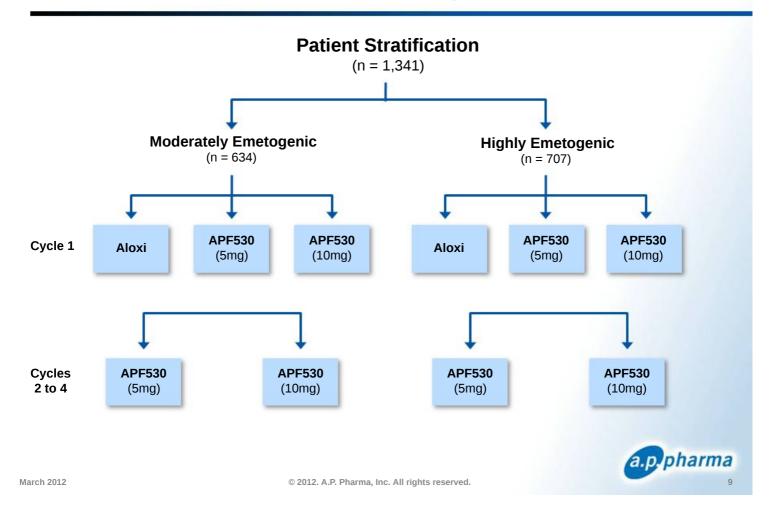
### **APF530 Pivotal Phase 3 Study Overview**

- Randomized, controlled, multi-center study
- 1,341 patients in primary efficacy population
- Two doses of APF530 (5 mg and 10 mg granisetron) compared to the approved dose of Aloxi
- Patients stratified by type of chemotherapy regimen (moderately or highly emetogenic)
- Primary end point compared complete response between groups in both the acute (day 1) and delayed (days 2-5) phase
  - Complete response defined as no emesis and no rescue medications
  - A ±15% margin was used to establish non-inferiority



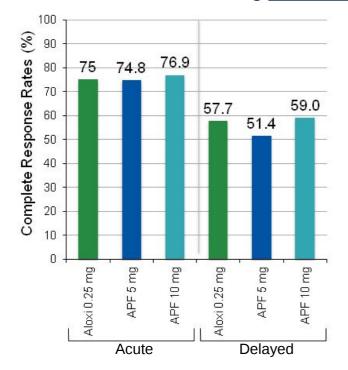
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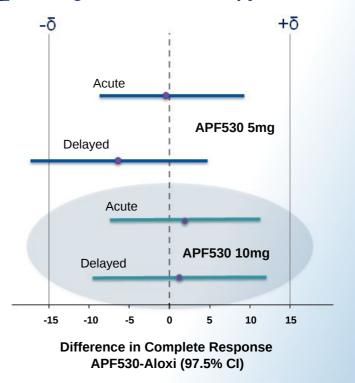
### **APF530 Phase 3 Study Design**



### **Primary Efficacy Results: Complete Response**

#### **Patients Receiving Moderately Emetogenic Chemotherapy**



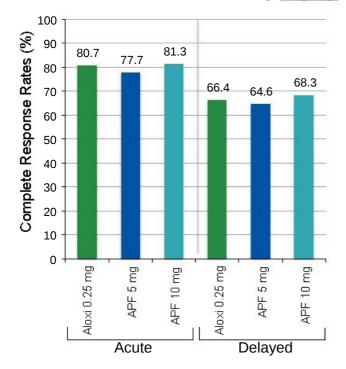


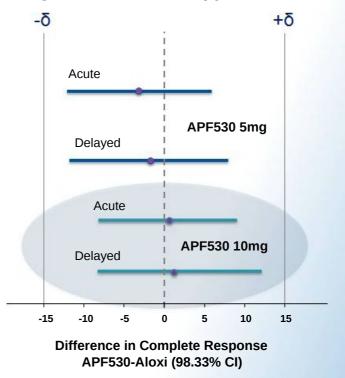


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### **Primary Efficacy Results: Complete Response**

#### Patients Receiving <u>Highly</u> Emetogenic Chemotherapy







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### **Safety Summary**

#### **Reported in Cycle 1**

	APF53	APF530 5 mg		APF530 10 mg		.25 mg
	N	%	N	%	N	%
Drug Related Serious Adverse Events <sup>1</sup>	1	0.2	0	0	0	0
Discontinued Due to Adverse Event	1	0.2	1	0.2	0	0
Frequent Adverse Events			3			
Gastrointestinal disorders	62 49 21	13.4 10.6 4.5	72 44 13	15.4 9.4 2.8	62 39 28	13.4 8.4 6.0
Nervous System <ul><li>Headache</li></ul>	31	6.7	47	10.0	45	9.7
Injection Site <sup>2</sup>					Placebo	(NaCI)
<ul><li>Bruising</li><li>Erythema (redness)</li><li>Nodule (lump)</li><li>Pain</li></ul>	78 33 22 16	16.8 7.1 4.7 3.4	93 51 50 33	19.9 10.9 10.7 7.1	41 14 3 5	8.9 3.0 0.6 1.1

<sup>&</sup>lt;sup>1</sup> Pulmonary embolism in morbidly obese patient on day 16

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<sup>2&</sup>gt;90% of injection site reactions were reported as mild; one patient discontinued due to injection site reaction

## **APF530's Efficacy with Difficult Chemo Regimens**

		Treatment		
		Chemotherapeutic Regimen	APF530 10 mg	Aloxi 0.25 mg
	Acuto	Cyclophosphamide/Doxorubicin	70.7%	65.7%
Moderately	Acute	All other regimens	84.4%	85.0%
Emetogenic	Dalayad	Cyclophosphamide/Doxorubicin	47.4%	46.3%
Delayed		All other regimens	72.9%	70.0%
		Cisplatin regimens	81.1%	75.5%
	Acute	Carboplatin/Paclitaxel	85.4%	89.8%
Highly		All other regimens	75.4%	67.6%
Emetogenic	•	Cisplatin regimens	66.0%	60.4%
	Delayed	Carboplatin/Paclitaxel	70.8%	71.4%
		All other regimens	65.2%	57.4%

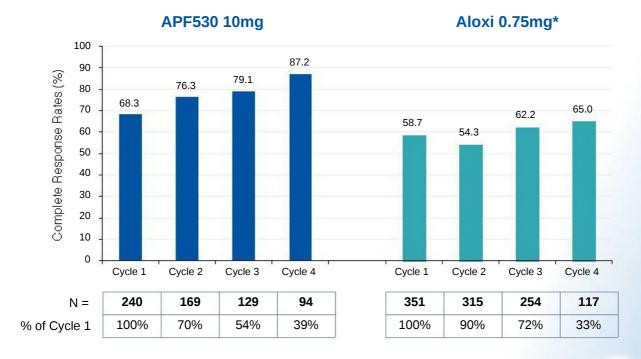


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## **APF530's Sustained Efficacy in Cycles 2-4**

# Complete Response Rates for Delayed-onset CINV in Patients Receiving Highly Emetogenic Chemotherapy



<sup>\*</sup> Sakai et al (Annals of Oncology, Vol. 19 Sept. 2008)



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### **Summary of APF530 Phase 3 Results**

- One of the largest, randomized, controlled clinical studies conducted in the CINV setting
- Non-inferiority to Aloxi was demonstrated
  - For both acute- and delayed-onset CINV
  - With both moderately and highly emetogenic chemotherapy
- APF530 was safe and well-tolerated
  - Incidence of adverse events comparable to Aloxi
- High response rates were observed in difficult chemotherapy regimens
- A high level of efficacy was maintained through multiple cycles of chemotherapy



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# **Regulatory Status**



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### **APF530 NDA Status**

- Submitted NDA in May 2009
- Received Complete Response Letter in March 2010
- FDA raised issues in three main areas:
  - Dosing system
    - Two-syringe system
  - Chemistry, Manufacturing, and Controls (CMC)
    - Sterilization
    - Characterization
  - Clinical/statistical
    - Specific studies
    - Presentation of data
- Held end-of-review meetings with FDA in 1Q 2011
  - No additional clinical efficacy studies requested
- Implementing plan to resubmit NDA in mid-2012



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### **Progress of NDA Resubmission**

#### Dosing System

- Change to single-syringe system completed
- Enhanced dosing instructions completed
- Overall, simpler and more convenient
  - Formative, non-clinical human factors study completed
  - Validation protocol under review by FDA

### Chemistry, Manufacturing, and Controls

- Change from bulk to terminal irradiation feasibility completed
- Additional specifications and assays for raw materials, polymer and drug product – in progress
- Manufacturing runs incorporating these changes in progress

#### Clinical/Statistical

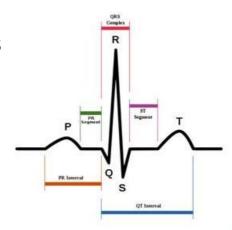
- Thorough QT study completed
- Metabolism study completed
- Phase 3 clinical data presentation revision in progress



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### **Thorough QT Study Background**

The QT interval represents the amount of time the heart's electrical system takes to repolarize after each beat



- Prolongation of the QT/QTc interval is associated with increased susceptibility to fatal cardiac tachyarrhythmias
- Thorough QT studies are intended to determine whether a drug has a threshold pharmacologic effect on cardiac repolarization
- Thorough QT studies are now routinely required by the FDA prior to drug approval

a.p. pharma

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### **Cardiac Safety Concerns in 5-HT3 Antagonist Class**

"Anzemet causes a dose-dependent prolongation in the QT, PR, and QRS intervals on an electrocardiogram (ECG) ... Anzemet injection should no longer be used to prevent nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy."

- FDA Drug Safety Communication, Dec. 17, 2010

"Ondansetron (Zofran) may increase the risk of developing abnormal changes in the electrical activity of the heart, which can result in a potentially fatal abnormal heart rhythm."

- FDA Drug Safety Communication, Sept. 15, 2011



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### **APF530 Thorough QT Study Design**

- Double-blind, single-site
- Four-way crossover
- 56 healthy male and female subjects
- Study Arms
  - SC APF530 1 g (granisetron 20 mg) 2x therapeutic dose
  - IV Granisetron 50μg/kg over 3 minutes 5x therapeutic dose
  - Oral Moxifloxacin 400 mg (Avelox®) positive control
  - Placebo 0.9% Normal Saline 0.84 mL
- Primary endpoint: the upper bound of the one-sided 95% confidence interval for placebo-adjusted, baselinesubtracted QTcF being less than 10 milliseconds at all time points



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### **APF530 Thorough QT Study Results**

### Primary Endpoint Achieved in Both Granisetron Dose Groups

- Both APF530 and IV granisetron dose groups did not approach or exceed the upperbound of 10 ms at any time point
- The primary end point was met irrespective of heart-rate correction methodology – QTcF, QTcI, QTcB
- PK/PD relationship was flat also showing no QTc signal

### Valid Study

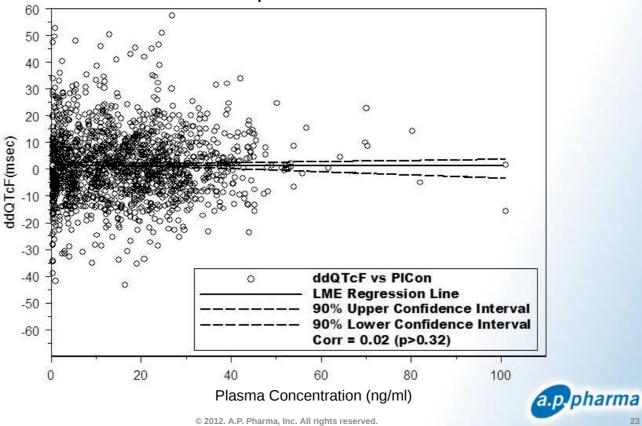
Moxifloxacin positive control group showed expected change – assay sensitivity reached



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### **Granisetron Thorough QT PK/PD Results**

#### ddQTcF vs. Granisetron Plasma Concentration Slope = -0.19



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### **Metabolism Study**

- Protocol reviewed by FDA prior to starting study
  - Single blind, single site
  - 14 healthy male and female subjects
  - Gather and analyze plasma and urine samples for metabolic products
- Results corroborated in humans the metabolism data previously observed in preclinical animal studies
  - Study results will be included in NDA resubmission



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### **U.S. Market Opportunity for APF530**

- More than 7 million cycles of chemotherapy administered each year
  - ~27% are highly emetogenic
  - ~46% are moderately emetogenic
- Significant unmet medical need for additional therapies to address delayed-onset CINV
- 5-HT3 antagonists are standard-of-care for CINV
  - Recommended in treatment guidelines NCCN, ASCO, ONS
  - An injectable 5-HT3 antagonist is co-administered with more than 90% of moderately and highly emetogenic regimens
- APF530 targets a \$900 million market opportunity in the US alone
  - In 2010, there were 5.14 million vials of injectable 5-HT3 antagonists administered for CINV
  - The average selling price for market leader Aloxi is \$175

Sources: Company-sponsored survey and analysis and Wolters Kluwer

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# 1<sup>st</sup> Generation 5-HT3 Antagonist Study Results

- Average Overall Complete Response\* rates
  - Moderately Emetogenic Chemotherapy ~ 42%
  - Highly Emetogenic Chemotherapy ~ 39%
- Overall Complete Response rates by study:

Moderately Emetogenic Chemotherapy - Ondansetron		
Gralla	Eisenberg	
50%	34%	

Highly Emetogenic Chemotherapy						
	Ondansetron Granisetron					
Aapro	Emend Label Studies			Emend Label	Saito	
25%	43%	52%	43%	33%	40%	

\*Overall Complete Response defined as no emesis and no rescue medications during 0 to 120 hours following chemotherapy



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### **Aloxi Study Results**

- Average Overall Complete Response rates
  - Moderately Emetogenic Chemotherapy ~ 57%
  - Highly Emetogenic Chemotherapy ~ 51%
- Overall Complete Response rates by study:

Moderately Emetogenic Chemotherapy					
Eisenberg	Gralla	Grunberg	Hajdenberg	APPA Ph 3	
46%	69%	59%	59%	52%	

Highly Emetogenic Chemotherapy			
Aapro	APPA Ph 3		
41%	62%		



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### **Antiemetic Treatment Patterns**

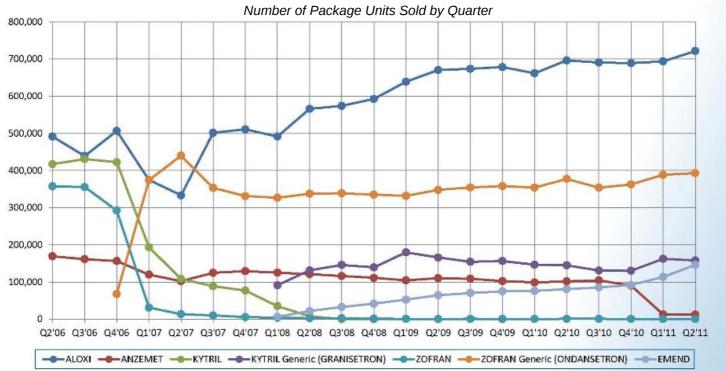
- Most chemotherapy patients will undergo 4 to 15 cycles of chemotherapy
- Doctors prefer to administer antiemetics on-site for moderately and highly emetogenic chemotherapy
  - Patient compliance is a significant concern
  - Average cost per CINV event ranges from \$4,000 to \$5,300
- Issues controlling CINV typically appear during the first few cycles
- If the initial prevention regimen is not effective, drugs are added and/or changed to address CINV in subsequent cycles
  - No long-acting injectable alternative to Aloxi is available to prevent delayed-onset CINV



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### **CINV Market Dynamics**





<sup>\*</sup> US Oncology data added starting Q1'09.

Source: Wolters Kluwer Usage in CINV estimated based on vial size

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### **Aloxi Market Performance**



#### **Pricing**

- Average Selling Price = \$175
- Medicare Reimbursement = \$186
- Wholesale Acquisition Cost ~ \$300 \$330

#### **Orange Book Patent Exclusivity**

- One patent expires April 2015
- Three patents expire January 2024



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### **CINV Market Dynamics: Conclusions**

- Aloxi has gained market share over last 3 years despite availability of generics for acute-onset CINV
  - From 48% in 2008 to 56% in 2Q 2011
- Kytril was widely used prior to Zofran® going generic
  - High physician acceptance of granisetron
- Aloxi dipped 30% when Zofran went generic but then regained 100% of its lost share two quarters later
- NK1 antagonists typically are only used as an adjunct to 5-HT3 antatgonists
  - Injectable Emend<sup>®</sup> units sold less than 10% of injectable units sold for CINV prevention



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### **APF530's Potential Competitive Positioning**

- Provides 5 days of prevention against chemotherapyinduced nausea and vomiting with a single injection
- Second, long-acting, injectable product on market
- Lack of complete effectiveness of available antiemetics indicates need for additional products to prevent CINV
  - Most patients undergo 4 to 15 cycles of chemotherapy

Product	Effective for Delayed- onset CINV	Cardiac Safety
Aloxi	Yes	Clean tQT results
Anzamet	No	QT effect – contraindicated for CINV
Zofran/ondansetron	No	Warning added to label
Kytril/granisetron	No	-
AFP530	Yes	Clean tQT results



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## **APF530 Commercialization Strategy**

- A.P. Pharma owns worldwide rights to APF530
- APF530 can be commercialized with a compact commercial infrastructure targeting oncologists
- Company evaluating partnering opportunities



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## **Financial Summary**

### Completed \$24MM PIPE in July 2011

Current resources expected to fund Company into 2013

Summary Statement of Operations (In thousands, except per share data)	Year Ended December 31, 2011
Revenue	\$ 646
Operating expenses	11,708
Other income (expenses) <sup>1</sup>	(752)
Net loss	\$ (11,814)
Net loss per share <sup>2</sup>	\$ (0.10)

Condensed Balance Sheet Data (In thousands)	December 31, 2011	December 31, 2010
Cash and cash equivalents	\$ 17,974	\$ 2,109
Working capital	\$ 14,547	\$ 941
Total assets	\$ 19,445	\$ 2,911
Total stockholders' equity	\$ 15,752	\$ 1,316

<sup>&</sup>lt;sup>1</sup> Includes discontinued operations



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<sup>&</sup>lt;sup>2</sup> Based on 120.3 million weighted average common shares outstanding

### A.P. Pharma Highlights

- Lead product candidate, APF530, is long-acting, injectable product for chemotherapy-induced nausea and vomiting (CINV)
  - Incorporates widely used 5-HT3 antagonist granisetron (Kytril®)
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### **Thank You**

A.P. Pharma, Inc.

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