

INTERMEZZO Objectives	Key results	Recommended Actions/Potential Actions
<p>Sales Force Effectiveness (1st wave completed 5-2012, 2nd wave completed 7-2012, 3rd wave completed 9-2012)</p> <p>- Quantitative study with physicians who have received Intermezzo sales calls to track sales rep performance/ message delivery</p>	<p>About 46% of physicians report that Intermezzo sales calls are the sole source of information they have on the brand</p>	<p>DTC advertising will also increase physician awareness as well as relationship marketing campaigns.</p>
<p>- Determine the influence that sales reps are having on physician behavior</p>	<p>Of physicians not prescribing, the main reasons are: 42% say lack of experience, 51% report managed care issues, 40% are satisfied with other brands, 17% do not have the right patients</p>	<p>Continue to work to remove managed care barriers, as this is the highest actionable objection to writing the brand. Emphasize availability of savings cards / trial cards, since these did not register as an often recalled message and can help overcome managed care objections.</p>
	<p>36% of physicians say that they have changed the way they discuss insomnia with their patients as a result of Intermezzo sales calls. Intermezzo's indication is recalled as the main message by 64% of physicians. 42% of physicians find this message to be persuasive. The :90 ad was liked by 81% of respondents. Though the fair balance increased in the :90 ad, dislikes have not significantly increased from the :60 ad. On an unaided basis, over 80% of respondents recalled Intermezzo name from the ad. Less than 20% of respondents recalled the Ambien name from the ad.</p>	<p>Must broaden the reach to physicians beyond the sales force via persistent e-marketing, DTC and other programs. There were 506K prescribers in the market from Apr-Jun 2012. Most physicians report that sales reps are their sole source of information so far and the reach of 275 representatives is limited.</p>

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INTERMEZZO Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Intermezzo :90 Ad Test Underway</u></p> <p>Compare revised commercial which includes a reference to Ambien and an additional :30 of fair balance to previous commercial and normative data to see the impact that these potential changes may have had on the commercial.</p>		<p>We were concerned initially that the increase in the length of the ad would be detrimental to its effectiveness. However, this research suggested otherwise and encouraged us to move forward with the advertisement.</p>
<p><u>Intermezzo Consumer Experience Study Underway</u></p> <p>Understand the patients' overall experience with Intermezzo from the point of filling the prescription, to first hand experiences with the drug.</p>	TBD	<p>Will be used to identify and overcome obstacles in adoption and patient persistence. May also be used for appropriate consumer messaging.</p>
<p><u>Intermezzo Consumer Brand Awareness Study</u></p> <p>Establish a baseline awareness of Intermezzo among consumers, which includes usage and interest levels, to enable assessment of marketing efforts over time.</p>	TBD	<p>Will be used to measure gains in awareness based on DTC and other early 2013 marketing and sales efforts, which is one of the key issues and objectives for the year.</p>

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OXYCONTIN Objectives	Key results	Recommended Actions/Potential Actions
<p><u>OxyContin and Butrans Call Sensitivity / Sizing Analysis</u></p> <p>Completed 10-2012</p> <p>To Determine the impact of shifting primary calls from Butrans to OxyContin.</p>	<p>- Looking at the periods Jul-Dec 2010 and Jun-Nov 2011, we saw a TRx upside of 12% for OxyContin when we went from no calls to a secondary call (P2) and 20% when we went from no calls to a primary call (P1).</p> <p>- Butrans had an upside of 63% when going from no calls to a P1 and 34% going from no calls to P2.</p> <p>- This was used to determine that a 50/50 split in primary calls using the current sales force to Butrans and OxyContin should have a net upside to Purdue of \$13M in 2013.</p>	<p>- The ultimate recommendation was to redistribute primary calls to a 50/50 split between OxyContin and Butrans in 2013.</p> <p>- This is being implemented in Jan 2013.</p>

OTC Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Slow Mag Attitude and Usage Analysis</u> Detailed profile of Slow Mag consumers and why they purchase Slow-Mag.</p>	<p>In Process</p>	<p>Recent sales trends indicate Slow-Mag consumers to be highly loyal. This survey is designed to determine why (product characteristics, availability, efficacy, etc.) consumers are loyal and provide a consumer profile so that future marketing efforts can most effectively used to target current and potential new customers using the most effective message.</p>
<p>Betadine Line Extension Focus Groups</p>	<p>TBD</p>	<p>Gain an understanding of first aid and wound care practices by consumers, and general opinions of the Betadine line of products as well as focus on gauging the interest of a Betadine swab product in the U.S. For the potential launch of new products.</p>
<p><u>Laxative Market Events Timeline Underway</u> In a format similar to what has recently been done for OxyContin, Butrans, and Slow-Mag, this may help to determine the impact of distribution, promotion and media events on the laxative line.</p>	<p>In Process</p>	<p>Actions will allow for more efficient allocation of resources to the most productive programs. In addition, the event timeline will allow us to see which external events impacted the product positively and negatively. This analysis also provides an understanding of the competitive landscape.</p>
<p><u>Laxative Attitude and Usage Analysis</u> Update our understanding of laxative category and brand behavior and ultimately what motivates the consumer to purchase a product.</p>	<p>In Process</p>	<p>Results will allow us to select and refine product attributes communicated to consumers, understand our competition, and work to find the best marketing and sales promotions to target the laxative consumer to build our consumer base.</p>

Comment [A17]: The typesize in this and several following "boxes" is not consistent with the remainder of the section.

BUTRANS Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Butrans Intermediate Dosage Strength Study Completed 11-2012</u></p> <p>Qualitatively understand the impact that availability of the new strengths will have on Butrans® prescribing</p>	<p>Participants are typically neutral to favorable about proposed launch of 7.5 and 15 mcg/hr dosage strengths. Offering the new strengths will mostly likely result in no change to the number of Butrans patients and just a redistribution of prescriptions among more strengths with the largest impact to the 10 mcg/hr strength.</p>	<p>Offering the additional new strengths will allow representatives to speak about "something new" with physicians to have something new with which they may interact with physicians.</p>
	<p>The 15 mcg/hr strength could help titration between 10 and 20 mcg/hr, however, the true unmet need is a strength greater than 20 mcg/hr. About half of participants note they would prefer to see a strength higher than 20mcg/hr either instead of, or in addition to, the new strengths.</p>	<p>Continue development of the higher dosage strengths.</p>
	<p>More use of 15 mcg/hr is predicted than 7.5 mcg/hr. Many consider the 5 mcg/hr and most likely the 7.5 mcg/hr strengths too weak. Releasing the 7.5 mcg/hr may cannibalize some 10 mcg/hr strength resulting in lower total Butrans sales... as a 10 mcg/hr script is worth more than a 7.5 mcg/hr script.</p>	<p>Adjust forecast accordingly.</p>

BUTRANS Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Butrans Fibromyalgia Qualitative Study Completed 12-2012</u></p> <p>To determine the feasibility of a new indication for fibromyalgia and to obtain physicians' reactions on using buprenorphine/Butrans for this indication.</p>	<p>Physicians describe a middle-aged female who often keeps meticulous notes of their symptoms. They might be overweight because exercise causes them pain. Pain is the most frequently mentioned symptom, followed by fatigue/sleep issues, and then depression. Physicians indicate that there are no formal guidelines for the treatment of fibromyalgia, although they say FDA approvals or studies in fibromyalgia do influence their choice of drugs. Most patients are on multiple products. Opioids are typically considered more appropriate for patients with severe fibromyalgia.</p>	<p>Based on this research, Butrans/buprenorphine appears to have a place in the fibromyalgia market. It fills an unmet need, as it is seen as unique, and these physicians indicate that they are always happy to add another option to their armamentarium.</p> <p>Prior to any decision to pursue an indication, quantitative research should be performed to validate these findings.</p>
	<p>Gabapentin, Cymbalta and Lyrica are seen as standards of therapy for patients with moderate or severe fibromyalgia. Savella is newer and perceived to have side effect issues. Physicians are somewhat interested in Butrans. Mean Level of Interest for PCPs was 6.9 and RHEUMs was 6.2 on a 10 point scale. These physicians tend to prefer the Placebo Controlled Add-on design, as it most closely approximates their real world treatment of fibromyalgia</p>	<p>It appears that physicians are receptive to the fibromyalgia indication for Butrans even if it may be second line to established treatments. Further consideration and investigation of this indication for Butrans is merited. As we look to design potential studies, we should keep these findings in mind.</p>

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BUTRANS Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Butrans Physician Quantitative Study Completed 12-2012</u></p> <p>To assess the perspectives of physicians who have discontinued usage of the 5mcg/hr patch, and those who have lapsed from using Butrans completely.</p>	<p>Overall satisfaction with Butrans is high. Most prescribers who have used the product like it, however, like any new product formulary coverage is the barrier.</p>	<p>We need to Convey to HCP's Butrans improved formulary coverage.</p>
	<p>The number one reason for Butrans discontinuation from this research is the inappropriate conversion of opioid experienced patients to Butrans. 87% of Current Butrans prescribers are not converting to the 5 mcg/hr dosage strength correctly compared to 23% for the 10 mcg/hr. This could set up a misperception of poor efficacy, lead to low patient satisfaction, and high discontinuation rates.</p>	<p>The sales force should focus on appropriate conversions. Programs are being implemented to do so. Another suggestion that may help clarify titration is to consider introducing a Butrans titration pack containing more than one dosage strength. This pack along with the titration guide may help HCPs better titrate Butrans.</p>
	<p>There is some confusion among HCPs regarding Butrans' Mode of Action and the use of supplemental analgesia. They misperceive that Butrans is an agonist/antagonist combination and may interfere with other opioids.</p>	<p>We need to educate HCPs as it relates to Butrans' Mode of Action so that they can use supplemental analgesia as they titrate Butrans.</p>

Comment [A18]: This sentence doesn't make sense. Perhaps you need to explain further what is meant by "not converting to the 5mcg strength correctly."

BUTRANS Objectives	Key results	Recommended Actions/Potential Actions
<p><u>Butrans Marketing Mix</u></p> <p>Underway</p> <p>To measure the promotion impact of each marketing channel and <u>associated</u> ROI</p>	<p>TBD</p>	<p>This project will ultimately result in an ROI for every major promotional channel within one model. Ultimately, this will allow us to optimize profit by reallocating spend through a predictive model. This was successfully performed last year with OxyContin.</p>
<p><u>Butrans Speaker Program (Q1 2012 attendees and Jun-Jul 2012 Cohorts)</u></p> <p>To Determine TRx impact and ROI of Speaker Program</p>	<ul style="list-style-type: none"> - Incremental Full Costs ROI: 0.19 (Rx based deciling and control) - Incremental TRx lift/HCP: 0.69 or 58% - Speaker programs with higher proportion of Primary specialists and medium ERO decile HCPs appear to generate greater lift - Attendees with >= 1 calls post attendance appear to show higher performance 	<ul style="list-style-type: none"> - Make all attempts to invite primary specialists and medium ERO decile HCPs for speaker programs to maximize program impact

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MANUFACTURING / SUPPLY CHAIN / PHARMACEUTICAL TECHNOLOGY

Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major product lines. Ensure project milestones are met and product moves into commercialization. Attain operational and management efficiency, continuously improving and assuring cost effectiveness.

Key Metrics: Manufacturing, Supply Chain and Pharmaceutical Technology

Manufacturing and Supply Chain	Q4 YTD			Full Year	
	Actual	Budget	Var	2012 Budget	2011 Actual
Tablets Manufactured (MM)	691	593	98	593	629
OxyContin	486	409	78	409	456
MS / MSER	196	163	32	163	165
Oxy APAP	-	21	(21)	21	-
Oxy Export	9	-	9	-	8
Export Packaging Bottles (000)					
Bottles Packed	310	-	310	-	308
Orders Shipped On-Time					
Wilson	99.6%	99.0%	0.6%	99.0%	99.8%
Rhodes	97.0%	99.0%	-2.0%	99.0%	99.1%
3rd Party	99.0%	99.0%	0.0%	99.0%	99.7%
Orders Shipped In-Full					
Wilson	99.0%	99.0%	0.0%	99.0%	99.6%
Rhodes	100.0%	99.0%	1.0%	99.0%	99.9%
3rd Party	100.0%	99.0%	1.0%	99.0%	99.6%
Inventory On-Hand (Months)					
OxyContin	2.1	2.5	(0.4)	2.5	2.6
BuTrans	5.5	3.0	2.5	3.0	3.3

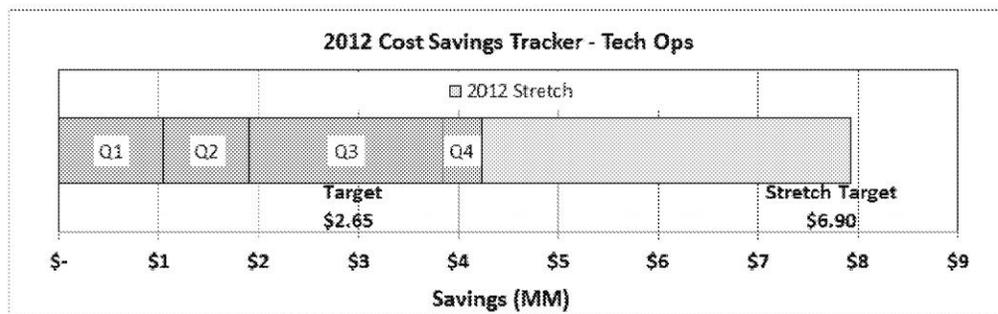
Pharmaceutical Technology	Q4 YTD			Full Year	
	Actual	Budget	Var	2012 Budget	2011 Actual
Research and Development Hours	29,878	40,633	(10,755)	40,633	29,784
Production Hours	3,233	6,474	(3,241)	6,474	4,289
Support Hours	26,645	34,159	(7,514)	34,159	25,495
Development Batches Manufactured	83	114	(31)	114	89

Comments on Key Metrics Table

Major surge in manufacturing activity at yearend to meet MSER and OxyContin requirements as new packaging line installed.

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2012 Savings



- Through Q4, 2012, negotiated savings of raw materials exceeded \$571K. Additional savings for Oxycodone (Noramco) and Morphine price reductions exceeded \$900K.

Comment [A19]: The cost saving tracker bar seems to be point to \$4 million plus, and if this is correct it deserves more comment than this one bullet point.

Infrastructure / Capital Projects

- The installation and qualification of the first of the two new packaging lines is complete, and commercial manufacture has commenced. As a result of this project, the Wilson site has moved from RFID to 2D serialization of the OxyContin product line. The second of the two new lines will commence installation in Q1, 2013.

Rx/ OTC Highlights

- Butrans - Successfully transitioned the US market to patches produced at LTS West Caldwell in November 2012, which will improve our lead time and salable inventory position.
- MSER (Rhodes Pharma) - Due to strong collaboration between Purdue and Rhodes Pharma, we have successfully dealt with significant market fluctuations. After some lost sales in early 2012, MSER business for Rhodes Pharma has recovered very well through Q4, 2012. Production in Wilson will maintain adequate supplies to support the growth of this business under Rhodes Pharma.

Comment [A20]: David - Is this still a correct statement, given the recent accelerated stability test report?

Risk Mitigation: Back-up of Key Products and Materials

- Wilson as a site of manufacture for Dilaudid tablets was submitted to FDA on December 27, 2012, as a CBE30.
- Sumitomo PEO for OxyContin - Qualification batches of Sumitomo's PEO-15 NF were manufactured as an alternate to Dow PEO in ONE.

Comment [A21]: Should this read, "as an alternate site of"?

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New Facility

- Short list of approximately five sites is under review for incentives, suitability and due-diligence. Expect to provide a project summary ~~to the Board~~ at the February BOD Meeting.

QUALITY

Sustain compliance with all laws and regulations related to cGxP from drug development through commercialization. Support the accurate and timely release of approved quality product. Assure integrity and qualification of all new product development, technology transfer and regulatory filings.

Sustained Compliance

ONF Support Activities: As previously reported, a single stability lot of ONF 10 mg tablets (WBL51) showed Out of Trend (OOT) results for unknown degradants at the 3 month stability pull. During monthly monitoring of the lot, the concentration of the degradant plateaued and remained within specification up to the label expiration date. When tested at its 24-month stability storage interval, the lot remained within specification. No additional testing is scheduled for this lot, but toxicology test results on the known degradants are expected in 1Q13.

Phase II implementation of Trackwise for Product Complaints is in progress, and scheduled to go live on January 28, 2013.

External Manufacturing

- Dilaudid
 - An initial field alert was filed December 6, 2012, for Dilaudid 1mg/mL ampule for a missing label identified via a complaint. Inspection of the returned vial confirmed the absence of the label, and it appears that no label had been applied. Hospira is investigating this incident.
 - Four lots of Dilaudid injection, 10-count were found with open carton flaps during incoming inspection at Wilson. Corrective actions were identified with Supplier Quality Assurance assistance, and are being implemented by Hospira.
- Butrans
 - During the review of Butrans lots initially produced at West Caldwell, a discrepancy was identified in a noncritical raw material supplier. The

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supplier used was not included in the supplement filed for West Caldwell and no change request had been submitted to cover the change in supplier, although the supplier has been used by LTS for some time. Release of the lots is pending receipt of appropriate change control documentation. Stability data supporting the change are available, and will be filed in the next annual report which will notify FDA of the change.

- Low dissolution Out of Specification (OOS) test results were identified in a clinical trial lot of Butrans 10mcg/h patches at the 30 month stability pull. The patches had been distributed to clinical sites in support of the BUP Pediatrics clinical trial. All patches from this lot are being withdrawn from the clinical sites and alternate supply made available.
- Slow-Mag Support Activities
 - Investigations into the DEM issue continue, and to date no root cause has been determined. Preliminary results from the *in vivo* genotoxicity testing showed that the risk of genotoxicity/carcinogenicity of DEM in humans is negligible, if any.
 - Hurricane Sandy caused disruption in production of the alcohol used for the enteric coating process. Although a definitive root cause for the DEM has not been identified, it is formed during the coating operation. The alcohol will be sourced from a different supplier under a risk mitigation plan including one-month accelerated stability data, DEM analysis, etc.

Support for New Products

- The Rhodes Oxy/APAP deficiency response was submitted to FDA on November 7, 2012, including process and stability data generated by Wilson and Totowa QC.
- All stability studies to support the Asia / Pacific and Latin America filings for ONF are available. Time zero blister testing will be performed in January 2013. The studies packaged in bottles were initiated in December 2012, with the one month 40°C/75%RH samples being tested in January 2013.

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RESEARCH & DEVELOPMENT

R&D's goal is to efficiently and effectively advance each pipeline project to and through the defined stage gates as described within each program's strategic development plan. R&D's objectives for 2012 are reflected in Purdue's Business Scorecard and focus on progress or completion of major milestones for each pipeline project. While there are many components within each program, emphasis is placed on those items whose progress, quality and outcome drive stage gate decisions and as a consequence, project progress to NDA submission, approval, or termination. Through 4Q2012, substantial progress has been made toward the budgeted plan.

Each of the following pipeline projects are addressed herein:

- Reformulated OxyContin® (OTR/ORF)
- Butrans® (BTDS)
- Targin® (ONU)
- Hydrocodone QD (HYD)
- TRPV-1 (VND)
- ORL1 (OAG)
- Intermezzo (INT)
- Abuse Deterrent Immediate Release Oxycodone / ADIR – (OCI)

Reformulated OxyContin (OTR/ORF)

2012 CORPORATE SCORECARD

On December 5, 2012 ~~we achieved~~ the OTR3001 stretch goal of enrolling 80 patients was achieved.

ORF Messaging

Under the auspices of the ORF Messaging Committee, we developed and disseminated reformulated OxyContin *in vitro*, abuse potential, and epidemiology data on the impact of the reformulation to various external audiences.

- 40 abstracts were accepted to various associations; 43 presentations (poster and oral).
- Four manuscripts were submitted in calendar year 2012 (2 accepted, 2 pending).

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Pediatric Program

- The pediatric exclusivity research program remains on-track for sNDA submission in January 2016.

Japanese sNDA for OxyContin in Non-malignant Pain

Agreement has been reached with respect to all clinical and non-clinical components to support the planned Japanese sNDA (non-malignant pain); the program is on track for a 2Q2016 submission to Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

- Substantial Clinical and Non-clinical support- has been supplied by Purdue to MPKK / Shionogi collaboration.

Prix Galien-USA

ORF was nominated as a "Final Candidate" in the Prix Galien awards category of "Best Pharmaceutical Product."

Butrans® (BTDS)

2012 CORPORATE SCORECARD

Corporate Scorecard Milestones for Butrans were met on or ahead of schedule.

- The Second Generation pilot PK study (BUP1504) sponsored by Mundipharma remains on plan, with Stage 1 PK results expected in February 2013.
- Clinical conduct of the thorough QTc trial (BUP1025) is complete, with the interim analysis completed per protocol on 4 October.
- High dose efficacy and safety studies (BUP3027 and BUP3028) are planned to initiate in 2013, pending favorable results from the thorough QTc trial (BUP1025) and the Second Generation pilot PK Study (BUP1504).

Other Butrans Updates

- Commercial production in West Caldwell was initiated in 4Q2012.
- The Butrans pediatric study program in support of PREA (Pediatric Research Equity Act) requirements is on track.

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- Development of the intermediate dose program (7.5mcg/hr & 15mcg/hr) is proceeding to plan; submission of the Prior Approval Supplement is targeted for late January 2013 - pending receipt of the 7.5mcg/hr strength stability data.

ONU

2012 CORPORATE SCORECARD

Corporate Scorecard Milestones for ONU were met on or ahead of schedule.

- The NDA submission (for the indication of Pain with abuse deterrent properties) planned for 2Q2013 may be impacted by additional analyses of cardiovascular safety data required by FDA; any resultant submission time-line delays will be minimized to the fullest extent possible.
- A multifaceted plan to expedite enrollment in the twin pivotal studies (ONU3704/3705) required to supporting label expansion (OIC prevention/treatment) has been created and will be implemented in 1Q13. These two pivotal studies define the critical path for sNDA submission, and as such, all efforts are being made to expedite their conduct and completion.
 - Data to support ONU's benefit in alleviating signs and symptoms of Opioid Bowel Dysfunction (vs. OIC) are being collected in pivotal trials and will also be addressed through additional means.

Hydrocodone QD (HYD)

2012 CORPORATE SCORECARD

All 2012 corporate scorecard milestones for HYD have been met or exceeded.

- On 12/7/2012, FDA's Analgesic and Anesthetic Advisory Committee voted strongly against approval of a potential first approval of a controlled-release hydrocodone product, Zogenix's Zohydro (twice-daily hydrocodone bitartrate extended-release capsules) - primarily because it is not an abuse-resistant formulation. The PDUFA date for Zohydro for this non-tamper resistant formulation is March 1st, 2013. If not approved, Purdue's HYD product will likely be the first controlled-release hydrocodone product to market.
- NDA filing in 2Q2014 and 3Q2015 launch dates remain on track.

Enrollment in the HYD Phase 3 program (pivotal study and open-label safety study) is on schedule and supportive of an on-time NDA submission.

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TRPV1 Lead (VND)

2012 CORPORATE SCORECARD

All 2012 corporate scorecard milestones for TRPV-1 have been met.

- Two human Proof-of-Concept studies (Osteoarthritis and Post -Herpetic Neuralgia) initiated in September, 2012 and are recruiting on schedule. This is the first time a Purdue new chemical entity ~~has~~will have reached this stage of development.

ORL1 (OAG)

The First-in-Human, single ascending dose study (OAG1001) has completed three cohorts.

- The study was paused to allow for thorough analysis of adverse events (somnia) and pharmacokinetic (low bioavailability) data. A ~~forward~~ plan of nonclinical experiments designed to better understand the cause of these adverse events has been agreed with Shionogi and was executed in 3-4Q12. The next decision point will be in Q12013, when the nonclinical results are available.

TRPV1 Back-up (VAN)

- The First in Human clinical trial (Single Ascending Dose) is ongoing in Japan and ~~is~~ expected to conclude in 1Q13.

Intermezzo (INT)

2012 CORPORATE SCORECARD

All 2012 corporate scorecard milestones for Intermezzo have been achieved.

Milestone	Target	Current Status
Post-Marketing Requirement: Patient compliance with dosing instructions in the setting of actual clinical use	4/2012	Submitted April 30, 2012
Post-Marketing Requirement: PK/PD in Pediatric ADHD	11/2012	Submitted November 29, 2012
Publication Plan Advance publication plan, comprised of 10 potential manuscripts, in accordance with prioritization	Preparation for submission to journals on target	On Plan; one manuscript submitted December 2012

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- Progress continues on the publication plan of previously completed studies, including new analyses that explain gender-specific dosing.

Abuse Deterrent Immediate Release Oxycodone /ADIR - (OCI)

- Testing of Purdue and Rhodes formulations was completed as planned, including oral PK, intranasal PK, Intranasal PD and non-clinical abuse deterrence studies.
- Based upon a comparative evaluation of *in vivo* and *in vitro* data collected for the two Purdue and Rhodes formulations, the team has recommended proceeding with development of the Cranbury (Purdue) formulation -- primarily since it appears to offer the greater abuse-resistance.

DISCOVERY RESEARCH

Purdue-Shionogi Collaboration ORL-1 Agonist Back-up Program

- The main goal of the ORL-1 back-up program is to identify compounds with similar or better efficacy, ADME profiles and low risk for kidney toxicity issues, as well as reduced side effects (fatigue/somnolence) compared to V117957.
- The main focus of the backup team is the elucidation of the mechanism of the observed ~~adverse~~clinical effects, then establishing a method of differentiating a backup molecule. This approach includes the evaluation of biomarkers and EEG in rodents. One notable and preliminary finding is that human neurons appear to be highly sensitive to ORL-1 agonists as compared to ~~rat~~ neurons ~~from rat~~. This species difference may provide a significant clue to help understand the clinical observations. One hypothesis based on this new data is that the drug exposure in man may not need to be as high as was needed in ~~the~~ rat for analgesia, meaning there may be a basis for a larger separation between analgesia and somnolence than ~~initially we first~~ thought.

Purdue-Shionogi Collaboration TRPV1 Back-up Program (083)

- The IND was filed in Japan, no clinical holds, and the SAD studies are underway. ~~Discovery~~Our research in the TRPV1 field is now finished successfully, with two molecules advanced into the clinic.

Sodium Channel (Nav) Blocker

- The Nav team has been working to complete the pre-bridging studies on ~~the~~our front-runner molecule, V121241. The AMES test for mutagenicity was negative and

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we are awaiting the results of the Chromosomal Aberration studies due in mid-January. The team's main focus has been to determine if the oral exposure of V121241 can be sufficiently elevated over the exposure at efficacy to allow this compound to enter toxicological studies. To this end, a vehicle screen, a salt/co-crystal screen and a Spray Dried Dispersion (SDD) feasibility study were run. These studies resulted in the selection of one vehicle and one SSD formulation for pharmacokinetic (PK) assessment in rats. The complete set of results from these studies is due in January. If sufficient exposure is reached, PK studies in dog and monkey will follow. This will allow the team to determine if V121241 meets the criteria to enter bridging studies.

- The chemistry and pharmacological teams are also working hard on the design & synthesis of suitable backup molecules in case V121241 drops out due to unacceptable findings.

Exploration of Signal-Biased Opiates

- In Q4 we implemented and validated a variety of cell based assays that will support the evaluation and design of new molecules as biased agonists of the mu and kappa receptors. We can now measure receptor binding, G protein-coupling, beta arresting recruitment, receptor internalization, and ERK activation. In addition we have implemented new imaging technologies that enable visualization of receptors in whole cells, thus enabling real-time observation of receptor trafficking in response to agonist activation. These systems will form the basis for ~~our~~ research in 2013. Already, there are many new insights that ~~will be presented~~we will present to the board during the Cranbury ~~Discovery Research meeting being~~Board meeting planned for March of 2013.
- We also implemented a TLR4 assay system to measure the off-target effect of known opiates on this glial cell system and have confirmed the known literature that many opiates are also off-target agonists at TLR4, and thus may produce neurogenic inflammation in vivo. With this assay in place, ~~our~~ chemists can design this mechanism out of the profile of our newer molecules.
- We have received the R and S isomers of DHE and we are profiling them in all ~~of~~ ~~our~~ assays for bias and TLR4 action. This data will be complete by the end of January 2013 and will hopefully shed light on possible mechanisms to understand the clinical results obtained thus far.
- Finally, we completed the data package that demonstrated that buprenorphine is a biased agonist and in very low doses can inhibit or reverse opiate-induced constipation in rodents. We further demonstrated that this also occurs following

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oral administration. Patent applications have been filed and future studies are being discussed.

LICENSING AND BUSINESS DEVELOPMENT

Advance Purdue's portfolio diversification strategy through in-licensing or acquisition, through an organized, systematic and strategic licensing review process. Champion the establishment of the new R&D Innovation effort, in the form of screening, business analysis, deal structuring and contract negotiation. Support Intellectual Property efforts related to new or existing products by acquiring and strengthening our IP portfolio as it applies to our in-line Rx products or new products and platforms. Continue to coordinate worldwide business development efforts, supporting Purdue Board-driven potential investment opportunities, by making strategic or financial investments in new companies, as directed by Purdue Board members.

Q4 2012 Full Year Results

	2012 Total	Declined in Level 1	Referred to R&D Innovation	Declined in Level 2	Declined in Level 3	Completed Deals	Active with BDC	On Hold Pending Data
4Q11 Existing opportunities active with BDC	10	0	0	2	8	0	0	0
4Q11 Existing opportunities on hold pending data	10	0	0	7	0	0	0	3
New opportunities 2012	205	146	46	4	0	1	6	2

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Total 2012	225	146	46	13	8	1	6	5
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Status at end of Q4 2012

Active with BDC	Transcept, Flexion, Rhythm, IBSA, Grunenthal, Xalud, Katama
Declined in Level 3	
Declined in Level 2	Convergence, Spinifex
Declined in Level 1	ImmuPharma, ReNew
Opportunities on Hold	Remain on Hold(pending new data): Xenoport, Afferent, Theravance TD-9855, Tranzyme, Pacira

Pain Projects Terminated in 2012

Spinifex	Angiotensin II (Type 2)
Array	MAP – Kinase P-38
Abbott	H-3 antagonist
Regeneron	Anti-NGF antibody
Convergence	NAV 1.7 sodium channel blocker

Other Major Opportunities Terminated in 2012

Tarsa	Oral calcitonin for osteoporosis
Theravance	Opioid antagonist for OIC
Albireo	IBAT inhibitor for constipation
Pearl	LAMA/ LABA for COPD
Optinose	Fluticasone device for chronic sinusitis

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ACTIVE LBD PROJECTS END OF Q4 2012

Company	Product	Indication	Status	Responsible Party	Screening Date
Transcept	Intermezzo ROW	MOTN	ROW Term sheet sent 12-6-12	Kraft	8/1/2011
Flexion	FX-006, IA sustained release steroid	Interarticular injection for sustained treatment of moderate OA of the knee	Phase 2 POC data June '13.	Darland	6/10/2012
Rhythm Therapeutics	RM-131 Ghrelin Agonist Peptide	Diabetic Gastroparesis	Currently conducting Phase 2 trial. Initial DD occurring. Waiting for data. Mtg. at JPM.	Meltzer	6/18/2012
IBSA	Flector Patch (topical diclofenac epolamine 1.3%)	Acute pain due to minor strains, sprains and contusions	IBSA approached Purdue due to their dissatisfaction with Pfizer as a partner. Purdue is developing a market forecast and first draft financial analysis. Pending Pfizer – IBSA dispute resolution.	Kraft	11/13/2012
Grunenthal	Tamper Resistant CR Morphine (MS Contin)	Pain	Late-stage term sheet	Kraft	9/28/2012
Xalud	XT-101 (IL 10 variant; intrathecal injection) long lasting	Neuropathic pain	Linda Watkins company	Downs	12/14/2012
Katama	Tolperisone – Dual voltage gated sodium and calcium channel blocker	Muscle Spasms	Follow up meeting scheduled for JPM	Kraft	12/14/2012

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CORPORATE COMPLIANCE

Assure compliance with Purdue's Corporate Integrity Agreement (CIA) and all Federal and State laws and regulations, as well as the PhRMA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

Corporate Integrity Agreement

Purdue's final Annual Report to the Office of Inspector General was submitted September 27th, and ~~the~~our^{our} OIG Monitor has already reviewed the Report and asked follow up questions. Responsive answers and materials were provided. This is a faster time frame than expected, and a positive development for formal close-out of ~~the~~Purdue's CIA.

Subsequent to submission of the Final Report, Compliance discovered an Intermezzo Sales Force District Manager was not performing job responsibilities during the term of the CIA with respect to "ride-alongs," ~~among other things~~ - a CIA requirement (DM terminated). A decision was reached to report to this to OIG, and extensive information was provided to OIG about our investigation and remedial actions). ~~We do not expect adverse impact to the close-out of the CIA from this matter.~~

Follow-Up Note: The letter from the OIG formally closing the CIA was received on January 28th. A phone call was received from the OIG Monitor on Friday January 11th during which, in response to our question, there was comment that OIG is "wrapping up" our CIA. ~~This is off the record.~~

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Overall

Through the Fourth Quarter, the Company continues to maintain a state of effective compliance, with all components of the Annual Compliance Scorecard above the established standards, ~~including Sales and Marketing, Manufacturing and Quality, and R&D.~~

While there are numerous compliance matters detected, investigated, and remediated on an on-going basis (64 during 4Q; 279 total for year), there have been no *significant* compliance matters to report for 4Q12, with the exception of the Intermezzo District Manager non-performance matter ~~noted~~discussed above.

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EXTERNAL AFFAIRS

Build support for appropriate pain care through policy development and implementation. Take appropriate action on external threats to optimal pain care. Promote Purdue's reputation in academic, community and scientific venues. Address proposed legislation and regulation that may affect the Company and its products. Develop and support innovative programs that safeguard public health and address abuse and diversion of prescription medication.

Build Support for Appropriate Pain Care through Policy Development and Implementation

- A group of U. S. Senators and U.S. Congressmen have now written to the Centers for Medicaid & Medicare Services (CMS) expressing their belief that CMS has misinterpreted the intent of the law by including abuse deterrent formulations in the definition of "line extension." Earlier in the year, the Food and Drug Administration (FDA), Office of National Drug Control Policy (ONDCP) and several members of Congress have contacted the Centers for Medicaid & Medicare Services (CMS) seeking a carve-out for abuse deterrent formulations from the line extension proposed regulation. Twenty-two organizations from the Pain Care Forum have also commented on the CMS regulations. The White House has expressed concerns to CMS as well. We have received very positive feedback from FDA and ONDCP that a satisfactory solution has may have been reached, but will not be sure until the final regulation is published. This is expected in 1Q or Q2 of 2013.
- Members of Congress introduced legislation, ([HYPERLINK "http://www.gpo.gov/fdsys/pkg/BILLS-112hr6160ih/pdf/BILLS-112hr6160ih.pdf" \t "_self"]), that would prevent FDA from approving a non-abuse deterrent controlled substance where a deterrent formulation of the same drug is already approved. The legislation has received considerable attention from Congress. More than 100 elected officials from State and Federal offices have written to HHS and/or the FDA in opposition of generics for the old formulations of Abuse Deterrent medicines. Articles have been generated from thought leaders and Members of Congress are contemplating potential amendments similar in nature to the STOPP Act. Work on this issue will continue into 2013.

Take Appropriate Action on External Threats to Optimal Pain Care

- FDA has announced ~~two~~ meetings in January and February 2013. Activities in preparation for those meetings are taking place at the Pain Care Forum and

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internally at Purdue. FDA meeting in January to consider hydrocodone (rescheduled); [HYPERLINK "http://www.ofr.gov/OFRUpload/OFRData/2012-30517_Pl.pdf"] and the February public meeting on the impact of labeling of opioid analgesic drug products [HYPERLINK "http://www.pharmcast.com/FederalRegistrar/Yr2012/Dec2012/121712/12192_Opioid.htm"].

Promote Purdue's Reputation in Academic, Community and Scientific Venues

- Scientific communications support was conducted surrounding the publication of data from the NAVIPPRO epidemiological study on the reformation of OxyContin in the November issue of the Journal of Pain.
- A new brochure "Advancing Medical Science" was developed as part of the Research and Development Advocacy Network (RADAN) to help recruit clinical investigators and facilitate patient enrollment in Purdue's clinical trials. The brochure is being distributed by Clinical Research, Medical Liaisons and Healthcare Alliance Development.
- Engagement was made with reporters from the Wall Street Journal that favorably impacted several stories written about the use of opioids and Purdue marketing efforts. While media outreach was limited due to concern over the DTC moratorium, stories were secured in Health and Allure, which are two influential women's magazines. In preparation for the consumer launch, Public Affairs recruited a group of healthcare professionals who will serve as media spokespeople for the brand.
- Conducted radio media tour with Lee Woodruff and Dr. Kalauokalani about the burden of pain and the Institute of Medicine Report. The radio media tour also highlighted the *In the Face of pain*® website as well as the Handbook for People with Pain. A total of 20 interviews were conducted with a cumulative audience of 11,171,800.

The Handbook for People with Pain launched the last week of the third quarter. A total of 11,441 were distributed since that time.

Address Proposed Legislation And Regulation That May Affect The Company And Its Products.

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- Regulations to support the Kentucky law that requires physicians to access the state prescription monitoring program before prescribing controlled substances continue to be negotiated, and new legislation will be introduced.

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Develop And Support Innovative Programs That Safeguard Public Health And Address Abuse And Diversion Of Prescription Medication.

SafeGuardMeds.org implemented a national awareness program to educate the public about proper storage and disposal of prescription medications. This included a continued partnership with the US Conference of Mayors. The Public Service Announcement campaign initiated in September 2011 has secured 13,580 airings, 288 million impressions and \$7,036,665 in media values.

- Purdue and the National Community Pharmacists Association conducted a Safeguard My Meds public education to promote safe storage and disposal of medications in the home.

HEALTH POLICY

The objective of the Health Policy Group is to help shape the public face of Purdue, enhance corporate visibility, and provide a supportive environment - by communication and other external activities. The group also supports Medical Education initiatives providing high-quality, relevant education resources that meet clinical needs and increase the awareness of non-drug value of Purdue Pharma as a compliment to the portfolio of drug products. Provide accurate and timely medical review of Materials that educate external customers (healthcare professionals, patients, general public, etc.) and the Sales Force on the safe and appropriate use of Purdue products.

Policy-Related

- Communication & External Affairs Committee
 - Senate Finance Committee responses: specific deliverables
 - Assisting Public Affairs with media response/standby statements, etc.
 - Detailed comparison of national opioid prescribing guidelines to complement Pain Care Forum work with CDC and respond to PROP
 - State prescribing regulations: OH - medical association leaders provided arguments; WV - rewrote definitions and other language to counter that proposed by State to enact "Pill Mill" statute
 - National Alliance for Model State Drug Laws sought assistance with Drugged Driving Legislation in response to communication from Purdue earlier in 2012

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- Medical Research
 - Consulted internally on issues relating to urine drug testing reporting in trials and created clinical guideline for in-office testing for use by investigators
 - ONU Clinical Investigators' Meetings 3704 & 3705: education on abuse/addiction/urine drug testing
 - Consulted with reference laboratories to clarify urine drug test reporting

- Risk Management
 - Chairs Prescribers Sub-team for REMS Participating Companies
 - Led translation of REMS Patient Counseling Document into Spanish
 - Internal subject-matter expert lead for Medical Education comprehensive urine drug testing modular DVD, as an addition to PERFORM®

- Sales and Marketing
 - Consulted in revision of anti-diversion brochures
 - Reviewed BuTrans Clinical Trials Exam with Sales Training to develop further educational material for Sales Force
 - Direct education of sales representatives (Level 200: Why Does My Back Hurt? – anatomy, physiology, pathology, and treatment of low back pain)

- Other collaborations
 - Tufts MSPREP: *Development of US Drug Control Policy*
 - DIA Risk Management: *Developing and Implementing Complex REMS*
 - 23rd Annual AMA Task Force on CME Provider/Industry Relations: Keynote Address – *Conflicts of Interest*; Panel discussion - REMS-Integrating Education with Patient Safety
 - Participant: 2012 Health Sector Assembly; Abuse-liability definitions workshop of ALERTT (subcommittee of FDA-Public/Private Partnership ACTION Network); Duke University Fuqua School of Business' Collaborative on Healthcare for Aging/Advanced Illness Populations

- Abstracts accepted for American Pain Society Annual Meeting (05/2013)
 - *Review of Opioid Conversion Recommendations from Select Clinical Practice Guidelines – All are Not Equal*
 - *Analysis of Guidelines for Treating Chronic, Non-cancer Pain with Opioids*
 - *Youth Health Risk Behaviors Associated with Nonmedical Use of Prescription Pain Relievers*

Healthcare Grants and Giving

116 healthcare educational and non-educational grants were reviewed (744 YTD)

- Sixty (52%) were approved for a total \$1,437,115.00 in 4Q12, plus

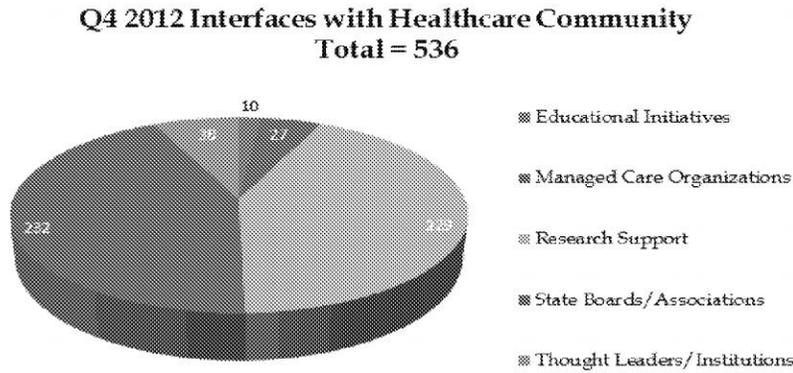
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Medical Science Liaisons (MSLs)

(Managed Health Systems, Alliance Outreach, Strategic Education Initiatives, Medical Research Support)

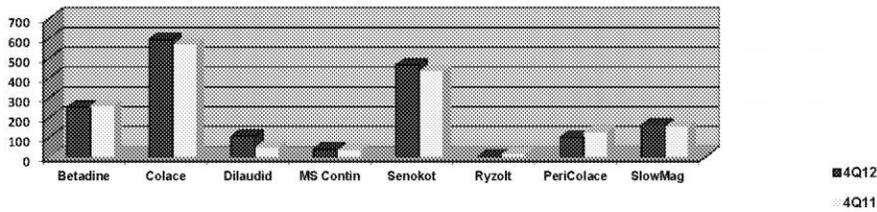
- Major areas of MSL interactions with the Healthcare Community include: 33% State Boards & Associations, 32% PPLP Research Support, 25% Educational Programs



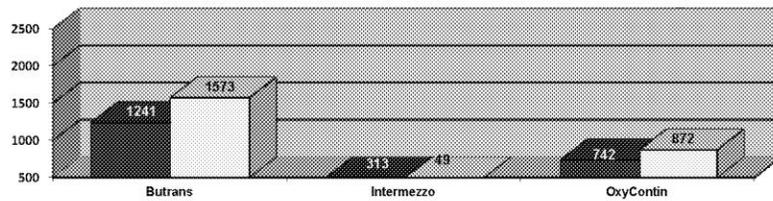
Note: 2012 year-end totals not included in this graphic due to a change in reporting format midyear.
*175 attendees in Education sessions

Medical Services

- 4Q12 Inquiries
 - 4,369 total inquiries
 - 25% decrease from 3Q12 and a 3% decrease from 4Q11
 - 81% of inquiries answered within (1) one business day
 - 98.7% answered within (10) ten business days



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- Specific Products

- BuTrans = 1,241 inquiries
 - 19% physicians, 62% consumers
 - Application instructions (142)
 - Application site reaction (78)
 - Adhesion (47)
 - Lack of Effect (41)
 - Dose conversion from other opioids (41)
 - AE Management (37)
 - Cardiovascular (12)
- Intermezzo = 313 inquiries
 - 58% physicians, 25% consumers
 - Comparison to other zolpidem products (29)
 - Gender-specific dosing (18)
 - Complex behaviors (11)
 - Oral Administration (10)
 - Driving Study (5)
- OxyContin = 742 inquiries
 - 9% physicians, 73% consumers
 - Lack of Effect (37)
 - Reformulation - what has changed (23)
 - Request for epidemiological-study data (13)
 - Withdrawal (13)

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HUMAN RESOURCES

Design, communicate and implement rewards programs that drive alignment and achievement of corporate and individual performance objectives. Staff positions with highly capable talent and assure employee engagement and retention. Develop employees through relevant and meaningful programs and assignments while providing for future succession requirements. Assure program and management compliance with all regulatory and legal requirements.

Staffing, Employee Engagement, Relations and Retention

- 200 full time employees have been recruited to Purdue in 2012. Total turnover for Purdue was 8.8% in 2012 compared to 5.0% in 2011. This increase is largely driven by turnover in the Field Sales Force, which is 12.8% YTD.
- [REDACTED] Director, R&D Innovation began his employment with Purdue on November 12, 2012, reporting to [REDACTED] Executive Medical Director.
- [REDACTED] joined the Analgesic Sales Force as Regional Manager, Northeast Region, effective October 11, 2012, reporting to [REDACTED] Area Director.
- All colleagues have been informed about the planned new newly-funded U.S. manufacturing facility to be built with the capability of providing back-up to the Wilson site, and advising that Totowa operations will be discontinued when this new facility is ready to begin production - likely is built and approved by the FDA, which is expected to occur in late 2015 or early 2016.
- An agreement has been reached with LinkedIn (a professional networking site) for 2013, whereby Purdue will have a career page on the LinkedIn site that will direct candidates to the Purdue career page to apply for positions, to facilitate the continued to use our own sourcing methods relying less on agencies for the recruitment of staff.
- 55 Colleagues were acknowledged for ten or more years of service at the December Town Hall Meeting in Stamford; 40 field members will be presented with awards at the National Sales Meeting.

Compensation & Benefits

- It was announced in November that Purdue will be amending the retirement benefits plans effective January 1st, 2013. Employees nearer to retirement will

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continue to participate in the Purdue Pharma L.P. Pension Plan ("Pension Plan"), while employees with a longer time period to prepare for retirement will shift from Pension Plan participation to a new benefit providing additional contributions to the Purdue Pharma L.P. and Retirement Savings 401(k) Plan.

Training & Development

- Executive Coaching continues for a number of leaders including one-on-one coaching to managers, on motivating subordinates, improving relationships with managers, leading change and improving team effectiveness.
- Several performance coaching sessions were held for managers and colleagues in handling difficult conversations, listening, supervisory skills, managing without authority, and presentation skills.
- Culture and Leadership Team Meetings were held in Totowa to review accomplishments in 2012 and set Objectives for 2013.
- Due to a highly successful Mentoring Program in the 2nd half of 2012, the Mentoring Program will again be offered in 2013 and will be expanded to include non-exempt employees as well as exempt employees.
- Human Resources partnered with Security, EHS and site management to introduce the Workplace Violence Prevention program to every location. A working gap analysis and threat response plan is under review at each site.

Environment, Facility and Regulatory Compliance

- EHS continues to work closely with the Cranbury site and Central Engineering on the new Kilo Lab design and Hydrogenation Lab Engineering projects. An outside expert has been retained to provide oversight on these high priority projects with the potential for significant risk issues.
- Purdue ranked high among companies evaluated by the American Cancer Society for overall health and wellness programs. To further enhance wellness initiatives, Purdue is offering a robust smoking cessation program at no cost to all employees, their spouses and their dependents. In addition, a certified coach trainer has been made available at a special rate to employees, in the Stamford Fitness Center.

Community Relations

During the 4th Quarter, we processed and approved 21 community grants totaling \$454,645, including \$350,000 in tax credit donations, \$24,645 in matching funds for

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contributions made by Purdue colleagues to the Red Cross Hurricane Sandy Fund and \$54,313 in matching funds for the United Way and Community Health Charities employee campaign. For the full year, we processed and distributed \$1,451,995 in community grants, of which \$635,000 earns a 100% Connecticut tax credit.

Facilities and Engineering

Phase 1 kitchen renovations were completed and Phase 2 work commenced in the server area, with a target completion date of February 11.

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