
**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) January 7, 2013

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") will deliver a corporate presentation at meetings during the week of January 7, 2013. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation, dated January 2013

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: January 7, 2013

/s/ John B. Whelan

John B. Whelan
President and Chief Executive Officer



Company Overview

OTCBB: APPA
January 2013

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: OTCBB: APPA.OB

Stock Price: \$0.60 (1/4/13)

Market Capitalization: \$280.3 million¹

Cash: \$60.0 million²

Debt: \$4.7 million²

¹ Based on 499.0 million fully diluted, as-converted common shares assuming the full conversion of convertible debt outstanding and 80 million warrants using treasury stock method; not including options

² As of September 30, 2012

Senior Management

John B. Whelan	President & CEO	Raven Biotechnologies Eos Biotechnology Hewlett Packard/Agilent
Michael A. Adam, Ph.D.	Senior Vice President & Chief Operating Officer	Spectrum Pharmaceuticals Pfizer/Agouron Bristol-Myers Squibb
Mark Gelder, M.D.	Senior Vice President & Chief Medical Officer	GE Healthcare Bayer Healthcare Wyeth
Robert Rosen	Senior Vice President & Chief Commercial Officer	Bayer Healthcare Sanofi-Synthelabo Imclone

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®)
 - 5-day delivery profile
 - Reduces both acute- and delayed-onset CINV with single injection
 - Patent coverage into 2024
- APF530 shown to be non-inferior to market leader Aloxi®
 - 1,341-patient, randomized, controlled, Phase 3 study
- FDA PDUFA Action Date of March 27, 2013
 - Resubmitted NDA for APF530 in September 2012
 - Addressed issues raised in Complete Response Letter
 - Product launch planned for 2H 2013
- APF530 targets a \$900 million market opportunity in US alone*
 - Recent competitive setbacks could enhance commercial uptake
 - Could be second, long-acting, injectable product on market
- A.P. Pharma has the potential to leverage its Biochronomer™ drug delivery technology into other opportunities

*Branded market estimate using 2011 units based on Wolters Kluwer and Aloxi ASP

January 2013

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Important APF530 Milestones

Milestone	Timing	Status
Successful End-of-Review Meetings with FDA	1Q 2011	✓
Successful Completion of Thorough QT and Metabolism Studies	1Q 2012	✓
Completed \$53.6MM PIPE Financing	3Q 2012	✓
Successful Completion of Human Factors Validation Study	3Q 2012	✓
Successful Completion of CMC Activities	3Q 2012	✓
Resubmitted NDA	Sept 2012	✓
Key Commercial Organization Hires	4Q 2012	✓
FDA PDUFA Action Date	March 27, 2013	
Target Product Launch	2H 2013*	

* Indicates expected milestone timing



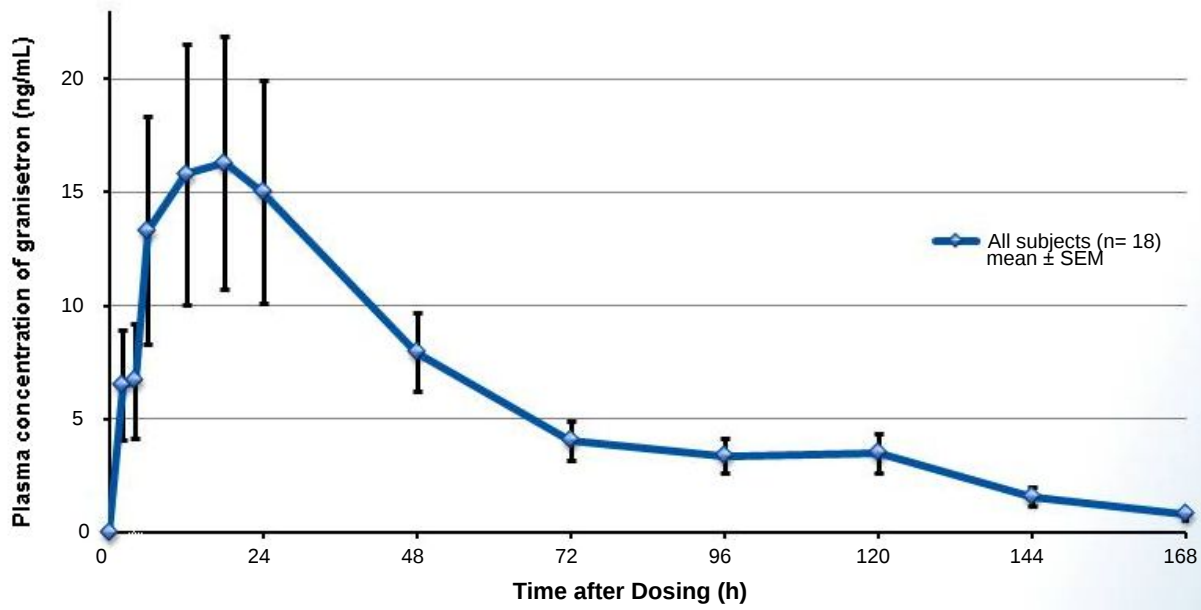
Clinical Summary

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

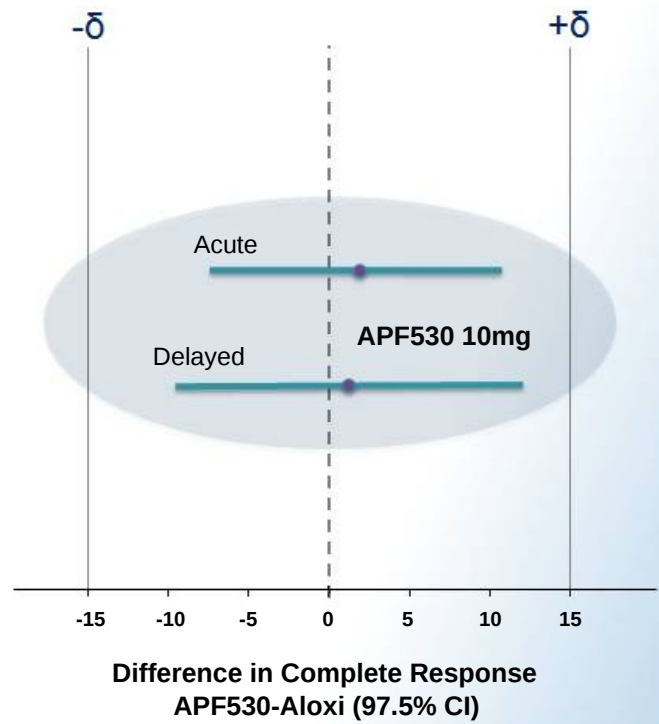
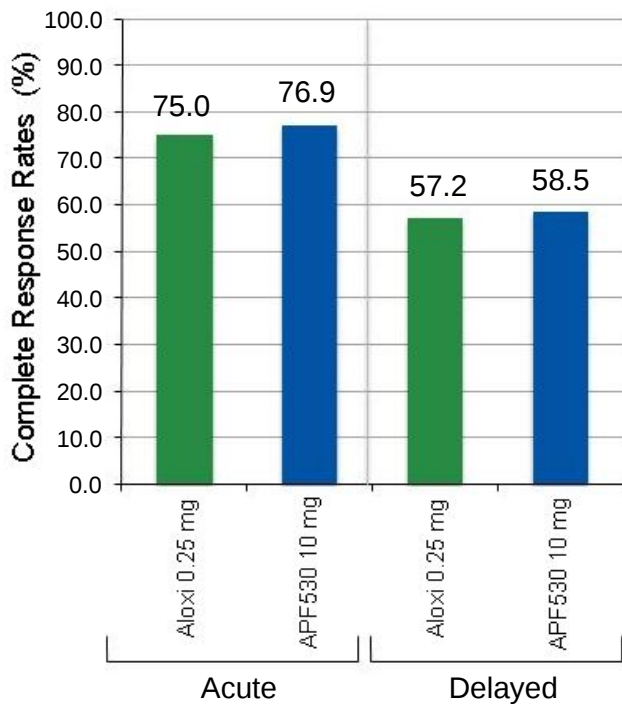
5-Day Profile: APF530 Pharmacokinetics

Granisetron is released rapidly following injection of APF530 and continues to be released over a 5-day period.



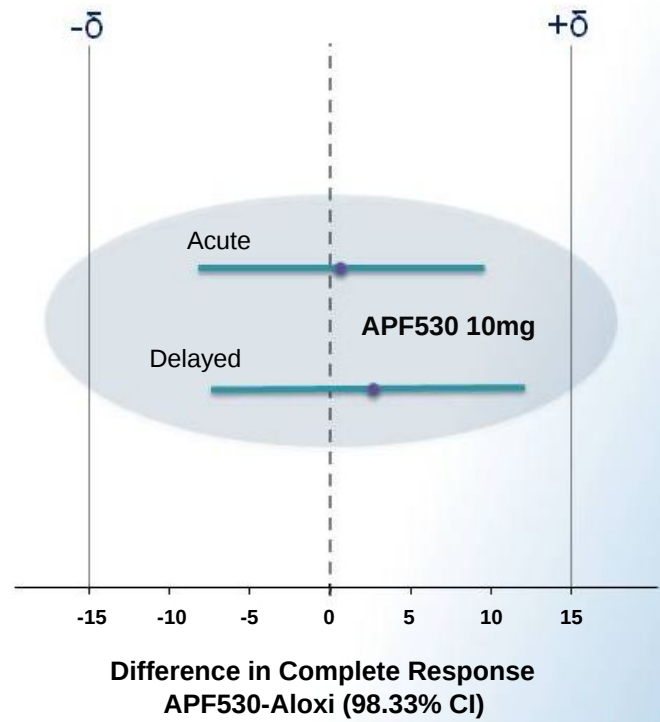
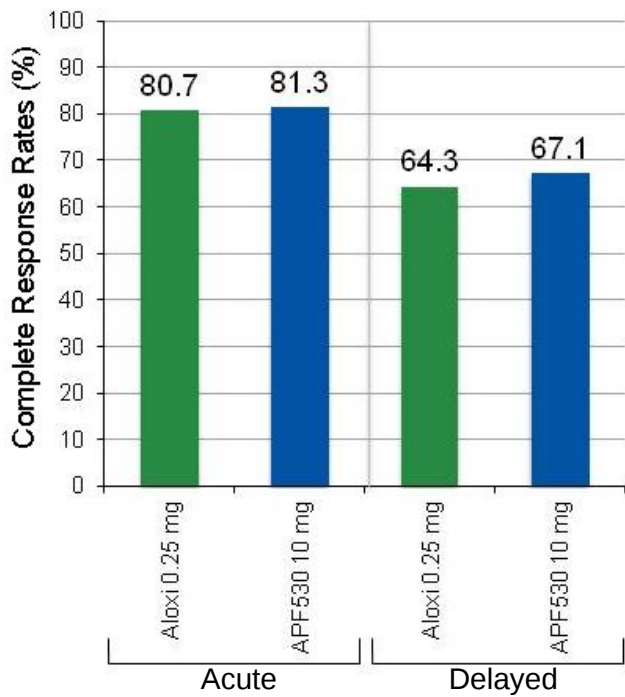
Primary Efficacy Results: Complete Response

Patients Receiving Moderately Emetogenic Chemotherapy



Primary Efficacy Results: Complete Response

Patients Receiving Highly Emetogenic Chemotherapy



Safety Summary

Reported in Cycle 1

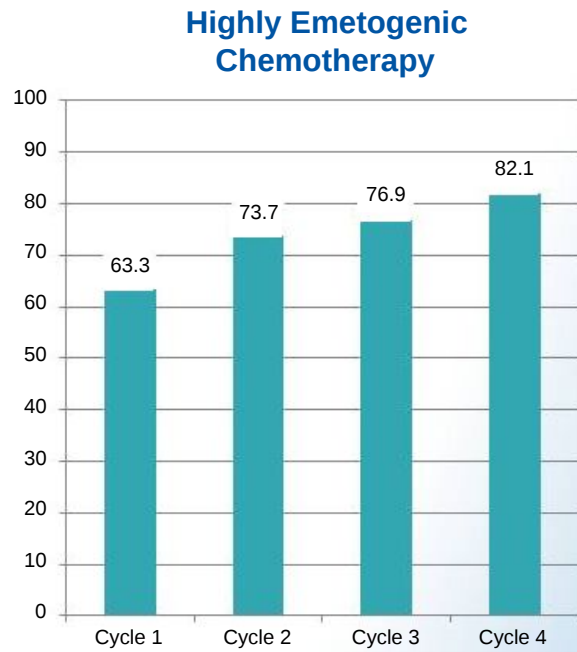
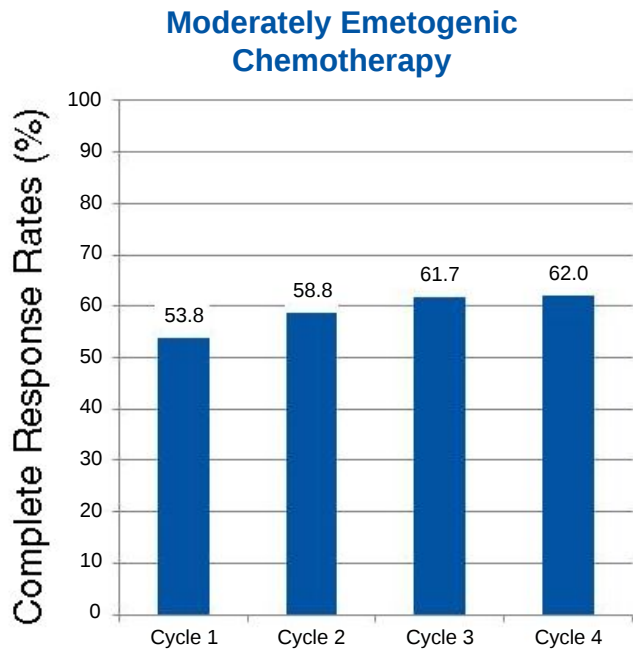
	APF530 10 mg		Aloxi 0.25 mg	
	N	%	N	%
Drug Related Serious Adverse Events ¹	0	0	0	0
Discontinued Due to Adverse Event ¹	1	0.2	0	0
Frequent Adverse Events				
Gastrointestinal Disorders				
▪ Constipation	72	15.4	62	13.4
▪ Diarrhea	44	9.4	39	8.4
▪ Abdominal pain	13	2.8	28	6.0
Nervous System				
▪ Headache	47	10.0	45	9.7
Injection Site ²				
			Placebo (NaCl)	
▪ Bruising	93	19.9	41	8.9
▪ Erythema (redness)	51	10.9	14	3.0
▪ Nodule (lump)	50	10.7	3	0.6
▪ Pain	33	7.1	5	1.1

¹ APF530 5 mg dose studied in separate arm of the phase 3 study; one pulmonary embolism in morbidly obese patient on day 16 (0.2%); one dyspepsia event (0.2%)

² >90% of injection site reactions were reported as mild; one patient discontinued due to injection site reaction

Efficacy through Multiple Chemotherapy Cycles

Overall Complete Response Rates¹ for APF530 10 mg



¹Overall Complete Response defined as no emesis and no rescue medications during 0 to 120 hours following chemotherapy

Overall Complete Response Rates¹

First Generation 5-HT3 Antagonists

MEC		HEC					
Ondansetron		Ondansetron				Granisetron	
Gralla	Eisenberg	Aapro	Emend Label Studies			Emend Label	Saito
50%	34%	25%	43%	52%	43%	33%	40%

Aloxi – Second Generation

MEC					HEC	
Eisenberg	Gralla	Grunberg	Hajdenberg	APPA Ph 3	Aapro	APPA Ph 3
46%	69%	59%	59%	52%	41%	62%

¹Overall Complete Response defined as no emesis and no rescue medications during 0 to 120 hours following chemotherapy. Protocol criteria may vary across studies.

APF530's Efficacy with Difficult Chemo Regimens¹

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

¹Data from post-hoc analysis. Not statistically significant.

Summary of APF530 Phase 3 Results

- One of the largest, randomized, controlled clinical studies conducted in the CINV setting
- Bioerodible polymer technology releases granisetron to prevent CINV over 5 days
- Non-inferiority to Aloxi was demonstrated at 10 mg
 - For both acute- and delayed-onset CINV
 - With both moderately and highly emetogenic chemotherapy
- APF530 was well-tolerated
 - Incidence of adverse events comparable to Aloxi
- Good response rates were observed in difficult chemotherapy regimens
- Efficacy was maintained through multiple cycles of chemotherapy



Regulatory Status

APF530 NDA Status

- Submitted NDA in May 2009 under 505(b)(2) filing pathway
- 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
- Resubmitted NDA in September 2012
- PDUFA Action Date of March 27, 2013

Addressed Complete Response Letter Issues

■ Dosing System

- Change to single-syringe system
- Enhanced dosing instructions
- Successfully evaluated in a Human Factors study

■ Chemistry, Manufacturing, and Controls

- Change from bulk to terminal irradiation
- Additional specifications and assays for raw materials, polymer and drug product
- Three registration lots completed implementing these changes

■ Clinical/Statistical

- Thorough QT study
- Metabolism study
- Phase 3 clinical data presentation revision

Improved Dosing System

Original Two-syringe System

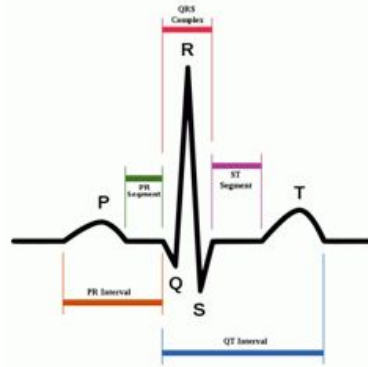


New Single-syringe System



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
- *FDA has raised QT cardiac safety concerns with 5-HT₃ antagonists*

Zofran Use in CINV Restricted

- Most widely used generic 5-HT3 now restricted
- FDA issued a Drug Safety Communication June 29, 2012
 - “The use of a single 32 mg intravenous dose of ondansetron should be avoided. New information indicates that QT prolongation occurs in a dose-dependent manner, and specifically at a single intravenous dose of 32 mg.”
 - “No single intravenous dose of ondansetron should exceed 16 mg due to the risk of QT prolongation.”
 - “The lower dose intravenous regimen of 0.15 mg/kg every 4 hours for three doses may be used in adults with chemotherapy-induced nausea and vomiting.”
- Results of Zofran tQT study
 - 32 mg IV dose causes 20 ms increase in QTcF
 - 8 mg IV dose causes 6 ms increase in QTcF
- FDA removed 32 mg dose from market December 4, 2012
- Impact on sales may be significant



Anzemet in CINV Previously Removed

- FDA issued a Drug Safety Communication Dec. 17, 2010
 - “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.”
- Anzemet label changed to remove CINV indication
- IV Anzemet sales fell to near zero in one quarter

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 50 µg/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, baseline-subtracted QTcF being less than 10 milliseconds at all time points

APF530 Thorough QT Study Results

■ Primary Endpoint Achieved in Both Granisetron Dose Groups

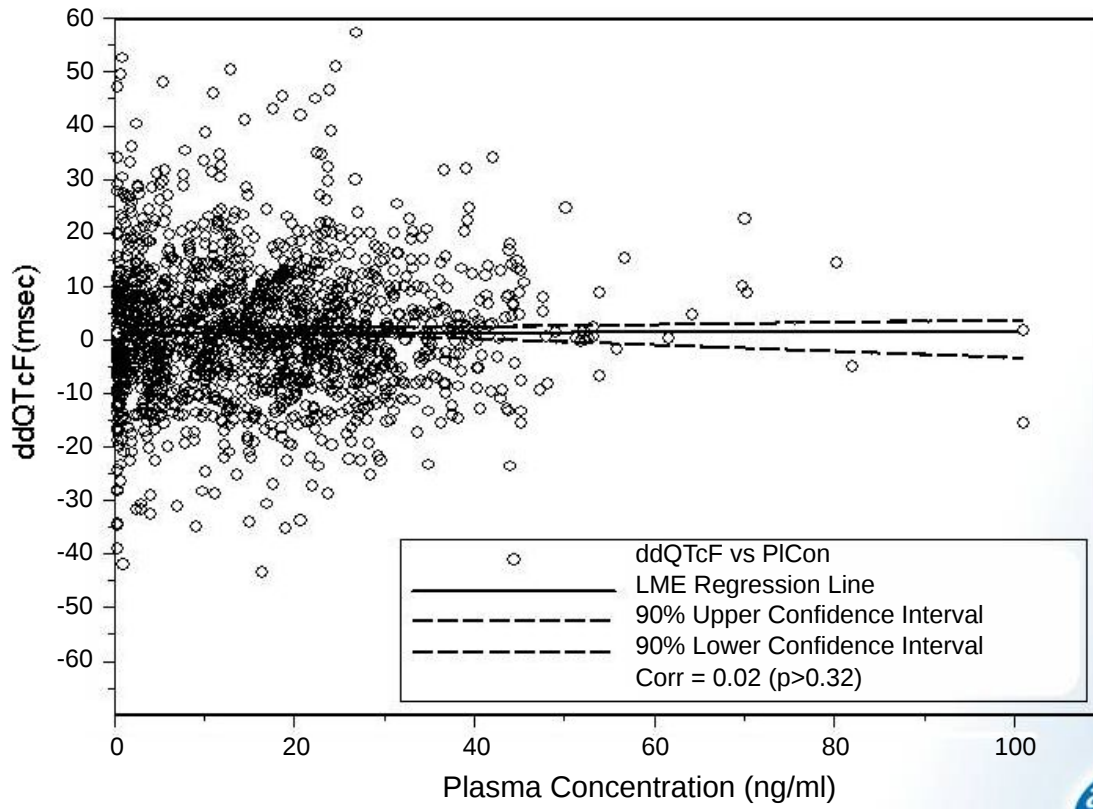
- Both APF530 and IV granisetron dose groups did not approach or exceed the upperbound of 10 ms at any time point
- The primary end point was met irrespective of heart-rate correction methodology – QTcF, QTcI, QTcB
- PK/PD relationship was flat – also showing no QTc signal

■ Valid Study

- Moxifloxacin positive control group showed expected change – assay sensitivity reached

Granisetron Thorough QT PK/PD Results

ddQTcF vs. Granisetron Plasma Concentration
Slope = -0.019



Metabolism/Fate of Polymer Study

- FDA requested study at end-of-review meeting in 1Q 2011
- Purpose of study is to demonstrate fate of polymer in human subjects
 - Confirm polymer breaks down into same hydrolytic end-products as seen in animals
 - Confirm lack of other detectable polymer-related metabolites
- Protocol reviewed by FDA prior to initiating study
 - Single blind, single site
 - 14 healthy male and female subjects
 - Gather and analyze plasma and urine samples for metabolic products
- Study objectives achieved
 - Confirmed polymer breaks down into same hydrolytic end-products as in animals
 - Confirmed lack of other detectable polymer-related metabolites

Human Factors Study

- Assess the Instructions-for-Use and usability of APF530 in simulated oncology setting
 - Follows June 2011 FDA guidance: “Applying Human Factors and Usability Engineering to Optimize Medical Device Design”
 - Initial risk assessment followed by iterative process of formative studies
- Validation study completed following formative studies
- New single-syringe design improves overall usability

	Mean Usability Scores ¹	
	<u>Previous Syringe</u>	<u>Current Syringe</u>
Ease	3.1	8.3
Comfort	5.2	9.4
Control	7.7	9.5

¹10 – very difficult, 10 – very easy

- All subjects successfully followed instructions
- Average injection time reduced by 45%



Commercial Opportunity

Continuing Unmet Need in CINV

NCI Statement On The Existing Unmet Need in CINV¹

“Despite the use of both first-generation and second-generation 5-HT₃ receptor antagonists, the control of acute CINV, and especially delayed nausea and vomiting, is suboptimal, and there is considerable opportunity for improvement with either the addition or substitution of new agents in current regimens.”

Need for long-acting antiemetic therapies

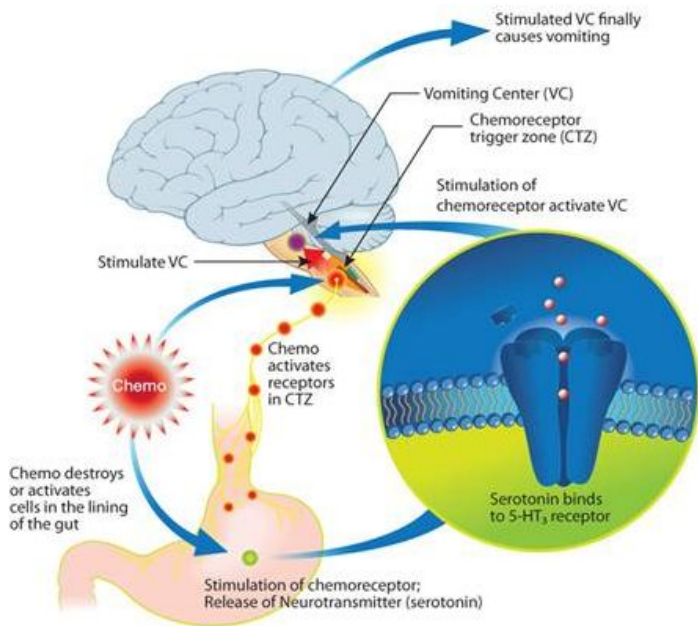
- Delayed CINV (days 2-5) remains particularly challenging to manage
- Significant portion of patients fail to respond to Aloxi

Need for antiemetic therapies with sustained efficacy

- CINV risk increases over multiple chemotherapy cycles

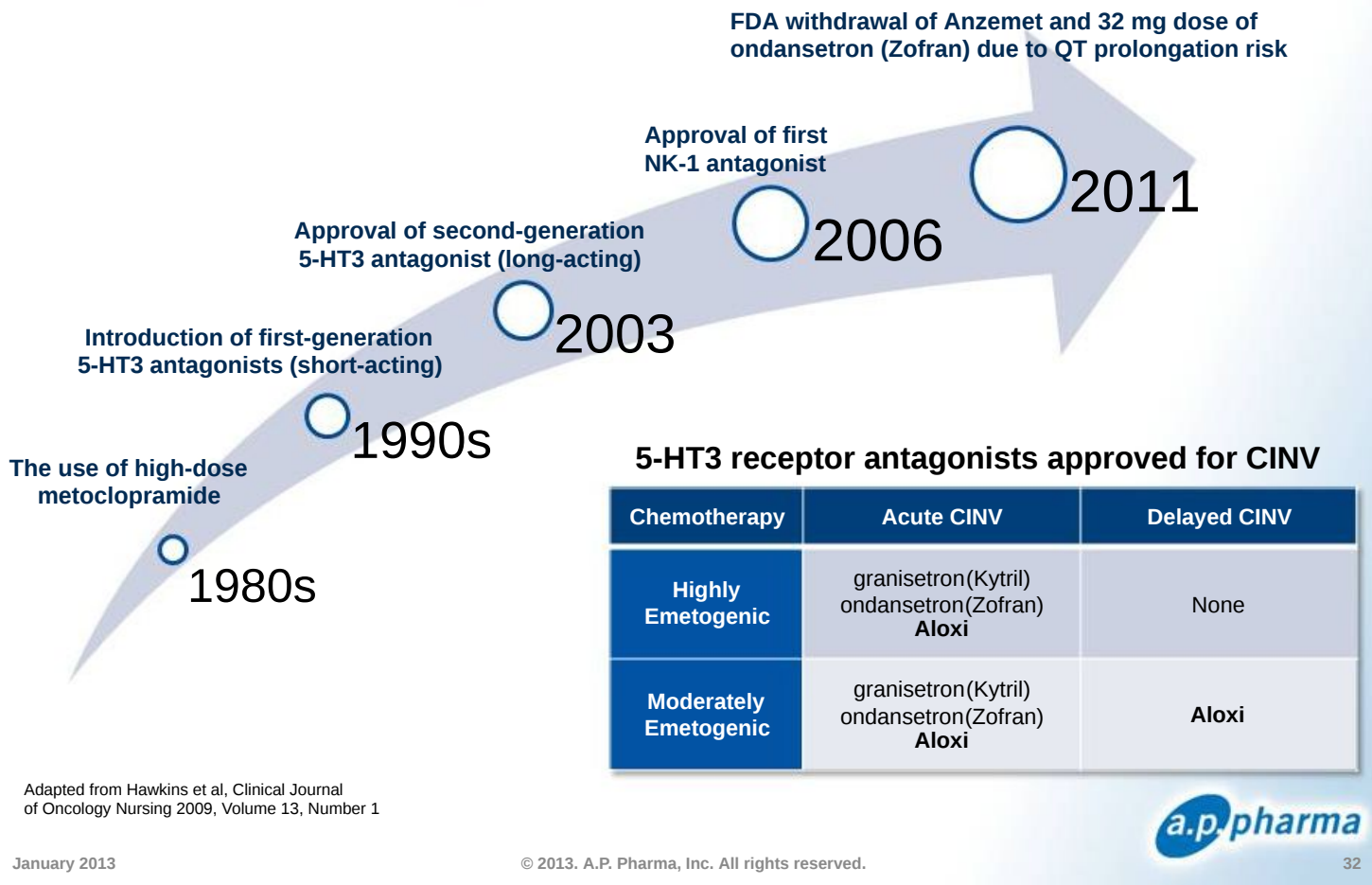
¹ Available at: http://www.cancer.gov/cancertopics/pdq/supportivecare/nausea/HealthProfessional/page6#Section_183

Addressing Debilitating Effects of CINV



- More than 7 million cycles of chemotherapy administered each year
 - ~27% are highly emetogenic
 - ~46% are moderately emetogenic
- Most chemotherapy patients will undergo 4-15 cycles of chemotherapy
- 5-HT₃ antagonists are standard-of-care for CINV
 - Recommended in ASCO, NCCN and ONS guidelines
 - NK-1 antagonists are only indicated in combination with 5-HT₃ antagonists
- An Injectable 5-HT₃ antagonist is co-administered with more than 90% of MEC and HEC regimens
- If initial regimen is non-effective, drugs are added or changed to address CINV in subsequent cycles

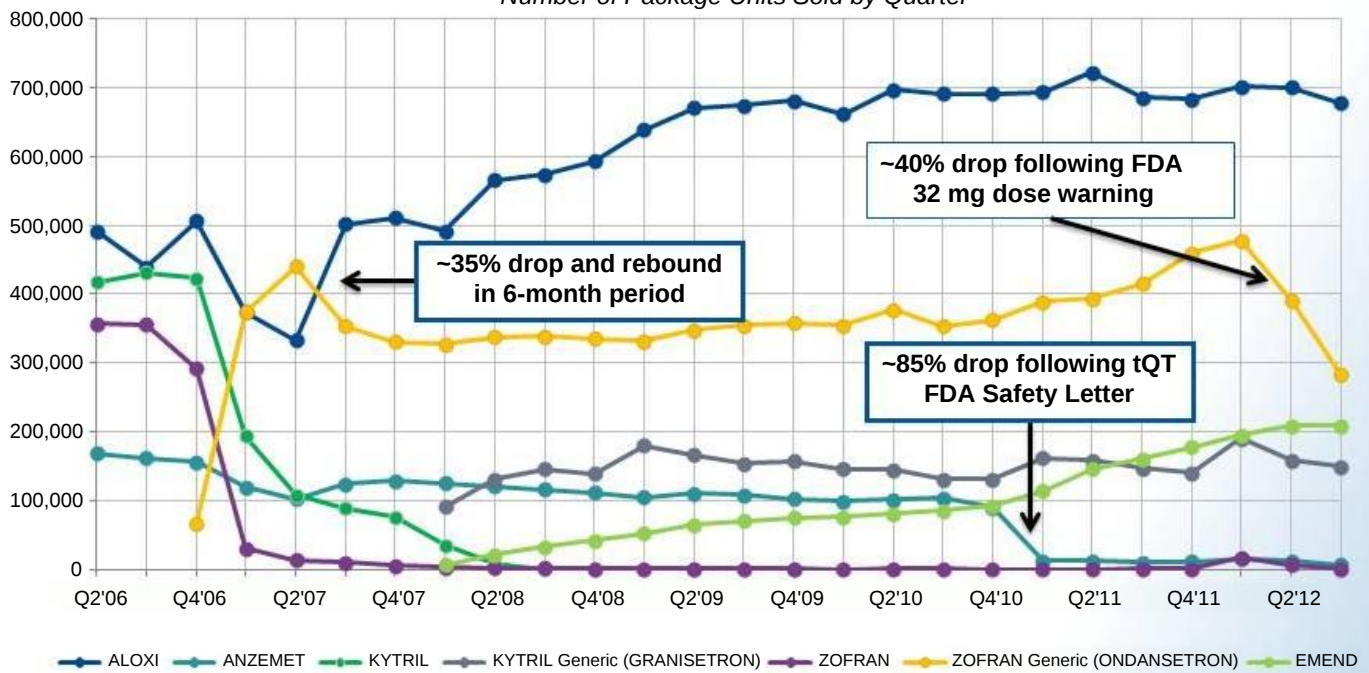
5-HT3 Antagonists Have Made a Substantial Impact



Adapted from Hawkins et al, Clinical Journal of Oncology Nursing 2009, Volume 13, Number 1

U.S. CINV Market Dynamics

Injectable Drugs for the Prevention of CINV
Number of Package Units Sold by Quarter

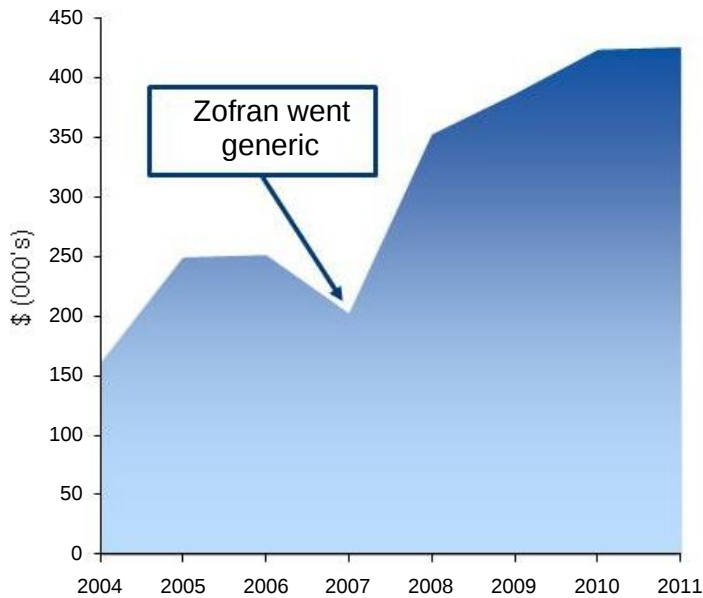


* US Oncology data added starting 1/2009.

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

Aloxi Market Performance

Aloxi Sales



Pricing

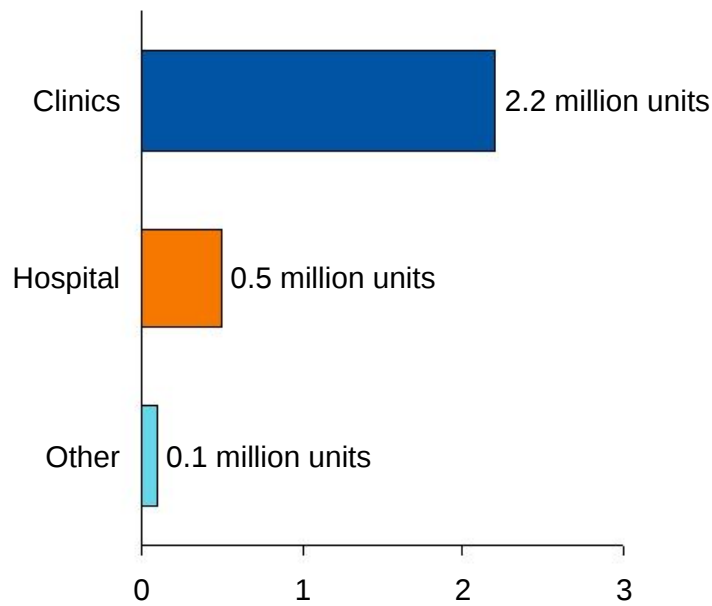
- Average Selling Price = \$175
- Medicare Reimbursement = \$186
- Wholesale Acquisition Cost ~ \$380

Orange Book Patent Exclusivity

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

~80% of Aloxi Is Used in Clinics

U.S. Aloxi Units by Class of Trade – 12 Months Ending June 30th 2012



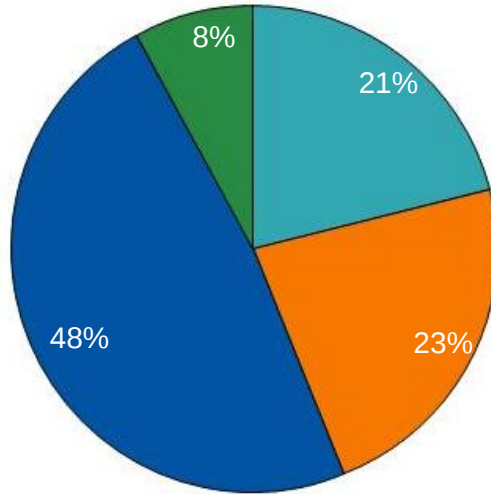
IMS Health and Source Healthcare Analytics (WKH) data and Eisai Co., Ltd. published sales figures



>90% of Aloxi Units Contracted Through GPOs

Clinic Units by GPO – 12 Months Ending June 30th 2012

USO Onmark ION Misc

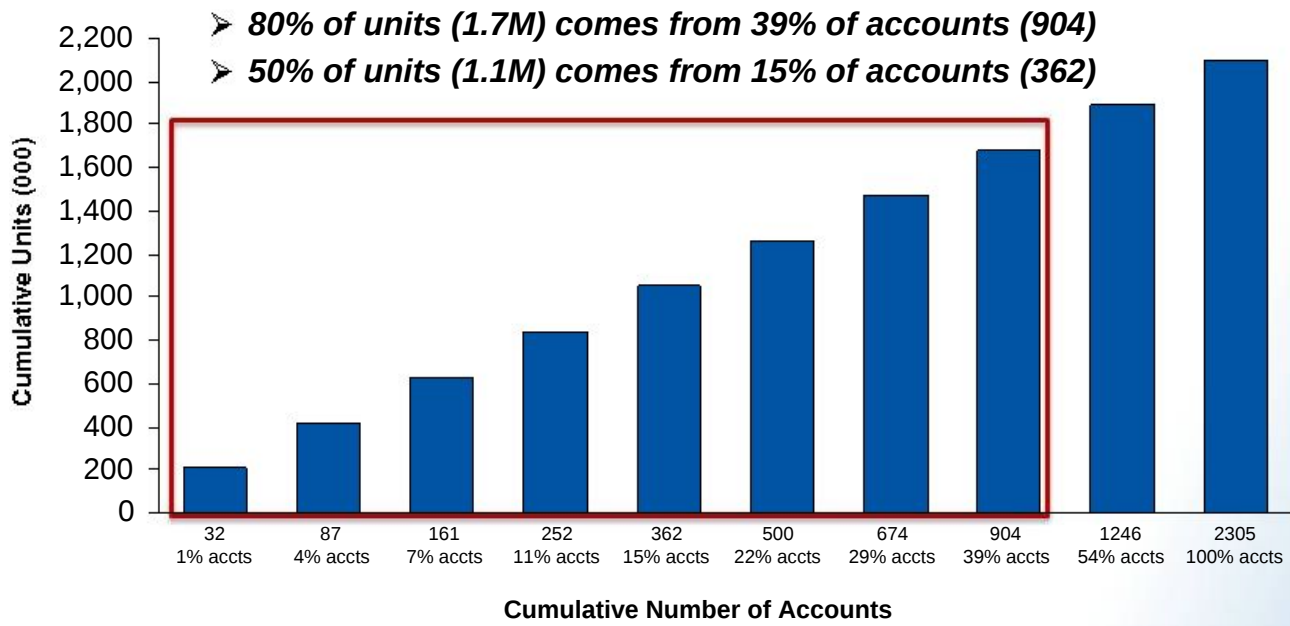


2.2 Million Clinic Units

IMS Health and Source Healthcare Analytics (WKH) data and Eisai Co., Ltd. published sales figures



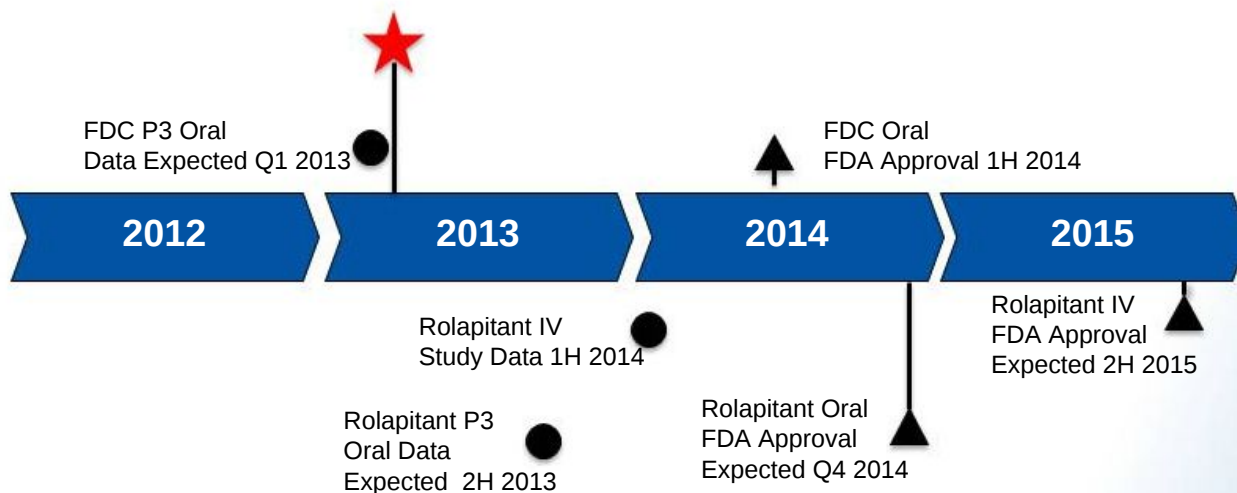
Aloxi Clinical Use Is Largely Concentrated



WKH Data Oct. 2012 – Clinic Analysis

No New Injectable 5-HT3 Drug on Horizon

APF530 FDA PDUFA Date



Candidate	Class	Indication	Sponsor	Possible Launch
APF530	5-HT3 Extended release	Prevention of CINV in MEC/HEC	A.P. Pharma	2H 2013
FDC**	FDC combines netupitant (NK-1) with palonosetron (Aloxi) in a single oral tablet	Prevention of CINV in MEC/HEC	Eisai / Helsinn	Oral 2H 2014
Rolapitant*	Long-acting NK-1	Prevention of CINV in MEC/HEC <u>only in combination with 5-HT3</u>	Tesaro	Oral 2H 2014 IV 2H 2015

*Company reports, Leerink Swann; **Clinical Trials.gov NCT01339260 FDC = Fixed Dose Combo; PDUFA date expected 12-15 months post P3 data
 EUR-1025 development program uncertain (once-a-day oral modified-release formulation of ondansetron)



APF530 Proposed Label

■ Proposed indication submitted in NDA

INDICATIONS AND USAGE

1.1 Chemotherapy-Induced Nausea and Vomiting

APF530 is indicated for:

- Moderately emetogenic cancer chemotherapy (MEC)- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses
- Highly emetogenic cancer chemotherapy (HEC)- prevention of acute nausea and vomiting associated with initial and repeat courses

APF530 Planned Market Positioning

- If approved by FDA, APF530 and Aloxi would be the only “long acting” 5-HT3 antagonists approved for the prevention of acute and delayed-onset CINV

		Acute Onset (0-24 Hours)		Delayed Onset (24-120 Hours)	
		Moderately Emetogenic	Highly Emetogenic	Moderately Emetogenic	Highly Emetogenic
Second Generation	APF530	✓	✓	✓	No Approved Products
	Aloxi	✓	✓	✓	
First Generation	Kytril Zofran	✓	✓		

APF530 and Aloxi Profiles

Attribute	APF530	Aloxi
Indication	MEC – acute and delayed CINV HEC – acute CINV	MEC – acute and delayed CINV HEC – acute CINV
MOA	5-HT3 receptor antagonist	5-HT3 receptor antagonist
Dosing	SC injection once per cycle	IV once per cycle
Long acting agent	Bioerodible polymer technology releases granisetron over 5 days	~ 40 hour half life
Efficacy	Non-inferiority to Aloxi	
	Effective in difficult chemotherapy regimens	Effective in difficult chemotherapy regimens
	Demonstrated efficacy through multiple cycles in MEC and HEC	
Safety	Headache, constipation, injection site bruising and pain Clean QT profile	Headache and constipation Clean QT profile

Summary

- \$900 million market potential for injectable 5-HT3 antagonists*
- APF530 demonstrated non-inferiority to the market share leader Aloxi
- APF530 product profile
 - 5-day release PK profile
 - Good response in difficult chemotherapy regimens
 - Efficacy through multiple cycles of chemotherapy
 - Clean QT results
- Current market dynamics are stale with minimal investment providing opportunities to become the market leader
- Competitive landscape creates opportunity with the removal of Anzemet and Zofran 32mg
- Greater than 80% of Aloxi sales are in the community setting and highly concentrated consistent with other supportive care products

*Branded market estimate using 2011 units based on Wolters Kluwer and Aloxi ASP

January 2013

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A.P. Pharma Product Lifecycle Considerations

- APF530 covered by multiple patents
 - 2 patents covering combination of polymer, excipients and drug expire in 2021
 - 3 patents covering APF530 expire in 2024
- Polymer-based injectable products are difficult to copy independent of IP
 - ANDA FDA requirements for injectable products
 - Must have same inactive ingredients in the same concentration as the reference listed drug
 - Polymers are complex mixtures of varying-length molecules, making characterization for “sameness” very challenging

Financial Summary

- Expect cash sufficient to fund commercial launch of APF530

Summary Statement of Operations (In thousands, except per share data)	Year Ended December 31, 2011	Nine Months Ended September 30, 2012
Revenue	\$ 646	\$ –
Operating expenses	11,708	15,203
Other income (expenses)	(752)	(408)
Net loss	\$ (11,814)	\$ (15,611)
Net loss per share ¹	\$ (0.10)	\$ (0.07)

Condensed Balance Sheet Data (In thousands)	September 30, 2012
Cash and cash equivalents	\$ 60,048
Total assets	\$ 61,761
Total stockholders' equity	\$ 57,517

¹ Based on 120.3 and 225.1 million weighted average common shares outstanding for the periods ended December 31, 2011 and September 30, 2012, respectively

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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 - Could be second, long-acting, injectable product on market
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January 2013

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Thank You

A.P. Pharma, Inc.

OTCBB: APPA

January 2013

