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) November 12, 2013

A.P. Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33221**	**94-2875566**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

123 Saginaw Drive **Redwood City CA**	**94063**
(Address of principal executive offices)	**(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 2.02. Results of Operations and Financial Condition

On November 12, 2013, A.P. Pharma, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 2013 (the "Earnings Press Release"). A copy of the Earnings Press Release is furnished as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

ITEM 7.01 Regulation FD Disclosure

On November 12, 2013, the Company issued a press release announcing the expansion of its pipeline of sustained release product candidates, as described in the press release furnished herewith as Exhibit 99.2.

The Company released a corporate update on November 12, 2013, a copy of which is furnished herewith as Exhibit 99.3. 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.

The information provided in Item 7.01 of this report, including Exhibits 99.2 and 99.3, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall the information or Exhibits 99.2 or 99.3 be deemed incorporated by reference in any filings under the Securities Act of 1933, as amended.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Earnings Press Release, dated November 12, 2013
99.2	Press Release, dated November 12, 2013
99.3	Corporate Presentation, dated November 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: November 12, 2013

/s/ Brian G. Drazba
Brian G. Drazba
Chief Financial Officer

For Immediate Release

A.P. Pharma Announces Third Quarter 2013 Financial Results and Highlights Recent Corporate Progress

REDWOOD CITY, Calif. – November 12, 2013 – A.P. Pharma, Inc. (OTCBB: APPA.OB), a specialty pharmaceutical company, today reported financial results for the quarter ended September 30, 2013.

“During the third quarter, we made significant progress toward resubmission of the NDA for Sustol™ (formerly known as APF530) targeted for the end of the first quarter 2014,” said Dr. Barry Quart, CEO of A.P. Pharma. “Today, we also separately announced an important expansion of our pipeline including unveiling a new program targeting the relief of post-surgical pain using our proprietary Biochronomer™ polymer platform and plans to pursue the expansion of our lead program for the treatment of chemotherapy induced nausea and vomiting.”

A.P. Pharma’s pain relief program utilizes the company’s polymer-based Biochronomer drug delivery platform to continuously release anesthetic agents directly at the source of pain over a period of several days. The company is targeting a prolonged period of anesthetic release such that therapeutic concentrations of active drug are achieved rapidly and maintained for at least 72 hours. The potential benefit of A.P. Pharma’s prolonged release profile is to achieve rapid pain relief, maintaining higher levels of active drug at the site of the pain over time to potentially provide greater relief from pain, and to maintain pain relief for up to 5 days following surgery.

The company’s expansion of its leading drug program for the treatment of chemotherapy-induced nausea and vomiting (CINV) is centered around a post-approval study to commence in 2014 which is designed to demonstrate the utility of its lead agent, Sustol™, in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently there is no approved 5-HT3 receptor antagonist for the treatment of delayed HEC.

Results of Operations

A.P. Pharma’s net loss for the third quarter of 2013 was $12.9 million, or $0.04 per share, compared to a net loss of $6.1 million, or $0.02 per share, for the third quarter of 2012. Loss from continuing operations was higher in the current fiscal quarter primarily due to increased spending related to manufacturing development expenses and higher personnel costs, including stock compensation expense, and expenses related to the resignation of the Company’s former chief executive officer during the third quarter of 2013.

Cash and cash equivalents as of September 30, 2013 were $22.6 million, compared to $53.5 million at December 31, 2012. Net cash used in operating activities was $31.1 million for the nine months ended September 30, 2013. The Company believes that its current cash resources are sufficient to fund its operations into 2014.

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About APF530

A.P. Pharma's lead product candidate, APF530, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT3 antagonist approved for the prevention of delayed-onset CINV. APF530 contains the 5-HT3 antagonist granisetron formulated in the Company's proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for APF530 because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks. The Company's lead product, APF530, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting. For further information, please visit the Company's web site at www.appharma.com.

(financial tables follow)

A.P. Pharma, Inc.
Condensed Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Operating expenses:				
Research and development	$ 5,885	$ 3,626	$ 23,188	$ 10,022
General and administrative	6,779	2,428	17,438	5,181
Total operating expenses	12,664	6,054	40,626	15,203
Operating loss	(12,664)	(6,054)	(40,626)	(15,203)
Interest expense, net	(209)	(195)	(614)	(402)
Loss from continuing operations	(12,873)	(6,249)	(41,240)	(15,605)
Income (loss) from discontinued operations	—	128	—	(6)
Net loss	$ (12,873)	$ (6,121)	$ (41,240)	$ (15,611)
Basic and diluted net loss per share:				
Loss from continuing operations	$ (0.04)	$ (0.02)	$ (0.13)	$ (0.07)
Net loss	$ (0.04)	$ (0.02)	$ (0.13)	$ (0.07)
Shares used to compute basic and diluted net loss per share	307,496	274,488	306,096	225,063

A.P. Pharma, Inc.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 22,597	$ 53,506
Prepaid expenses and other current assets	763	584
Total current assets	23,360	54,090
Property and equipment, net	2,857	1,752
Other long-term assets	153	130
Total assets	$ 26,370	$ 55,972
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,250	$ 1,912
Accrued expenses	2,360	1,750
Convertible notes payable to related parties, net of discount	888	492
Total current liabilities	5,498	4,154
Stockholders' equity:		
Common stock	3,110	3,024
Additional paid-in capital	242,589	232,381
Accumulated deficit	(224,827)	(183,587)
Total stockholders' equity	20,872	51,818
Total liabilities and stockholders' equity	$ 26,370	$ 55,972

Forward-looking Statements

This news release 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 the potential approval of APF530 and the potential timing for such approval, if approved at all, as well as risks relating to qualifying for listing on the NASDAQ Capital Market, capital resources and liquidity, satisfactory completion of clinical studies, progress in research and development programs, launch and acceptance of new products and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. 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.

Contacts

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Michael Rice
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Email: mrice@lifesciadvisors.com

and

Corporate Contact:
A.P. Pharma, Inc.
Stephen R. Davis, Executive Vice President and Chief Operating Officer
Office Phone: 650-366-2626

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Exhibit 99.2

For Immediate Release

A.P. Pharma Announces Pipeline Expansion

☐ *First program moving into development is a long-acting anesthetic for post-surgical pain* ☐

☐ *Planned post marketing study for Sustol with goal of label expansion in delayed onset CINV in patients receiving HEC regimens* ☐

REDWOOD CITY, Calif. – November 12, 2013 – A.P. Pharma, Inc. (OTCBB: APPA.OB), a specialty pharmaceutical company, today reported it has initiated a program to expand its pipeline of sustained release products, including a new program targeting the relief of post-surgical pain. The company also announced it will pursue a post-approval expansion of its leading drug program for the treatment of chemotherapy-induced nausea and vomiting (CINV) with the goal of demonstrating the utility of its lead agent, Sustol™(formerly known as APF530) in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently there is no approved 5-HT3 receptor antagonist for the treatment of delayed HEC.

“AP Pharma continues to make significant progress toward resubmission of the NDA for Sustol targeted for the end of the first quarter 2014,” said Dr. Barry Quart, CEO of A.P. Pharma. “Our plan to initiate a new clinical trial to further expand the potential label is an indicator of our high level of confidence in this product and is part of a broader plan to build a CINV franchise. With the anticipated FDA approval of our lead product, it will be much more efficient to develop and register other drugs utilizing the same proprietary, Biochronomer™, sustained-release technology. We are very excited to move our most advanced program for post-surgical pain relief into full-scale development. This product candidate has the potential to significantly reduce the need for opiates post-surgery and reduce the length of hospital stay post-surgery.”

Post-surgical Pain Program

A.P. Pharma’s pain relief program utilizes the company’s polymer-based Biochronomer drug delivery platform to continuously release anesthetic agents directly at the source of pain over a period of several days. The company is targeting a prolonged period of anesthetic release such that therapeutic concentrations of active drug are achieved rapidly and maintained for at least 72 hours. The potential benefit of A.P. Pharma’s prolonged release profile is to achieve rapid pain relief, maintaining higher levels of active drug at the site of the pain over time to potentially provide greater relief from pain, and to maintain pain relief for up to 5 days following surgery. The current market leader, Exparel®, reduced mean pain intensity only during the first 24 hours following study drug administration; between 24 and 72 hours after study drug administration, there was minimal to no difference between EXPAREL and placebo treatments.

- more -

In animal models, the company has demonstrated continuous release of the pain-relieving agent bupivacaine for more than seven days and release of the agent ropivacaine for greater than five days. Bupivacaine and ropivacaine are well established anesthetic agents that provide short term pain relief. Based on the superior profile of ropivacaine, the company is focusing its development efforts on this anesthetic agent.

A.P. Pharma expects to move its pain program into human clinical trials in 2014. The Company will pursue approval utilizing the Food and Drug Administration's 505(b)(2) approval process, which provides for much faster and less costly development than traditional drug approval. In 2012 approximately 24.8 million procedures were performed that were associated with post-operative pain.

Expansion of CINV Opportunity

A.P. Pharma is currently pursuing the approval of Sustol for the treatment of acute and delayed CINV in patients administered moderately emetogenic chemotherapy (MEC) agents and for the treatment of acute CINV in HEC. Currently, there is no long-acting 5-HT3 receptor antagonist approved for the treatment of delayed HEC. However, published results of large clinical trials shows that approximately 35 percent of patients receiving HEC agents experience breakthrough CINV in the delayed phase with the currently available standard three-drug regimen, leaving a significant unmet medical need for better therapy.

With the goal of addressing this significant unmet medical need and to further differentiate Sustol from all other 5-HT3 antagonists, A.P. Pharma plans to initiate a clinical study in 2014 designed to establish the utility of Sustol in the treatment of delayed onset CINV in patients receiving HEC regimens. The randomized two-arm study will compare approximately 500 HEC administered patients receiving Sustol plus the NK-1 inhibitor fosaprepitant to a similar number of HEC administered patients receiving ondansetron plus fosaprepitant. The company expects this study to complete following the resubmission and resulting PDUFA date for Sustol. If the study is successful, the company will seek to expand the Sustol label (if approved) to incorporate delayed HEC treatment on a post-approval basis.

In another example of the utility of the company's Biochronomer platform, the company has demonstrated in animal models the simultaneous and prolonged release of three drugs commonly administered individually for the treatment of CINV. In this study, the company combined granisetron, dexamethasone and an NK-1 inhibitor to achieve desired pharmacokinetic levels of these drugs over a period of five days. The company is evaluating this three-drug combination as a potential lifecycle extension to its lead program for the treatment of CINV.

About Sustol (formerly known as APF530)

A.P. Pharma's lead product candidate, Sustol, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT3 antagonist approved for the prevention of delayed-onset CINV in patients receiving MEC; none are

approved for delayed-onset CINV in patients receiving HEC. Sustol contains the 5-HT3 antagonist granisetron formulated in the Company's proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for Sustol because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

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Forward Looking Statements

This news release 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 the potential approval of APF530 and the potential timing for such approval, if approved at all, as well as risks relating to qualifying for listing on the NASDAQ Capital Market, capital resources and liquidity, satisfactory completion of clinical studies, progress in research and development programs, launch and acceptance of new products and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. 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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Stephen R. Davis, Executive Vice President and Chief Operating Officer
Office Phone: 650-366-2626

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Exhibit 99.3

Company Overview

OTCBB: APPA

November 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:	$0.46 (11/8/2013)
Market Capitalization:	$237 million[1]
Cash:	$23 million[2]
Debt:	$5 million[2]

[1] Based on 516 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, 2013

Senior Management

Barry D. Quart, PharmD	Chief Executive Officer	Ardea Biosciences Agouron Pharmaceuticals Pfizer
Robert Rosen	President & Chief Commercial Officer	Bayer Healthcare Sanofi-Synthèlabo Imclone
Stephen Davis	Chief Operating Officer	Ardea Biosciences Neurogen
Mark Gelder, M.D.	Senior Vice President & Chief Medical Officer	GE Healthcare Bayer Healthcare Wyeth
Paul Marshall	Senior Vice President Technical Operations	Amylin Amgen Baxter International
Brian Drazba	Vice President, Finance & Chief Financial Officer	ISTA Pharmaceuticals Insight Health Corp Arthur Andersen & Co

Highlights

- Lead product candidate, SUSTOL™ (formerly known as 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; however, effective exclusivity actually longer due to polymer
- SUSTOL shown to be non-inferior to market leader Aloxi®
  - 1,341-patient, randomized, controlled, Phase 3 study
- SUSTOL targets a large market opportunity, with approximately 7 million doses of chemotherapy annually in US alone*
  - Recent competitive setbacks could enhance commercial uptake
  - Could be second, long-acting, injectable product on market
- Plans to leverage our Biochronomer™ drug delivery technology, development capacity and commercial expertise for other opportunities:
  - Long-acting anesthetic for post-surgical pain
  - Triple-combination for CINV is under evaluation
  - Potential for several others

*TDR August 2006 internal report

Strategic Product Development

- Framework
  - Large, established markets with high unmet need
  - Rapid development & approval pathway based on reformulations and 505(b)(2) strategy
  - Premium pricing through innovation and product differentiation
  - Clearly defined value proposition
  - Opportunities to optimize ROI through life cycle management (franchise extension)
  - Low cost of entry
- Pipeline
  - Chemotherapy-induced nausea and vomiting
    - SUSTOL
    - Potential for triple-drug combination
  - Post-operative pain management
    - Long-acting local anesthetic
  - Potential for several others

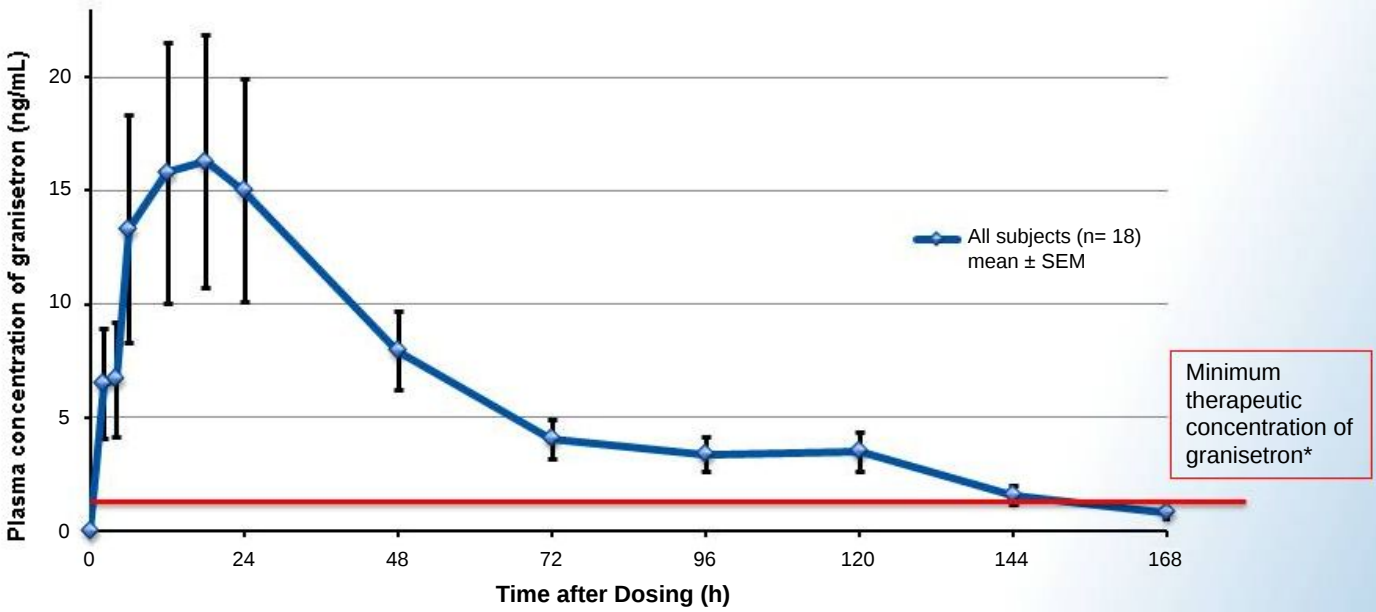
SUSTOL Clinical Summary

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 (results from 10 mg dose group presented)
- 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

5-Day Profile: APF530 Pharmacokinetics

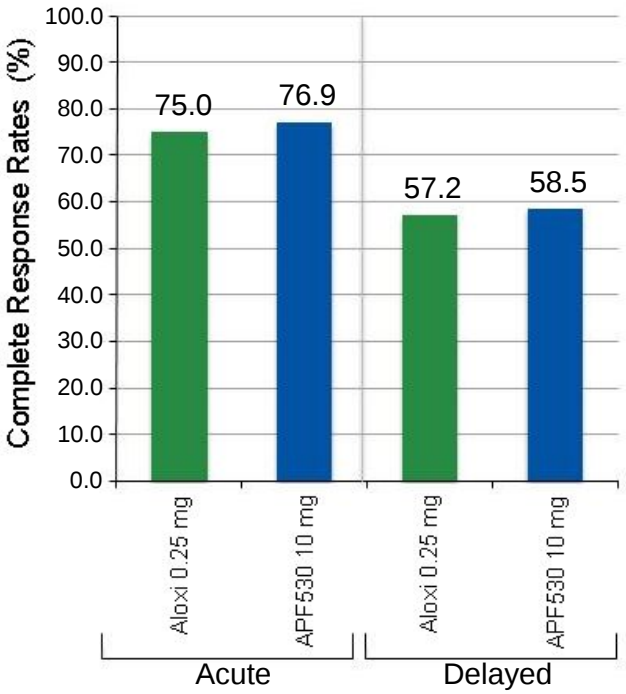
Granisetron is released rapidly following injection of APF530 and continues to be released over a 5-day period, providing long-acting coverage for CINV

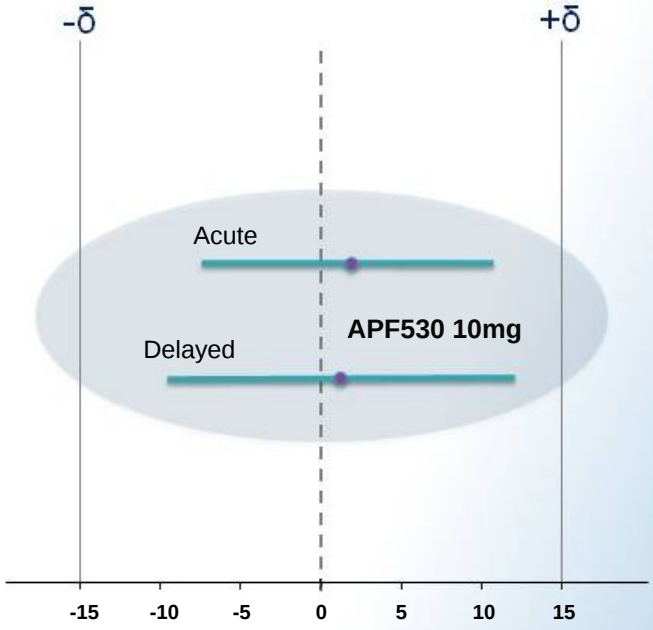


*Data from patent application 20120258164 for transdermal granisetron

Primary Efficacy Results: Complete Response

Patients Receiving Moderately Emetogenic Chemotherapy

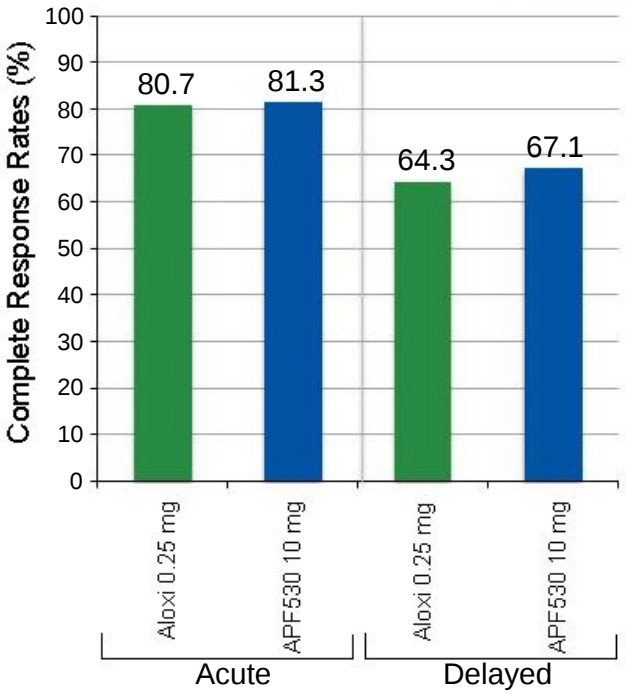


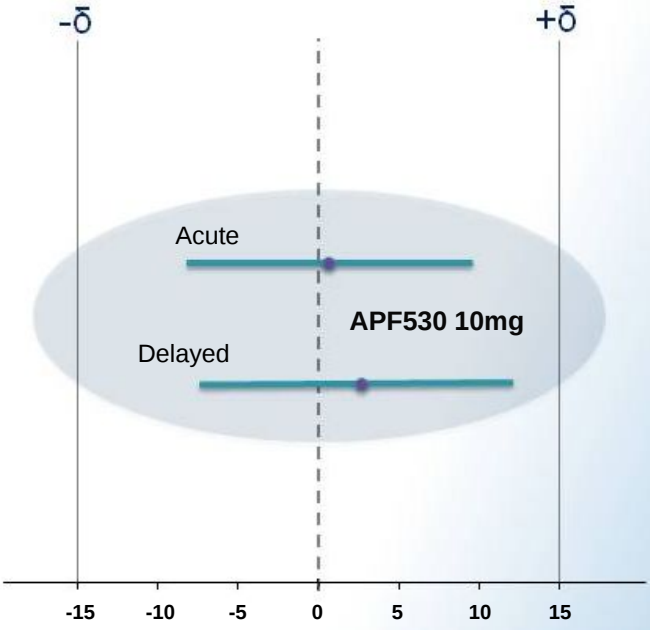


Difference in Complete Response
APF530-Aloxi (97.5% CI)

Primary Efficacy Results: Complete Response

Patients Receiving Highly Emetogenic Chemotherapy





Difference in Complete Response
APF530-Aloxi (98.33% CI)

Safety Summary

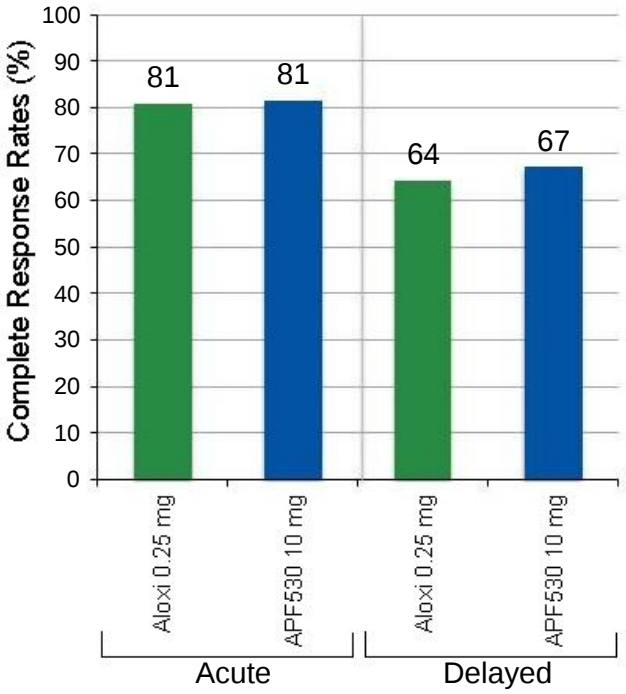
Reported in Cycle 1

	APF530 10 mg[1]		Aloxi 0.25 mg	
	N	%	N	%
Drug Related Serious Adverse Events	0	0	0	0
Discontinued Due to Adverse Event	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

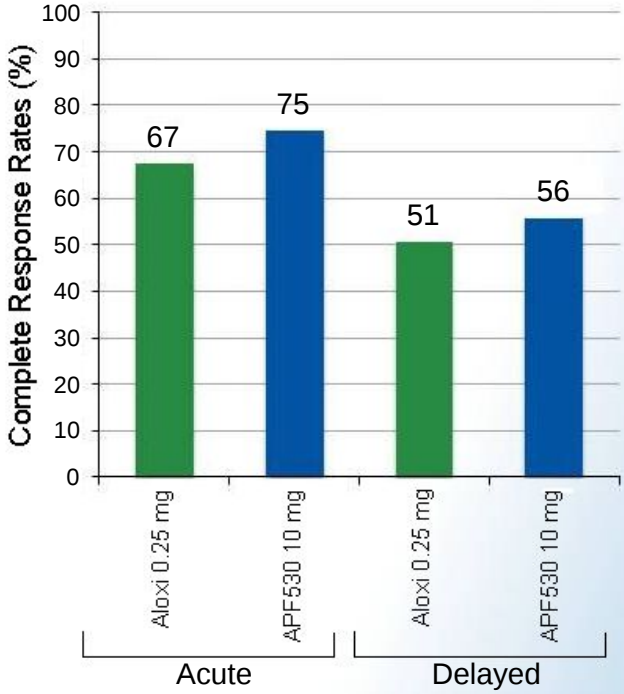
[1] Safety results with the 5 mg dose of APF530 studied in separate arm of the phase 3 study are not included
[2] >90% of injection site reactions were reported as mild; one patient discontinued due to injection site reaction

FDA Requested ASCO 2011 Reanalysis Improves Difference Between SUSTOL and Aloxi

Protocol Specified HEC Population



ASCO 2011 Guideline HEC Population



Largest Differences Between Arms is Seen With Most Difficult Chemo Regimens[1]

			CR Rates by Treatment	
		Chemotherapeutic Regimen	APF530 10 mg	Aloxi 0.25 mg
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%

[1]Data from post-hoc analysis. Not statistically significant.
Highlighted HEC regimens were considered HEC in both protocol specified Hesketh and 2011 ASCO Guidelines

Summary of Clinical Results

- Bio-erodible polymer technology releases granisetron to prevent CINV over at least 5 days
- Large, randomized, Phase 3 study conducted: APF530 10 mg showed non-inferiority to Aloxi
  - 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
  - Injection site reactions where predominately mild
- Good response rates were observed in difficult chemotherapy regimens
- Efficacy was maintained with reanalysis using ASCO 2011 guidelines and through multiple cycles of chemotherapy
- TQT study showed APF530 has no clinically significant effect on QT; differentiated from Zofran(ondansetron) and Anzemet(dolasetron)

SUSTOL Regulatory Status

SUSTOL NDA Status

- Submitted NDA in May 2009 under 505(b)(2) filing pathway
- Received Complete Response Letter in March 2010
- FDA raised major issues in multiple areas
- Resubmitted NDA in September 2012
- Received Complete Response Letter March 2013 raising three main issues:
  - CMC: correction of PAI issues and revision of one in-vitro release method
  - Requirement for Human Factors Validation Study with commercial product
  - Re-analysis of the existing Phase 3 study using the ASCO 2011 guidelines for categorization of MEC and HEC

New Management Team Is Addressing the CRL

- Chemistry, Manufacturing, and Controls
  - Sites with PAI issues are being eliminated from the supply chain, with work transferred to well established site with no PAI issues
    - Transition is almost complete
    - Secondary benefit of consolidating manufacturing and release efforts is that there has been a substantial improvement in the COGS
  - New in-vitro release method has been developed and being validated
  - Plan to produce three validation batches of finished product in advance of re-filing to supply Human Factors Study
- Human Factors Validation Study
  - Will be conducted as soon as commercial material available
- Re-analysis of Phase 3 using new ASCO 2011 Guidelines
  - Re-analysis complete
  - Complete dataset and programs supplied to FDA and found acceptable
- Re-submission is now planned for late 1Q2014

SUSTOL Life-Cycle Management Plans to Obtain Post-Approval Indication for “Delayed HEC”

Palonosetron lacks an indication in delayed HEC because it was unable to demonstrate superiority vs. ondansetron

Goal for New HEC Study is a Differentiated Target Product Profile*

	SUSTOL
Indication	MEC – acute and delayed CINV HEC – acute **and delayed CINV**
Dosing	SC injection once per cycle
Duration of action	Bioerodible polymer technology maintains super-therapeutic levels of granisetron over 5 to 7 days
Study	• SUSTOL vs. palonosetron • **SUSTOL + fosaprepitant vs. ondansetron + fosaprepitant**
Efficacy Results	• Non-inferior to palonosetron • Effective in prevention of acute & delayed CINV in MEC and acute CINV in HEC • **SUSTOL superior to ondansetron** • **Effective in prevention of delayed CINV in HEC**
Safety Results	• Headache, constipation, injection site bruising and pain. Majority of AEs were mild • Clean QT profile

*Text in blue is based on the successful outcome to the planned HEC trial

Physician Feedback

"[The delayed HEC study] solidifies my impression of [APF530] & gives even more confidence in its clinical profile."
–Oncologist, Urban, Mid-sized, Multi-specialty Practice

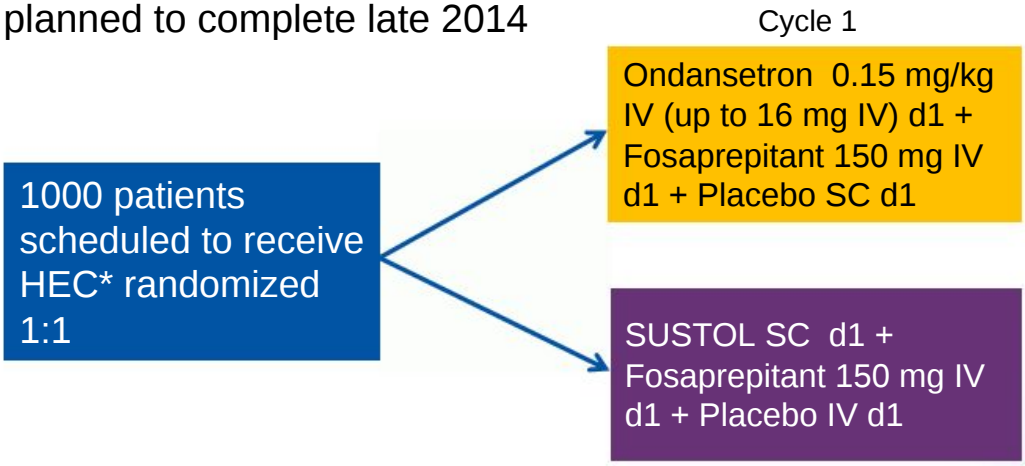
"Well, it appears to be certainly longer-acting, and the real differentiator appears to be in the delayed setting"
–Oncologist, Suburban, Large Private Practice

"We'd probably try a few patients on it and as long as we're getting the sense that it is doing what it's claimed to do, ***then we may make the full switchover...***
– Oncologist, Urban, Group Practice

Source: August 2013 qualitative market research with n=30 oncologists

Planned Phase 3 “Delayed” HEC Study Schematic

- Study design has been accepted by FDA for obtaining expanded indication
- Study is powered to show superiority (10% difference) to three drug “standard of care” for HEC
- Study planned to complete late 2014

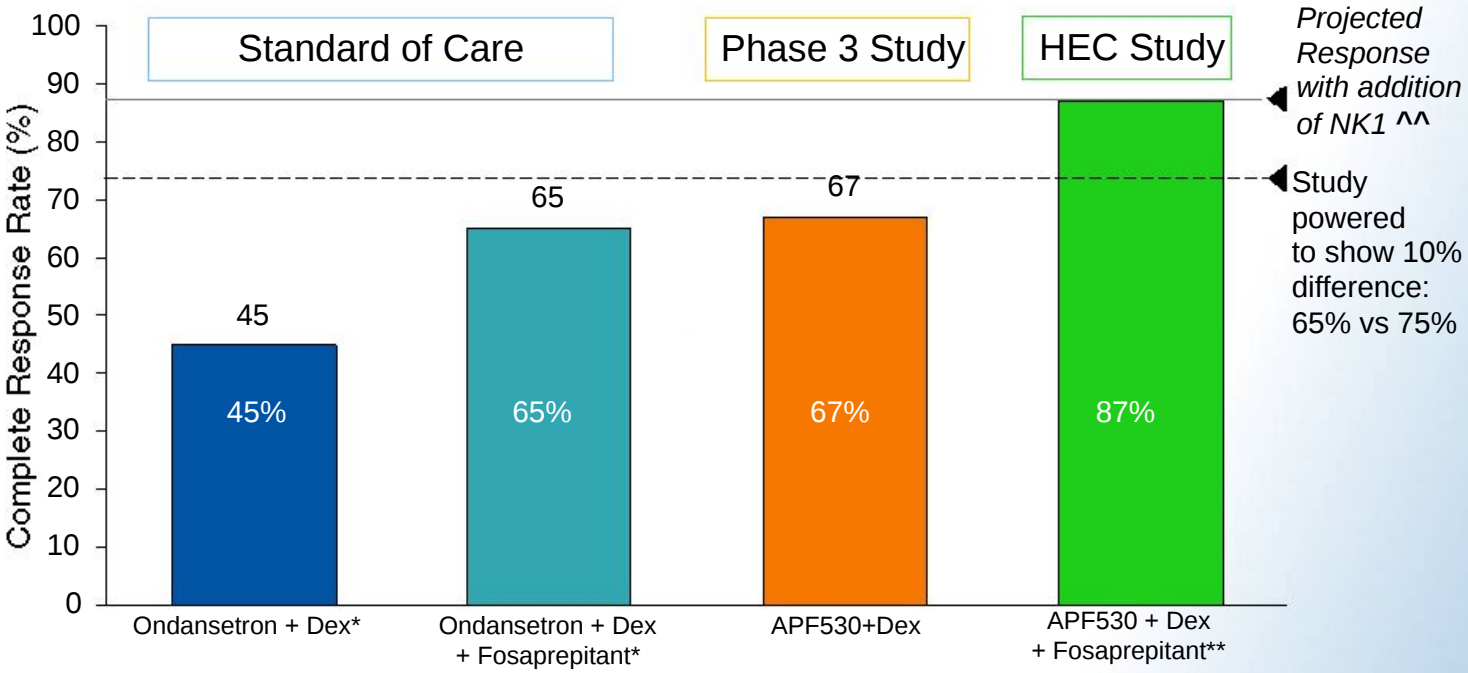


1) All subjects will receive dexamethasone 12 mg IV on day 1 and 8 mg PO on days 2-4
2) All subjects will be allowed to receive “rescue” medications as needed at the discretion of their treating physician

* HEC agents as defined in the 2011 ASCO CINV Guidelines

New SUSTOL Study in Delayed HEC Has a High Likelihood of Success Based on Previous Results

- Study powered for a 10% difference between arms
- 20% difference is expected with the addition of fosaprepitant,



^^*Average Complete Response rate improvement when adding an NK-1 RA to a 5-HT3 RA and Dex is ~15 - 20% in the delayed phase*

** Poll-Bigelli; Cancer, 97:12, 3090, 2003*

SUSTOL Commercial Opportunity

Continuing Unmet Need in CINV

NCI Statement On The Existing Unmet Need in CINV[1]

"Despite the use of both first-generation and second-generation 5-HT_3 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

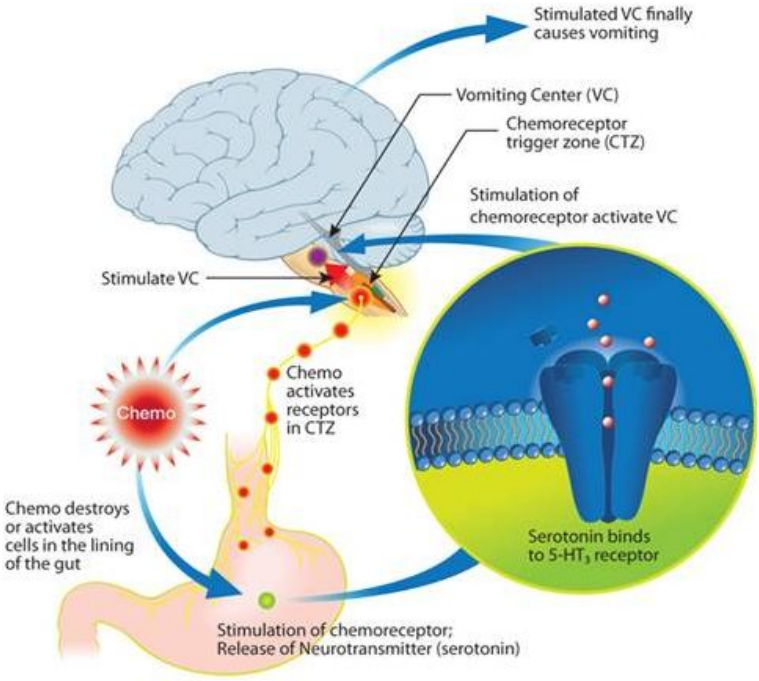
- Delayed CINV (days 2-5) remains particularly challenging to manage
- Significant portion of patients fail to respond to palonosetron

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

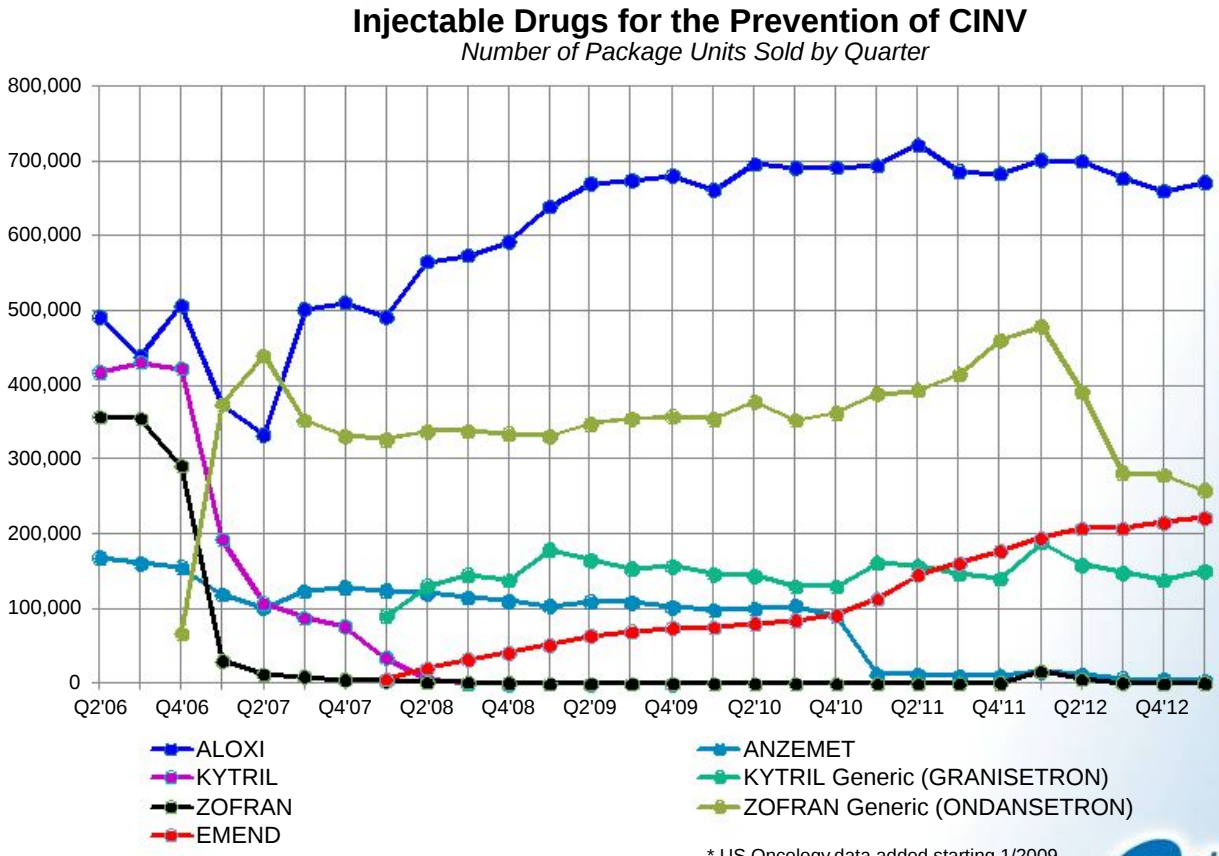
Addressing Debilitating Effects of CINV



- 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 MASCC guidelines
  - NK-1 antagonists are only indicated in combination with 5-HT3 antagonists
- An Injectable 5-HT3 antagonist is co-administered with more than >80% of MEC and HEC regimens
- If initial regimen is non-effective, drugs are added or changed to address CINV in subsequent cycles

*TDR August 2006

U.S. CINV Market Dynamics



* US Oncology data added starting 1/2009.

Source: WK 07/2013

Physicians View SUSTOL As Highly Competitive vs. Palonosetron

- Physicians responded favorably to HTH study design vs. palonosetron – good sample size, clinically meaningful endpoints, & strong comparator
- PK profile and efficacy results were viewed as clinically meaningful – SUSTOL viewed as a long-acting agent with sustained efficacy over multiple days
- SUSTOL is perceived as a clinically equivalent alternative to palonosetron for most physicians
- SUSTOL safety profile is similar to palonosetron and very manageable

"Well designed, well done clinical trial, the kind of trial you want to see. I think that's very favorable."
– Oncologist, Mid-sized Community Practice

"I think it's an incrementally better product than palonosetron. The whole idea is probably the longer [PK profile]."
– Oncologist, Large Community Practice

"I think [APF530] is great…we need something which has a much longer [duration of action]…I would certainly use it."
– Oncologist, Urban, Community Practice

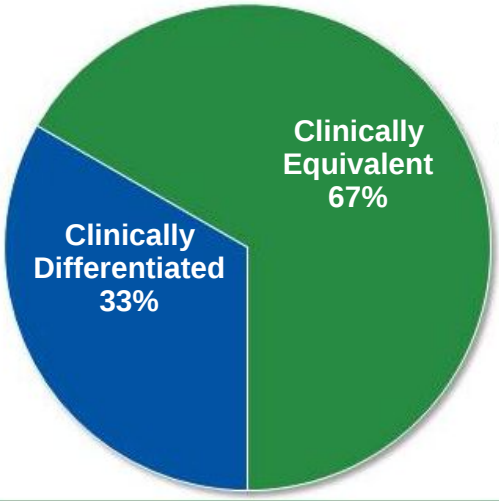
"It has [few] side effects…very comparable to medications we are currently using."
– Oncologist, Suburban, Large Practice

Source: August 2013 qualitative market research with n=30 oncologists

Despite lack of commercial presence, a significant portion of physicians view SUSTOL as differentiated

Question: "Based on the design and results of these studies, how do you perceive SUSTOL vs. palonosetron?"

"Well, this product in comparison to palonosetron seems to be better. So, I would have no problems using a better agent …The bottom line is that your data show that this therapy was better than palonosetron."
– Oncologist, Community Practice



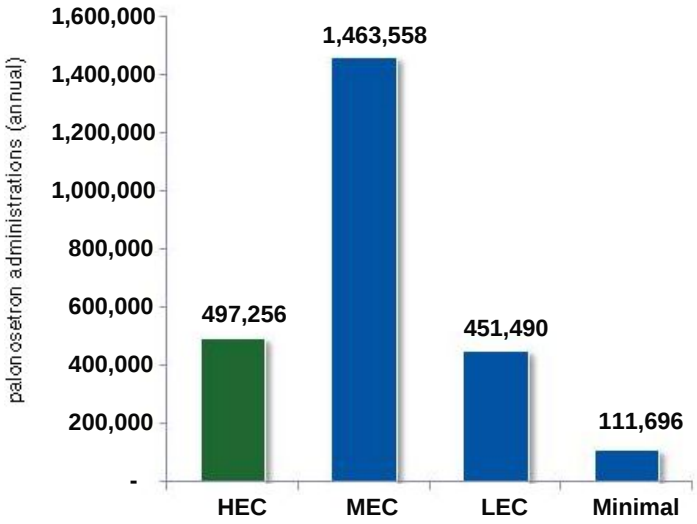
""The [first] study is compared with palonosetron and it seems like they are equivalent. I'm OK with that."
–Oncologist, Large Community Practice

"Also… even if there were no delayed data in HEC, I would still use it because then it would be very comparable to the current medication that I'm using."
–Oncologist, Mid-sized Community Practice

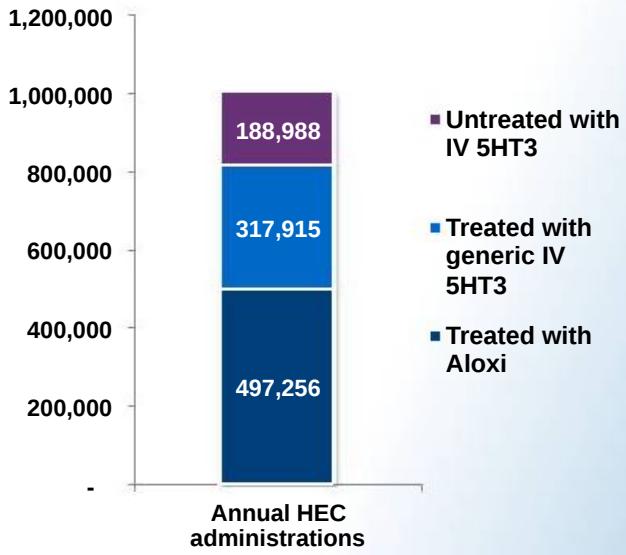
Source: August 2013 qualitative market research with n=30 oncologists

HEC regimens represent a significant market opportunity for SUSTOL

HEC regimens account for ~20% (500K) of palonosetron administrations



Of all HEC administrations, ~20% are given without concomitant IV 5-HT3 – inconsistent with clinical guidelines



[1] *IntrinsiQ data from July 2012 – June 2013*

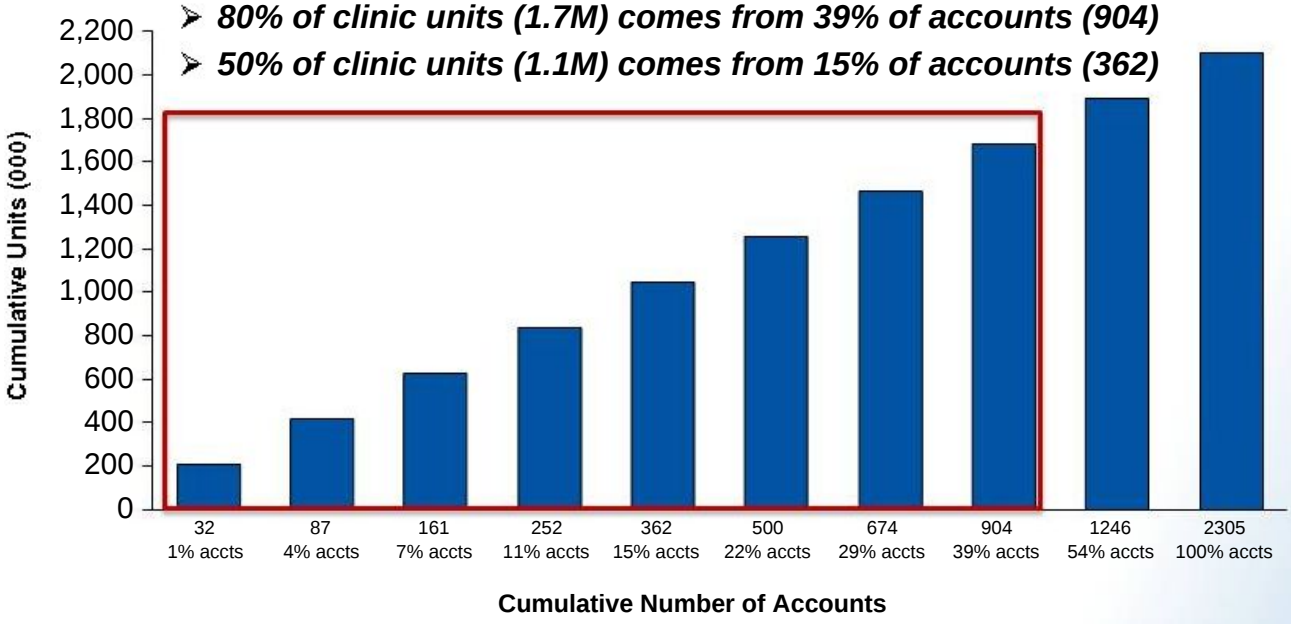
SUSTOL has the potential to be the next generation 5-HT3 receptor antagonist (RA)

5-HT3 RAs	1st generation	2nd generation	3rd generation
Products	ondansetron granisetron	palonosetron	**SUSTOL**
Duration of action	Short acting ~ 8 hr half-life	Longer acting ~40 hr half-life	**Long acting** **PK profile 5-7 days**
Indications	Prevention of CINV in emetogenic chemo including high-dose cisplatin	MEC – acute & delayed CINV HEC – acute CINV	**MEC – acute & delayed CINV** **HEC – acute & delayed CINV***

*Obtaining delayed HEC will be based on completion of new clinical trial

Palonosetron Clinical Use Is Highly Concentrated

- ***80% of all units (2.2M) comes from community clinics***
- ***80% of clinic units (1.7M) comes from 39% of accounts (904)***
- ***50% of clinic units (1.1M) comes from 15% of accounts (362)***



WKH Data Oct. 2012 – Clinic Analysis

Summary

- CINV market is a large, concentrated commercial opportunity
  - Over 2.7MM annual units of palonosetron[1]
  - >80% of use is in the community practice setting – highly concentrated among large practices[1]
- Physicians view a non-inferior SUSTOL profile as highly competitive
  - 5-7 day PK profile
  - Non-inferior to market leader palonosetron based on large, head-to-head trial
  - Good response in difficult chemotherapy regimens including AC and cisplatin
  - Sustained efficacy over multiple cycles of chemotherapy
  - Efficacy in palonosetron failures
  - Favorable safety profile with clean QT results
- Differentiated profile would position SUSTOL as the next generation IV 5-HT3
  - Delayed CINV, especially in HEC regimens, is the biggest area of unmet need
    - No 5-HT3 drugs approved specifically for delayed CINV in HEC
    - Palonosetron failed to show superiority to ondansetron in delayed HEC
  - High likelihood of clinical success versus ondansetron
  - Supports differentiated value proposition vs. palonosetron
- HEC regimens represent a significant market opportunity
  - 20% of palonosetron administrations are given with HEC regimens[2]
  - 20% of patients receiving HEC regimens do not receive concomitant treatment with an IV 5-HT3[2]

1. Wolters Kluwer 2012, 2. Intrinsiq 2013

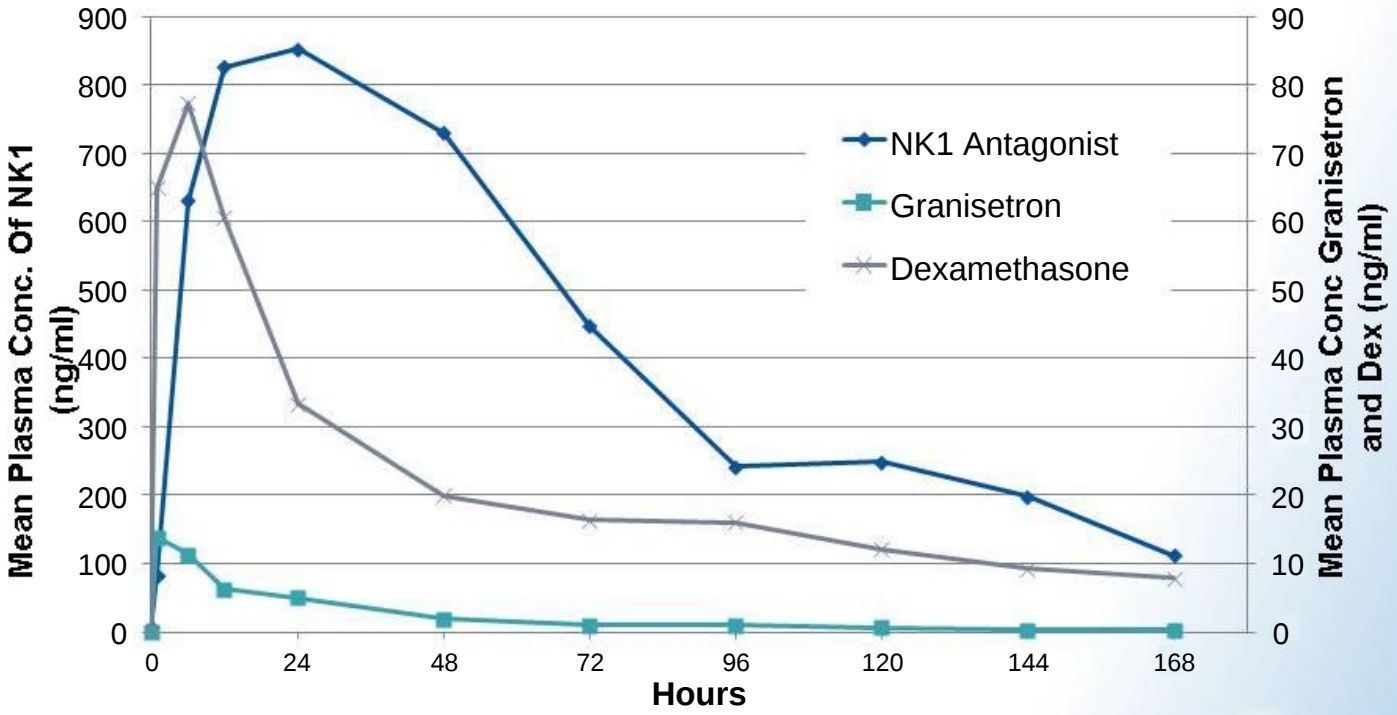
New Product Initiative

SUSTOL Product Lifecycle Considerations

- SUSTOL 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
- Obtaining the delayed HEC indication will further differentiate SUSTOL from all other 5-HT3 products
- Creating additional product opportunities with SUSTOL will further leverage our investment in the HEC program
- One opportunity under evaluation is a three-drug combination containing SUSTOL, an NK1 antagonist and dexamethasone

Biochronomer Triple-Drug Combination for CINV in Dogs

- Single shot with all three of the drugs recommended for HEC
- Registration could be based primarily on bioequivalence

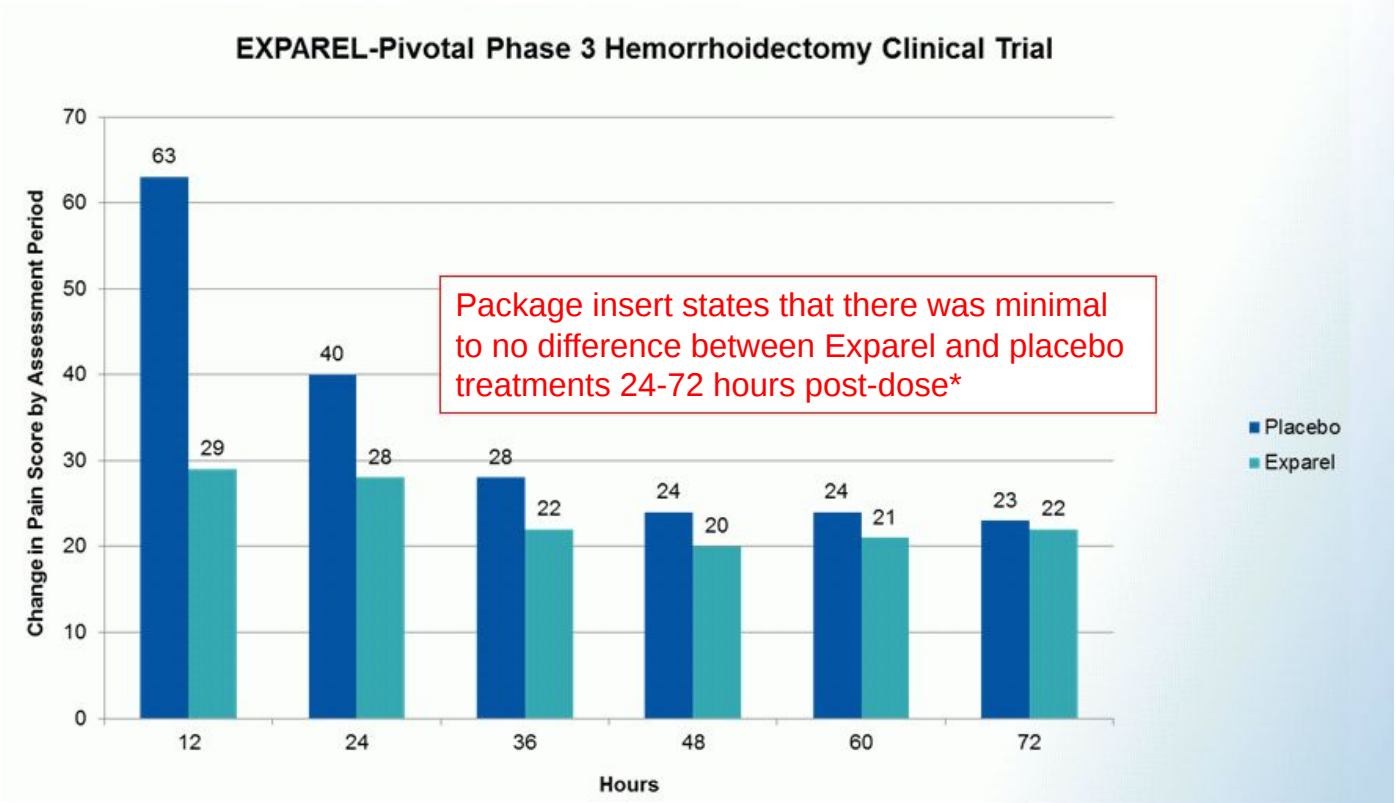


Profile of each component of triple-drug combo is similar to individual agents

Biochronomer™ Bupivacaine/Ropivacaine: Post-Surgical Pain Control

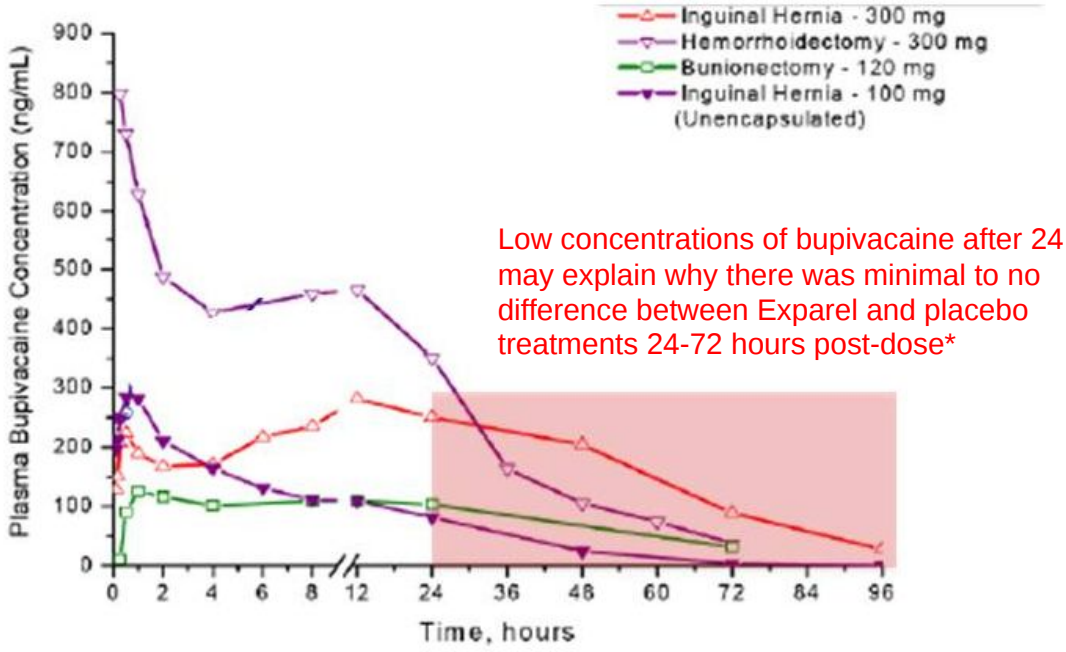
- Opportunity to use our polymer for post-surgical pain control utilizing the 505(b)(2) process
  - Once we have an FDA approved polymer, manufacturing site and syringe filler, the next products using the polymer will be much easier and cheaper to develop
- We believe the leading product in this market, EXPAREL, can be substantially improved by:
  - Prolonging the period of anesthetic release, so peak concentration are seen at 48-72 hours rather than 12-24 hours as seen with EXPAREL
  - Potentially using a better anesthetic agent, ropivacaine

Greatest Benefit for EXPAREL Is First 12 Hours



Adapted from EXPAREL Product Monograph
*US Package Insert

Mean Plasma Bupivacaine Concentrations After EXPAREL From FDA Clinical Pharmacology Review

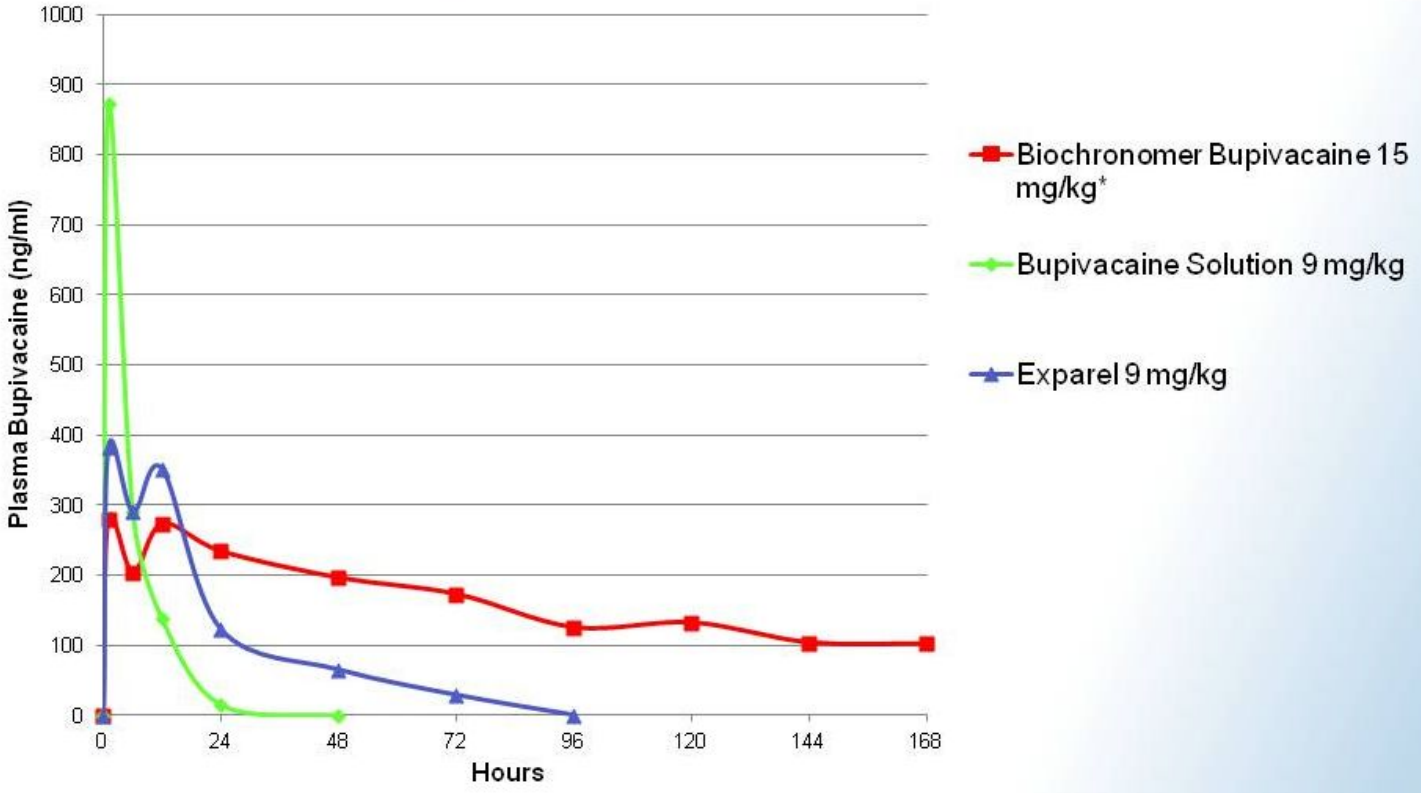


Low concentrations of bupivacaine after 24 hr may explain why there was minimal to no difference between Exparel and placebo treatments 24-72 hours post-dose*

The mean plasma concentration-time profiles of bupivacaine after administration of SKY0402 by infiltration exhibit two peaks. There is an early peak at a median time of 0.25 to 2 hours that followed by a second peak that occurs at a median time of 12 to 24 hours.

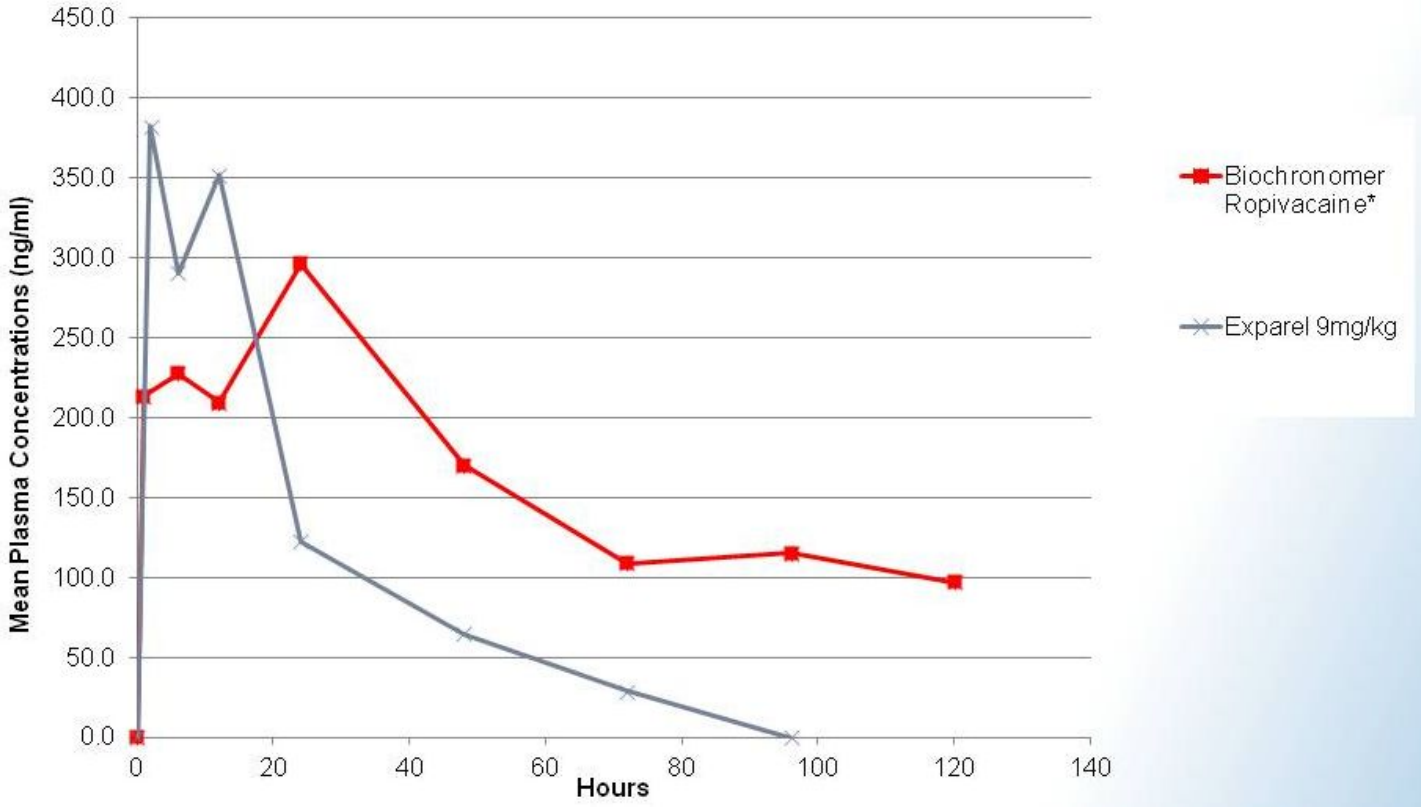
Data from FDA Clinical Pharmacology Review; NDA 22-496 EXPAREL; * US Package Insert

Biochronomer™ Bupivacaine Has Superior PK Profile in Dogs



*Projected from 7.5 mg/kg dose; EXPAREL data from Richard, et. al. 2012

Biochronomer™ Ropivacaine Has Superior PK Profile in Dogs



*Dose adjusted to match bupivacaine; EXPAREL data from Richard, et. al. 2012

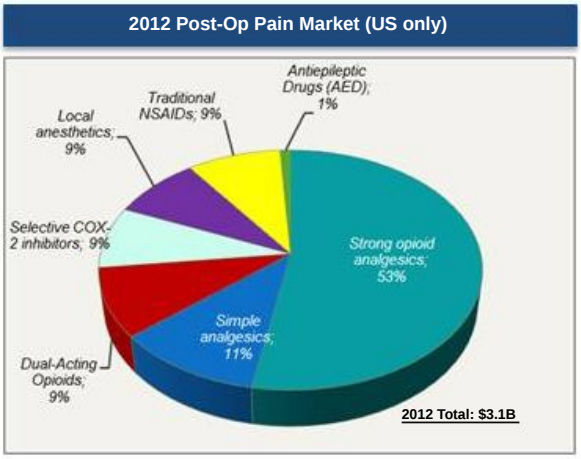
Post-Operative Pain Management
Commercial Considerations

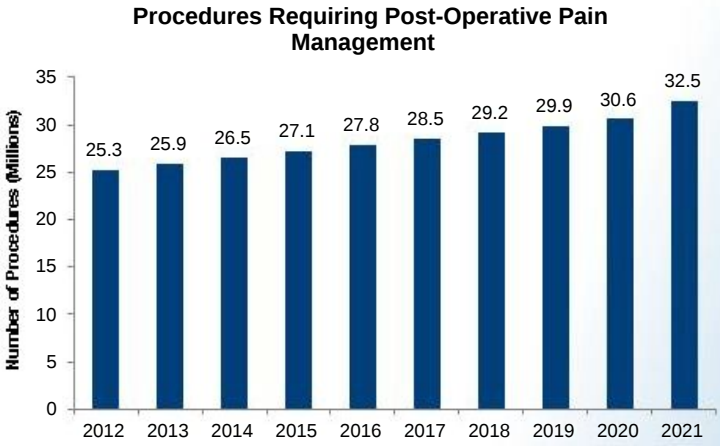
Post-operative pain market represents an attractive opportunity for product development

Market Size	• As of 2012, approximately 24.8 million procedures associated with post-operative pain were conducted in the US. Expected to grow to 32.3 million by 2022 • US post-operative pain market sales* are expected to grow 1.6% annually from ~$3.1 billion in 2012 to ~$3.6 billion by 2022 • Market growth is primarily driven by the increasing number of procedures and by new reformulations
Treatment Paradigm	• Patients are typically treated with a combination of NSAIDs, opioids, local anesthetics and/or simple analgesics • Strong opioids currently hold approximately half of the market sales
High Cost of Post-Operative Pain	• Pain is a major driver of inpatient admissions and increased length of stay • Reimbursement will increasingly be tied to measures of quality and ratings of patient experience – both of which are significantly impacted by pain • Costs of opioid addiction & opioid-related adverse events are significant concerns
Unmet Needs	• Longer-acting local anesthetics (>3 days) with improved safety profiles • Potent opioid-sparing analgesics with improved tolerability and less severe side effects compared to opioids

Source: Decision Resources, Acute Pain Pharmacor, December 2012; Decision Resources, Post-operative Pain Pharmacor, May 2006

Innovation in a large, growing disease area with high unmet need will drive significant dollar market growth





By 2020, 10% penetration into the 30M procedures requiring post-op pain management equates to $850M+ opportunity at a price of $285/unit

Source: Decision Resources, Post-Operative Pain Pharmacor, May 2006; Decision Resources, Acute Pain, December 2012

As a potential development candidate, ropivacaine has advantages over bupivacaine

	Bupivacaine	Ropivacaine	Notes [1]	KOL Feedback[2]
Efficacy	✓	✓	• Both molecules have similar efficacy, onset of action, and analgesic potency	*"Both of these products work well for blocking pain… the issue is that they are short acting." – Orthopedic Surgeon*
Safety		✓	• Lower CV and CNS toxicity • Overall better side-effect profile	*"Safety is where ropivacaine has a clear advantage. It is widely known in our institution that bupivacaine has more cardiovascular toxicity." – Anesthesiologist*
MOA		✓	• Ropivacaine has been shown to have shorter depth and duration of motor block compared to bupivacaine	*"The goal is to achieve sensory blockade without significant motor blockade. In this way, ropivacaine seems to perform better." – Orthopedic Surgeon*
Clinical Flexibility		✓	• Considered more clinically versatile by physicians • Approved for use in children	*"For all these reasons, a long-acting bupivacaine is a 'hit'… but a long-acting ropivacaine would be a 'home run'." – Orthopedic Surgeon*

1 Sources: [1] Scott, et al. Anesth Analg 1989; 24: 514-518; [2] Knudsen K, et al. Br J Anesth 1997 78; 507-514; [3] Bertini, et al. Reg Anesth Pain Med 1999; [4] Chelly JE, et al. J Orthop Trauma 2003; [5] Turner G, et al. Br J Anesth 1996; 76:606-610; [6] Writer WDR, et al. Br J Anaesth 1998; 81: 713-717. [6] McGlade, et al. Anaesth Intensive Care 1998;26:515-520; [7] Arikan OK, et al. J Otaryngol Head Neck Surg 2008; 37(6): 836-43; [8] Ivani G, et al. Can J Anaesth 1999; 46(5): 467-469; [9] Pitimana-aree S, et al. Reg Anesth Pain Med 2005; 30(5): 446-51; http://www.naropin-us.com/about_benefits.php
2 Source: KOL interviews October 2013

Summary – Pipeline offers significant opportunity for commercial value creation

Chemotherapy-induced nausea and vomiting

- Large, concentrated commercial opportunity
- Physicians view a non-inferior SUSTOL profile as highly competitive with palonosetron
  - 5-7 day PK profile
  - Non-inferior to market leader palonosetron based on large, head-to-head trial
  - Sustained efficacy over multiple cycles of chemotherapy & efficacy in palonosetron failures
  - Favorable safety profile with clean QT results
- With successful outcome in planned HEC trial, a differentiated profile with delayed-HEC indication would position SUSTOL as the next generation IV 5-HT3
- HEC regimens represent a significant market opportunity

Post-Operative Pain

- Large, growing market
- High unmet need
- 3-5 day local anesthetic depot would offer clinical differentiation
- Clear value proposition given the costs of post-operative pain
- Rapid development and approval pathway
- Potential opportunity for pain franchise through line extensions

1. Wolters Kluwer 2012, 2. Intrinsiq 2013

Financial Summary

Summary Statement of Operations (In thousands, except per share data)	Nine Months Ended September 30, 2013
Revenue	$ –
Operating expenses	40,626
Other income (expenses)	(614)
Net loss	$ (41,240)
Net loss per share[1]	$ (0.13)

Condensed Balance Sheet Data (In thousands)	September 30, 2013
Cash and cash equivalents	$ 22,597
Total assets	$ 26,370
Total stockholders' equity	$ 20,872

[1] Based on 306.1 million weighted average common shares outstanding for the period ended September 30, 2013.