

Adverse Event Reporting

Please report all suspected adverse reactions associated with the use of the specific ER/LA opioid analgesic to the appropriate company. You may also report adverse events directly to the FDA's MedWatch Reporting System:

- by calling 1-800-FDA-1088 (1-800-332-1088),
- online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatchonline.htm> or
- by mail using the fillable portable document format (PDF) Form FDA 3500, available at <http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>.

Patient Counseling Document and Medication Guide

The Patient Counseling Document (PCD) on Extended-Release/Long-Acting Opioids is a tool unique to this REMS designed to facilitate important discussions with your patients for whom you select an ER/LA opioid analgesic. The PCD should be provided to the patient and/or their caregiver at the time of prescribing. It contains important safety information about the drug products subject to this REMS and includes space for you to write additional information to help your patients use their ER/LA opioid analgesic safely.

Patients and their caregivers should be counseled on: the importance of taking these medicines exactly as you prescribe them, the need to store ER/LA opioid analgesics safely and securely—out of the reach of children, pets, and household acquaintances to avoid risks from unintended exposure, the importance of not sharing these medications, even if someone has the same symptoms as the patient, and the proper methods of disposal of unneeded ER/LA opioid analgesics.

It is important that you encourage your patients to read the relevant Medication Guide when they pick up their prescription from the pharmacy. The Medication Guide provides important information on the safe and effective use of the specific ER/LA opioid analgesic prescribed.

Interstitial Pop-Up

The interstitial pop-up is displayed when a website visitor clicks on non-RPC member links on the website pages. The interstitial pop-up is not displayed when a website visitor clicks on the Medication Guides or the U.S. Prescribing Information links on the Products covered under the ER/LA Opioid Analgesics REMS Program page.

Thank you for visiting www.er-la-opioidrems.com.

By clicking "Continue" below, you will be leaving the ER/LA Opioid Analgesics REMS website. RPC is not responsible for the privacy policy, the content or the accuracy of any website accessed through a link.

Medication Guide

BUTRANS® (BYOO-trans)

(buprenorphine) Transdermal System, CIII

BUTRANS is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about BUTRANS:

- Get emergency help right away if you take too much BUTRANS (overdose). BUTRANS overdose can cause life-threatening breathing problems that can lead to death.
- Never give anyone else your BUTRANS. They could die from taking it. Store BUTRANS away from children and in a safe place to prevent stealing or abuse. Selling or giving away BUTRANS is against the law.

Do not use BUTRANS if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before applying BUTRANS, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- heart rhythm problems (Long QT syndrome)
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you:

- have a fever.
- **are pregnant or planning to become pregnant.** BUTRANS may harm your unborn baby.
- **are breastfeeding.** BUTRANS passes into breast milk and may harm your baby.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

While using BUTRANS:

- Do not change your dose. Apply BUTRANS exactly as prescribed by your healthcare provider.
- See the detailed Instructions for Use for information about how to apply and dispose of the BUTRANS patch.
- Do not apply a BUTRANS patch if the pouch seal is broken, or the patch is cut, damaged, or changed in any way.
- Do not apply more than 1 patch at the same time unless your healthcare provider tells you to.
- You should wear 1 BUTRANS patch continuously for 7 days.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop using BUTRANS without talking to your healthcare provider.**

While using BUTRANS Do Not:

- Take hot baths or sunbathe, use hot tubs, saunas, heating pads, electric blankets, heated waterbeds, or tanning lamps. These can cause an overdose that can lead to death.
- Drive or operate heavy machinery, until you know how BUTRANS affects you. BUTRANS can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of BUTRANS are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, itching, redness or rash where the patch is applied. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of BUTRANS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Distributed by: Purdue Pharma L.P., Stamford, CT 06901-3431, www.purduepharma.com or call 1-888-726-7535

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issue: July 2012

Butrans 
(buprenorphine) Transdermal System

Reference ID: 3292562

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PURDUE-COR-00000865

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/s/

JUDITH A RACOOSIN

04/15/2013

2.3. Quality Overall Summary Introduction

INTRODUCTION

Please refer to NDA 22-272 CBE-0, supplement S-015/sequence S-0150 (currently under review by the FDA) submitted October 18, 2012 for additional background information related to this amendment. Also, please refer Sequences S-0171 and 0182 and to the November 15, 2013 FDA Purdue Teleconference regarding this topic. The information provided in this amendment was provided to the FDA via e-mail on December 10, 2013 in preparation for a second teleconference scheduled by the FDA for December 13, 2013. The FDA requested a second teleconference to discuss reviewer questions regarding supplement S-015.

The purpose of this amendment is to formally submit the updated stability data (see table below) and a revised statistical analysis based on the new data (see document ORF-Deg-Prods- Stats-V-cmpds-Rev-12092013), (document ORFStabilityFileDefinition9Dec13) and (document PURDUEORFSTABILITY9DEC13-SAS). The following is the summary information previously submitted via e-mail.

Pre – Meeting Summary for December 13, 2013 FDA Teleconference

FDA Request:

The impurity peak in the 10 mg tablets exceeds the limit during stability, the statistical analysis and the review of the results suggest the reduction of expiry dating period and we would like discuss the options

Purdue Response:

Please reference our previous discussion from November 15, 2013 and the updated Statistical Analysis Report included with this summary.

Since our last meeting, Purdue has collated the most current stability data available for the 10 and 15 mg strengths of OxyContin® tablets. An updated statistical analysis report incorporating the new data is included in this package for your review. Purdue is also submitting this updated analysis as a formal amendment to S-015 to aid in the FDA's review of this supplemental application. The following new data have been added to the statistical analysis:

New Stability Data

STRENGTH (mg)	BATCH	PACKAGE	NEW TIME POINTS (Months)
10 mg	XW7S60	10 Count Blister	24, 36
	XW7S70	10 Count Blister	24, 36
	WBA60A	10 Count Blister	18, 21, 24
	WBA80A	10 Count Blister	18, 21, 24
	WBL51	100 Count Bottle	37
	WER41	100 Count Bottle	12, 18, 24
	WKB71	100 Count Bottle	12, 18
15 mg	WBR81	100 Count Bottle	18, 22, 24

The shelf life specification for degradants V120921 and V120137 (V compounds) is NMT 0.2%. All data remained within the NMT 0.2% specification through the current approved expiration date of 24 months based on real time long term data. The 24 month shelf life is also supported by the updated statistical analysis.

In our previous meeting there were questions regarding the rounding convention used by Purdue. The rounding convention used by Purdue is consistent with Purdue's internal rounding SOP and that described in the current USP/NF General Notices section 7.20 and the Current ICH Q3BR(2) Attachment 2, Examples 1 and 2 that is used for establishing identification and qualification thresholds for unknown degradation products.

USP General Notices Section 7.20 Rounding Rules (Excerpted)

When rounding is required, consider only one digit in the decimal place to the right of the last place in the limit expression. If this digit is smaller than 5, it is eliminated and the preceding digit is unchanged. If this digit is equal to or greater than 5, it is eliminated and the preceding digit is increased by 1.

Example Specification NMT 0.2%

Raw Result	Digit to right greater than or equal to 5	Rounded Result
0.249	No	0.2
0.250	Yes	0.3

As stated in our previous meeting and included in supplement S-015, mitigation efforts by the polyethylene oxide manufacturer (Dow Chemical) have been implemented to minimize the formation of the V compounds. A more discriminating analytical method has been developed and approved by the FDA (Supplement S-013) for use when the peak at 0.8 RRT (comprised of V120137 and two additional co-eluting constituents) exceeds 0.2% in the 10 mg strength. All batches manufactured and placed on the stability program prior to and after mitigation measures were adopted have remained within the NMT 0.2% specification through at least 24 months in all packaging configurations.

Conclusion

Based on the mitigation measures identified and implemented by Dow Chemical, formation of the V compound degradants has been minimized. If results for the V120137 peak at RRT 0.8 are above 0.2%, they can be more accurately determined using the more discriminating analytical method for the 10 mg strength to confirm that the drug product will meet the current approved 24 month expiration date.

The additional long term data provided in this report clearly show that the 10 mg drug product remained within specifications through the approved 24 month shelf life. All strengths and packaging configurations remain within the NMT 0.2% degradant specification through 24 months. Please refer to the Statistical Analysis Report (document ORF-Deg-Prods- Stats-V- cmpds-Rev-12092013) included in this submission for additional information.

2.3. P.8. STABILITY (OXYCODONE HYDROCHLORIDE 10-80 MG, CONTROLLED RELEASE TABLETS)

New stability data have been obtained on the 10 and 15 mg batches previously submitted (see QOS Introduction). A new statistical analysis report (see document ORF-Deg-Prods- Stats-V-cmpds-Rev-12092013) is also provided with the attendant SAS and definition files, please see (document orfstabilityfiledefinition9dec13) and (document purdueorfstability9dec13-sas).

The revised statistical analysis using the longer term data on the 10 and 15 mg batches clearly shows that the drug product (all strengths and all package configurations) remain within the NMT 0.2% degradant specification through 24 months. Please see the summary below and the statistical analysis report (document ORF-Deg-Prods- Stats-V-cmpds-Rev-12092013) for details.

SUMMARY

Data included in this report are from ORF degradation products V120921 and V120137. Data were collected after storage at the recommended long term condition of 25°C/60%RH. Data reported as <LOQ or ND were excluded when calculating shelf lives. Shelf lives are listed in Table 1. Shelf lives greater than 36 months are listed as 36 months. The minimum of all shelf lives is 36 months.

Table 1. Calculated Shelf Lives				
Strength	Tablet Count (ct) per Package	V120921 Calculated Shelf Life (months)	V120137 Calculated Shelf Life (months)	Minimum Shelf Life (months)
10 mg	10 ct blister	36	36	36
	10 ct bottle	36 (a)	36	36
	100 ct bottle	36	36	36
	120 ct bottle	36	36	36
15 mg	100 ct bottle	36(d)	36	36
40 mg	10 ct bottle	36 (b)	36(c)	36
	120 ct bottle	36 (b)	36(c)	36
80 mg	10 ct bottle	36 (b)	36(c)	36
(a) No batch with more than one result \geq LOQ. All observed values \leq 0.11. No analysis. (b) All observed values ND or <LOQ. No analysis. (c) Each batch has only one value \geq LOQ. All observed values=0.10. No analysis. (d) One batch. Only two values \geq LOQ, 0.11and 0.12. No analysis.				

Purdue
Quarterly Report to the Board
4th Quarter, 2012

January 28, 2013

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FINANCE

The Department goals are to assure 2012 sales, profitability, efficiency, cash flow, compliance and pipeline objectives are supported by proactive, future-focused and meaningful financial analysis. Assure that Purdue's financial reporting and forecasting provide transparency into business results, and that financial internal controls are in place.

Topics covered:

- 2012 Financial Performance
 - Purdue's Equity Investment in Infinity Pharmaceuticals
 - 2013 Budget
 - Executive Audit Committee
 - Pension Investment Committee
 - Information Technology
-

2012 Financial Performance

\$ Millions	2012			2011	2010	2013 Budget
	Actual / Estimate (1)	Nov LE	Budget			
Net Branded Revenues	2,206	2,210	2,353	2,222	2,350	2,410
Operating Profit Margin (after Incentives and Settlements)	1,004	994	1,094	1,186	1,544	1,125
EBITDA	1,044	1,009	1,070	1,178	1,545	1,067
Net Profit Before Tax	1,014	979	1,038	1,146	1,472	1,035
Owner's Equity	685	651	661	492	577	765
Non-tax Distributions	472	463	448	575	390	538
Days Sales Outstanding	34.7	35.0	35.0	33.9	33.5	35.0
Accounts Receivable Outstanding > 90 Days Past Due	< 1%	< 1%	< 1%	< 1%	< 1%	< 1%
Capital Spending	29	35	36	27	30	35
Unrestricted Cash on Hand	756	716	771	607	437	600
Available Liquidity	756	716	771	607	437	600
Available Liquidity - Average Months Sales	4.1	3.9	3.9	3.3	2.2	3.0
Headcount	1,666	1,782	1,782	1,699	1,623	1,784

Notes:

1. The numbers above are our best estimate. Pre-audit financials will be published in February 2013 and audited financials in April 2013.
2. Please also see Ed Mahony's January 11th, 2013 e-mail titled "December Finance Flash Report" for sales by products and comments on cash balance, etc.

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3. Purdue ended December 2012 with \$797 million in cash, of which \$756 million is unrestricted cash and \$41 million is restricted cash (\$24.0 million settlement trust, \$17 million cash collateralized letters of credit).
4. We expect to meet our \$500 million equity target for 2012 year-ended external reporting.
5. Operating profit is lower than budget and prior year due to increases in R&D (pipeline progressing) and increasing S&P (launching new products).

2013 Budget

The 2013 budget was approved by the Board with net sales at \$2.4 billion, EBITDA at \$1.1 billion, and 1,784 headcount.

Executive Audit Committee

Members: Stuart Baker, [REDACTED] Ed Mahony, and Bert Weinstein

Purpose: To ensure the effectiveness of internal controls, integrity of financial statements and performance of internal and external auditors

Frequency: Quarterly

- The Committee approved the proposed 2012 audit fee for Purdue, OSR and the Employee Benefit Plan Audits of \$725,500 which represents a reduction of \$231,500 or 24% from the actual 2011 fee of \$957,000. The decrease is due to efficiencies by E&Y and Purdue as well as a reduction in the hourly rate.
- Refer to the September Board Report for a summary of audits performed by IAF through Q3 2012. Most recent audits performed included:

Review of unapproved Butrans carton distributed to the Field Sales Force

- Opportunities to improve operational efficiency and record keeping were:
 - A Butrans carton was correctly approved via the labeling review process for use commercially. That same carton needs to go through a separate "Material Approval Process" to the extent it is used by sales training. Individuals should be advised that a different use of the same item requires separate approval through the Material Approval Process.
 - Not all items shipped to the sales force were requested through the required bulk distribution request and therefore did not get entered into SAP. All shipments from the Canal Street warehouse should be recorded through the

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SAP enterprise system to ensure accurate accounting of what is shipped, to whom and when.

Senokot diversion

- Approximately \$3.8 million of Senokot donated to AmeriCares was diverted into normal sales channels. Recommendations noted to improve controls and procedures were:

Comment [A1]: It should be stated if this figure is Purdue's cost or the retail value.

- Identify on the package/bottle that the product donated is not for resale.
- Require all charities to divulge, prior to Purdue's donation, the ultimate destination of the product.
- Develop procedures to ensure that the product was distributed as intended.
- Match the product donation values and quantities with the specific need.
- Revise the product donation SOP to include additional approvals by departments such as Marketing, Corporate Security, Corporate Communications, etc.

Sales training materials follow up audit

- IAF performed follow-up audits of training materials used in two separate sales training classes to ensure that (1) all sales training materials used were approved prior to the class, (2) archived and (3) compared back to the training agenda for completeness. Recommendations were:
 - Remind users of the automated system ("Aprimo") to exercise care to ensure that the training materials used in class are the same (i.e. have the same digital asset number) as the identical item stored in the Aprimo system.
 - Sales Operations and Training should randomly select material used in sales training classes and ensure that the materials have been approved and recorded in the Aprimo system.

Pension Investment Committee

Members: Stuart Baker, [REDACTED] and Ed Mahony.

Frequency: 4 to 5 meetings per year

Purpose: The Pension Investment Committee oversees the investment managers and investments made in the Purdue defined benefits plan and, the investment choices offered to employees in Purdue's defined contribution 401(k) plan

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Defined Benefits Pension Plans

- PPLP Plan - The plan's Accumulated Benefit Obligation² is projected at \$230 million at 12/31/2012 and the plan assets were \$231 million at 12/31/2012. Purdue made \$16.2 million of contributions (spread out evenly during the year) to the plan in 2012.
- The plan investments returned 13.7% for the 12-month ended 12/31/2012. The fund assets are invested in: (a) passive equity indexed funds, and (b) actively managed fixed income funds - which have outperformed passive fixed income. The plan's one-year return ~~outper-~~performed the portfolio benchmark passive index by 2.2%.

Change to PPLP Defined Benefits Pension Plan

- Effective January 1, 2013, the PPLP Plan will be closed to new entrants and closed for future service credits for about 54% of current employees.
- PPLP has created an ~~new~~ additional savings plan with three-year vesting and 100% participation for ~~these~~ employees no longer eligible for the PPLP Defined Benefit Plan.
- This change is expected to save \$85 million over 20 years and reduce actuarial, interest rate, and investment return risk.

Defined Contribution Pension Plan

- Purdue Pharma LP also offers employees an optional 401(k) defined contribution savings plan. The company's contribution to this plan was \$6.3 million in 2012 and is defined as a percentage of the employee's contribution to the plan. The 401(k) plan ~~funds'~~ assets total \$265 million and \$310 million at the end of 2011 and 2012 respectively.

² Pension plan liability calculation above is calculated under ERISA/IRS guidance. Accounting guidance projects future benefits so liabilities are higher, but less relevant to our funding decisions.

MARKETING & SALES

The Department's goals are to assure 2012 sales and market share targets are met or exceeded. 2012 ex-factory net sales budget is \$2,351.5 mm. Operate within approved S&P budget of \$343.4 mm, with a target savings goal of \$7.9 mm.

Meet or exceed total prescriber call targets of 752,417 with Butrans in 83% primary positions and OxyContin in 17% primary positions. OxyContin will be in the second position in at least 90% of Butrans' primary calls and Butrans will be in the second position in at least 90% of OxyContin's primary calls. Senokot-S Tablets will be in third position on at least 35% of all primary calls.

Compliance with all relevant policies, government law and regulations will be closely monitored.

Gross Sales Budget: \$3,167.9MM

Net Sales Budget: \$2,351.5MM

2012 (\$MM)	Actual		Budget		Prior Year	
	Gross Sales	Net Sales	Gross Sales	Net Sales	Gross Sales	Net Sales
Q1	674.0	507.5	724.0	537.1	725.2	552.7
Q2	764.0	556.4	798.9	596.1	762.2	583.7
Q3	749.6	531.8	792.8	592.0	726.3	543.7
Q4	817.3	607.5	852.2	626.2	757.4	530.0
Total	3,004.9	2,203.1	3,167.9	2,351.5	2,971.2	2,210.1

Note: Net sales for all periods reported have been restated to reflect include patient savings card discount expense and the proposed Medicaid rebate adjustment.

2012 year to date actual net sales of \$2,203.1 mm was lower than budget by \$148.4 mm or 6.3%. This variance was driven by:

- OxyContin net sales of \$2,012.7 mm were \$96.0 mm or 4.6% less than budget due to ~~driven~~ by lower sales/demand and an increase in product returns reserve.
- Butrans net sales of \$84.4 mm were \$11.6 mm or 12.1% less than budget due to ~~driven~~ by lower sales/demand.
- Intermezzo net sales of \$5.1 mm were \$38.3 mm or 88.2% less than budget due to lower sales/demand.

2012 actual net sales of \$2,203.1 mm were lower than 2011 by \$7.0 mm or 0.3%. This variance was driven by lower OxyContin net sales of \$18.2 mm due to the increase ~~in~~ ~~driven~~ by product returns reserve and lower Ryzolt net sales of \$17.2 mm, offset by an increase in Butrans net sales of \$28.4 mm.

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Operating Budget

The department will operate within the total 2012 S&P budget of \$343.4 mm, which is 14.6% of total net sales budget of \$2,351.5 mm.

2012	Actual		Budget		Prior Year	
	\$MM	% net sales	\$MM	% net sales	\$MM	% net sales
Q1	68.3	13.4%	78.4	14.6%	54.1	9.8%
Q2	78.1	14.0%	81.6	13.7%	55.4	9.5%
Q3	76.8	14.4%	83.6	14.1%	59.1	10.9%
Q4 ⁽¹⁾	83.1	13.7%	99.7	15.9%	60.7	11.4%
Total	306.2	13.9%	343.4	14.6%	229.3	10.4%

(1) Q4 Expenses have been estimated pending year end closing procedures.

S&P expense of \$306.2 mm was \$37.2 mm lower than budget due to lower salary and related expenses of \$14.6 mm (primarily sales bonus related), lower Intermezzo promotional spend of \$14.3 mm due to ~~toriven~~ by a delay in DTC spending, lower Butrans promotional spend of \$2.6 mm due to ~~toriven~~ by less speaker programs and lower agency fees, lower spend on contract sales force of \$1.7 mm, and all other of \$4.0 mm.

S&P expense of \$306.2 mm was \$76.9 mm higher than prior year, primarily due to ~~expenditures associated with the Intermezzo launch (CSO and promotional spend).~~

Business Unit Performance

Each Branded Business Unit will strive to maintain its budgeted contribution on net sales: OxyContin \$1,656.4 mm/78.5% of net sales, Butrans negative \$56.3 mm, Intermezzo negative \$71.7 mm, Laxatives \$19.4 mm/38.4 % of net sales. Full year targets and results are detailed below.

	2012 Target Gross (\$MM)	2012 Target Net (\$MM)	2012 Target Product Contribution (\$MM)	2012 Target Product Contribution (%)	YTD Actual Gross (\$MM)	YTD Actual Net (\$MM)	YTD Actual Product Contribution (\$MM)	YTD Actual Product Contribution (%)
OxyContin	\$2,877.4	\$2,108.7	\$1,656.4	78.5%	\$2,777.1	\$2,012.7	\$1,579.3	78.5%
Butrans	\$135.8	\$95.9	(\$56.3)	N/A	\$112.9	\$84.4	(\$55.9)	N/A
Intermezzo	\$49.2	\$43.4	(\$71.7)	N/A	\$16.6	\$5.1	(\$84.2)	N/A
Laxatives	\$51.9	\$50.6	\$19.4	38.4%	\$51.5	\$50.3	\$18.1	31.0%

(1) Product Contribution has been estimated pending year end closing procedures.

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- OxyContin's product contribution of \$1,579.3 mm was lower than budget by \$77.1 mm. This variance was driven by lower net sales of \$96.0 mm offset by lower variable expenses of \$10.7 mm and lower S&P and R&D expenses of \$8.1 mm.
- Butrans product contribution of (\$55.9 mm) was higher than budget by \$0.4 mm. This variance was primarily driven by lower net sales of \$11.6 mm offset by lower S&P and R&D expenses/other of \$12.0 mm.
- Intermezzo's product contribution of (\$84.2 mm) was lower than budget by \$12.5 mm. This variance was primarily driven by lower net sales of \$38.3 mm offset by lower variable expenses of \$8.3 mm and lower S&P and R&D expenses of \$17.5 mm.
- OTC's product contribution of \$18.1 mm was lower than budget by \$1.4 mm. This variance was primarily driven by higher S&P and R&D expenses of \$1.1 mm.

Purdue Analgesic Sales Force

In order to maximize the Analgesic Sales Force effectiveness we will meet or exceed total prescriber call targets of 752,417 for 2012. A daily call average of 7.1 prescribers per day has been established for 2012. The 2012 Budget call plan by product is shown below:

Butrans will be in the primary position in 83% of calls and second position in at least 15% of total calls. OxyContin will be in primary position in 17% of calls and second position in at least 75% of total calls. Senokot/Colace will be in third position in at least 35% of all calls. Full Year 2012 Performance by product is detailed below:

Comment [A2]: The call target presented here don't appear to match with those back in the second paragraph of the S&M section, although the "budget" numbers in the table below do match that initial paragraph.

2012 Sales Calls					
Primary Calls	Actual	Budget	Var	Actual	Budget
Butrans	574,393	626,417	(52,024)	82%	83%
OxyContin	123,832	126,000	(2,168)	18%	17%
Total Primary Calls	698,225	752,417	(54,192)	100%	100%
Secondary Calls	Actual	Budget	Var	Actual	Budget
OxyContin	458,437	563,775	(105,338)	80%	90%
Butrans	112,891	113,400	(509)	91%	90%
Total Secondary Calls	571,329	677,175	(105,846)	82%	90%
Tertiary Calls	Actual	Budget	Var	Actual	Budget
Laxatives	309,490	263,346	46,144	44%	35%
Total Tertiary Calls	309,490	263,346	46,144	44%	35%
Total Presentations %	Actual	Budget	Var		
Butrans	98%	98%	0%		
OxyContin	83%	92%	-8%		
Laxatives	44%	35%	9%		

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Result: 2012 total calls were below target due to goal-driven by lower days on territory due to vacancies (averaging 4.6%) and slightly lower call averages per day. During 2012, 82% of primary calls went to Butrans. Overall, OxyContin received 18% of primary calls due to an increase in Q3 and Q4.

2012	Call Goal	Calls Made	Difference	% to Goal	Butrans Total % of all	OxyContin Total % of all	Senokot/ Colace Total % of all
Q1	171,024	179,554	8,530	105%	99%	82%	41%
Q2	190,662	183,636	(7,026)	96%	98%	84%	45%
Q3	199,466	180,723	(18,743)	91%	98%	84%	47%
Q4	191,264	153,890	(37,374)	80%	98%	84%	46%
Total	752,417	697,803	(54,614)	93%	98%	83%	44%

Comment [A3]: The headings of the last three columns aren't really clear, at least to anyone who doesn't already know what the data represents

Source: Report Gallery - Metrics Report (weeks of 1/1 - 12/28/2012)

Result: The average physician calls per day for 2012 was 7.0. This is slightly below the objective of 7.1 calls per day.

2012	Daily Average Call Target	Daily Call Average Actual	Prior Year
Q1	7.1	7.0	6.7
Q2	7.1	7.0	7.2
Q3	7.1	7.0	7.2
Q4	7.1	7.0	7.1

Intermezzo Sales Force

In order to maximize Intermezzo Sales Force effectiveness, the 2012 Budget prescriber call target is 328,860 with a daily call average of 8.0 prescribers per day.

Result: 2012 total sales calls were below overall target due to vacancies and the reduction of the contract sales force from 275 to 90 reps in December. Calls per day began to increase in Q3, but were lower in Q4.

2012	Call Goal	Calls Made	Difference	% to Goal
Q1	0	0	0	0
Q2	112,505	112,120	(385)	100%
Q3	112,505	110,867	(1,638)	99%
Q4	103,850	75,369	(28,481)	73%
Total	328,860	298,356	(30,504)	91%

Source: Phoenix Territory Management System

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Result: The average physician calls per day for 2012 ~~was~~ 6.8 calls per day. This is below the objective of 8.0 calls per day.

2012	Daily Average Call Target	Daily Call Average Actual
Q1	N/A	N/A
Q2	8.0	6.8
Q3	8.0	7.1
Q4	8.0	6.6

Marketing Department Key Initiatives

There are several key initiatives for each brand that are being implemented in an effort to support the activities of the sales force. Below is a top-line review of 4th Quarter activities:

- **Butrans® Brand Team**

Action Plan Materials

In the 4th quarter, representatives were trained on the updates to the Butrans Full Prescribing Information and they began distributing the new FPI with materials. Marketing worked to update all print and electronic materials for ~~use and~~ distribution in Q1 2013

Butrans Patient Savings Program

Marketing recommended updates to the Butrans Patient Savings Program including increasing the trial offer for new commercially insured patients from \$75 to \$100 and the savings offer from \$40 to \$50 for 2013. This recommendation was based on an analysis where the new offer increased top line sales and maintained profitability

- Utilization of Butrans Patient Savings Program has increased prescribing 226% compared to control
- Butrans Patient Savings Program has increased NBRx 28%
- ROI: 3.74 based on IMS study

Comment [A4]: It should be noted what NBRx means

Butrans Trial Card Incentive

The Butrans Trial Card Incentive was executed in Q4. This consists of a bonus where representatives are incentivized on Butrans Trial Card redemptions since the cards are proven to increase NBRx prescriptions.

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Butrans Speaker Programs

- In Q412, we conducted 386 speaker events which provided Butrans education to approximately 3,900 HCPs. Recent analysis shows a 195% increase in Rxs over control for HCPs who have attended these events.
- The Physician's Television Network, an at home education via pre-recorded video of a speaker presenting Butrans, achieved ~~the~~our goal of 5,250 views of the Butrans promotional video.

Butrans Experience Program

We distributed 2,500 additional kits to our representatives for prescribers new to the program, and an additional 150 kits to those already enrolled. Also in the Butrans Experience Program, we added 500 enrolled patients, and added 1,000 enrolled HCPs. This program has resulted in an increase of 0.76 Rxs per enrollee, with an overall ROI of 2.6, one of the highest seen for any of our initiatives.

Comment [A5]: Paragraph should be re-written avoiding use of the first person (e.g. "we" and "our").

Butrans Journal Ads

We continue to place journal ads in various pain-related journals, reaching specialists, PCPs, and NP / PAs.

Comment [A6]: Same comment as above

Public Affairs

Public Affairs completed and launched the Doctor's Channel series on Butrans with the following topics: Patient Savings Program, Dosing and Titration, Appropriate Regulatory Prescribing and Instructions for Use. The series will air for one year and is shown to HCPs in various practices including pain management, anesthesiology, family medicine and internal medicine

Market Research

- Quantitative Discontinuation Research Completed
- Fibromyalgia Qualitative Research Completed
- Additional Strengths Research Completed
- ImpactRx Research Completed

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eMarketing

Comment [A7]: Same comment as above.

- o In the 4th quarter, we continued to implement the Butrans HCP Relationship Marketing Program. It includes the interactivity of invitations, an eMail series on Butrans-related topics, the Initiations Case Study program, eDetails, as well as a Butrans Web portal and Web sites that contains available materials (such as the Patient Education Brochure and the Butrans Initiation and Titration guide) for healthcare professionals to download and use to educate themselves, peers, and patients. This eMarketing initiative reinforces the branding, positioning, and key selling messages of Butrans.
- o eMail delivery was suspended in November and December as labeling updates were needed for each of the eMails and this required MRL review. Despite this suspension we were able to achieve our annual goal of 800,000 eMail messages. eMails should come back on line in January.
- o Recent data on achievement of goal for each of the various components of the Relationship Marketing Program can be seen in the below two charts:

Comment [A8]: ditto

The Butrans National Program has REACHED		85%	of the 73.5K HCPs	
Targeted Tactics		YTD	Goal	% Achieved
Recruitment Emails	Number Sent	898,588	800,000	112.3%
	Delivery Rate	96%	85%	113.0%
eDetail eMails	Number Sent	36,609	55,000	66.6%
Initiations	Starts	1,081	550	196.5%
Invites	Invites Sent	22,860	4,400	519.5%
Open Tactics		YTD	Goal	% Achieved
SEM	Impressions	2,257,677	990,000	228.0%
	Position	3.30	3	Lower than target
Portal	Visits	81,469	55,000	148.1%
	Page Views per Visit	2.04	2.00	102.1%
Display – PurdueHCP.com	Impressions	56,893	Program ended	
Display – Butrans.com	Impressions	87,378	1,274,646	6.9%

Note: SEM = Search Engine Marketing, Portal represents Visits to Purdue HCP.com

OxyContin® Tablets Brand Team:

- In the 4th quarter, we continued to reinforce the “Individualize the Dose” campaign with a greater emphasis placed on the OxyContin Managed Care Status and Patient Savings Program. As a result, the following promotional materials were updated and provided to Sales Representatives in October: Core Visual Aid, Appropriate Patient Case Vignettes, and the Patient Savings Program Sell Sheet.

Comment [A9]: ditto

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- A "Medicare Part D" three wave direct mail and email campaign was developed by the OxyContin Brand Team to reinforce the broad formulary coverage of OxyContin to HCPs. 70% of HCPs received the promotion via email and 30% via direct mail. Deployment occurred during October and continued through December.
- A sensitivity analysis was performed and as a result, the OxyContin Savings program offerings for both the Relay Health pharmacy program and the MediMedia Savings Card program have been increased to up to \$90 in potential savings, once a patient pays the initial \$25 out-of-pocket expense during the January 2013 through March 31, 2014 program period. All collateral materials were updated to reflect the new program offering (Savings Card kits, combined program (Relay Health/ MediMedia) HCP detail sheet, and pharmacist information sheet specific to the Savings Card program). Group numbers from 2012 will be automatically rolled over to reflect the new 2013 offering in all states except for Vermont, and pharmacy alerts are being sent out (beginning in January) to minimize confusion and disruption in the marketplace.
- The OxyContin Relay Health eVoucher Program was initiated in March 2012 for new-to-brand patients for OxyContin. After only 60 days, the Relay Health Program showed a positive ROI of 1.16 and incremental revenue of \$1.77MM. In the 4th quarter, there were a total 103,127 redemptions for this program with 263,790 redemptions for 2012. The Patient Savings Card is currently driving a positive ROI of 4.3 and a 14.6 TRx lift per HCP. There were a total of 44,877 redemptions for the Savings Card program in the 4th quarter and 696,551 redemptions for 2012. Currently, 3% of prescriptions are redeemed with a Savings Card and 7% through Relay Health.
- Based on a previous positive ROI of 2.8, the OxyContin Brand Team developed an updated Product Theater Video for the Professional Television Network (PTN). This video program was made available in December and will reach a minimum of 3,000 target HCPs. The content was repurposed from the Product Theater slide deck and video recorded with [REDACTED] a national KOL in Pain Management. We will conduct an ROI analysis of this program at a future date.
- In the 4th quarter we continued to implement the OxyContin HCP Relationship Marketing Program. It includes the interactivity of invitations, an eMail series on OxyContin-related topics, the Conversions case study program, as well as PurdueHCP.com Web portal that contain available materials (such as the Formulary status, Patient Saving Cards and the Conversions case study program) for healthcare professionals to engage with to educate themselves, peers, and patients. This

Comment [A10]: ditto

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eMarketing initiative reinforces the branding, positioning, and key selling messages of OxyContin.

Recent data on achievement of goal for each of the various components of the Relationship Marketing Program can be seen in the below two charts:

The OxyContin National Program has REACHED		90%	of the 60.4K HCPs	
Targeted Tactics		YTD	YTD Goal	% Achieved
Recruitment Emails	Number Sent	1,198,618	900,000	133%
	Delivery Rate	94%	85%	110%
eDetail eMails	Number Sent	69,314	55,000	126%
Open Tactics		YTD	YTD Goal	% Achieved
SEM	Impressions	3,309,414	2,832,300	117%
	Position	2.47	3.00	Higher than target
Portal	Visits	81,469	55,000	148%
	Page Views per Visits	2.04	2.00	102%
Display	Impressions	4,614,783	4,316,314	107%

The OxyContin National Program has ENGAGED		13%	of the 60.4K HCPs	
Targeted Tactics		YTD	YTD Goal	% Achieved
Recruitment Emails	Open Rate	3.3%	3%	111%
eDetails	Unique Starts	337	330	102%
	Registrations	742	550	135%
Portal	Savings Cards	569	55	1,035%
	Open Rate	27.3%	20%	136%
Conversions	Starts	267	55	485%
Open Tactics		YTD	YTD Goal	% Achieved
SEM	Clicks	42,313	40220	105%
	CTR	1.3%	1.42%	90%
Portal	Fingertip Formulary	271	110	246%

Note: CTR on the chart above represents click through rate

Intermezzo® Brand Team

- Patient Savings Programs were implemented in April. These include an eVoucher (at retail pharmacy) and Savings Card.
 - Through December 29, 11,807 redemptions have been processed (8,683 for eVouchers and 3,124 for Savings Cards).
 - YTD, 34% of prescriptions filled have been accompanied by either eVoucher or Savings Card.
- The Intermezzo sampling program was implemented and executed via mail directly to physician's offices (those who request samples). Additionally, we implemented a "Trial Offer" sampling program which provides patients the ability to obtain three Intermezzo tablets free of cost.
 - Through December 29, 97,525 sample units of the 1.75 mg and 85,984 of the 3.5 mg have been delivered to physician offices.

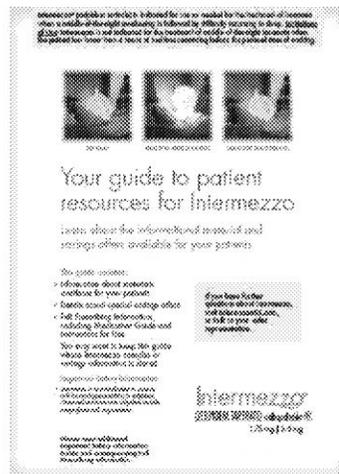
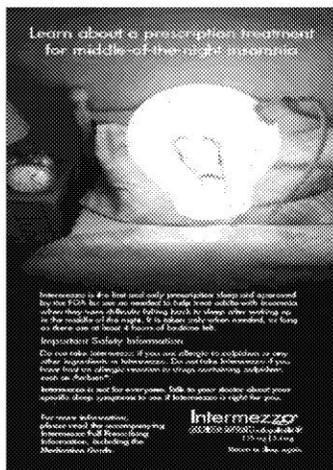
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- o YTD we have 3,921 unique patients enrolled in the “Trial Offer” program.

Comment [A12]: ditto

- The sales force continues to leverage the Core Visual Aid and patient assessment materials provided during their District Meetings in June.
 - a. Additional sales tools will be introduced during District Meetings the week of October 8th, including materials targeted toward pharmacists, a clinical backgrounder that provides additional details regarding the two Intermezzo efficacy studies and a piece that reminds HCPs of the Intermezzo indication and how to write a prescription.
 1. The October meetings did not take place due to the restructuring of the Intermezzo Sales Force (ISF).
 2. However, once the restructuring was completed new materials were provided to the ISF specific to the Direct-To-Consumer Campaign (DTC).
 3. These included the DTC Patient Brochure and Patient Materials Sales Aid.



Comment [A13]: Delete these figures, they are too small to read and don't add anything within this context, and by now everyone who reads this report will have seen the DTC Ads

- The Intermezzo Direct-To-Consumer campaign launched during the fourth quarter.
 - a. The Intermezzo DTC print and digital campaign started in November/December and will continue through March 2013.
 1. The national print campaign began on 11/27 and the digital campaign launch on 12/18, which includes myintermezzo.com (the consumer website).
 2. Print included an ad in Time Magazine's Person of the Year Issue.
- The DTC television commercial was approved for use by the FDA and began airing on Video-on-Demand sites such as HULU and NBC.com on 12/19/12.

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- a. The national broadcast airing of the Intermezzo commercial began airing on 1/7/13 and will continue through March 2013.
- The Speakers Bureau began with nine national KOLs trained within FDA guidelines.
 - a. We have now trained additional regional/local KOLs to a total of 92 speakers.
 - b. To date we have completed 250 speaker programs, with 1600 confirmed HCP attendees.
 - c. The speaker programs are currently averaging nine HCP's per event.
 - d. The Intermezzo Sales Force has continued to schedule speaker programs leading into Q1, 2013.

Comment [A14]: ditto

Comment [A15]: ditto

eMarketing

Intermezzo HCP eMarketing initiatives continued in the 4rd quarter with a multi-channel approach including eMails, Online Advertising and Website Visits. YTD end of November over two million HCP eMails were sent to the 100,000 HCP targets, ten million online media impressions were delivered to HCPs and over 76,000 visits to IntermezzoRx.com occurred. All of these eMarketing initiatives exceed their goals. The three tables below provide the specific metrics and results for the initiatives.

YTD Email Performance	Volume	Open Rate	Click to Open Rate	IntermezzoRx.com Visits	PurdueHCP.com Visits
Total	2,072,457	2.8%	8.3%	2,285	422
Announcement	58,848	3.2%	9.7%	61	N/A
Awareness	1,318,636	2.7%	8.3%	1,330*	59*
Product Theater	515,166	2.8%	8.4%	444	N/A
Recruitment	85,627	2.7%	5.7%	438	363
HMG	238,893	2.0%	5.5%	-	-

	Impressions			Clicks			CTR	CPC
	Forecast	Actual YTD	% to Forecast	Forecast	Actual YTD	% to Forecast	Actual YTD	Actual YTD
Paid Search	4,038,150	5,807,689	143.8%	27,056	73,527	271.8%	1.27%	\$1.92
Display Banners	5,005,000	4,814,490	96.2%	5,005	7,726	154.4%	0.16%	\$58.94
Total	9,043,150	10,622,179	117.5%	32,061	81,253	253.4%	0.76%	\$7.34

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2012 YTD (Jan – Nov) Site Performance	
Total IntermezzoRX.com Visits	76,700
Non-Media Visits	16,119
Display Visits*	4,481
Paid Search Visits*	56,100
IntermezzoRx.com Registrations	646
PurdueHCP Intermezzo Visits	1,066

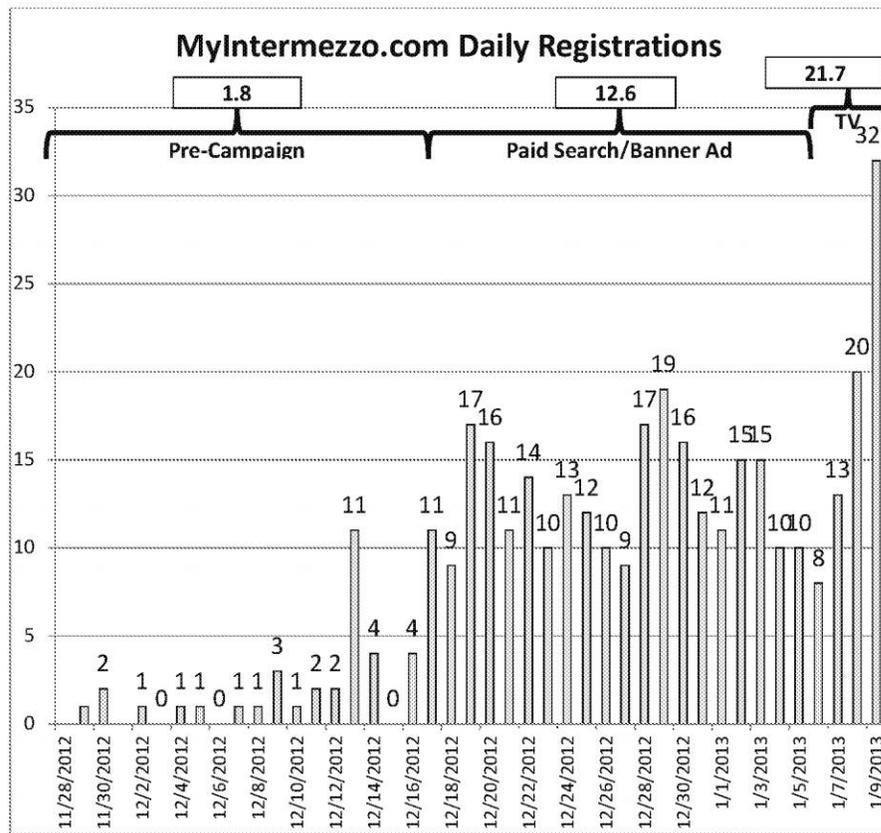
Intermezzo Consumer eMarketing initiatives started in the 4th quarter of 2012. The major initiatives launching included the Online and Mobile versions of the myIntermezzo.com consumer website, Intermezzo Online Banner advertising, Intermezzo Search advertising on Google, Yahoo and Bing search engines and Consumer CRM program.

- o In 2012 there were 125,000 visits to myIntermezzo.com. The majority of these were driven by banner ads and search marketing ads.
- o Over 132 million online banner ad impressions were generated in December driving 178,000 visits to myIntermezzo.com. Search marketing with ads on Google, Yahoo and Bing generated over 28,000 visits to myIntermezzo.com.

Site Name	Total Impressions	Total Clicks	Post-Impression Conversions/ Latent Visits	Total Visits
MaxPoint	64,528,415	63,638	1,297	64,935
Hulu	10,098,716	52,770	8,082	60,852
[HYPERLINK "http://NBC.com"]	8,232,662	25,416	3,878	29,294
Yahoo!	39,622,474	17,599	453	18,052
iVillage	9,187,124	3,808	154	3,962
WebMD	983,504	535	382	917
DISPLAY TOTAL	132,652,895	163,766	14,246	178,012
Search TOTAL		28,103		28,103
Overall Total	132,652,895	191,869	14,246	206,115

- o There were 231 registrations to the myIntermezzo CRM program. Banner ad promotion drove registrations into the myIntermezzo CRM program in December and early reports in January show TV advertising is driving even more registrations per day.

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Laxatives Brands

- Consumer and HCP promotions continued throughout the 4th quarter:
 - National "Purchase Incentive" Program
 - Account Specific Sweepstakes Promotions at key retailers (e.g. WalMart, Walgreens and Rite Aid)
 - Print advertising in demographic specific magazines such as Women's Day, Better Homes and Gardens, and Readers Digest
 - Instant redeemable coupon promotions
 - Customer Relationship Marketing (CRM) to loyal customers
 - Facebook and Twitter campaign

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- o Direct Mail to non-called on HCPs to facilitate brand recommendations

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Managed Care

"Managing Care" through the Managed Care/Payer channel model continues its expansion into all aspects of U.S. healthcare. With the November 2013 elections, the Affordable Care Act mandates will accelerate into the healthcare system. Affordable Care Organizations (ACOs) and State Health Exchanges creation and development will increase in importance to the pharma industry, but also their expanded breadth into the patient populations they cover will impact sales and marketing of pharmaceutical products.

The tables below depict the formulary status of Purdue products in three major payer channels. Included in the tables are the percentages and number of lives in each formulary category/tier, and a brief summary follows each channel with major customers and developments/status changes in the 4th quarter of 2012.

Commercial Formulary Status ~ 211 Million lives in this channel

	OxyContin		Butrans		Intermezzo	
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%
Preferred/2nd tier	181	86.0	62.2	30	22.1	10.5
Preferred/3rd tier	7.6	4.0	107	51	87.9	41.8
Step Edit/Prior Auth	9	3.8	19	9	55.9	27.2
Not Covered	13.6	6.2	23.5	10	45.2	20.5

- OxyContin (Commercial)
 - OxyContin continues to maintain "best in class" access and is the only extended-release opioid brand in its market with more unrestricted access than restrictions.
 - OxyContin commercial national market share exceeds 27%. All major Pharmacy Benefit Managers and most national health plans cover OxyContin on their formularies.
- Butrans (Commercial)
 - Butrans continues to achieve improved formulary access (30% of commercial lives in a preferred position).
 - Recent formulary elevation to 2nd tier at Aetna (approximately 8mm lives nationally) has been followed by an extensive national pull-through program that will continue into 1Q13. We anticipate a greater than 30% lift in prescriptions with 2nd tier formulary access.
 - ODS, an Oregon state-wide health plan and has moved Butrans to 3rd tier.

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- Intermezzo (Commercial)

Comment [A16]: Please re-write to remove first-person nouns in the remainder of the S&M Section.

- From launch, the commercial channel has been the focus for Intermezzo.
- While we have achieved our 2012 target of over 50% of commercial lives at 2nd tier or 3rd tier unrestricted access, we still have approximately 48% of commercial lives with some kind of restriction before the patient can receive Intermezzo. Most of these restrictions are at the point of sale where the pharmacist verifies that the patient has received a prescription for generic zolpidem in the last 4-6 months.
- ProCare, a regional PBM (for self-funded employer groups) in Atlanta, GA moved Intermezzo to 2nd tier unrestricted from 3rd tier with restrictions effective January 1, 2013.
- We were notified by CVS/Caremark, a large national PBM, that starting January 1, 2013, they would not be covering Intermezzo at any formulary tier and if Caremark covered patients wanted Intermezzo the patient would have pay 100% of the cost.
 1. Our colleagues in Medical and Law worked with us on a clinical letter to the Chief Medical Officer of Caremark outlining why we believe this to be the wrong formulary decision.
 2. We are working to re-engage Caremark's clinical and commercial teams to re-review this decision.
 3. This non-coverage will affect the lives covered in the below table in 1Q2013.

Medicare Part D ~ 30 Million lives in this channel

	OxyContin		Butrans		Intermezzo	
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%
Preferred	16.8	56.0	0.3	1.1	0.009	0.4
Non-Preferred	1.8	5.9	2.6	8.9	0.012	5.7
Step Edit/Prior Auth	3.1	10.0	1.2	4.0	1.1	2.6
Not Covered	8.1	28.1	25	86.0	28.7	90.4

- OxyContin (Med D)

- OxyContin continues favorable formulary status for 2012 Medicare Part D formularies with more than 56% of seniors having access to a preferred formulary position and the corresponding favorable copay.
- OxyContin Medicare Part D national market share exceeds 22%
- There is continued pressure from the Med D health plans for increased brand rebates (both OxyContin and Butrans) to keep formulary position in this highly genericized market.
- Generic fentanyl patch (market share of 26.1%), generic extended- release morphine (market share of 29.4%), and methadone (market share of 16%) all

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have market share increases in the last 12 months in this channel. 91% of all prescriptions filled in this channel in 4Q12 were for generics.

- Butrans (Med D)
 - Butrans has had a slow uptake in the Medicare Part D channel, due mostly to two factors:
 1. The payers advocating increased generic utilization and substitution of all brands
 2. The cost sensitivity of the senior citizen population with fixed incomes and increasing prescription utilization with high out-of-pocket costs
 - Currently, negotiations are on-going for inclusion on 2013 Medicare Part D formularies.

Medicaid ~ 48 Million lives in this channel

	OxyContin		Butrans		Intermezzo	
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%
On PDL Formulary	1.3	3.1	5.7	11.9	2.5	5.1
Prior Auth Required	46.5	96.9	42.2	88.1	45.3	94.8

- The Medicaid market continues to be a channel dominated by the individual States mandating use of generics. State budget shortfalls dominate the news and many States believe these shortfalls are accelerated by expenditures from their Medicaid recipients.
 - In 2012 many States have moved their Medicaid populations to Managed Medicaid, where private commercial health plans bid to the State a specified amount per patient per month to financially cover the total health care for a percentage of the States' Medicaid recipients.
 - If the health plan exceeds this monthly cost allotment, the health plan pays the excessive cost from their pocket, if the health plan's cost is lower than the State's per patient per month specified amount the health plan profits.

Forecasting, Analytics and Market Research

Typically, during the fourth quarter our dominant project is finalizing the 2013 budget forecasts. We also conducted numerous secondary data studies monitoring the impacts of opioid prescribing limitations in Washington and Florida. We undertook research to support the launches of ONU and HYD. Finally, in analytics, in addition to the projects below, we are monitoring the Butrans experience program, speaker programs; savings card ROI, the impact of relationship marketing and many other product specific endeavors. The projects below represent a non-comprehensive sample of some of our key undertakings in our department.

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