# Purdue Quarterly Report to the Board 2nd Quarter, 2012

July 27, 2012

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#### **MARKETING & SALES**

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 position and OxyContin in 17% primary position. 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/Colace 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	Actual		Виа	lget	Prior Year		
(\$MM)	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	556.3	798.9	596.1	762.2	583.7	
Q3			792.8	592.0	726.3	543.7	
Q4			852.2	626.2	757.4	530.0	
Total	1,438.0	1,063.8	3,167.9	2,351.5	2,971.2	2,210.1	

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

2012 year to date actual net sales of \$1,063.8 mm were lower than budget by \$69.4 mm or 6.1%. This variance was driven by:

- OxyContin gross sales of \$1,330.4 mm that were \$69.4 mm or 5% below budget mainly due to lower Rx demand and lower trade inventory than forecast.
- Butrans gross sales of \$48.9 mm that were \$9.2 mm or 16% below budget due to lower Rx demand.
- Ryzolt gross sales of (\$6.3 mm) driven by product discontinuance and returns.

2012 year to date actual net sales of \$1,063.8 mm were lower than 2011 by \$72.6 mm or 6.4%. This variance was driven by lower OxyContin sales of \$69.0 mm and lower Ryzolt sales of (\$12.8 mm), offset by higher Butrans sales of \$16.3 mm.

#### **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 \$2.4 billion.

2012	Actual		Виа	lget	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			83.6	14.1%	59.1	10.9%	
Q4			99.7	15.9%	60.7	11.4%	
Total	146.3	13.6%	343.4	14.6%	229.3	10.4%	

Note: S&P expense has been restated to exclude patient savings card discount expense.

S&P expense of \$146.3 mm was \$13.7 mm lower than budget primarily due to lower salary and related expenses of \$5.1 mm (primarily bonus related), lower promotional spend of \$2.8 mm (detailed below), lower spend on fleet and other miscellaneous costs related to the Contract Sales Organization of \$0.9 mm, and all other of \$4.9 mm.

- OxyContin promotional under-spend is due to lower special promotions due to delays in eMarketing initiatives and delays in spend due to label updates.
- OTC promotional under-spend is due to timing of consumer ad media and samples.

S&P expense of \$146.3 mm was \$36.8 mm higher than prior year primarily due to 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 \$1,656.0 mm/ 78.5% of net sales, Butrans negative \$55.9 mm, Intermezzo negative \$72.4 mm, Laxatives \$19.4 mm/38.4 % of net sales. Full year targets and results are detailed below.

2012 Target Gross	2012 Target Net	2012 Target Product	2012 Target Product	YTD Actual Gross	YTD Actual Net	YTD Actual Product	YTD Actual Product Contribut
(\$MM)	(\$MM)	Contribut	Contribu	(\$MM)	(\$MM)	Contribu	Contribut

			ion (\$MM)	tion (%)			tion (\$MM)	ion (%)
OxyContin	\$2,877.4	\$2,108.7	\$1,656.0	78.5%	\$1,330.4	\$970.7	\$747.5	77.0%
Butrans	\$135.8	\$95.9	(\$55.9)	N/A	\$48.9	\$41.0	(\$28.0)	N/A
Intermezzo	\$49.2	\$43.4	(\$72.4)	N/A	\$13.9	\$3.3	(\$33.8)	N/A
Laxatives	\$51.9	\$50.6	\$19.4	38.4%	\$25.1	\$24.5	\$9.8	40.2%

OxyContin's product contribution of \$747.5 mm was lower than budget by \$39.9 mm. This variance is primarily driven by lower gross sales of \$69.4 mm offset by lower variable expenses of \$14.9 mm and lower S&P expenses (promo/sales force) of \$6.1mm.

Butrans' product contribution of (\$28.0 mm) was higher than budget by \$0.9 mm. This variance is primarily driven by lower gross sales of \$9.2 mm offset by lower variable expenses of \$2.9 mm and lower S&P and R&D expenses of \$5.6 mm.

Intermezzo's product contribution of (\$33.8 mm) was lower than budget by \$3.5 mm. This variance was primarily driven by higher gross sales of \$2.7 mm and lower S&P expenses (CSO) of \$2.4 mm offset by a higher returns reserve of \$9.0 mm.

OTC's product contribution of \$9.8 mm was higher than budget by \$0.3 mm. This variance was primarily driven by lower S&P expenses of \$1.0 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. Budget calls per product are as follows.

- Butrans will be in the primary position in 83% of calls and second position in at least 15% of calls.
- OxyContin will be in primary position in 17% of calls and second position in at least 75% of calls.
- Senokot/Colace will be in third position in at least 35% of all calls. Q2 Performance by product detailed

#### below

Sa	Sales Calls (YTD)			
Actual	Budget	Var	Actual	Budget
313,000	301,119	11,881	86%	83%
49,800	60,568	(10,768)	14%	17%
362,800	361,687	1,113	100%	100%
Actual	Budget	Var	Actual	Budget
250,263	271,007	(20,744)	80%	90%
45,123	54,511	(9,388)	91%	90%
295,386	325,518	(30,132)	81%	90%
Actual	Budget	Var	Actual	Budget
153,203	126,590	26,613	42%	35%
153,203	126,590	26,613	42%	35%
Actual	Budget	Var		
99%	98%	0%		
83%	92%	<b>-9</b> %		
42%	35%	7%		
	Actual 313,000 49,800 362,800  Actual 250,263 45,123 295,386  Actual 153,203 153,203  Actual 99% 83%	Actual         Budget           313,000         301,119           49,800         60,568           362,800         361,687           Actual         Budget           250,263         271,007           45,123         54,511           295,386         325,518           Actual         Budget           153,203         126,590           153,203         126,590           Actual         Budget           99%         98%           83%         92%	Actual         Budget         Var           313,000         301,119         11,881           49,800         60,568         (10,768)           362,800         361,687         1,113           Actual         Budget         Var           250,263         271,007         (20,744)           45,123         54,511         (9,388)           295,386         325,518         (30,132)           Actual         Budget         Var           153,203         126,590         26,613           153,203         126,590         26,613           Actual         Budget         Var           99%         98%         0%           83%         92%         -9%	Actual         Budget         Var         Actual           313,000         301,119         11,881         86%           49,800         60,568         (10,768)         14%           362,800         361,687         1,113         100%           Actual         Budget         Var         Actual           250,263         271,007         (20,744)         80%           45,123         54,511         (9,388)         91%           295,386         325,518         (30,132)         81%           Actual         Budget         Var         Actual           153,203         126,590         26,613         42%           Actual         Budget         Var           99%         98%         0%           83%         92%         -9%

**Result:** 2012 YTD total calls are above goal. However, Q2 total sales calls are below overall target due to vacancies and slightly lower calls per day offset by higher days on territory. During Q2, 82% of Primary calls went to Butrans. OxyContin received 18% of primary calls, which is 9 points up from Q1 (average YTD of 14%).

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						
Q4	191,264						
Total	752,417	363,190	1,503	101%	99%	83%	42%

Source: Report Gallery - Metrics Report (weeks of 1/1 - 6/30/2012)

**Result:** The average physician calls per day for Q2 2012 is 7.0. This is slightly below the objective of 7.1 calls per day.

	Daily Average	Daily Call	
2012	Call Target	Average Actual	Prior Year

Q1	7.1	7.0	6.7
Q2	7.1	7.0	7.2
Q3	7.1		7.2
Q4	7.1		7.1

#### **Intermezzo Sales Force**

In order to maximize Intermezzo Sales Force effectiveness we will meet or exceed total prescriber call targets of 328,860 in 2012. A daily call average of 8.0 prescribers per day has been established for 2012.

**Result:** 2012 Q2 total sales calls are slightly below overall target due to lower calls per day offset by higher days on territory.

2012	Call Goal	Calls Made	Difference	% to Goal
Q1	0	0		0
Q2	112,505	112,120	(385)	100%
Q3	112,505			
Q4	103,850			
Total	328,860	112,120	(385)	100%

Source: Phoenix Territory Management System

**Result:** The average physician calls per day for Q2 2012 is 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	
O4	8.0	

# **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 2<sup>nd</sup> Quarter activities:

# **Butrans**® Brand Team:

• In May we introduced a new initiative called "Butrans Experience Program". The objective of this initiative is to increase number of physicians who "trial" Butrans by

getting them to initiate Butrans therapy in up to five patients. This is a national pilot involving approximately 2,620 physicians. Each sales representative will enroll five healthcare professionals. The program is managed by InfoMedics, a company that specializes in providing physicians with direct feedback from their patients about their treatment experience and satisfaction levels with the therapy. The physician accomplishes this by enrolling patients into the "Experience Program", which in turn allows the patients to communicate experiences via patient self-assessment tools that are provided to the physician between office visits. Each patient who enrolls in the program completes a survey at enrollment and again at 7, 15, 30, and 60 days to track their experience. This assists the physician in appropriate management of the patients, and increases involvement of the patient to better assess the Butrans "experience". InfoMedics has implemented similar programs across various categories and demonstrated very positive results.

- During the 2nd quarter, 300 speaker programs were conducted. This level of implementation met the objective established. There are 900 speaker programs budgeted for the remainder of 2012, and based on ROI analysis conducted for programs held in 2011 - these programs profitably contribute to the growth of Butrans.
- To assist in creating greater awareness and educating on Butrans, proper patient selection, use of supplemental analgesia and initiating with the correct dose, we have introduced the Butrans Lunch & Learn Presentation Kit:
  - The Kit will be used by sales representatives to deliver a presentation that highlights key topics for Butrans to a small group of physicians and/or health care professionals
  - The Kit will help reps deliver a strong, effective in-service by providing them with a selection of prepared presentation materials including a presentation implementation guide, instruction sheet, and pre- & post-presentation surveys. Presentation options for include:
    - Application & Rotation Video
    - INITIATIONS
    - Physician's Insights Video- Butrans & Buprenorphine video featuring Dr. Raffa
    - Physician's Insights Video- Clinical Trials video featuring Dr. Hale
    - Physician's Insights Video- Dosing & Administration video featuring Dr. Pergolizzi
    - Physician's Insights Video- Application & Disposal video featuring Dr. Cole
- In the 2nd quarter, we continued to implement the Butrans physician 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 site 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.

- Relationship Marketing targeted HCPs are sent branded Butrans eMails every two weeks:
  - Over 90K eMails were sent in Q2 with an open rate of 3.6% which was higher than our forecast of 3.0%
  - Calls to Action include Use Savings Cards, Do the eDetail, Do the Initiations interactive experience, etc.
- Representatives are using paper invitations to recruit targeted HCPs to
  - o Over 44K invitations were delivered in Q2 which is 110% of forecast
- Representatives are presenting the Initiations In-service to targeted HCPs to educate them on the appropriate patients to initiate Butrans
  - o Over 9K in-services were delivered during Q2 which is 162% of forecast
- The implementation of the Patient Savings Program for Butrans continues to represent a significant part of promotional budget. This program is designed to reduce the out-of-pocket costs for patients who are prescribed Butrans. YTD, 40% of all prescriptions are filled using redemption of the Patient Savings Card, the RelayHealth eVoucher, or the "Trial Offer" savings card. This Trial Offer is designed specifically for "new-to-brand" patients. It reduces the initial patient copay to \$0, with Purdue covering up to an additional \$75 of the first prescription. Refill prescriptions for these patients change to the original savings program which consists of \$15 co-pay, with Purdue covering up to an additional \$40. Since introduction in January, 11,664 patients have redeemed this offer. We are measuring impact of this program on refill prescriptions.

#### OxyContin<sup>®</sup> Tablets Brand Team:

- The OxyContin Brand Team developed and introduced two new important tools to support promotional efforts. In order to support the appropriate conversion and titration of OxyContin, the brand team introduced the OxyContin Conversion and Titration Guide aligned with the new "Individualize the Dose" campaign. In addition, the OxyContin Core Message Summary Leave Behind was introduced. This Leave Behind reinforces the branding, positioning, and key selling messages of OxyContin.
- Based on positive experience with the Butrans RelayHealth eVoucher component of the Patient Savings Program, we designed a similar program for new-to-brand

patients for OxyContin. This was introduced to the Analgesic Sales Force at the National Sales Meeting. YTD there have been 88,764 redemptions for this program. We are monitoring this program to measure impact on overall prescription trends, "new-to-brand" share capture and ROI. The Patient Savings Program is currently driving a positive ROI of 4.3 and a 14.6 TRx lift per HCP. Currently 4% of total prescriptions are redeemed with a Savings a Card and 6% through Relay Health.

- Due to changes in FDA perspective on dosing conversion tables, we needed to remove the conversion tables in the OxyContin FPI. As a result the brand team developed changes to all marketing & sales support material that referenced the conversion table. The new pieces will be rolled out to the field during the fourth quarter.
- Also, brand management worked with medical/regulatory to prepare for the classwide REMs for extended-release opioids to identify changes to the FPI and any corresponding changes to marketing & sales material and to determine what actions need to be taken to comply with the class-wide REMSs.
- Sales Representatives are presenting the OxyContin "Conversions" In-service to targeted HCP in order to educate on the appropriate patients to convert to OxyContin.
  - o Over 3K In-services were presented in Q2 which is 172% of forecast
- The OxyContin Relationship Marketing Program continues from the January targeting of 57K HCPs:
  - o In the second quarter, 292K eMails were sent to targeted HCPs with an open rate of 3.6% which was above our forecasted rate of 3.0%
  - Targeted HPCs are sent branded OxyContin eMails every two weeks
  - The calls to action include Savings Cards utilization, engaging in the OxyContin eDetails, Visiting the PurdueHCP.com, participating in the OxyContin Conversions interactive experience, and the appropriate prescribing of OxyContin
- 192 eDetail starts with 114 completions were achieved YTD with the three existing eDetails
  - o 10K eMails were sent recruiting HCPs to engage with the eDetails
- Online advertising continues for OxyContin on Google, Yahoo and Bing search engines and major HCP websites. In the second quarter we had approximately

- 1.6MM search impressions leading to 22K visits to the website at a cost of \$4.51, well below our forecast of \$5.18/visit
- Display advertising started in May and yielded 1.6mm impressions leading to 2.4K visits to the website at an average click thru rate of 0.16% above the target rate of 0.10%. During the 2<sup>nd</sup> quarter, we continued to place OxyContin Journal ads on a monthly basis.
- A "Conversion" direct mail campaign was sent in April to Decile 8-10 OER
  prescribers, broken out by Confident (35,100) and Delaying (12,345) Treaters. This
  mail campaign utilized patient case vignettes to educate HCPs on the appropriate
  conversion to OxyContin.

#### Intermezzo® Brand Team

- Patient Savings Programs were implemented in April. These include an eVoucher (at retail pharmacy) and Savings Card approach, similar to Butrans. Through July 7, 2,432 redemptions have been processed (1,721 for eVouchers and 711 for Savings Cards). YTD, 30% of prescriptions filled have been accompanied by either eVoucher or Savings Card.
- The Speakers Bureau began with nine national KOLs trained within FDA guidelines. We have completed 26 speaker programs, with 193 attendees. We have now trained additional regional/local KOLs (in June) and the Intermezzo Sales Force is scheduling programs for July-December. We have budgeted for 550 programs in 2012, and will be monitoring the impact of these programs to determine ROI.
- We implemented a sampling program via mail directly to physician's offices (those who request samples) and we are offering a "Trial Offer" sampling program which provides patients the ability to obtain three Intermezzo tablets free of cost. The patient receives a prescription for the "Trial Offer" and fills this at a retail pharmacy. YTD we have 1,141 patients enrolled in the "Trial Offer" program and 25,633 sample orders have been received to ship to physicians offices.
- FDA approved visual aids were introduced to the sales force the week of June 25<sup>th</sup>. These pieces are designed to effectively message and position Intermezzo. Prior to availability of the pieces, the sales force was utilizing "interim sales aids" which did not include full graphics, detailed information from the two pivotal trials, or graphic depictions of the PK profiles for the 1.75mg and 3.5mg tablets. We also introduced two assessment tools that assist the HCP in identifying patients who meet Intermezzo's indication. One of the major barriers to use is identification of

- appropriate patients, via proper assessment. The introduction of new visual aids, as well as the assessment tools should provide a boost to prescription trends.
- eMarketing initiatives continued in the 2<sup>nd</sup> quarter, with acceleration in June and a series of email "blasts" which are designed to increase awareness of Intermezzo. These reinforce the messages/positioning seen in the new visual aids. These email initiatives are targeting approximately 100,000 HCPs. In addition, we are focusing efforts on 44,000 of the highest potential prescribers with a "Relationship Management" initiative.

#### **Laxatives Brands**

- Several promotions continued in the 2<sup>nd</sup> quarter
  - National Consumer Sweepstakes
  - Print advertising in demographic specific magazines such as Women's Day,
     Better Homes and Gardens, and Readers Digest
  - o "At-shelf" purchase incentives such as instant redeemable coupons.
  - Customer Relationship Marketing (CRM) to loyal customers
  - o Twitter campaign

# **Managed Care**

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 2<sup>nd</sup> quarter of 2012

#### Commercial Formulary Status ~ 213 Million lives in this channel

	OxyContin		Butrans		Intermezzo	
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%
Preferred/2nd tier	182.3	85.5	54.2	25	21.7	10.4
Preferred/3rd tier	4.7	2.2	107	51	92.3	42.9
Step Edit/Prior						
Authorization	11	5.1	23.8	11	44.9	21.6
Not Covered	15.2	7.2	28.3	13	52.4	25.2

- 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 26%
- Butrans (Commercial) continues to achieve improved formulary access (25% commercial lives in a preferred position).
  - Three significant accomplishments in the "commercial" book of business occurred during the 2<sup>nd</sup> QTR.
    - Express Script and Medco (two of our largest pharmacy benefit customers, which encompass over 35 million commercial lives) approved Butrans for inclusion on Tier 2 "preferred-brand" formulary listings. This puts Butrans at the lowest co-pay level for branded products.
    - Envision, a pharmacy benefit manager covering mid-size regional employers has also moved Butrans to 2<sup>nd</sup> tier during the 2<sup>nd</sup> QTR
  - We anticipate a greater than 30% lift in prescriptions with 2<sup>nd</sup> tier formulary access
- Intermezzo's (Commercial) commercial channel has been our focus from launch
  - We have achieved our 2012 target of over 50% of commercial lives at 2nd tier or 3rd tier unrestricted access.
  - We still have approximately 25% of commercial lives with some kind of restriction before the patient can receive Intermezzo, as well as an additional 20% of commercial lives in plans where Intermezzo is "Not Covered".
  - We are continuing our efforts to reverse the restrictions by:
    - implementing a rebate strategy for unrestricted access
    - increased focus on clinical presentations by our Medical team

#### **Medicare Part D** ~ 30 Million lives in this channel

	OxyCont	OxyContin		Butrans		ZO
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%
Preferred	17.8	58	0.3	1.2	0.009	0
Non-Preferred	1.7	6	2.7	9.2	0.012	0
Step Edit/Prior						
Authorization	2.4	8.4	1.2	4	0.275	0.2
Not Covered	7.9	27.6	25	85.6	28.7	99.8

#### OxyContin (Med Part D)

- OxyContin continues favorable formulary status for 2012 Medicare Part D formularies with more than 58% of seniors having access to a preferred formulary position and favorable co-pay
- OxyContin Medicare Part D national market share exceeds 21%
  - Generic fentanyl patch (market share of 26.1%), generic extendedrelease morphine (market share of 29.2%), and methadone (market share of 16%) all have market share increases in the last 12 months in this channel
  - 86% of all prescriptions filled in this channel are for generics

#### Butrans (Med Part D)

- Butrans has had a slow uptake in the Medicare Part D channel, due mostly to two factors:
  - The payers advocating increased generic utilization and substitution of all brands via a "therapeutic alternative" formulary approach.
  - 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

#### • Intermezzo (Med Part D)

- We are not on any formularies as of launch
- The focus of our efforts is the commercial book of business for the first year of launch
  - Our targeted patient is 35-55 year old females, therefore not Medicare Part D patients
  - We do not have any clinical support for use in elderly; specifically the two pivotal trials did not include patients over 64 years old.

#### **Medicaid** ~ 48 Million lives in this channel

	OxyCont	OxyContin		Butrans		Intermezzo	
	Lives (mm)	%	Lives (mm)	%	Lives (mm)	%	
On PDL							
Formulary	1.5	3.1	7.9	16.5	2.3	4.8	
Prior							
Authorization							
Required	46.8	96.9	40.3	83.5	46	95.2	

The Medicaid market continues to be a channel dominated by the individual States, generally 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 the last 12-15 months many States have moved their Medicaid populations to "Managed Medicaid", where private commercial health plans bid to the State for a fixed cost on a "per patient per month" basis, to financially cover the total health care for a percentage of the State's Medicaid recipients.

- If the health plan exceeds this monthly cost allotment, the health plan pays the
  excessive cost, if the health plan's cost is lower than the State's per patient per
  month specified amount the health plan profits.
- We are currently re-evaluating our approach to Medicaid for the 2013 contracting process to determine if there is a rationale for bidding to "Managed Medicaid" providers in a way that demonstrates a positive ROI.

#### OxyContin (Medicaid)

We only have "preferred brand" formulary status in Missouri, with 1.5 mm lives. In all other States, a prior authorization is required before a patient is allowed to have OxyContin. In most cases, a patient must first be prescribed generic MS Contin. Only if that "fails" due to efficacy or unacceptable side-effects, can a patient obtain OxyContin.

#### **Butrans** (Medicaid)

We had a success in the  $2^{nd}$  QTR for Wisconsin Medicaid. They added Butrans to the Preferred Drug list in  $2^{nd}$  quarter, the only other products included were generic MS Contin and generic Duragesic.

# Forecasting, Analytics and Market Research

During the second quarter, we have undertaken, or developed plans, to undertake numerous market research projects each with the goal of driving the business through actionable insights. For the purposes of brevity, we will list below some of the *key* projects recently completed or undertaken directly associated with the top three prescription brands.

Intermezzo Projects	Status	Objectives	Results/actions
Sales Force Effectiveness	Underway (ongoing monthly tracking)	<ul> <li>Quantitatively track sales rep performance/message delivery from a physician perspective.</li> <li>Compare to two branded competitors.</li> <li>Determine the influence that sales reps are having on physician behavior</li> </ul>	The results, combined with other data, can be used to refine the details of repphysician interactions.
Market Tracking Study	Underway	Measure awareness of Intermezzo in called on and non- called on physicians, perceptions, and barriers to use and compare to other products in the market.	Determine awareness compared to budget assumptions, determine barriers to use, assist in adapting marketing/sales efforts. Help identify hurdles to adoption for us to develop mitigation strategies.

<b>Butrans Projects</b>	Status	Objectives	Results/actions
Physician Qualitative Study	Complete	Evaluate physicians' experience with Butrans. Gain insight as to why some patients remain on Butrans, why others leave and why others never try Butrans. Help explain discontinuation rate after first month trial of Butrans.	Determined that physicians may not be targeting the appropriate patient with the appropriate dose of Butrans and that physicians are not properly titrating. As a result of this and pending quantitative study sales/marketing has implemented an adjustment in messages and promotional tactics to ensure correct initiation/titration.
Butrans / Nucynta-ER Analysis	Completed	Determine if Nucynta-ER impacted the Butrans launch	Nucynta-ER had an impact on Butrans New-to-Brand share, primarily in terms of absorbing new patients who could have been initiated on

			Butrans.
Butrans Persistence Studies	Ongoing	Determine Butrans patient persistence (length of therapy) across cohorts over time and by strength. Also compare to selected opioids	Butrans persistence is similar to other ERO's, however, for the 5mcg strength there is higher than anticipated discontinuations rates at 30 days. Numerous actions have been taken as a result of this work (seeking label changes and revised messages regarding titration and use of the 5mcg strength.)
Butrans Brand Vision	Underway	Evaluate Butrans and its competition in the opioid analgesics market on key dimensions that affect market share.	This allows us to diagnose perceptions of and attitudes regarding Butrans in the market against benchmarks. We can then implement new messages or reprioritize marketing mix to emphasize or changes these perceptions in order to influence prescribing behavior.

OxyContin Projects	Status	Objectives	Results/actions
ERO Opioid Length of	Completed	Determine the LOT of new	OxyContin's LOT has
Therapy (LOT) Project		OxyContin patient and	increased over time. The
		compare to other ERO's. Also	average NEW patient
		determine if LOT has changed	remains on OxyContin for
		over time.	125 days, just above the
			market average of 122 days.
ERO Marketplace	Underway	Conduct a analysis of market	Develop plans to adapt to
	(Gathering	trends and "future cast" how	market/physicians needs
	proposals)	the ERO market may be	over the next 5 years.
		transformed in 5 years	Inform forecast for the ERO
			market.
Physician Targeting	Underway	Determine OxyContin call	Based on the information
		sensitivity and ROI on	gathered and calculations to
		physician calls.	date, we believe OxyContin
			will benefit from additional
			primary calls on select high
			ROI targets.

#### MANUFACTURING / SUPPLY CHAIN / PHARMACEUTICAL TECHNOLOGY

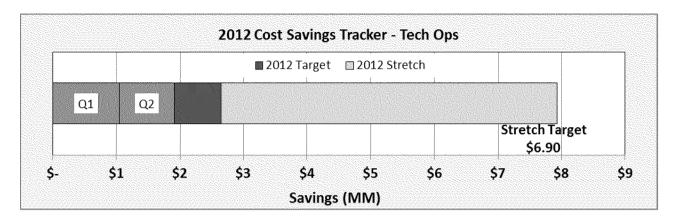
Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major 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		Q2 YTD		Full	Year
Manuracturing and Supply Chain	Actual	Budget	Var	2012 Budget	2011 Actual
Tablets Manufactured (MM)	311	277	34	593	629
OxyContin	221	194	27	409	456
MS / MSER	83	83	0	163	165
Oxy APAP	-	-	-	21	_
Oxy Export	6	-	6	_	8
Export Packaging Bottles (000)					
Bottles Packed	206	-	206	-	308
Orders Shipped On-Time					
Wilson	99.0%	99.0%	0.0%	99.0%	99.8%
Rhodes	99.0%	99.0%	0.0%	99.0%	99.1%
3rd Party	98.0%	99.0%	-1.0%	99.0%	99.7%
Orders Shipped In-Full					
Wilson	99.0%	99.0%	0.0%	99.0%	99.6%
Rhodes	99.0%	99.0%	0.0%	99.0%	99.9%
3rd Party	99.5%	99.0%	0.5%	99.0%	99.6%
Inventory On-Hand (Months)					
OxyContin	2.1	2.5	(0.4)	2.5	2.6
BuTrans	3.5	3.0	0.5	3.0	3.3
Intermezzo		TBD		TBD	

Pharmaceutical Technology	Q2 YTD			Full Year	
Tharmaceutical reciniology	Actual	Budget	Var	2012 Budget	2011 Actual
Research and Development Hours	15,035	19,603	(4,568)	40,633	29,784
Production Hours	2,110	3,123	(1,013)	6,474	4,289
Support Hours	12,925	16,480	(3,555)	34,159	25 <i>,</i> 495
Development Batches Manufactured	53	53	_	114	89

#### 2012 Cost Savings



 Additional savings are being identified in our third party supplier business relationships, and in our distribution / transportation operations to support our total savings goal.

# **Infrastructure / Capital Projects**

• IMA (Packaging Line Manufacturer) will ship the first new packaging line the week of July 16, 2012. The project now includes the transition from RFID to 2D labeling. This transition will occur during the first quarter of 2013, and will result in an annual savings of approximately \$800,000.

# **Third Party Manufacture**

- Dilaudid Injectables from Hospira remain a supply challenge due to the unpredictable forecasted demand. Purdue is working with Hospira to improve the relationship and delivery performance; however, we expect the supply issues to remain through the later part of the year.
- MSER for Rhodes Pharma (RP) has also become a significant supply challenge due to un-forecasted increases in demand as RP has grown the market share from 29% to 42% in the last few months. Wilson is responding to this new demand with increased production output; however, API availability and DEA quota will be the challenge in maintaining these new sales levels. Purdue is working with RP to improve the forecast accuracy going forward.
- Intermezzo A team has been assembled to improve Intermezzo's security of supply by qualifying a new API source and alternate source of key excipients.
- Butrans The supply team is expecting to transition the US market to patches produced at LTS West Caldwell by November 2012.

# OTC/Laxative Highlights

 Peri-Colace – The project to have Purdue Canada produce Peri-Colace for the US market (as well as Senokot) will be completed in July 2012.

# **DEA Requirements / Compliance**

- DEA Inspection Readiness Plan is in place in Wilson with an anticipated inspection beginning the week of July 23rd.
- EHS The Wilson facility received a Storm Water No Exposure Certification from the North Carolina Department of Environment and Natural Resources (NCDENR). This resulted after a thorough review of our past record and an onsite inspection of the facility by state officials. This exempts the site from permit and sampling requirements and is indicative of the strong reputation the site has with the state environmental authorities.
- Security camera hardware upgrades for enhancing system stability are in-process.

#### 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**

• An FDA inspection took place in Stamford on May 21-25, 2012. The inspection focused on the Butrans REMS and PPLP Pharmacovigilance activities. Review of the odor product complaints trend for Slow-Mag led the Investigator to examine the presence of diethoxymethane (DEM) in the product. The investigator agreed with the investigation steps and the PPLP actions in place, but did not feel that sufficient risk mitigation steps (market action) had been taken given the unknown toxicity of DEM. The inspection resulted in a two item 483 being issued related to the lack of sufficient risk mitigation, and the lack of a validated test method, a formal specification, and controls to reduce the level of DEM at the time of inspection closure. All Butrans REMS, Adverse Event, and Product Complaint processing was found to be acceptable with no deficiencies identified. A full response to the FDA 483 was submitted on June 11, 2012.

• Investigations into the Slow-Mag and DEM issue continue. An analytical method has been validated for the quantification of DEM levels in the product. Analyses of both the current and previous formulations demonstrate the presence of DEM. Manufacturing campaign two of three for the current formulation demonstrates levels of DEM above the threshold of concern of 0.3 micrograms/tablet calculated from the maximum daily exposure limit for genotoxic materials (per the draft FDA guidance document). *In vitro* test results for genotoxicity were inconclusive, requiring completion of *in vivo* tests which are being scheduled. A meeting with the FDA District Office has been requested to discuss the status of the investigation and to obtain their input into actions.

# • 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 three month stability pull. Monthly monitoring of the lot was initiated at the sixmonth time interval, and has continued with the 20-month testing recently completed. The level of the degradant has plateaued and remains within specification. At the 21-month stability test point, the lot will be at its 24-month expiration.
  - 1. A meeting with the FDA Atlanta District Office occurred on April 25, 2012. The FDA District Office was satisfied with the progress of Purdue activities in relation to the degradants.
  - 2. A second meeting will be requested to discuss the genotoxicity test results upon report availability scheduled for mid-July 2012.
- A Field Alert Report was filed on June 13, 2012, concerning OxyContin 60 mg
   Tablets (WKM61) manufactured in Wilson. The API supplied by Rhodes
   Technologies was the subject of an investigation initiated by Rhodes
   Technologies into a limited number of pink colored API particles detected
   during reprocessing operations. No product actions are required.
- Rhodes Pharma used Lachman Associates to perform a three-day audit (May 29-31, 2012) of Wilson's Quality Systems and processes as they relate to production of MSER and development projects. Corrective action plans are in development for observations shared verbally during the wrap-up meeting.

#### **External Manufacturing**

- Butrans Update:
  - The supplement for manufacture of Butrans at the LTS West Caldwell site was approved on April 20, 2012. The site was not inspected as a part of the approval process.
  - Sporadic issues with the dissolution procedure have continued to occur in both West Caldwell and Totowa laboratories. The investigation into the root

- cause continues, but the problem is analytical and not product performance related. An alternative validated dissolution method has been approved which will correct the analytical issue, and will be submitted to the FDA in the next annual report.
- o LTS was forced to make a sudden supplier change for an excipient, oleyl oleate, used in the manufacturing of Butrans. This is the second instance of a similar issue indicating the need for increased LTS oversight of their suppliers. The Quality Advisory Group (QAG) discussed the issue, and Bard will work with LTS to affect improvements.

# Intermezzo Support:

- O Shortly after release of Intermezzo, Patheon, the manufacturer, notified Purdue of an investigation of black specks and magnetized particles discovered after screening two of the excipients during the manufacture of a batch. The black particles were identified and posed no risk to patients. Examination of associated retain samples resulted in the discovery of a third type of black particle. The black particle was identified as phenolic resin for which the source has not been identified. A health hazard assessment is in progress for potential patient ingestion of the phenolic resin.
- SPI, the manufacturer of Buffered Soda used in the production of Intermezzo, reported a three-month stability failure for one of three lots produced in the last campaign of this excipient. Investigation into the problem is ongoing, as failure at this time point is atypical. The recent batches were the first ones produced in two years, and the release values were at the low end of the specification range. Transcept had previously identified the need to expand the specification range, and a CBE-30 supplement is scheduled to be filed to accomplish this.

#### **Support for New Products**

• Validation and stability testing of OxyAPAP lots produced to support the Rhodes regulatory filing is underway in Totowa. Methods for impurity testing have been revalidated in support of the reformulation of the product.

#### 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 2Q2012, 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)
- AHI (FAAH)
- Abuse Deterrent Immediate Release Oxycodone (ADIR)
- Ryzolt

#### Reformulated OxyContin (OTR/ORF)

Corporate Scorecard Milestones for OTR/ORF are on or ahead of schedule

ORF Messaging and Exclusivity: The ORF Messaging and Exclusivity Group has progressed its plan to ensure that the in vitro, in vivo (pharmacokinetic and abuse liability), and epidemiology data collected to date are communicated to appropriate audiences in a time frame supportive of Purdue's business and public health objectives.

- The group's charter focuses on the following goal: "Ensure that there are sufficient data, approaches, and messaging externally to enable OxyContin to remain the branded ER oxycodone product well beyond 2013".
- To date, 15 of 28 accepted abstracts have been presented at various association meeting venues.
- Nine additional abstracts submitted to various associations are pending acceptance.

- Forward looking plans include further abstract submissions and presentations through 4Q2012.
- A medical communications vendor is assisting with Purdue's publication strategy in support of the group's charter. Plans are to have 15 manuscripts submitted by February 2013. One has already been submitted and is pending acceptance.

## **Pediatric Exclusivity**

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

- Lessons learned through this program have been applied to other pediatric and adult study programs.
- To date, 63 children have been enrolled compared to 13 children enrolled as of October 2011.

# Japanese sNDA for OxyContin in non-malignant pain

- The Japanese sNDA (non-malignant pain) is on track for 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

#### 10mg ORF

A meeting was held with FDA's Atlanta District Office on April 25, 2012 to discuss an out of trend investigation, status and forward plan for the 10mg ORF lot. The FDA agreed with our plans, and we continue to track the observed levels of the degradant.

#### **Butrans® (BTDS)**

Corporate Scorecard Milestones for Butrans are on or ahead of schedule.

#### High dose program

The planned high dose program is on track with an interim analysis of data from the Thorough QTc Trial (BUP1025) planned for 4Q12. The results from this analysis will be used to inform our study design and initiation of higher dose pivotal studies BUP3027 and BUP3028 in 2013.

#### 2nd Generation program

- The 2nd Generation Butrans® Program is advancing as per plan.
- The refined prototypes to be tested in the clinic yield a 33% reduction in patch size and 27% (or greater) reduction in drug load versus the current commercial product.

# Intermediate strength development (7.5 mcg/hr & 15 mcg/hr)

Development of intermediate strengths is proceeding between Purdue and LTS. Approval of these strengths will be based primarily on a CMC submission if Purdue's request for a bio waiver is granted (high probability). A draft timeline has been developed projecting a 4Q2013 market launch.

#### Manufacturing site transfer to West Caldwell, NJ

The Prior Approval Supplement for the LTS Manufacturing Site Transfer from Andernach, Germany to West Caldwell, New Jersey was approved by FDA on the PDUFA date, April 20, 2012; commercial production at this site will begin 4Q2012.

#### ONU (Targin)

All corporate scorecard milestones for ONU are on schedule.

- The NDA submission (for the indication of Pain with abuse deterrent properties) planned for 2Q2013 is on track with all submission elements on or ahead of established timelines.
  - o A pre-NDA meeting with FDA is scheduled to occur on September 13, 2012.
  - o 615 patients have been enrolled in the ONU3701 study, and we completed the Last Patient First Visit on July 5, 2012.
- The sNDA submission for label expansion (Opioid Induced Constipation) planned for 2Q2014 remains on track, with efforts being made to stimulate enrollment in each of the two required pivotal (OIC) studies.
  - 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.
  - We remain on target with 134 patients enrolled in ONU3704 and 24 patients enrolled in ONU3705.

#### **Hydrocodone QD (HYD)**

All corporate scorecard milestones for HYD are on schedule.

- 2Q2014 NDA filing and 3Q2015 launch dates are on track.
- The competitive landscape has changed in a favorable direction with <u>high</u> <u>likelihood</u> of Purdue's HYD (once-daily, tamper abuse deterrent hydrocodone) <u>to be</u> the first long-acting hydrocodone market entrant.
  - Teva/Cephalon has reported that its single pivotal study for CEP-33237 (twice daily hydrocodone) is negative and that their NDA submission

- planned for 4Q2012 will not be possible; the viability of this potential competitor is considered low.
- Zogenix's Zohydro (twice daily hydrocodone) NDA is under review at FDA, however, several potential deficiencies are likely to delay and/or prevent approval of this product (e.g. lack of a tamper-resistant formulation, lack of safety information related to potential ototoxicity and/or cardiac repolarization).
- 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.
- 693 patients have been enrolled in the HYD3003 study and we completed the Last Patient First Visit on July 6, 2012. We have enrolled 140 patients in HYD3002 (double blind study).

# TRPV1 (VND)

All corporate scorecard milestones for TRPV-1 are on schedule.

- Positive results were received from the human experimental pain / biomarker development study (VND1004). This study demonstrates that TRPV1 has a positive effect on thermal pain.
- Plans to initiate two human Proof-of-Concept studies (Osteoarthritis and Post Herpetic Neuralgia) remain on track for September, 2012; this will be the first time a
  Purdue new chemical entity 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 event (somnolence) 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 will be executed in 2H 2012. The next decision point will be in 1Q2013 when the nonclinical results are available.

#### Intermezzo (INT)

All corporate scorecard milestones for Intermezzo are on schedule.

• To meet the post-approval commitment from the US Consumer Product Safety Commission (CPSC), CMC work toward the new package configuration (change

from blister in a pouch to tablet in a pouch) for both Intermezzo tablet strengths (1.75 mg and 3.5 mg) is on track.

• A recently devised R&D-driven strategy for the brand includes publication of modeled PK data that supports differentiation from immediate release formulations of zolpidem on the basis of safety.

# AHI (IPI-940)

- The planned human Proof-of-Concept study in Post-Herpetic Neuralgia is delayed by one year due to contamination and rejection of clinical supplies manufactured by Infinity's contract manufacturer (Pii).
- The process to manufacture new API and clinical supplies has initiated, with a new planned study start date of 1Q2013.

#### Abuse Deterrent Immediate Release Oxycodone / ADIR - (OCI)

- In March 2012, R&D created a project team charged with developing an <u>A</u>buse <u>Deterrent Immediate Release drug delivery platform for oxycodone.</u>
  - In collaboration with Rhodes Pharma, an IND was submitted on May 9th, 2012, with oral administration commencing under a pilot PK/PD investigation (OCI1001) on May 21st
  - Selection of a final formulation for definitive testing is planned to occur by 4Q12

#### Ryzolt Pediatric Program

NOTE: The Board approved a plan to discontinue the sale of Ryzolt on June 22, 2012; the NDA will be withdrawn by the end of 2012, and no pediatric program will commence.

# **New Disciplines**

Through 2Q12, Purdue's organizational capabilities have been enhanced through on-boarding of key leaders, and the creation of several new disciplines within R&D: R&D Innovation, Health Outcomes & Pharmacoeconomics, and Medical Affairs. These disciplines are already contributing to the near and long term success of our current and future products. The initiatives described below are considered mission-critical, and will help drive Purdue's 10-year plan and overarching vision to become known as "The" Pain Management Company:

#### **R&D Innovation**

• Identify and recommend for pursuit novel external analgesic drug development opportunities at the Pre-Proof of Concept stage.

 Create strategy and an execution plan that will deliver novel non-drug product technologies designed to address key stakeholder needs in the market (e.g. objective measures of pain and medication compliance, devices, services, novel surveillance mechanisms for abuse and diversion); such technologies may become a Purdue offering or take the form of a separate business opportunity.

# Health Outcomes & Pharmacoeconomics (HOPE)

The Health Outcomes and Pharmacoeconomics (HOPE) department is developing strategies to support commercial objectives to demonstrate value to payers. The HOPE strategies are an integral part of the overarching product strategies and support market access, formulary placement, and the demonstration of Patient Reported Outcomes (PROs) that will drive reimbursement. Cross functional teams that include commercial, medical, scientific communications, project management, and legal representation guide the development of HOPE strategies and execution of tactics.

#### **Medical Affairs**

The Medical Affairs group has been recreated following a seven year absence. Its objectives target both <u>externally</u> (Key Opinion Leader planning and engagement, planning and conduct of Investigator Initiated Trials, recruitment of investigators for registration trials), and <u>internally</u> facing deliverables (design and conduct of Phase IIIb/IV Clinical Studies, publication planning and communication strategy, and provision of competitive clinical intelligence to internal stakeholders) in support of lifecycle management for Purdue's current and future marketed products.

#### **DISCOVERY RESEARCH**

#### TRPV1 Back-up Antagonist Program (VAN)

- The main objective of the TRPV1 back-up program is to identify and develop a compound that has similar or better efficacy than V116517, but reduced risk for effects on body temperature and thermal sensation. We are also investigating mechanisms associated with pharyngeal pain and dysesthesia.
- V120083 was selected as a back-up candidate to V116517 in April of 2012 and all of
  the IND enabling studies have been completed and the results meet or exceed the
  stage-gate criteria with one exception. A genotoxic impurity has been detected
  during the synthesis of the material and currently the team is working on a
  resolution that will drive a go or no-go decision for IND filing in August of 2012.

# Purdue-Only TRPV1 Antagonist Program (517)

In collaboration with the Medical School at the University of Wisconsin, we are evaluating the mechanistic role and possible clinical utility of TRPV1 channel blockers in pain associated with sickle cell disease. Our collaborators have established a translatable animal model of this condition, we have completed all legal agreements, and the work will initiate in July/August with results available in early Q4.

#### 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 team has identified one potent and selective peripheral ORL-1 compound (V120063), however the preliminary result of monkey cardiovascular system study showed a less than 10 fold safety margin which may prevent further development of this lead. The final report of this study will be available by the end of July.
- Due to an unexpected adverse event (somnolence) in the Phase 1 clinical trial of V117957, a work plan to evaluate the issue has been established. The primary purpose of these studies is to determine the mechanism underlying the clinical observations and to provide data to inform a go/no-go decision for further clinical studies on V117957. A secondary purpose is to inform the back-up strategy to ensure a lower risk molecule with differentiation from V117957.

#### Peripheral Kappa Agonist (PKA)

V120557, a compound that is effective in visceral pain and reverses opioid induced constipation, was shown to be effective in inflammatory pain. It displays no motor deficits at 10X the minimally effective dose in inflammatory pain. Preliminary data with an antagonist suggests the efficacy in the visceral pain model is through kappa.

#### Sodium Channel (Nav) Blocker

- With the goal of assessing the cardiovascular (CV) safety margin of a peripheral Nav antagonist, the Nav team selected two compounds to enter Maximum Tolerable Dose (MTD) studies in dogs – V121216 and V121241. Both of these compounds had shown efficacy in rat neuropathic pain testing and were without Rotarod deficits at the efficacious doses.
- In the MTD studies, V121216 was not able to achieve the target plasma concentration and was dropped from further consideration. On the other hand, the target plasma concentration of V121241 was achieved and this compound was progressed to CV studies. Testing was completed the first week of June and results are expected in July 2012.

#### **Exploration of Signal-Biased Opiates**

The research team is deeply pursuing biased opiate ligands and has recently established a panel of new in vitro assay systems to support the effort. Currently, the focus is on the discovery of new mu agonists with minimal/non-existent side effect or euphoria. A second priority is the design of central kappa agonists with minimal/no dysphoria.

#### **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 increases 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.

#### **Risk Management Activities**

REMS Participating Companies (RPC, formerly the IWG)

- Prescribers Subteam Lead Created communication document drafts and negotiated approval of same with FDA.
- Negotiated improved educational Blueprint with FDA, allowing emphasis on important content for prescribers, as opposed to administrative content.

#### **Healthcare Grants and Giving**

- 212 healthcare educational and non-educational grants were reviewed.
- Seventy-six (36%) were approved for a total \$1,602,133.29.

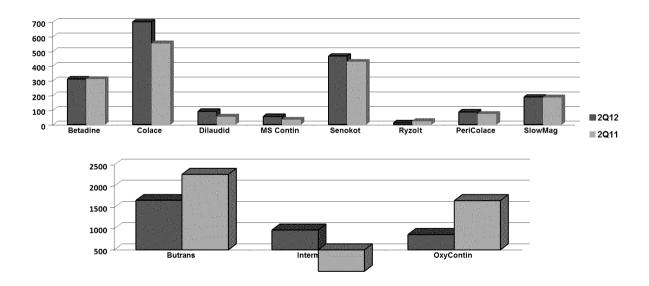
#### **Medical Liaison**

Medical Liaisons in Alliance Outreach, Managed Health Systems and Strategic Educational Initiatives continue to focus on providing education and support of PPLP products and research to internal and external customers. Notable progress toward 2012 objectives:

- Pain care and risk minimization resource packets were presented to forty-nine (49) state healthcare professional organizations in 2Q12.
- Product support focused on providing education, clinical information, and research support to healthcare professionals, such as formulary decision-makers and investigators:
  - o Butrans®
    - 1. Three (3) clinical discussions Managed Care customers (YTD=6)
    - 2. Four (4) posters presented in collaboration with Medical Research (YTD=6)
    - 3. BUP3031 Pediatric Study Recruitment of sites continues with 17 approved, plus two open to enrollment (YTD=2)
  - o Intermezzo®-Five clinical discussions Managed Care customers (YTD=12)
  - ORF/OTR OTR3001 Pediatric Study site-specific enrollment support plans are in place; 48 US sites open to enrollment

# Medical Inquiries Received Regarding Purdue Products

- 5,761 Inquiries
  - o 9% increase from 1Q12 (3.8% decrease from 2Q11)
  - o 76% answered within one (1) business day, 97.4% within ten (10) days
  - 972 inquiries regarding Intermezzo<sup>®</sup>



#### **Library & Information Services**

\$44,000 saved through favorable contract renewals, negotiated savings, use of articles from our repository and, cancellation of information products which have shown appreciable drops in usage. YTD savings is \$209,500.

#### 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 CIA term comes to an end July 30<sup>th</sup>. There have been no Reportable Events in year five, and no unfavorable communications with the Office of Inspector General. We expect to complete the full term of the CIA with a favorable review, although the formal close of the CIA review by OIG may well take up to six months past July 30<sup>th</sup>.
- Communications to Employees regarding the end of the CIA term have begun, stressing the importance of continued compliance and the fact that there will be only limited changes to Purdue's compliance-related activities..

#### **Call Note Review Process**

Greater effectiveness and cost-savings has been accomplished with new call note reviews. Call notes had previously been performed by contract attorneys, employing up to six on a full-time basis. With the transfer of this function to Compliance in late 2011, a new approach to risk assessment was undertaken, reducing use of key word searches in favor of word searches based on productivity of results, with analysis of call notes on a random basis increased. This has resulted in the work being completed by two people in half their working time, with a back-log of 4-5 months eliminated, and call notes reviewed within three weeks following the close of each current month. This real time review resulted in earlier identification and investigation of any issues.

#### Public Citizen Freedom of Information Act (FOIA) Request

Recall, in 2010 Public Citizen requested copies of certain Purdue (and Pfizer) CIA Annual Report filings, and was largely denied access. Public Citizen since has appealed to the DC District Court, and together with Law we have collaborated with OIG on a common defense of the OIG's denial of access. The matter is now finally submitted to the Court for decision on the basis of affidavits and briefs of the parties.

#### 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.

The table below shows a tabular summary of the review activity within LBD in the second quarter of 2012.

The broad metrics show that the group processed 106 opportunity requests through the new system. More relevantly, we took 16 opportunities into the BDC process, and referred 27 opportunities to R&D Innovation, which is charged with reviewing and evaluating pre-POC drugs/devices/platform technologies/discovery technologies, etc.

The active projects within LBD in Q2 are shown in the table below. Our goal in 2012 is to deeply evaluate 25-30 projects in level two, and ultimately bring forward 5 – 10 level three projects - which would qualify for full negotiations, detailed due diligence, and ultimately term sheets. We have two projects at that level today; Theravance and Tarsa.

#### Q2 2012 Results



# LBD Active Projects listed below

COMPANY	PRODUCT	INDICATION	BDC LEVEL + STATUS	RESPONSIBLE PARTY	SCREENING DATE
Tarsa	Oral rsCT Calcitonin	Osteoporosis	Level 3 Term sheet being worked on by Purdue	Yao	5/26/11
Theravance	TD-1211 oral	OIC	Level 3 Positive phase 2b data reported July 2012. Purdue to analyze data and further consider deal terms.		11/19/2010
Convergence	Nav 1.7 blocker oral	Neuropathic pain	Level 2 Phase 2 data due late Aug. 2012. Convergence will run a WW deal process once data becomes available.		1/10/2012
Spinifex	EMA-401 Angiotensin II Type 2 receptor antagonist oral capsule	Neuropathic pain	Level 2 Spinifex is conducting a 154 patient Phase 2 PHN trial dosing the drug BID for 28 days in Australia. Results due July/Aug. 2012		1/10/2012
Array	ARRY-797, p38 MAP Kinase Inhibitor	OA	Level 1B Phase 2 a data due Aug. 2012		10/24/2011
Cara Therapeutics	CR-845	Post-operative pain	Level 2 Phase 2b data under review		7/31/2008
Flexion	FX-0005, SR p38 inhibitor	OA	Level 1B Phase 2 study ongoing		6/10/2012
Regeneron	REGN475, NGF antibody	Chronic pain	Level 2 Confidential meeting on June 22. POC appears to		5/18/2012

			be met. Development costs \$300 - \$400M.	5/18/2012
ImmuPharma	Lupuzor	Systemic Lupus Erythematosus	Level 1B  Mundipharma is not proceeding.  POC not yet confirmed. US to look at market.	5/24/2012
ReNew	Ultimate Flora probiotics; CleanseSmart intestinal cleaner, Ultimate Fish oils, omega oils, TripleFiber, Digest More Enzymes	Digestive Health	Level 1B	6/28/2012

#### **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

- The Pain Care Forum hosted Dr. Douglas Throckmorton, Deputy Director, FDA as a speaker at the meeting this quarter.
- 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 commented on the CMS regulations. The White House has expressed concerns to CMS.
- Members of Congress are reviewing a third draft of legislation that would prevent FDA from approving a non-deterrent controlled substance where a deterrent formulation of the same drug is already approved. The legislation has received considerable comment from FDA and it seems that FDA's positions are consistent with that of Purdue.
- The National Hospice and Palliative Care Organization has launched "Live Without Pain," a national education campaign to empower patients and family caregivers to advocate for expert pain relief in all care settings through education and how to resources.
- American Osteopathic Association's "Break Through Your Pain" campaign in the states of Washington, Kentucky, Massachusetts and Florida reached an estimated audience of more than 175 million individuals through a combination of TV, radio, print and online media coverage. This campaign is supported through an unrestricted grant by Purdue Pharma.

# Take Appropriate Action On External Threats To Optimal Pain Care

Public Affairs developed a company response regarding a letter from the Senate
Finance Committee and conducted media relations to communicate the company
response to the media. We conducted targeted outreach to key opinion leaders and
professionals/patient organizations named in the letter to alert them to the
company's letter and communicate our plans to respond.

# Promote Purdue's Reputation In Academic, Community And Scientific Venues

- Nine states are now operational with the National Association of Boards of Pharmacy (NABP) Interconnect Hub program which allows state prescription monitoring programs (pmps) to share data across state lines. Twenty states have signed agreements to participate and other states are currently in discussion.
- A press announcement and communications guidance document was developed for employees surrounding the presentation of data from the epidemiology studies with the reformulation of OxyContin at the annual meeting of the American Pain Society. Placement of articles was secured in Medscape, Physicians Prescribing Reference and Reuters Health. Public Affairs attended the APS meeting and alerted key opinion leaders to the poster presentations on the epidemiological data. Purdue provided communications guidance surrounding the presentation of in vivo liking studies and epidemiological data at the annual meeting of the College on Problems of Drug Dependence.
- Public Affairs issued a press release announcing Purdue's PERFORM module to help clinicians recognize and deter prescription drug abuse in their practice.
- Materials were developed under the Research and Development Advocacy Network (RADAN) to help recruit clinical investigators and facilitate patient enrollment in Purdue's clinical trials and distributed RADAN flyer at American Pain Society annual meeting.
- The Purdue corporate web site home page has been redesigned and updated.

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

 16 states have introduced legislation (in some states such as New York as many as 12 bills) that addresses restrictions or regulations on controlled substance prescribing. Also, in at least six states (Kentucky, Ohio, Maine, Tennessee, Vermont and West Virginia) Governors/ Attorneys General have formed task forces to address controlled substances prescribing as a result of prescription drug abuse and diversion.

- Florida passed a bill that allowed for an exemption for Rheumatologist from the pain clinic restrictions.
- Kentucky passed a bill that requires physicians to access the state prescription monitoring program before prescribing controlled substances.
- A New Mexico bill requiring mandatory CME for Pain Management and restrictions on CII prescriptions to a maximum of seven days was defeated.
- New Hampshire passed a bill to implement a prescription monitoring program.
- New York passed the ISTOP bill that updates the state prescription monitoring program, allows access for pharmacists and makes hydrocodone containing products CII controlled substances.
- Massachusetts approved through a budget bill, the use of copay coupons and allows physician dinner/speaker programs. Previously, it was the only state that prohibited their use.
- Mississippi introduced a bill to specifically restrict OxyContin. The bill was defeated.
- Tennessee passed a bill that requires prescribers to access the state prescription monitoring program when initiating a course of treatment with an opioid and then every year thereafter.
- Purdue convened a multi-functional planning team to develop company messages
  and a position supporting the appropriate use of opioids in the treatment of chronic
  non-malignant pain for the May 30-31 FDA meeting "Assessment of Analgesic
  Treatment of Chronic Pain: A Scientific Workshop." Key opinion leaders and
  professional associations were informed of the upcoming workshop and were
  encouraged to voice their position on the appropriate use of opioids for chronic nonmalignant pain.

# <u>Develop And Support Innovative Programs That Safeguard Public Health And Address Abuse And Diversion Of Prescription Medication.</u>

• Public Affairs drove awareness of the national program SafeGuardMeds.org 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 11,525 airings, 252 million impressions and \$6,008,057 in media values to date.

- Proactive media relations were conducted to promote RxPATROL and the Law Enforcement Liaison & Education program. Public Affairs achieved positive delivery of Purdue's anti-diversion/anti-abuse messages by garnering more than 85 stories to an estimated 2 million readers/views for both RxPATROL and LELE.
- Rx for Understanding, a new curriculum developed in partnership with the National Education Association Health Information Network has been launched. In accordance with National Health Education Standards this program helps middle school teachers educate 5<sup>th</sup> through 8<sup>th</sup> grade students on the dangers of prescription drug abuse. Press announcements to enhance company reputation as part of the solution to prescription drug abuse were launched in coordination with the National Education Association.
- Purdue collaborated with the American Medical Association Foundation to announce new grant awards for community programs addressing prescription drug abuse. Press announcement with AMAF were coordinated to announce the grant program, thereby further enhancing the company's reputation.
- In Maine, Melissia Petro, Regional Director, State Government Affairs was appointed to a Prescription Drug Abuse Task Force by the Attorney General and assigned to the sub group responsible for making recommendations regarding the state prescription monitoring program.

#### 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

- 129 employees have been recruited to Purdue YTD 2012. Turnover in 2012 is 3.9% YTD compared to 2.4% at the same time in 2011.
- Three Director level positions have been filled within the Stamford R&D organization:
  - M.D., Senior Medical Director reporting to
     Ph.D., Director, Clinical Pharmacology, reporting to Dr. Stephen Harris

    Director, Outsourcing and Vendor Alliance Management
  - Director, Outsourcing and Vendor Alliance Management, reporting to
- has joined Corporate Field Sales Training & Development as Associate Director, reporting to
- joined Medical Affairs as Associate Director, reporting to Bridget Martell.
- Yahghong (Stella) Li joined Regulatory Affairs reporting to Mary Carpenter as Associate Director.
- has been named Executive Director and Plant Manager at our Wilson site and will begin his employment in August.
- Recruiting is in the final stages for three critical positions in Wilson:
  - Associate Director, GxP Training
  - o Associate Director, Pharm Tech Services
  - Sr. Manager, Finance
- A search is under way for the position of Director of Toxicology for Cranbury.

- The Supplier Quality Assurance organization in Totowa is being reorganized with the intent of broadening skills and roles, improving process efficiencies and providing improved stakeholder alignment.
- Early response from District Managers on the use of pre-employment testing in Field Sales indicates positive results.
- An "e-Chain of Custody" electronic pilot program has been implemented for the
  administration of drug screening of new employees in Stamford. The process will
  replace the paper forms we currently provide new hires at all sites, Field Sales and
  Zero Chaos, our consultant hiring company. Turnaround time for drug screening
  results has decreased from 10 days to under a week.

# **Training & Development**

- Level 600 training for new District Managers was conducted to prepare for the management of employee relations issues in the Field.
- Human Resources conducted development workshops in Totowa and Wilson in June targeting Problem Solving, Decision Making, and Project Management.
- A Functional Organization Review session was held with key Tech Ops leadership
  in Wilson in June to analyze the business scorecard, talent review, succession plans,
  employee development, performance gaps and retention in Wilson.
- Human Resources facilitated an offsite meeting for BBU leaders as an update to the BBUs Operating Principles Guide, to draft individual BBU charters and to develop action plans addressing individual and collective improvement opportunities.
- A Leading for Success Managers II Program incorporating new material from the Harvard High Potentials Leadership Program was conducted, with a focus on the dual roles of managers in providing management oversight and leadership, and an eight-step process for leading change. Sales and Marketing Directors participated in Presentation Skills coaching which included ideas on building a compelling business case. A Leading for Success Professionals I Program was held for directors, managers and individual contributors on practicing a core set of skills, also featuring new material.
- Corporate Succession Planning is well underway. An upcoming meeting with senior management is scheduled to finalize actions and development planning.
- The Medical Education Department participated in a Team Effectiveness training session to strengthen trust, communication and collaboration.

• Human Resources held the annual College Fair with eight colleges represented. Forty-five employees met with various schools and inquired about Purdue's tuition reimbursement program.

# **Rhodes Technologies and Rhodes Pharmaceuticals**

- Purdue Human Resources supported the Rhodes organization by facilitating an April 17 meeting which included:
  - o Compensation budget utilization
  - o Recommendations for 2012 compensation design
  - Transparency of compensation information to the Rhodes Board and Board of MNP Consulting
  - Organizational planning

# **Environment, Facility and Regulatory Compliance**

 The Wilson facility was inspected by North Carolina's Department of Environment and Natural Resources, Water Quality and Surface Water group. The site has been granted the "No-Exposure Certification," thereby releasing the Wilson site from the required regulatory burden. Wilson must maintain non-exposure conditions and be recertified annually.

# **Efficiency and Effectiveness**

- Human Resources recruiting staff members have been trained to use LinkedIn and Bullhornreach.com as candidate search tools, reducing the use of outside search firms.
- Restructuring of the Litigation Support group took place in June resulting in the reduction of five positions.

# Full-Time Turnover Report YTD 6/30/2012

	Begin	End	Ave #	Termina-	% Term		Resigna-	0/0	Total	YTD T/O
	Count	Count	EE's	tions	EE's	Retired	tions	Resigned	T/O	Rate
S&P										
Sales	631	633	632	8	1.3%	1	29	4.6%	38	6.0%
Marketing	45	46	46	1	2.2%	0	2	4.4%	3	6.7%
Sales Support	23	28	26	0	0.0%	1	1	4.3%	2	8.7%
Field Ops, Support & Admin	15	14	15	0	0.0%	0	3	20.0%	3	20.0%
Total S&P	714	721	718	9	1.3%	2	35	4.9%	46	6.4%
% of X-FTE's				19.6%		4.3%	76.1%			
G&A										
Administrative Services	34	34	34	0	0.0%	0	0	0.0%	0	0.0%
Business Development	7	7	7	0	0.0%	0	0	0.0%	0	0.0%
Corporate Compliance	9	11	10	О	0.0%	0	0	0.0%	0	0.0%
EHS	5	6	6	0	0.0%	0	0	0.0%	0	0.0%
Executive	11	13	12	0	0.0%	0	1	9.1%	1	9.1%
External Affairs	18	18	18	0	0.0%	0	0	0.0%	0	0.0%
Finance	60	60	60	0	0.0%	0	0	0.0%	0	0.0%
General Counsel	47	45	46	0	0.0%	0	0	0.0%	0	0.0%
Human Resources	23	23	23	0	0.0%	0	0	0.0%	0	0.0%
IT	92	97	95	0	0.0%	0	2	2.2%	2	2.2%
Procurement	13	13	13	O	0.0%	0	0	0.0%	0	0.0%
QA	24	30	27	O	0.0%	0	0	0.0%	0	0.0%
Security	16	14	15	0	0.0%	1	0	0.0%	1	6.3%
Total G&A	359	371	365	0	0.0%	1	3	0.8%	4	1.1%
% of X-FTE's				0.0%		25.0%	75.0%			
IRD/US										
Discovery	46	47	47	1	2.2%	0	0	0.0%	1	2.2%
Cranbury Support	10	13	12	O	0.0%	0	0	0.0%	0	0.0%
Drug Safety & Pharma	36	35	36	0	0.0%	0	0	0.0%	0	0.0%
Health Policy	38	40	39	0	0.0%	0	0	0.0%	0	0.0%
Medical Research	75	85	80	0	0.0%	0	2	2.7%	2	2.7%
Nonclinical & R&D	47	49	48	0	0.0%	0	0	0.0%	0	0.0%
Program Management	22	24	23	0	0.0%	0	1	4.5%	1	4.5%
Regulatory Affairs	23	24	24	O	0.0%	0	1	4.3%	1	4.3%
Total IRD/US	297	317	307	1	0.3%	0	4	1.3%	5	1.7%
% of X-FTE's				20.0%		0.0%	80.0%			
MFG/OPERATIONS										
PF Labs Salaried	17	18	18	0	0.0%	0	0	0.0%	0	0.0%
PPMD	55	57	56	0	0.0%	0	0	0.0%	0	0.0%
Wilson NC	189	188	189	2	1.1%	1	10	5.3%	13	6.9%
Total MFG/OPERATIONS	261	263	262	2	0.8%	1	10	3.8%	13	5.0%
% of X-FTE's				15.4%		7.7%	76.9%			
Total PURDUE	1,631	1,672	1,652	12	0.7%	4	52	3.2%	68	4.2%
The state of the s	# TO TO THE STREET		7 T T (T							
RHODES Technologies	145	147	146	1	0.7%	0	1	0.7%	2	1.4%
RHODES Pharma	22	25	24	0	0.0%	0	1	4.5%	1	4.5%
Total MFG/OPERATIONS	167	172	170	1	0.6%	0	2	1.2%	3	1.8%
Total MIAMI	4	5	5	0	0.0%	0	0	0.0%	0	0.0%
Grand Total	1,802	1,849	1,826	13	0.7%	4	54	3.0%	71	3.9%
% of X-FTE's	1,004	****	£,0#U	18.3%	U . 1 7 V	5.6%	76.1%	~ *U / U	1.4	V.7/10
70 OJ A-1 IES				10.370		5.070	70.170			

# FINANCE/INFORMATION TECHNOLOGY

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 financial reporting internal controls are in place.

# **Financial Performance First Half 2012**

	June Year-to-Date			Full Year	
	2012 YTD	2012 YTD	2011 YTD		
Expressed in 000's	Actual	Budget	Actual	2012 Budget	2011 Actual
Net Branded Revenues	1,063,833	1,133,253	1,136,433	2,351,488	2,210,115
Operating Margin	483,770	512,861	631,843	1,094,217	1,186,089
EBITDA	482,061	497,737	619,498	1,070,182	1,173,772
Net Profit Before Tax	468,123	484,823	605,427	1,038,083	1,145,824
Owner's Equity	624,308	696,423	681,176	661,224	491,636
Non-tax Distributions	129,543	242,000	210,546	448,000	575,246
Days Sales Outstanding	35.4	35.0	35.1	35.0	33.9
Accounts Receivable Outstanding > 90 Days Past Due	< 1%	< 1%	< 1%	< 1%	< 1%
Capital Spending YTD	13,203	17,750	8,999	35,500	26,823
Unrestricted Cash on Hand	788,096	734,400	602,889	771,202	606,494
Available Liquidity	788,096	734,400	602,889	771,202	606,494
Available Liquidity - Average Months Sales	3.7	3.2	2.7	3.9	3.3
Headcount	1,672	1,730	1,630	1,788	1,633

#### Notes

- See full financial report for detail.
- Profit is lower than prior year due to increases in R&D (pipeline progressing), increasing S&P (launching new products) and lower sales (OxyContin).
- A \$113 million non-tax distribution was made in July bringing year-to-date to \$242 million.

# Financial Performance Full Year 2012

The mid-year update presented in June projected:

	2012 Mid-			Variance
	year	2012	Variance	FAV/ADV
(\$mm)	Update	Budget	FAV/ADV	%
Gross Branded Product Sales	\$3,019.0	\$3,167.9	(\$148.9)	-4.7%
Net Branded Sales	\$2,237.9	\$2,351.5	(\$113.6)	-4.8%
Operating Margin (before Incentive, Settlements & Other Items)	\$1,018.2	\$1,133.6	(\$115.4)	-10.2%
Operating Margin % Net Branded Sales	45.5%	48.2%	-2.7%	-5.6%
Pre-Tax Profit (Loss)	\$922.7	\$1,038.1	(\$115.4)	-11.1%
EBITDA	\$953.4	\$1,072.0	(\$118.6)	-11.1%
Tax Distributions	\$418.4	\$429.2	(\$10.8)	-2.5%
Non-Tax Distributions	\$381.5	\$448.0	(\$66.5)	-14.8%
Total Equity (all Companies in Pharmaceutical Group reported to Management Revisions)	\$621.5	\$661.2	(\$39.7)	-6.0%
Total Equity (US Operating Companies – Bank Reporting Group)	\$600.0	\$600.0	\$0.0	0.0%
Unrestricted Cash	\$701.9	\$771.2	(\$69.3)	-9.0%

#### Notes

- Lower than budget gross sales of \$148 million primarily due to lower OxyContin sales. Management reported that additional S&P resources are being allocated to OxyContin.
- An increase in R&D spend of \$28 million due to (1) a decision to develop an Oxycodone IR TR formulation, 2012 cost \$11 million, (2) timing and resupply of clinical materials for the ONU and Butrans higher strength studies, 2012 cost \$9 mm, and (3) adding 165 sites to ensure patient enrollment targets are met in the ONU pain plus OIC efficacy studies \$5 million.
- Management is identifying spending reductions of \$15 million to partially fund the higher R&D spending.

# **Executive Audit Committee**

Members: Stuart Baker, Jack Crowley, Mark Geraci, 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

Below is a summary of the most recent Audit reports.

# Review of Butrans Speaker Program (performed by Corporate Compliance)

- Corporate Compliance performed an audit of the Butrans speaker programs to determine whether the cost per person was compliant with requirements of the Sunshine Act. The audit concluded that the program recordkeeping often included paperwork errors in numbers of attendees, room rental charges, etc. The Audit did not detect compliance violations.
- Subsequent to the audit, there has been additional training of Logistics Innovations (the third party that administers the programs) and closer oversight by the sales and finance departments has been implemented. These changes are expected to improve the accuracy of record keeping.

# Review of Contracts Supporting Payments to Major Vendors (performed by Internal Audit)

- Internal audit performed an audit of all vendors that Purdue paid more than \$100,000 during the twelve months ended September 30, 2011 to ensure that, where appropriate, a contract is in place and all work was competitively bid in accordance with company policy.
- Recommendations from the audit were:
  - Office of the General Counsel should update and circulate the guidelines that explain when a contract is required. Current status: In process.
  - The current \$50,000 limitation for competitive bidding should be clarified –
    does the limit relate to an individual purchase or to the total annual purchase
    for a vendor. Current status: The policy is being reviewed.
  - Manufacturing should consider more extensive, competitive bidding. Current status: The recommendation relates to materials used in production which are highly regulated and typically single or dual sourced. Implementing competitive bidding from non-approved sources would not add value.

#### **Treasury**

Purdue's cash holding is currently invested in Treasury bills and US Government Securities mutual funds primarily in accounts registered to Purdue. These investments earn approximately 0.05-0.07% per annum.



See attached for Purdue's investment portfolio. <u>Capital Committee</u>

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Members: David Long, Ed Mahony, David Lundie, Larry Pickett

Frequency: 2-3 times per year

Purpose: The Capital Committee recommends (1) an annual capital plan, (2) a long

term capital, and (3) limits of authority for capital approvals to the President. The Capital Committee also reports postmortems on major

capital projects to the President.

# 2012 Outlook

- Management agreed to reduce the budget by \$5.9 million of approved 2011 capital due to under spending, savings, and cancelled projects.
- 2011 carryover, net of the above reductions, is \$27.5 million. In addition, the Board approved \$35.0 million of 2012 new projects these result in a total capital pool of \$62.5 million.
- Cash capital spend for 2012 is expected to be on budget at \$35.0 million with \$13.2 million spent year to date June 2012. We expect spend in the 2<sup>nd</sup> half to include the sales force computer equipment replacement (\$2.0 million), the Cranbury high potency lab fit out (\$1.6 million), the Cranbury hydrogenation lab (\$0.9 million) and computer hardware (\$4.5 million).
- A President Capital Reserve of \$2.5 million was set up in the 2012 Budget to fund projects that had not been fully vetted by budget time last year. The following reports on the status of this reserve:

Opening Balance in 2012 Budget	\$2.5
Projects approved:	
SAP access control system enhancements	(0.1)
Continuous power supply engineering study	(0.4)
Trackwise system for product complaints	(0.45)
Data disposition (1)	(0.3)
Dashboard for licensing and product opportunities	<u>(0.4)</u>
	(1.65)
Balance in President Reserve as of June 30 <sup>th</sup>	<u>\$0.85</u>

<sup>(1)</sup> This project allows Purdue to categorize stored IT data with the objective of removing unnecessary data, better identifying the data required to respond to legal requests and more. The payback on this project is less than one year through the elimination of storage costs.

# **2013 Budget Preparation**

Purdue has initiated the 2013 budget process and has issued the following guidelines to all executive and departments heads:

- Sales 2013 sales are expected to be at or about 2012 levels.
- Expense Expenses and headcount are not expected to grow from 2012 by more than inflation, and in some areas we will be looking for reductions.
- <u>R&D</u> Early indication is that to progress all the projects in the pipeline, the R&D budget will have to increase substantially. We will prepare the proposed spend accordingly, but will prioritize as the budget develops.
- <u>S&P</u> BBU budgets will be critically evaluated. Continued support for OxyContin, Butrans and Intermezzo is currently anticipated.
- <u>Headcount Budgets</u> Headcount needs, if any, should first be funded by efficiencies.
- <u>Product In-Licensing / Acquisitions</u> A place holder for new product licenses or acquisitions will not be included in the 2013 Budget.

# **Trade Inventory**

During 2011 and first half of 2012, OxyContin trade inventory operated at about 70 to 80 days demand. The expectation is that this will continue or decline as the trade improves its inventory management practices.

Summary of OxyContin inventory at the trade:

\$ millions	12/31/2009	12/31/2010	6/30/2011	9/30/11	12/31/11	3/31/12	6/30/12
Wholesaler	254.4	195.7	199.2	186.9	224.6	188.2	208.4
Pharmacy	427.2	438.1	421.5	406.9	347.0	369.7	337.9
Hospital/Other	4.1	3.3	4.1	4.0	5.0	4.1	4.0
Total \$	685.7	637.1	624.8	597.8	576.6	562.0	550.3
Total Days	75.8	75.6	75.1	69.8	72.6	75.4	78.5

Butrans inventory at the trade is down to about 70 days – a normal level:

\$ millions	9/30/11	12/31/11	3/31/11	6/30/12
Wholesaler	5.3	7.0	6.0	7.7
Pharmacy	12.6	10.8	12.4	10.7
Hospital/Other	0.1	0.1	0.1	0.5
Total \$	18.0	17.9	18.5	18.9
<b>Total Days</b>	139.0	117.2	79.9	72.1

Intermezzo inventory at the trade is \$12.8 million – a return reserve of \$9.0 million has been established based on current Rx demand and inventory shelf life expiration. As demand increases, this reserve will be decreased.

\$ millions	6/30/12
Wholesaler	7.9
Pharmacy	4.9
Hospital/Other	0
Total \$	12.8

# **Pension Investment Committee**

Members: Stuart Baker, David Long, 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.

#### **Defined Benefits Pension Plans**

Purdue Pharma employee benefit package includes a defined benefit pension plan. This plan provides employees with a pension benefit calculated based on pay and years of service. Purdue contributes to a Trust Fund and that fund pays the employees' pension benefit. Purdue Pharma is ultimately liable to pay the benefits and until those benefits are completely paid out, the liability is uncertain and will change due to changes in many factors including, beneficiary life expectancy, turnover, pay raises, return on assets, and interest rate used to calculate lump sum payouts.

• PPLP Plan - At 12/31/12, the plan's Accumulated Benefit Obligation<sup>1</sup> was \$220 million and the plan assets were \$191 million. Purdue made \$7.1 million of contributions to the plan in Q2-2012 and budgeted to make \$28 million of

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<sup>&</sup>lt;sup>1</sup> 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.

contributions spread equally over 2012. The relatively high 2012 contribution is due to lower than expected investment return in 2011 and a decrease in discount rate used to determine future liability.

The plan investments returned approximately 1.0% for the 12-month ended 6/30/12. The fund assets are invested in: (a) passive equity indexed funds, and (b) actively managed fixed income funds – which have outperformed passive fixed income.

 PF Labs (Union) Plan - PF Labs has a smaller defined benefit plan - \$6.6 million in assets - covering ex-employees, the plan is well funded and small contributions are being made.

# Defined Contribution Pension Plans - 401(k)

- Purdue Pharma LP also offers employees an optional 401(k) defined contribution savings plan. The company's contribution to this plan was \$5.9 million in 2011 and is defined as a certain limited percentage of the employee's contribution to the plan. The 401(k) plan assets total \$265 million and \$290 million at the end of 2011 and Q2-2012, respectively. Purdue employees choose how these funds are invested from a diversified list of mutual funds that are vetted and monitored by the Committee, Fidelity and an outside consultant.
- The plan offers employees a broad range of active and passive investment options. The funds offered are generally very good performers in their classes. Marginal and poor performers are frozen to new investment and/or removed. Nearly all

funds in Purdue's lineup are rated by Morningstar at 3-star or higher.

# Information Technology

# **Top Projects & Initiatives**

- The Health Care Practitioner (HCP) Portal is a Purdue website set up for HCP's who, once registered, have access to product information, formulary coverage, a sales representative visit request form, etc. The website is managed internally by IT at a significant savings from the previous vendor. Hosting savings alone are \$275K annually. The entire site was recently redeveloped, highlighting the addition of Intermezzo, as well as now being integrated with Managed Care Formulary information, which we believe HCP's will find very helpful.
- The IT team implemented an application called UPS Worldship which provides UPS labeling, parcel, and rate tracking functions to Rhodes Pharma at the Wilson distribution center. This will reduce group shipping costs by \$2,184,400. Rhodes Pharma successfully shipped the first orders under this UPS method on July 2.
- As presented at the board meeting on June 20, IT off-shoring currently used extensively in Purdue, is being evaluated by for Europe. The group is considering establishing off-shore goals in line with industry standards (50% inhouse, 50% off-shore). Approximately \$40 million in savings have been realized in the off-shore program at Purdue over the past six years.

# Efficiency Initiative

Purdue's management team is undertaking targeted deep-dive expense analysis with a goal of delivering \$50 million in savings to Purdue's bottom line by 2Q 2013. The areas of focus are:

- IT-Worldwide This study was completed in Q1 and presented to senior management and the Board. The study identified approximately \$8 million in savings. Larry Pickett and are beginning to implement some of the proposed changes and will report back in 4Q 2012.
- Sales Force This project will be initiated at the end of 4Q 2012 or 1Q 2013.
   Estimated savings could be in the range of 5% or \$5 million.
- Clinical Trial (CRO) Costs called "Project Breakthrough" and have undertaken organizational and contracting changes which are delivering substantial savings.
- There will also be negotiated cost savings, vendor rebates, etc. delivered by and department heads throughout Purdue.