Key Metrics: Manufacturing, Supply Chain and Pharmaceutical Technology

Manufacturing and Supply Chain	Q2 YTD			Full Year	
	Actual	Budget	Var	2013 Budget	2012 Actual
Tablets Manufactured (MM)	**336**	**363**	**(27)**	**726**	**691**
OxyContin	184	205	(21)	394	486
MS / MSER	147	126	21	246	196
Oxy APAP	-	32	(32)	86	-
Oxy Export	5	-	5	-	9
Export Packaging Bottles (000)					
Bottles Packed	171	-	171	-	310
Orders Shipped On-Time					
Wilson	100.0%	99.0%	1.0%	99.0%	99.6%
Rhodes	100.0%	99.0%	1.0%	99.0%	97.0%
3rd Party	99.5%	99.0%	0.5%	99.0%	99.0%
Orders Shipped In-Full					
Wilson	99.5%	99.0%	0.5%	99.0%	99.0%
Rhodes	100.0%	99.0%	1.0%	99.0%	100.0%
3rd Party	100.0%	99.0%	1.0%	99.0%	100.0%
Inventory On-Hand (Months)					
OxyContin	2.3	2.5	(0.2)	2.5	2.1
BuTrans	5.4	3.0	2.4	3.0	5.5

Pharmaceutical Technology	Q2 YTD			Full Year	
	Actual	Budget	Var	2013 Budget	2012 Actual
Research and Development Hours	**17,136**	**15,909**	**1,227**	**22,273**	**29,878**
Production Hours	2,791	2,591	200	3,628	3,233
Support Hours	14,345	13,318	1,027	18,645	26,645
Development Batches Manufactured	**79**	**75**	**4**	**77**	**83**

Notable Comments for the Period

- Successfully completed the qualification of the second new packaging line in Wilson while supporting commercial demand from a single line using multiple shifts over the last 6 months. The new packaging lines had technical issues yet no impact on ONF supply, and was also able to clear the Rhodes MSER order backlog.

- ONF inventory increased to $104.5 million due to higher API shipping levels, slower market demand and less flexibility of a single packaging line. This will be adjusted to match the lower market demand in next quarter.

- MS Contin / MSER - Scale-up and process optimization is complete with great potential for improved operational efficiencies. The new batch size is 6X previous scale, and is planned to be part of routine manufacture in Q3, 2013

- Intermezzo – With the sales of Intermezzo not realizing forecast, production was cancelled at Patheon and Sharp. Future production is being evaluated for Q3 2013 based on the expiry dating of the current stock and need to supply the market in 2014.

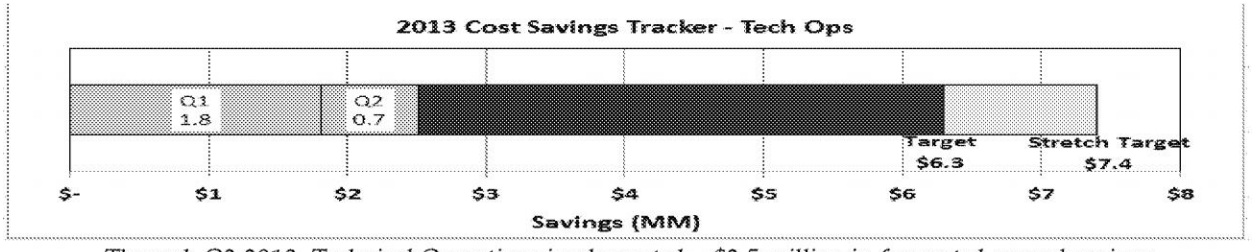
- Butrans – Maintained supply as the validation and commercial tech transfer to LTS in West Caldwell was suspended in January 2013 due to an Out of Specification investigation. GMP issue is now resolved (see Quality Report).

- Senokot XTRA – Product has been moved to CPC, and currently evaluating an XTRA product that also includes DSS which could be marketed as Senokot or Peri-Colace.

Risk Mitigation: Back-up of Key Products and Materials

- Totowa successfully manufactured and released four clinical placebo lots in addition to three 20 mg commercial lots of ONF during Q2 2013.

- Dow - First two lots of the custom grade Polyox material has been received, which will address the degradant issue. This custom Polyox will also be used by our affiliates in Europe.



Through Q2 2013, Technical Operations implemented ~ $2.5 million in forecasted annual savings.

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.

Update on Internal GMP Investigations / Audits and Regulatory Audits

- ONF
  - As previously reported, the investigation into an Out of Trend (OOT) stability result for unknown degradants in ONF lot WBL51 required in vivo genotoxicity testing. A follow-up field alert report was filed with the FDA Atlanta District at the end of May 2013. The reports for this testing demonstrated favorable results for the lack of genotoxicity in humans. A final field alert report is in preparation to provide the reports to the FDA Atlanta District.
  - An increased number of complaints for short counts of tablets in bottles for ONF were received in Q2 2013 due to technical issues with the new packaging lines. Investigation identified two root causes – one procedural in the event of an alarm, and the other a software issue. Corrective actions are in progress.

- Totowa received their biannual FDA inspection on April 16 -22, 2013. The site received one minor 483 observation. The response to the observation was filed on time, and all FDA commitments were completed by June 30, 2013. The EIR (Establishment Inspection Report) has been received.

- Butrans
  - The investigation into the Out of Specification (OOS) test result reported in the last quarterly report is nearing completion. Investigation is for the degradant Buprenorphine N-Oxide at the 3-month 40°C/75%RH stability sample for a 7.5 mg clinical lot produced at LTS West Caldwell, and at the 3-month stability interval for the 40°C/75%RH 5mg validation lot supporting the introduction of the first West Caldwell produced batches to the market. The identified root cause is the incorrect orientation of the release liner on the patch. Restart of activities at West Caldwell in Q3 2013 is pending completion of the investigation report.
  - A field alert was filed on June 24, 2013, for foreign matter associated with a complaint received from a pharmacist. The patch contained a black stain under the release liner for the unused patch. The investigation is underway.

- Slow-Mag Support – The report to close out the investigation into the DEM issue is in progress. No root cause has been determined. The final response to the FDA 483 providing the *in vivo* genotoxicity results (non-genotoxic) was filed with the FDA NE District on June 18, 2013.

- ONF approval for Chile was received, and all documents have been prepared to support the first product shipments scheduled for the beginning of Q3 2013.

- The Korean FDA (KFDA) inspected the Wilson manufacturing site on March 11 – 14, 2013. The inspection report was delayed slightly and was received in Wilson on April 30, 2013. Wilson provided their responses to all observations to Mundipharma Korea by the requested deadline to allow translation prior to submitting to KFDA for review.

- Wilson received an Almac Qualified Person inspection on June 18-19, 2013, associated with Wilson production of clinical supplies. The site received two minor observations, one related to validation including a specific EU requirement, and the other to the lack of Quality Agreements for contract laboratories. The latter is also covered in a new FDA draft guidance.

- Fisher Scientific Services - Due to a trend of high numbers of human errors in the packaging of PPLP clinical supplies, there was a For-Cause Audit of Fisher Scientific Services in late June 2013. No major observations were identified, but there were recommendations for improved management oversight of each packaging run.

- Trackwise Software Project - Auditing module has been initiated, and User Requirements are currently being collected. The project is scheduled for completion in Q3 2013, and will enhance our audit management capability.

RESEARCH & DEVELOPMENT

R&D's goal is to efficiently and effectively advance each pipeline project up to and through the defined stage gates as described within each program's strategic development plan. R&D's objectives for 2013 are reflected in Purdue's Business Scorecard and focuses 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 2Q 2013 substantial progress has been made toward the budgeted plan.

Each of the following pipeline projects are addressed herein:

- Reformulated OxyContin® (OTR/ORF)
- Cross-Pediatric Program (OxyContin/Butrans/Hydrocodone)
- Butrans® (BTDS)
- Targiniq (ONU)
- Hydrocodone QD (HYD)
- TRPV1 Lead (VND)

- TRPV1 Back-Up (VAN)
- ORL1 (OAG)
- Intermezzo (INT)
- Abuse Deterrent Immediate Release Oxycodone / ADIR – (OCI)
- MS Contin Reformulation – to an AD Formulation

Reformulated OxyContin (OTR/ORF)

All R&D scorecard activities for reformulated OxyContin remain on track:

- Approved labeling supplement related to abuse-deterrence (revised product label)
- Messaging regarding a) evidence base for use of opioids to treat chronic, non-cancer pain, and b) abuse deterrent properties/outcomes driven by reformulated OxyContin
- Pediatric exclusivity research program

On April 16, 2013, the FDA concluded that original OxyContin was withdrawn from sale for safety reasons due to the reformulated version demonstrating lower potential for abuse than original OxyContin, and, as a result, the FDA barred generic versions of original OxyContin that lack abuse-deterrent features from the market. The decision established that the FDA recognizes that an opioid's benefit/risk profile can change due to the availability of an alternative product with a lower potential for abuse. Concurrent with and related to this decision, on April 16 FDA also approved Purdue's labeling supplement to describe the abuse-deterrent features of reformulated OxyContin. This revised product labeling and promotional materials include detailed text characterizing the physicochemical properties of the formulation, in vitro testing results, intranasal in vivo abuse potential data and label claims for both.

Reformulated OxyContin epidemiological studies are ongoing. FDA's advice letter on post-marketing requirement studies was received on May 23 requesting the following changes to the postmarking epidemiological studies requirement: a) extend studies for at least 2 extra years, b) annual update to be provided to FDA on January of each year, c) revision of 6 formal post-marketing studies to 3 formal post-marketing studies and provide justification of supplemental studies. Purdue-sponsored studies, as well as non-Purdue studies are being published in peer reviewed journals. Multiple publications, abstracts, posters and presentations of these data are planned for 2013 and beyond.

Support for Independent Associated Companies

Purdue assistance, including support from R&D continues with Independent Associated Companies for ORF approval. Activities supporting Latin America are: a submission in Mexico is planned for July 2013, submissions in 12 remaining Latin American countries are planned for 4Q 2013 and pre-launch activities are underway in Chile for ORF 10, 20,

and 40 mg. Mundipharma Colombia sponsored a symposium on the *New Abuse-Deterrent Opioids-Characteristics and Innovative features of the OxyContin formulation* at the Colombian chapter of the International Association for the Study of Pain (IASP) on June 22. In the Asia Pacific territory, a submission is planned for June 2013 for Hong Kong, and a submission is planned for several Mundipharma Asia Pacific countries for 2Q-3Q 2013. Purdue R&D continues to provide technical support for the ongoing review of ORF by the Australian TGA.

10mg ORF - degradants

Preliminary results indicate that the combined in vivo micronucleus/ comet assay in rats, performed on two identified degradation products, was not genotoxic. The weight of evidence indicates that neither ORF degradant poses a genotoxic risk to humans. On May 24, a field alert was sent to the FDA's Atlanta District informing them that the degradation products are not genotoxic. The final reports of these studies will be submitted to FDA, when completed, projected by end of July 2013.

Cross-Pediatric Program (OxyContin/Butrans/Hydrocodone)

A cross pediatric program team was formed in May 2013 to recognize efficiencies and apply experience and best practices developed for OTR3001 to transfer to BUP3031 and to future pediatric studies.

OTR3001 (Safety Study) Enrollment		
Milestone/Target by December 2013	**Rating**	**Current Status**
≥ 127 patients	5	98 patients enrolled of N=154 as of June 27, 2013
119 patients	3	
< 112 patients	1	

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

BUP3031 (Safety Study) Enrollment		
Milestone/Target by December 2013	**Rating**	**Current Status**
≥ 15 patients	5	

10 patients	3	6 patients enrolled of N=40 as of June 25, 2013
≤ 7 patients	1	

Several current OTR3001 sites have been identified for co-conduct with BUP3031. This will recognize efficiencies greatly reducing the time for new Butrans sites to become activated and open to enrollment.

Hydrocodone pediatric study protocol (HYD4001) was internally approved and signed off on June 13, 2013 and will be submitted to the FDA by the end of June. Conduct of HYD4001 will not initiate until the results of the adult audiology findings are evaluated and understood. The proposed PREA commitment date is March 2018 for final report submission to the FDA.

Butrans® (BTDS)

All R&D scorecard activities for Butrans remain on track:

- Progress Butrans PREA (pediatric research) program (This scorecard activity has been transferred to the Cross-Product Pediatric Team and has been reported in that section)
- Stage-Gate analysis required to make go/no-go decision for 2nd Generation and higher strength patches (This scorecard activity was completed in May with the decision to pursue development of the new LTS 2nd Generation prototypes and the decision to pursue higher doses without conducting additional Phase 3 clinical trials)

Other Butrans Updates

The FDA notified Purdue that the action date for the pre-approval supplement supporting registration of the Butrans 15 mcg/h patch is July 27, 2013.

The out-of-specification (OOS) stability investigation for 7.5 mcg/h patches continues at the LTS facility in West Caldwell without identification of root cause. Commercial production in West Caldwell remains on hold until the investigation is completed. Manufacturing in Andernach and planning for the submission of a Prior Approval Supplement for 7.5 mcg/h patches has been initiated.

Results from the Higher Dose Thorough QTc trial (BUP1025) confirm results of Study BUP1011 which demonstrated a small positive effect (per ICH E14 Guideline) on delaying the QT interval with treatment of Butrans 40mcg/h (achieved with 2 X 20mcg/hr patches).

The Law Department is assessing IP/exclusivity timelines relative to the latest 2nd Generation development and BUP1025 results.

New 2nd Generation formulation prototypes have been developed that appear to be reproducible and meet the target in-vitro profile. Stability testing is ongoing to support IMPD submission and initiation of pilot PK trial in September 2013.

Targiniq (ONU)

The following R&D scorecard activities are presented below:

- The initial NDA filing is on track for end of September, 2013.
- Twin pivotal studies required to support planned sNDA submission (opioid induced constipation) are enrolling at a rate inconsistent with current submission and launch plan.

The NDA submission (for the indication of Pain with abuse deterrent properties) is on track for September 2013. If approved, the product label is expected to characterize Targiniq as a safe and effective opioid analgesic with pharmacologic abuse deterrent properties. The favorable safety and tolerability data (inclusive of GI events) generated in the single US pivotal study (ONU3701) will be submitted for inclusion in the product label, along with wording that speaks to the purpose and/or mechanism of action of the naloxone component. However, there will be no direct comparison to OxyContin's tolerability data in this label.

A multi-faceted plan to expedite enrollment in the replicate pivotal studies (ONU3704/3705) required to support label expansion (OIC treatment) is being implemented. These two pivotal studies define the critical path for sNDA submission for the OIC/bowel effects indication, and all efforts are being made to expedite their conduct and completion - and the revised target sNDA submission date is 4Q2015. A stage gate strategy will be implemented in 3Q13 to determine the effect of efforts to increase enrollment rate and re-evaluate overall likelihood of success of these studies.

Hydrocodone QD (HYD)

All R&D scorecard activities for HYD remain on track:

- Enrollment in the HYD Phase 3 program (pivotal study and open-label safety study) is on schedule and supportive of an NDA submission in Q2 2014.

TRPV1 Lead (VND) 116517

All R&D scorecard activities for TRPV-1 remain on track:

- Complete enrollment in two Proof-of-Concept studies in support of go/no-go decision

Two human Proof-of-Concept studies (Osteoarthritis and Post -Herpetic Neuralgia) initiated in September, 2012 and are recruiting on /close to schedule (OA study fully enrolled, PHN study amended to accelerate enrollment). A go/no-go decision for one or both potential indications (general nociceptive pain and neuropathic pain) is targeted for late 2013/early 2014.

TRPV1 Back-up (VAN) 120083

All R&D scorecard activities for VAN remain on track:

- Progress first-in-human experiment under Japanese IND

The First in Human clinical trial (Single Ascending Dose) and a Multiple Ascending Dose study (including Caucasian subjects) have been successfully conducted in Japan, results pending draft study report (expected in 3Q13).

ORL1 (OAG)

All R&D scorecard activities for ORL1 remain on track.

Intermezzo (INT)

All corporate scorecard milestones for Intermezzo are on track.

Milestone	Target	Current Status
Post-Marketing Requirement: Patient compliance with dosing instructions in the setting of actual clinical use	4/2013	Submitted on April 30, 2013
Post-Marketing Requirement: PREA Phase 2 dose-finding study	No longer applicable	FDA waived the requirement for PREA entirely in May 2013
Advance publication plan, comprised of 5 potential manuscripts, in accordance with prioritization	Preparation for submission to journals on target	On Plan; one manuscript published; 3 under review at journals; 1 being readied for submission to journal; 9 insomnia-related posters presented at annual international Sleep meeting

Progress continues on the publication plan of previously completed studies, including new analyses of post dose sleep architecture as measured during the sleep laboratory study.

Abuse Deterrent Immediate Release Oxycodone /ADIR - (OCI)

All R&D scorecard activities for OCI remain on track:

- Initiate abuser panel study in June
- Complete clinical and registration batches in Wilson plant. (Manufacture of clinical supplies were completed April 26 in Wilson)

An End-of- Phase 2 Meeting was held at FDA May 21, 2013 with the following key outcomes:

- The Agency communicated their concern regarding potential for GI adverse effects related to sodium lauryl sulfate (SLS), the excipient added as an aversive agent to reduce the potential that OCI will be snorted by abusers. They have requested the safety data from the pilot PK study and our assessment of maximum daily dose of IR oxycodone upon which the Agency would base the non-clinical requirements for qualification of the corresponding amount of SLS.
- The Agency agreed to review our toxicology risk assessment for SLS ahead of the NDA submission but could not provide a timeline for review.
- The Agency also requested that we add a 30mg dose to the BA/BE study and a 30mg OCI intact tablet oral dose plus placebo to the IN abuse study.

Study plans have been revised and documents are in preparation for FDA review as requested at the End-of-Phase 2 meeting.

In addition, study designs are being assessed in the event it is determined that a small PK/Safety study is needed to support GI tolerability of OCI prior to submission.

MS Contin Reformulation

A project has been initiated to reformulate MS Contin using the PEO-based platform developed for ORF. Technical development has commenced, and a project team created.

DISCOVERY RESEARCH

Purdue-Shionogi Collaboration ORL-1 Agonist Program

- Confidentiality agreements are in place and the meeting was held with two Harvard professors, both sleep experts (one testified in the Michael Jackson trial), to discuss the rat EEG results and possible mechanisms of ORL-1 induced sleep. Both professors are excited about our data, feel that there is a need in the field for something new, and are working with us to define additional experiments that could support a proposal for ORL-1 agonists in a sleep indication. They also suggested that there is a large unmet need for a dual sleep-inducer/pain reliever, so this is being pursued in the coming months.
- In the 2nd quarter the backup program continued to focus on pharmacological studies to elucidate the site and mechanism of action of the observed clinical effects from V117957 and establish a method of differentiating a backup molecule. Efforts have begun to generate an ORL1 receptor knockout rat, which will allow us to confirm whether these effects are on or off-target. Our chemistry remains focused on new chemical series and synthesis of "pharmacological tool" compounds in collaboration with Shionogi.

Sodium Channel (Nav) Blocker

- In the 2nd quarter the Nav team determined that V121241 had insufficient exposure to assess in toxicology studies. An alternative compound (V121130) is currently being evaluated in a 2-week rat toxicology study. Headline data will be available later in the summer.
- The chemistry team remains focused on synthesizing compounds with improved pharmaceutical properties over V121130. The chemistry effort has increased the solubility and reduced the half-life of the compounds. This should translate into improved pharmacokinetic (PK) properties and a closer correlation between efficacy and exposure.

Exploration of Signal-Biased Opiates

- We have fully evaluated both R and S isomers of DHE in the various in vitro assays of arrestin bias, and shared the data with Mundipharma. We do not see significant mu receptor bias in these molecules, although we are about to also look at kappa where there may be differences.
- We have fully evaluated the Trevena lead compound, TRV130 in vitro and in vivo and our data is similar to what Trevena has recently published, except that we do see evidence of constipation and respiratory depression in rats dosed with their molecule.

- We have selected two molecules that are novel, and show biased signaling in vitro for further scale-up, pharmacokinetic testing, and live animal testing. This data will help define the features of potential developmental candidates in the future.
- We have initiated academic collaborations with the University of Colorado and the University of Jena to study TLR4-opioid signal overlap, and mu receptor phosphorylation "barcodes", respectively. The appropriate agreements are currently being reviewed by both organizations and we hope to initiate the collaborative research later in the summer.

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.

Q1 2013 Results	Total	Declined in Level 1	Referred to R&D Innovation	Declined in Level 2	Declined in Level 3	Transferred to Inter-national Colleagues	Active with BDC	On Hold Pending Data
4Q12 Existing opportunities Active with BDC	7	1	0	4	0	0	2	0
New Opportunities 2Q13	64	46	8	0	0	5	5	0
Total	**71**	**47**	**8**	**4**	**0**	**5**	**7**	**0**

Q2 2013 Results	Total	Declined in Level 1	Referred to R&D Innovation	Declined in Level 2	Declined in Level 3	Transferred to Inter-national Colleagues	Active with BDC	On Hold Pending Data
1Q13 Existing opportunities Active with BDC	7	2	0	0	0	1	4	0
New Opportunities 2Q13	80	63	3	2	0	0	14	0
Total	**87**	**65**	**3**	**2**	**0**	**1**	**18**	**0**

Annual Total	Total	Declined in Level 1	Referred to R&D Innovation	Declined in Level 2	Declined in Level 3	Transferred to Inter-national Colleagues	Active with BDC	On Hold Pending Data
4Q12 Existing opportunities Active with BDC	7	1	0	4	0	1	1	0
New Opportunities Screened 1Q 13 & 2Q13	144	116	9	2	0	0	17	0
Total	**151**	**117**	**9**	**6**	**0**	**1**	**18**	**0**

ACTIVE LBD PROJECTS END OF Q2 2013

Company	Product & Level Status	Indication	Status	Responsible Party	Screen Date
Flexion	Fx-006: CR triamcinolone/ polylactic-co-glycolic acid (PLGA) formulation intra-articular (IA) injection for osteoarthritis in the knee Level 2	OA Knee	Phase 2b 220 patient dose ranging study comparing 3 separate doses of FX-006 to Kenalog (IR steroid). End point pain reduction on VAS scale. Flexion presented data to Purdue on June 27th. Purdue reviewing opportunity at July 18 BDC.	Darland	1/6/13
Rhythm	RM-131 Ghrelin Agonist Peptide Level 2	Diabetic Gastro paresis	Ph2 data to be available Sept. Market research completed, creating forecasts and financial valuation.	Downs	6/18/12
Astra Zeneca / Pozen	Vimovo (naproxen esomeprazole) Acquisition of product from Astra Zeneca. Gross sales in 2012 of $40 million in U.S. and $40 million ex U.S. Level 2	Relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with NSAIDs.	Presenting sales forecast and "re-launch" budget estimate to BDC on July 18 for a decision. Astra Zeneca conducting a private process to sell this product worldwide (product was developed by Pozen).	Downs	5/23/13

Company	Product & Level Status	Indication	Status	Responsible Party	Screen Date
Zalicus	Z-160-selective N-type calcium channel blocker (oral 375mg, BID) Level 2	Neuropathic & nociceptive pain	CDA has been executed. Awaiting 2 Ph2 trials, one for PHN and one for lumbosacral radiculopathy, 2H13.	Kraft	1/7/13
Concert	CTP-354 deuterated version of Merck's L-838417 GABA(A) Level 2	Spasticity and chronic pain	Significant number of pre-clinical experiments conducted on the molecule. Phase 1 ongoing.	Darland	6/21/13
Aerial BioPharma	ADX-NO5 (Sigma Opioid Receptor Modulator) Level 1b	Excessive daytime sleepiness associated with narcolepsy	Phase 2b data due September 2013. Confidential meeting scheduled in Stamford on July 9, 2013.	Darland	5/3/13
Afferent	AF-219 - P2X3 antagonist Level 1B	Pain	Assess POC data in August 2013.	Darland	1/6/13
Ricanto	TABEX® (cytisine tablets) partial agonist $\alpha 4$, $\beta 2$ nicotinic receptor; from Cytisus Laburnum plant Level 2	Smoking cessation	In Rappaport's division; Need phase I and II studies to complete U.S. package; Due diligence will confirm U.S. requirements for filing; developed and marketed in Bulgaria by Sopharma Pharmaceuticals.	Dolan	3/8/13

Company	Product & Level Status	Indication	Status	Responsible Party	Screen Date
AgeneBio	Combination of low dose CR levetiracetam (Keppra®) and donepezil Level 2	slowing the progression of amnestic mild cognitive impairment (aMCI) due to Alzheimer's disease	Inventor has patented this low dose combo for MCI Alzheimer's; new company is being formed; seeking investors	Dolan	6/21/13
Pathologica	PA300 - S-adenosyl-methionine decarboxylase (SAMDC) anti-inflammatory Level 1	Anti-inflammatory for pain, multiple sclerosis, autoimmune diseases	Detailed presentation by Pathologica to occur during the early fall 2013. Company studying oral M.S. as well as pain development strategy.	Dolan	5/3/13
JB Thera-peutics	BT-101 (synthetic cannabinoid) Level 1b	Treatment resistant neuropathic pain	Confidential meeting to evaluate JBT-101 (ajulemic acid) scheduled for July 10.	Downs	4/11/13
SK Life Sciences	SKL-11197 oral tablet / Peripheral-acting 15-LOX and ion channel blocker Level 2	Diabetic neuropathic pain	Placed On Hold following advice from SK that the Ph2 study in diabetic neuropathic pain did not reach significance. They are evaluating the study results to understand possible causes.	Downs	5/3/13
Lexicon	LX-1033 TPH inhibitor molecule undisclosed Level 2	IBS-d	Phase 2 data is expected July 2013.	Kraft	5/31/13

Company	Product & Level Status	Indication	Status	Responsible Party	Screen Date
Epiphany Biosciences	EPB-348 (valomaciclovir, antiviral) Level 1b	Shingles Mononucleosis	Phase 2b met endpoints for Shingles. Phase 2a met endpoints for mono. Assess phase 3 costs. Review the mononucleosis market.	Kraft	5/9/13
Zeria	Acotiamide oral tablet: Reversible acetylcholinesterase inhibitor Level 1b	Functional dyspepsia	Confidential meeting to evaluate acotiamide for U.S. Ph3 development scheduled for July 22. GI regulatory consultant Larry Goldkind pre-briefing scheduled for July 11.	Downs	5/3/13
Array BioPharma	TrkA Inhibitor Discovery level Level 3	Neuropathic Pain	MTA in place. Product being tested in Cranbury. Initial term sheet received from Array.	Kyle / Kraft	N/A
Grünenthal	KV7 (KCNQ) Channel opener Discovery level Level 1	CNS indications: pain, bipolar, anxiety, epilepsy, addiction	Confidential meeting to be scheduled.	Kyle / Kraft	5/3/13

Company	Product & Level Status	Indication	Status	Responsible Party	Screen Date
Marinus	Ganaxolone oral suspension & tablet Level 1	Fragile X Syndrome	Orphan indication with high medical need. Marinus seeks $1.5M in clinical trial support to accelerate Ph2 development for which we could seek an option to license. Preparing proposal to invest in the Ph2a study of ganaxolone study in Fragile X Syndrome to obtain an option right to the product for the orphan indication.	Downs	6/28/13

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.

Key Compliance Issues in 2Q13

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

While there are compliance matters detected, investigated, and remediated on an on-going basis, there have been no *significant* compliance matters to report.

Physician Payments - Sunshine Act Reporting Commences

Effective August 1st, pharmaceutical, biologics, and device firms must begin collecting payments and other transfers of value to physicians and teaching hospitals, for public website posting by CMS on September 30, 2014.

- All Purdue employees, Board Members, and certain contractors will accordingly need to accurately record and report payments and transfers of value to physicians, including meals, gifts, consulting fees, grants, R&D activities, etc.
- Purdue has developed over a period of two years its proprietary "Whole$um" system for aggregation and reporting of federal Sunshine data as well as state law requirements.
- Live training, web-based training, and other means employed to prepare employees and others for Sunshine Act reporting.
- Independent audit of Whole$um system by Navigant Consulting, under aegis of IAF, is currently underway to verify preparedness and accuracy.

EXTERNAL AFFAIRS

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

Build Support For Appropriate Pain Care Through Policy Development And Implementation

- A group of U. S. Senators and U.S. Congressmen, FDA, ONDCP, the White House, and 22 Pain Care Forum organizations have weighed in with the Centers for Medicaid & Medicare Services (CMS) expressing their belief that CMS has misinterpreted the intent of the law by including abuse deterrent formulations in the definition of "line extension." Very positive feedback from FDA and ONDCP has been received that a satisfactory solution will be reached, however this will not be certain until the final regulation is published. Senators have raised this issue with statements of support at two Congressional hearings, where CMS officials have also testified.

- Members of Congress introduced legislation, (H.R. 6160), that would prevent the FDA from approving a non-deterrent controlled substance where an abuse deterrent formulation of the same drug is approved. The legislation has received considerable attention from Congress. Key Senators, Minority Leader McConnell, and Assistant Majority Leader Schumer have informed FDA that they support the concept of the STOPP Act and a bipartisan group of members in the Senate and the House are contemplating potential amendments similar in nature to the STOPP Act.

    - Letters were solicited from approximately 150 state elected officials and local law enforcement to the FDA discouraging non-abuse resistant generic formulations of opioids. 48 State Attorneys General signed a joint letter through the National Association of Attorneys General to the FDA discouraging approval of non-abuse deterrent generic formulations of opioids as well as letters from 2 Governors. Senators and House Members introduce Sense of the Senate (S. Res. 97) and Sense of the House Resolutions (H. Res. 161) favoring ADF and encouraging FDA to exercise their authority and not approve generics without ADF.
    - FDA on April 16th made an affirmative decision withdrawing the old formulation of OxyContin and not permitting non-deterrent formulations to be approved.

Take Appropriate Action On External Threats To Optimal Pain Care

- An internal subcommittee of the Communications External Affairs Committee (CEAC) has been developed to address the issue of patient access to pain medications. The Pain Care Forum has also initiated a Patient Access sub-team to address the increasing barriers patients are experiencing at a pharmacy level when trying to obtain their medications. Access issues have been identified in multiple states, with the majority occurring in Florida. These issues stem from the Drug Enforcement Authority (DEA) actions against pharmaceutical wholesalers and chain drug stores, and their subsequent response in an effort to avoid further DEA action.

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

- Fifteen states are now operational with the National Association of Boards of Pharmacy (NABP) Interconnect Hub program which allows state prescription monitoring programs to share data across state lines. Ten more states have signed

Memorandums of Understanding (MOU) to participate. Purdue supported this initiative.

- A direct mail campaign to recruit investigators and enroll patients for pediatric clinical trials was targeted to over 1,500 pediatric hematologists and oncologists in June. The package included a cover letter, our new "Advancing Medical Science" brochure and a pediatric flyer. Within one week, inquiries were being received expressing interest in becoming investigators for pediatric clinical trials. This also served to increase Purdue's visibility as a leader in pain management among pediatric healthcare professionals.

- Media relations were conducted with national business and healthcare professional trade media to communicate the value of reformulated OxyContin. Specific efforts leveraging epidemiological data presentations and proactive outreach surrounding the '042 patent expiration, updated product labeling and FDA's decision regarding the company's Citizen Petition relating to generic formulations. These efforts resulted in more than 838 favorable stories (including an Associated Press story that appeared in 625 newspapers) for the OxyContin brand. Scientific communications support was also conducted in support of data presentations for Butrans. General education about Intermezzo and middle-of-the-night awakenings secured 10 media placements.

- Many healthcare professional and patient advocacy groups covered information related to the new formulation of OxyContin in their e-newsletters, list serves, and other communications vehicles.

- The redesigned *Voices of Hope* section on *In the Face of Pain*® website was launched which gives greater visibility and more streamlined viewing for pain advocates and third-party organizations.

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

- State legislation to address prescription drug abuse was introduced in many states this session. Two specific concerns were Massachusetts HB 1786 which rescheduled OxyContin to a CI controlled substance and Mississippi HB 599 which set a 75 unit limit per RX on OxyContin. Both bills were defeated.

- Florida and California have introduced bills that would require pharmaceutical companies to pay for or be allowed to pay for the state prescription monitoring programs. In both cases, the language was removed in order to pass the bills.

- Ohio is finalizing guidelines that will require prescribers to perform additional activities specific to prescribing controlled substances for chronic non-cancer pain once a "trigger dose" of 80mg morphine equivalence is reached.

- Awareness of Purdue's comprehensive efforts to combat prescription drug abuse continues to increase. Proactive media relations were conducted to promote RxPATROL, and the Law Enforcement Liaison & Education Program. In the second quarter of 2013, Public Affairs achieved positive delivery of Purdue's anti-diversion/anti-abuse messages by garnering 59 stories reaching more than 1.5 million readers/viewers for both RxPATROL and LELE.

- The US Conference of Mayors announced a grant from Purdue, surrounding the 2014 Prescription Drug Abuse Recognition Program awards for outstanding initiatives to address Rx Drug Abuse at their annual meeting. A press release accompanied the live announcement event.

- The National Education Association launched its RX for Understanding National High School Curriculum at its annual meeting. A press release occurred in conjunction with the meeting. Purdue provided funding for the development of the high school curricula and it will join of the current middle school curricula in helping teachers to address the issues surrounding prescription drug abuse.

HEALTH POLICY

The Health Policy Group helps shape the public face of Purdue, enhances corporate visibility, and cultivates a supportive environment through communication and collaboration (e.g., presentations, participation with external entities, and support of Purdue Governmental Affairs). Medical Education provides high-quality, relevant resources to meet clinical and learning needs that complement the drug product portfolio. Medical Services responds to external queries on our products and provides medical review of Materials for the Sales Forces and external customers (e.g., healthcare professionals, patients, regulators, and general public). Library & Information Services deliver resources to meet the scientific and business needs of Purdue.

Policy-Related

- Communication & External Affairs Committee
    - Currently working on patient access issues; unintended consequences of "pill-mill" laws; creating talking points on the benefits of abuse-deterrent formulations; and building an evidence base to demonstrate that a significant contribution to the supply of opioids used non-medically is from excess prescribing for acute pain (e.g., dentists, emergency rooms), not for patients with chronic pain.

- Medical Research
    - Consulting with an R&D task force to standardize elements of the informed consent process across clinical trials.
    - Serving on long-term opioid effectiveness publication team.

- Risk Management activities
    - Extended-release/Long-acting Opioid Analgesics REMS Program Companies (RPC) – chair of Prescribers' Sub-team; active in drafting External Communications guidance for RPC use; submitted Spanish translation of Patient Counseling Document to RPC.
- Sales and Marketing
    - Consulting with PAP to finalize a spine education poster.
    - Educating of Sales Representatives on low back pain and other topics.

- Medical Services
    - Edited the response letter to inquiries to the Long-Term Studies of OxyContin® in Chronic Non-Cancer Pain by healthcare professionals.
    - Directing compilation of patient vignettes about difficulty obtaining prescribed opioids. 105 contacts YTD, most from Florida, over half involving OxyContin.

- Other external collaborations
    - Abuse Liability Evaluation for Research, Treatment, and Training (ALERTT) Working Group of the ACTTION public-private partnership with FDA on *Recommendations for Quantifying Abuse-Related Events in Clinical Trials* (one journal article published from this group to date).
    - American Pain Society – co-authored three posters. Several influential researchers, FDA, and ONDCP personnel, and trade media, showed high interest in them.
        1. *Youth Health Risk Behaviors Associated With The Nonmedical Use of Prescription Pain Relievers* - Poster