

---

---

**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) September 19, 2011**

---

**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)

**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)
  - 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))
- 
-

**ITEM 8.01 Other Events.**

A.P. Pharma, Inc. (the "Company") updated its corporate presentation on September 19, 2011. 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](http://www.appharma.com). The Company does not undertake to update this presentation.

**ITEM 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation, dated September 2011

**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: September 19, 2011

/s/ John B. Whelan

John B. Whelan  
President and Chief Executive Officer



## Company Overview

OTCQB: APPA.PK  
September 2011

# 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.

# Stock Summary

---

**Company:** A.P. Pharma, Inc.

---

**Ticker:** OTCQB: APPA.PK

---

**Stock Price:** \$0.25 (9/16/11)

---

**Market Capitalization:** \$98.1 million<sup>1</sup>

---

**Cash:** \$23.6 million<sup>2</sup>

---

**Debt:** \$1.5 million<sup>3</sup>

<sup>1</sup> Based on 392.5 million as-converted common shares assuming the full conversion of convertible debt outstanding or subject to purchase rights, and 80 million warrants; not including options and 4M warrants with an exercise price of \$0.88/share

<sup>2</sup> Pro forma as of June 30, 2011 including net proceeds from July 1, 2011 PIPE funding

<sup>3</sup> As of June 30, 2011

# Management

---

<b>John B. Whelan</b>	President, CEO & CFO	Raven Biotechnologies Eos Biotechnology Hewlett Packard/Agilent
<b>Michael A. Adam, Ph.D.</b>	Senior Vice President & Chief Operating Officer	Spectrum Pharmaceuticals Pfizer Bristol-Myers Squibb
<b>John Barr, Ph.D.</b>	Senior Vice President, Research and Development	Cortech
<b>Kristin Ficks</b>	Head of Commercial Operations	Gemini Healthcare Celgene Eisai/MGI Pharma

# A.P. Pharma Highlights

---

- Lead product candidate, APF530, is long-acting, injectable product for chemotherapy-induced nausea and vomiting (CINV)
  - Incorporates widely used 5HT3 antagonist - 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 1H 2012
- APF530 targets a \$900 million market opportunity in US alone
  - Could be second, long-acting, injectable product on market
- A.P. Pharma has pipeline of additional products based on its Biochronomer™ drug delivery technology





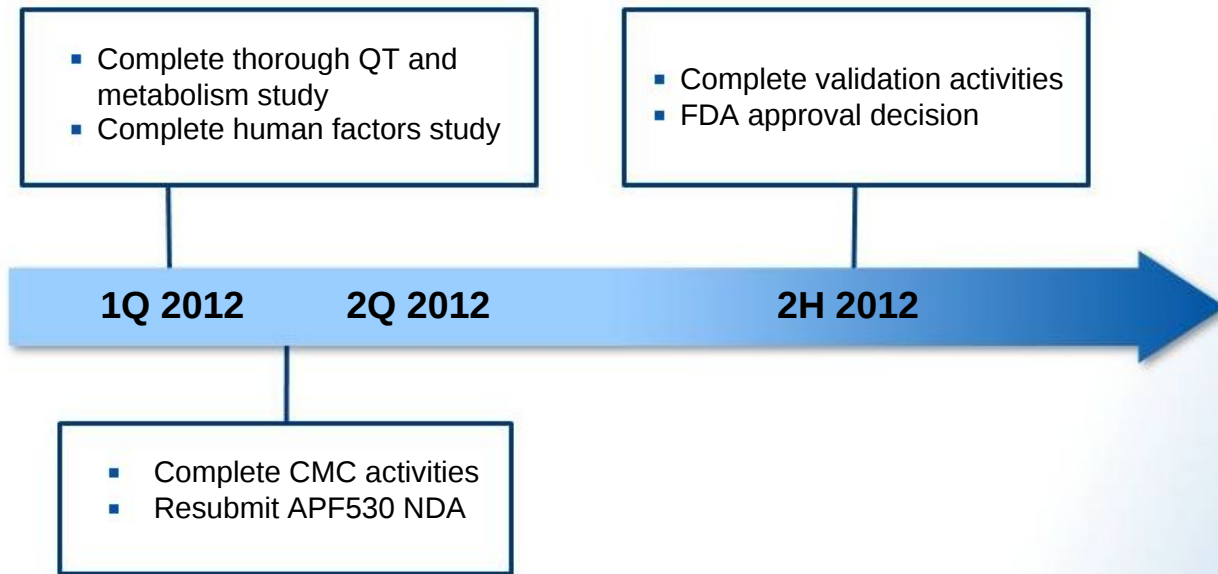
# Product Pipeline

Product Candidate	Potential Indication	Drug	Target Duration	Preclinical	Phase 1	Phase 2	Phase 3	NDA
<b>APF530</b>	Chemotherapy-induced nausea and vomiting	Granisetron	5 days					
<b>APF112</b>	Post-surgical pain relief (opiate-sparing)	Mepivacaine	3 days					
<b>APF580</b>	Sustained pain relief	Buprenorphine	7 days					
<b>APF328</b>	Post-surgical pain and inflammation (orthopedic surgery)	Meloxicam	Up to two weeks					
<b>APF505</b>	Chronic pain and inflammation (osteoarthritis)	Meloxicam	Up to six weeks					

All leverage same polymer technology used in APF530



# APF530 Milestones 2011 - 2012





# Clinical Summary

September 2011

© 2011. A.P. Pharma, Inc. All rights reserved.



# APF530 Pivotal Phase 3 Study Overview

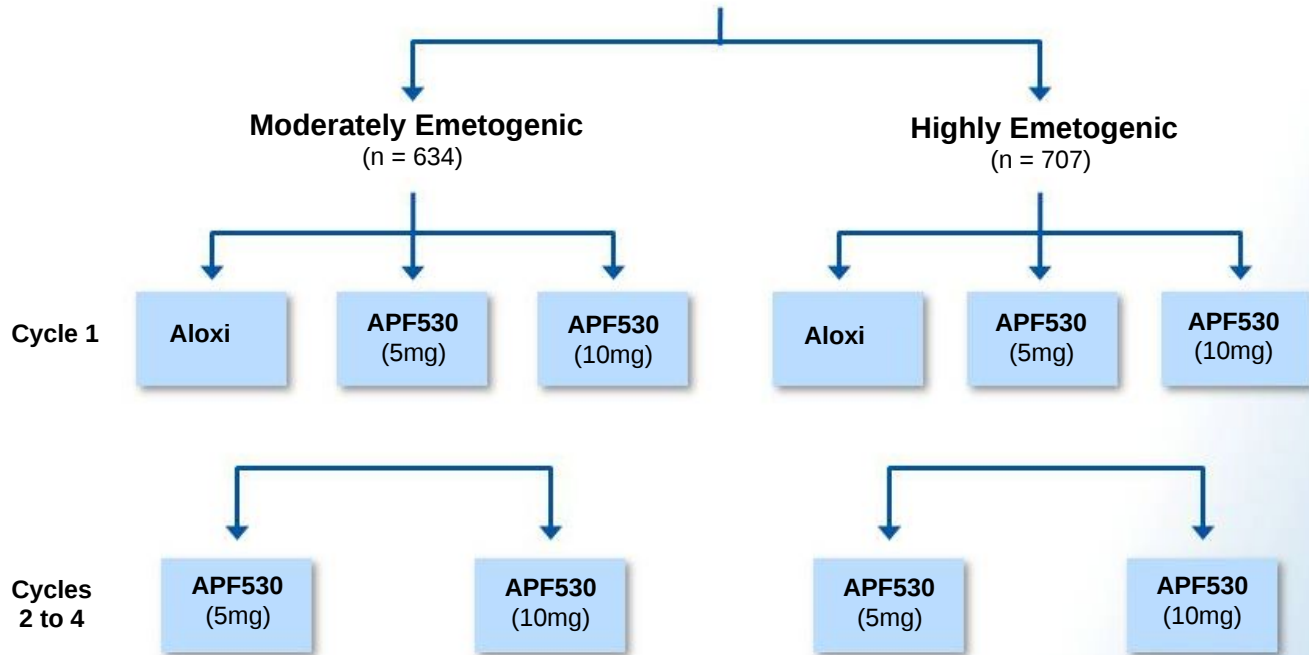
---

- 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  $\pm 15\%$  margin was used to establish non-inferiority

# APF530 Phase 3 Study Design

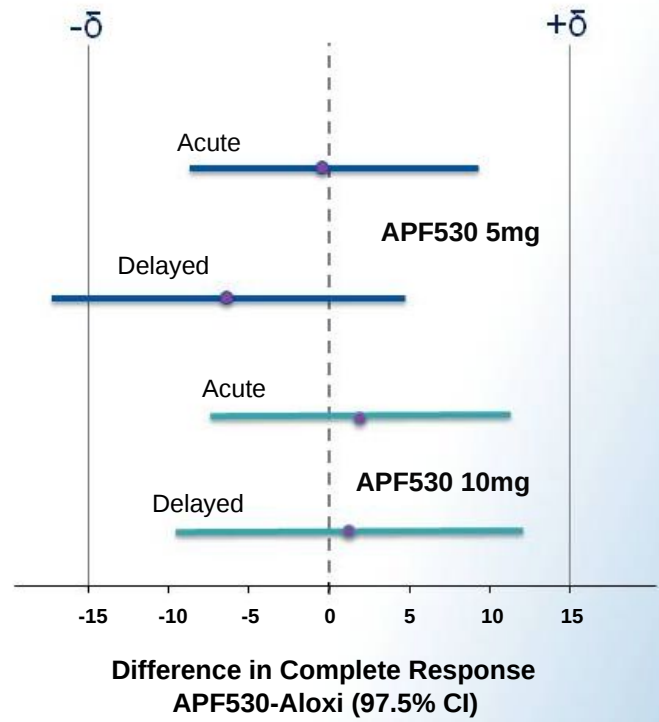
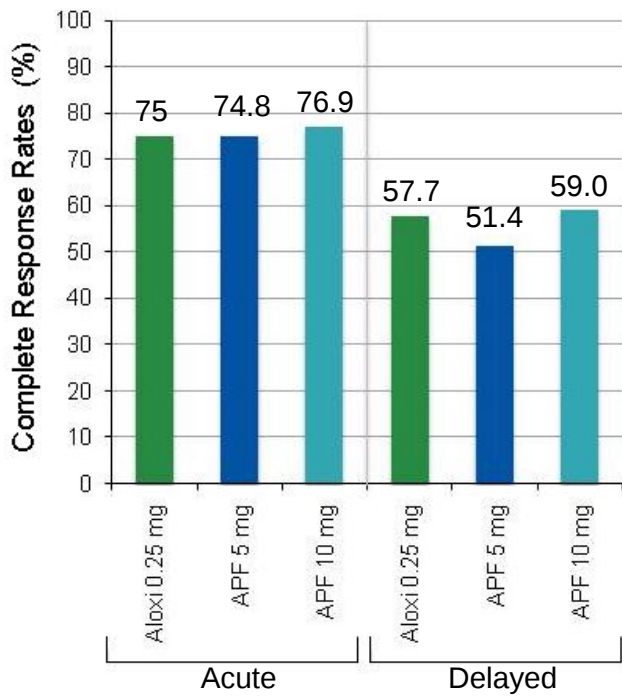
## Patient Stratification

(n = 1,341)



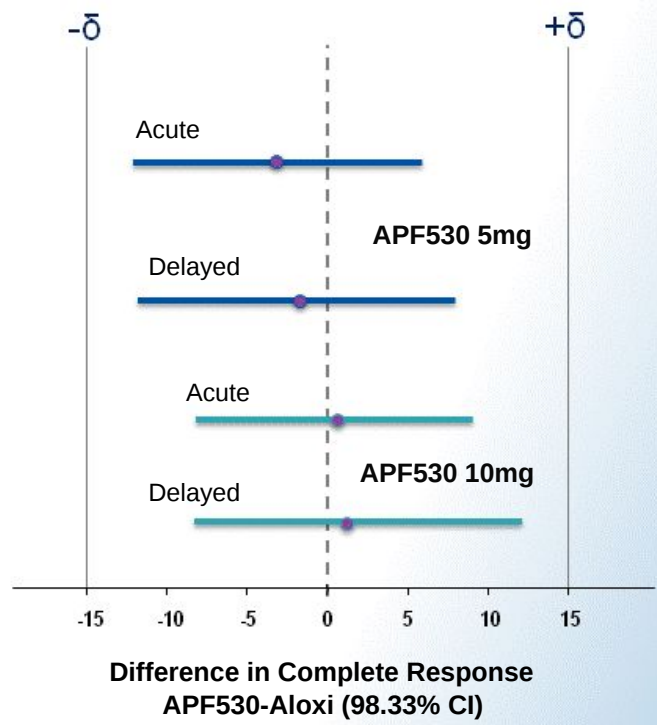
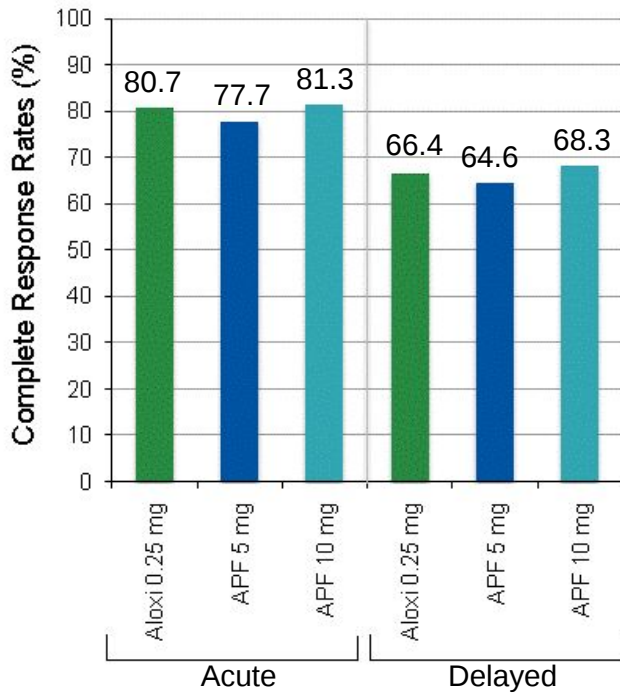
# Primary Efficacy Results: Complete Response

## Patients Receiving Moderately Emetogenic Chemotherapy



# Primary Efficacy Results: Complete Response

## Patients Receiving Highly Emetogenic Chemotherapy



# Safety Summary

## Reported in Cycle 1

	APF530 5 mg		APF530 10 mg		Aloxi 0.25 mg	
	N	%	N	%	N	%
<b>Serious Adverse Events</b>	1	0.2	0	0	0	0
<b>Discontinued Due to Adverse Event</b>	1	0.2	1	0.2	0	0
<b>Frequent Adverse Events</b>						
<b>Gastrointestinal disorders</b>						
▪ Constipation	62	13.4	72	15.4	62	13.4
▪ Nausea	56	12.1	60	12.8	41	8.9
▪ Diarrhea	49	10.6	44	9.4	39	8.4
▪ Abdominal pain	21	4.5	13	2.8	28	6.0
<b>Nervous System</b>						
▪ Headache	31	6.7	47	10.0	45	9.7
<b>Injection Site*</b>					<b>Placebo (NaCl)</b>	
▪ Bruising	78	16.8	93	19.9	41	8.9
▪ Erythema (redness)	33	7.1	51	10.9	14	3.0
▪ Nodule (lump)	22	4.7	50	10.7	3	0.6
▪ Pain	16	3.4	33	7.1	5	1.1

\* >90% of injection site reactions were reported as mild; one patient discontinued due to injection site reaction



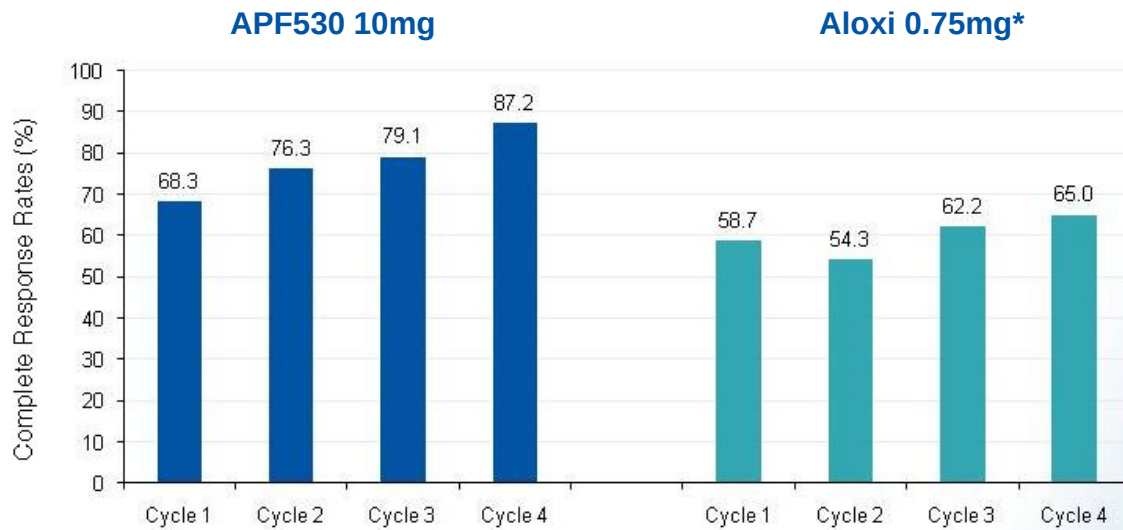
# APF530's Efficacy with Difficult Chemo Regimens

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



# APF530's Sustained Efficacy in Cycles 2-4

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



N =	<b>240</b>	<b>169</b>	<b>129</b>	<b>94</b>
% of Cycle 1	100%	70%	54%	39%

<b>351</b>	<b>315</b>	<b>254</b>	<b>117</b>
100%	90%	72%	33%

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

# Summary of APF530 Phase 3 Results

---

- 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



# Regulatory Status and Strategy

September 2011

© 2011. A.P. Pharma, Inc. All rights reserved.



17

# 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
- Implementing plan to resubmit NDA in 1H 2012



# Outcome of FDA Meetings

---

## ■ Dosing System

- Changed to single-syringe system
  - Single glass syringe for storage and administration
  - Smaller needle: switch from 1" x 16 gauge to 5/8" x 18 gauge thin-wall
- Enhanced dosing instructions
- Overall, simpler and more convenient
  - Non-clinical human factors study planned

## ■ Chemistry, Manufacturing, and Controls

- Changed from bulk to terminal irradiation
- Additional specifications and assays for raw materials, polymer and drug product

## ■ Clinical/Statistical

- Thorough QT study – Initiated in August 2011
- Metabolism study
- Revised presentation format for Phase 3 data
- No additional clinical efficacy studies requested





# Commercial Opportunity

September 2011

© 2011. A.P. Pharma, Inc. All rights reserved.



20

# 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
- 5HT3 antagonists are standard-of-care for CINV
  - Recommended in treatment guidelines – NCCN, ASCO, ONS
  - An injectable 5HT3 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 5HT3 antagonists administered for CINV
  - The average selling price for market leader Aloxi is \$179

Sources: Company-sponsored survey and analysis and Wolters Kluwer

September 2011

© 2011. A.P. Pharma, Inc. All rights reserved.



21



# 1<sup>st</sup> Generation 5HT3 Antagonists 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

# 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%

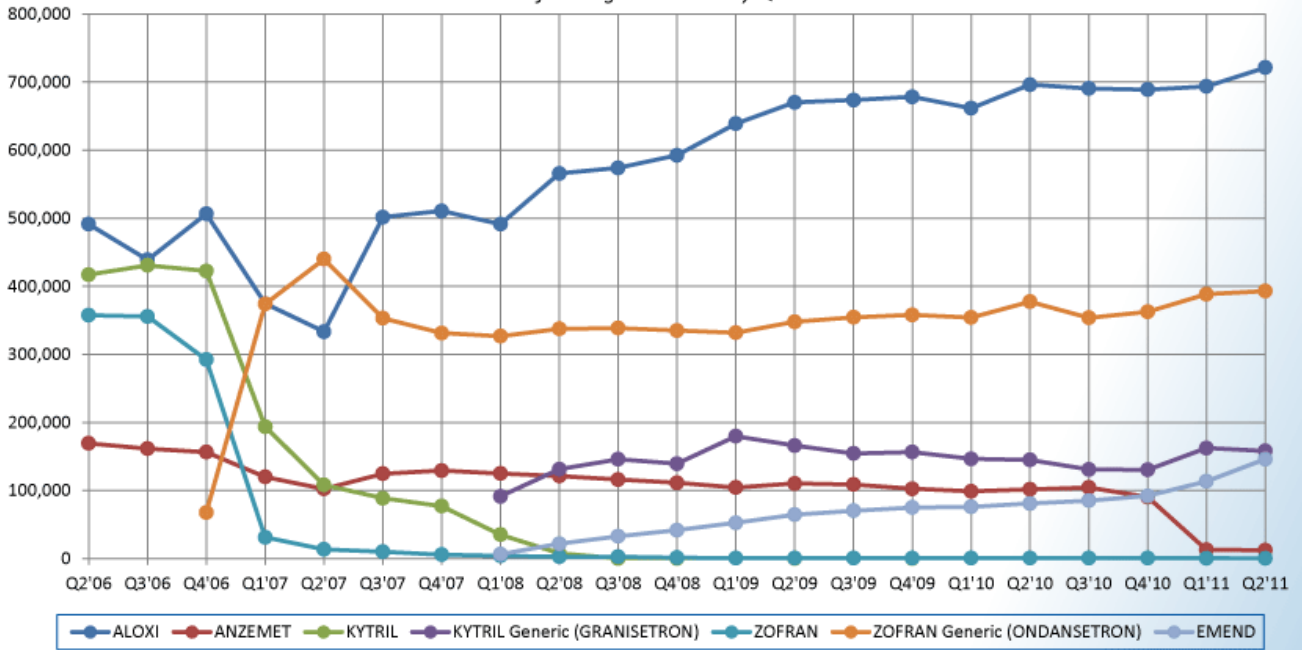
# Antiemetic Treatment Patterns

- 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

# CINV Market Dynamics

## Injectable Drugs for the Prevention of CINV

Number of Package Units Sold by Quarter



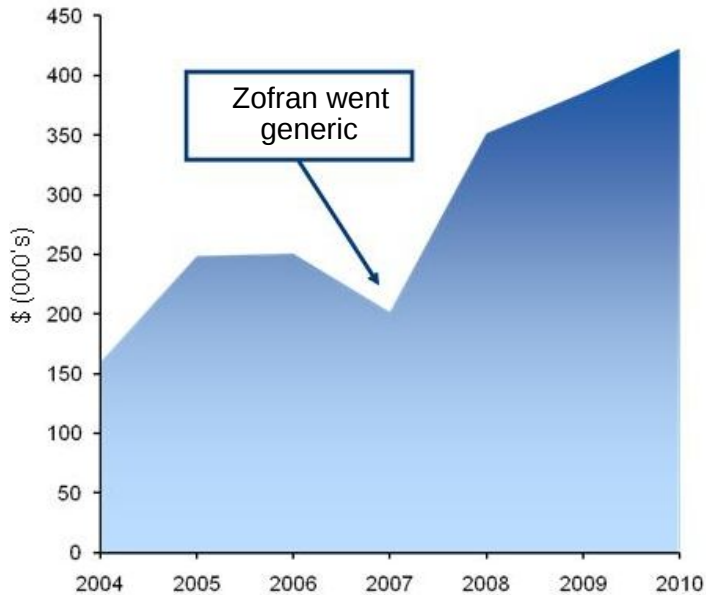
\* US Oncology data added starting Q1'09.

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



# Aloxi Market Performance

## Aloxi Sales



## Pricing

- Average Selling Price = \$179
- Medicare Reimbursement = \$189
- Wholesale Acquisition Cost ~ \$300 - \$330

## Orange Book Patent Exclusivity

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

# 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 5HT3 antatgonists
  - Injectable Emend® units sold less than 10% of injectable units sold for CINV prevention

# Competitive Landscape

- APF530 would be one of two injectable products approved for preventing delayed-onset CINV
  - 5HT3 antagonists are standard-of-care
  - 1<sup>st</sup> generation products have limited effectiveness in preventing delayed-onset CINV
  - Patients continue to experience CINV despite currently available products
  - Most chemotherapy patients will undergo 4 to 15 cycles of chemotherapy
- Large Phase III study supporting APF530's use
  - Non-inferior efficacy to Aloxi
  - Similar safety profile to granisetron and Aloxi
  - High response rates were observed in difficult chemotherapy regimens
  - A high level of efficacy was maintained through multiple cycles of chemotherapy

# APF530 Commercialization Strategy

---

- A.P. Pharma owns worldwide rights to APF530
- APF530 can be commercialized with a compact commercial infrastructure targeting oncologists
- Company to evaluate partnering opportunities before and after FDA approval



# 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)	Six Months Ended June 30, 2011
Revenue	\$ 646
Operating expenses	3,501
Other income (expenses) <sup>1</sup>	(496)
Net loss	\$ (3,351)
Net loss per share <sup>2</sup>	\$ (0.08)

Condensed Balance Sheet Data (In thousands)	June 30, 2011	Dec 31, 2010
Cash and cash equivalents	\$ 21,331 <sup>3</sup>	\$ 2,109
Working capital	\$ 18,626	\$ 941
Total assets	\$ 22,121	\$ 2,911
Total stockholders' equity	\$ 18,892	\$ 1,316

<sup>1</sup> Includes discontinued operations

<sup>2</sup> Based on 40.1 million weighted average common shares outstanding

<sup>3</sup> Includes \$20.3 million in advance proceeds received in June 2011

# A.P. Pharma Highlights

- Lead product candidate, APF530, is long-acting, injectable product for chemotherapy-induced nausea and vomiting (CINV)
  - Incorporates widely used 5HT3 antagonist - 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 1H 2012
- APF530 targets a \$900 million market opportunity in US alone
  - Could be second, long-acting, injectable product on market
- A.P. Pharma has pipeline of additional products based on its Biochronomer™ drug delivery technology



# Thank You

A.P. Pharma, Inc.

OTCQB: APPA.PK

September 2011

